Committee for Risk Assessment (RAC)
Committee for Socio-economic Analysis (SEAC)

Annex to Background Document

to the Opinion on the Annex XV dossier proposing restrictions on intentionally added microplastics

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ANNEX TO BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON INTENTIONALLY ADDED MICROPLASTICS

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A.1. Examples of definitions for 'microplastics'

Table 1: Examples of definitions and scope used in national legislation on 'microplastics'

Example	Definition	Scope	Reference/further information	Definition elements
EU Ecolabel	'microplastic' means particles with a size of below 5 mm of insoluble macromolecular plastic, obtained through one of the following processes: (a) a polymerisation process such as polyaddition or polycondensation or a similar process using monomers or other starting substances; (b) chemical modification of natural or synthetic macromolecules; (c) microbial fermentation;	EU Ecolabel (hand dishwashing detergents) The product group '**hand dishwashing detergents**' shall comprise any detergent falling under the scope of Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents which is marketed and designed to be used to wash by hand items such as glassware, crockery and kitchen utensils including cutlery, pots, pans and ovenware. The product group shall comprise products for both private and professional use. The products shall be a mixture of chemical substances and shall not contain micro-organisms that have been deliberately added by the manufacturer. For the purpose of this Decision, the following definitions shall apply: (1) 'ingoing substances' means substances intentionally added, by-products and impurities from raw materials in the final product formulation [(including water-soluble foil, where used)];	COMMISSION DECISION of 23.6.2017 establishing the EU Ecolabel criteria for hand dishwashing detergents C(2017) 4227 final	• Based on particles • "macromolecular plastic" • three synthesis process within scope • Includes solubility (but does not specify solvent) • <5 mm

Example	Definition	Scope	Reference/further information	Definition elements
BE	'Microplastic': solid particle, of less than 5 mm, used as an ingredient in consumer products and consisting in whole or in part of synthetic polymers that are insoluble in water and non-biodegradable in the aquatic environment. 'Polymer' shall mean a polymer as referred to in Article 3(5) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;	**Article 10.** Definitions associated with replacement of 'plastic microbeads' in cosmetic rinse-off products and oral care products. 1. 'Cosmetic product': any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours (Article 2(1)(a) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products); 2. 'Rinse-off product': a cosmetic product intended to be removed after application on the skin, the hair or the mucous membranes (Regulation (EC) No 1223/2009 on cosmetic products, preamble to Annexes II to VI, point 1); 3. 'Oral care product': a cosmetic product intended to be applied on teeth or the mucous membranes of the oral cavity (Regulation (EC) No 1223/2009 on cosmetic products, preamble to Annexes II to VI, point 1); 4. 'Plastic microbead': microplastic used as an ingredient with an abrasive effect and/or	Communication from the Commission - TRIS/(2017) 02636 2017/465/B Draft Sector Agreement to support the replacement of microplastics in consumer products	• Based on particles • Includes 'solid' • synthetic polymer (REACH definition) • solubility (water) • biodegradable (in aquatic environment) • 5 mm

Example	Definition	Scope	Reference/further information	Definition elements
		for cleaning, depending on the form and structure of the particle; 5. 'Placing on the market': pursuant to Article 2(3) of the Act of 21 December 1998 on product standards to promote sustainable production and consumption patterns and to protect the environment, public health and employees.		
FR	Draft 4. 'Particle': a piece of matter with well-defined physical boundaries; 5. 'Solid plastic particles': any solid plastic particle, particularly microparticles smaller than 5 mm, wholly or partly composed of plastic and obtained by a hot forming process; Final 4. "Particule" : un fragment de matière possédant des contours physiques bien définis ; 5. "Particules plastiques solides" : toute particule solide, notamment les microparticules de taille inférieure à 5 mm, composée en tout ou en partie de matière plastique et obtenue par un procédé de façonnage à chaud ;	Prohibition on the placing on the market of rinse-off cosmetic products for exfoliation or cleaning that contain solid plastic particles, from 1 January 2018. Exception is made for particles of natural origin not liable to persist in the environment, release active chemical or biological ingredients, or affect animal food chains. In this context, it sets out the application procedures for the third paragraph of point III of Article L541-10-5 of the Environmental Code and, in particular, the definitions and characteristics of these cosmetic products.	Communication from the Commission - TRIS/(2016) 03143 Decree prohibiting the placement on the market of rinse-off cosmetic products for exfoliation or cleaning that contain solid plastic particles, provided for in the third paragraph of point III of Article L541-10-5 of the Environmental Code	• particle • solid • "plastic" • "hot forming process" • 5 mm

Example	Definition	Scope	Reference/further information	Definition elements
IT	From 1 January 2020, the production and marketing on national territory of exfoliating rinse-off cosmetic products containing microplastics, i.e. water insoluble solid plastic particles of 5 mm or less, as defined in Commission Decision (EU) 2017/1217 of 23 June 2017, are banned. Plastic, within the meaning of this paragraph, is considered a polymer, as defined in Article 3(5) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, that is modelled, extruded or physically shaped into various solid forms and which, during use and subsequent disposal, maintains the forms defined in the intended applications.'.	The production and marketing on national territory of exfoliating rinse-off cosmetic products containing microplastics	2018/258/I Draft technical regulation banning the marketing of non-biodegradable and non-compostable cotton buds and exfoliating rinse-off cosmetic products or detergents containing microplastics.'	• particle • solid • polymer REACH definition with extra conditions (*that is modelled, extruded or physically shaped into various solid forms and which, during use and subsequent disposal, maintains the forms defined in the intended applications)* • solubility (water) • <5mm ⚠ refers to COM 2017 definition for microplastics for ecolabel for "handwashing detergents" (*Commission Decision (EU) 2017/1217 of 23 June 2017)*
SE	Plastic: a polymer within the meaning of Article 3(5) of Regulation *(EC) No 1907/2006* of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a	**§ 4 a** It is prohibited to make available on the market a cosmetic product that is intended to be rinsed off or spat out after being used on the head, hair, mucous membranes or teeth, and contains microplastics which have been added to cleanse, exfoliate or polish.	Communication from the Commission - TRIS/(2017) 01661 2017/284/S (Sweden) Draft Ordinance amending the Chemicals Products	• particle • solid • polymer • solubility (water)

Example	Definition	Scope	Reference/further information	Definition elements
	European Chemicals Agency, amending Directive *1999/45/EC* and repealing Council Regulation (EEC) No 793/93 and Commission Regulation *(EC) No 1488/94* as well as Council Directive *76/769/EEC* and Commission Directives *91/155/EEC*, *93/67/EEC*, *93/105/EC* and *2000/21/EC*, to which additives or other substances may have been added, Microplastics: solid plastic particles that are smaller than 5 mm and insoluble in water,	The ban does not apply to cosmetic products containing microplastics that only consist of naturally occurring polymers. **§ 4 b** The Swedish Chemicals Agency may notify regulations on exemptions or, in individual cases, grant an exemption from the ban in § 4 a for cosmetic products containing microplastics, which are 1. manufactured using naturally occurring polymers as a raw material, and 2. quickly broken down into monomers in the aquatic environment and do not pose any risk to aquatic organisms.	(Handling, Import and Export Prohibitions) Ordinance (1998:944)	• 5 mm
UK	"microbead" means any water-insoluble solid plastic particle of less than or equal to 5 mm in any dimension; "plastic" means a synthetic polymeric substance that can be moulded, extruded or physically manipulated into various solid forms and that retains its final manufactured shape during use in its intended applications;	These Regulations prohibit the use of microbeads as an ingredient in the manufacture of rinse-off personal care products and the sale of any such products containing microbeads "rinse-off personal care product" means any substance, or mixture of substances, manufactured for the purpose of being applied to any relevant human body part in the course of any personal care treatment, by an application which entails at its completion the prompt and specific removal of the product (or any residue of the product) by washing or rinsing with water, rather than leaving it to wear off or wash off, or be absorbed or shed, in the course of time;	Communication from the Commission - TRIS/(2017) 01983 2017/353/UK (United Kingdom) The Environmental Protection (Microbeads) (England) Regulations 2017 Entry into force 1 Jan 2018 (manufacturing), 30 Jun 2018 (supply)	• particle • solid • Non-REACH polymer/plastic definition • solubility (water) • 5 mm (any dimension)

Example	Definition	Scope	Reference/further information	Definition elements
		(a) a "personal care treatment" means any process of cleaning, protecting or perfuming a relevant human body part, maintaining or restoring its condition or changing its appearance; and (b) a "relevant human body part" is— (i) any external part of the human body (including any part of the epidermis, hair system, nails or lips); (ii) the teeth; or (iii) mucous membranes of the oral cavity;		
NI	microbead" means any water-insoluble solid plastic particle of less than or equal to 5mm in any dimension; plastic" means a synthetic polymeric substance that can be moulded, extruded or physically manipulated into various solid forms and that retains its final manufactured shape during use in its intended applications;		Communication from the Commission - TRIS/(2018) 01172 2018/205/UK (United Kingdom) The Environmental Protection (Microbeads) (Northern Ireland) Regulations 2018	as UK
Scotland	"microbead" means any water-insoluble solid plastic particle of less than or equal to 5mm in any dimension;		Communication from the Commission - TRIS/(2018) 00266	as UK

Example	Definition	Scope	Reference/further information	Definition elements
	"plastic" means a synthetic polymeric substance that can be moulded, extruded or physically manipulated into various solid forms and that retains its final manufactured shape during use in its intended applications;		2018/48/UK (United Kingdom) The Environmental Protection (Microbeads) (Scotland) Regulations 2018	
Wales	"microbead" ("microbelen") means any water insoluble solid plastic particle of less than or equal to 5mm in any dimension; "plastic" ("plastig") means a synthetic polymeric substance that can be moulded, extruded or physically manipulated into various solid forms and that retains its final manufactured shape during use in its intended applications;		Communication from the Commission - TRIS/(2018) 00230 2018/42/UK (United Kingdom) The Environmental Protection (Microbeads) (Wales) Regulations 2018	as UK
Canada	***microbeads*** means the plastic microbeads set out in item 133 of the List of Toxic Substances in Schedule 1 to the *Canadian Environmental Protection Act, 1999*. (*microbilles*) 133 Plastic microbeads that are ≤ 5 mm in size	Manufacture and importation • **3** (1) A person must not manufacture or import any toiletries that contain microbeads, unless the toiletries are also natural health products or non-prescription drugs, in which case the prohibition applies on or after July 1, 2018. • Marginal note:Sale	Microbeads in Toiletries Regulations Canada Gazette, Part II: Vol. 151, No. 12 - June 14, 2017.	• "plastic" • 5 mm

Example	Definition	Scope	Reference/further information	Definition elements
		(2) A person must not sell any toiletries that contain microbeads on or after July 1, 2018, unless the toiletries are also natural health products or non-prescription drugs, in which case the prohibition applies on or after July 1, 2019.		
California	(c) "Plastic microbead" means an intentionally added solid plastic particle measuring five mm or less in every dimension.	personal care products containing plastic microbeads that are used to exfoliate or cleanse in a rinse-off product, including, but not limited to, toothpaste. "Personal care product" does not include a prescription drug, as defined in Section 110010.2 of the Health and Safety Code	An act to add Chapter 5.9 (commencing with Section 42360) to Part 3 of Division 30 of the Public Resources Code, relating to waste management 2015	• particle • solid • "plastic" • 5 mm (all dimension) • intentionally added
US	"(A) the term 'plastic microbead' means any solid plastic particle that is less than five mm in size and is intended to be used to exfoliate or cleanse the human body or any part thereof;	to prohibit the manufacture and introduction or delivery for introduction into interstate commerce of rinse-off cosmetics containing intentionally-added plastic microbeads intended to be used to exfoliate or cleanse the human body or any part thereof; the term `rinse-off cosmetic' includes toothpaste	H.R.1321 - Microbead-Free Waters Act of 2015 "(Sec. 2) This bill amends the Federal Food, Drug, and Cosmetic Act to ban rinse-off cosmetics that contain intentionally-added plastic microbeads beginning on January 1, 2018, and to ban manufacturing of these cosmetics beginning on July 1, 2017. These bans are delayed by one year for cosmetics that are over-the-counter drugs."	• particle • solid • "plastic" • 5 mm

Example	Definition	Scope	Reference/further information	Definition elements
Illinois	"Plastic" means a synthetic material made from linking monomers through a chemical reaction to create an organic polymer chain that can be moulded or extruded at high heat into various solid forms retaining their defined shapes during life cycle and after disposal. "Synthetic plastic microbead" means any intentionally added non-biodegradable solid plastic particle measured less than 5 mm in size and is used to exfoliate or cleanse in a rinse-off product.		2014 Public Act 098-0638 s	• particle • solid • "plastic" - synthetic material made by linking monomers - moulded, extruded at high heat into solid forms - retain share during life cycle and disposal • biodegradable • 5 mm
Wisconsin	Plastic" means a synthetic material made from linking monomers through a chemical reaction to create an organic polymer chain that can be moulded or extruded at high heat into various solid forms that retain their defined shapes throughout their life cycle and after their disposal Synthetic plastic microbead" means any intentionally added non-biodegradable, solid plastic particle measuring less than 5 millimetres at its largest dimension that is used to		2015 WISCONSIN ACT 43	as Illinois but with extra criteria for size • 5 mm at its largest dimension

Example	Definition	Scope	Reference/further information	Definition elements
	exfoliate or cleanse in a product that is intended to be rinsed off.			
New Zealand	microbead means a water-insoluble plastic particle that is less than 5 mm at its widest point Microbeads are synthetic, non-biodegradable plastic beads, used in personal care products such as bath products, facial scrubs and cleansers, and toothpastes		Waste Minimisation (Microbeads) Regulations 2017 Regulatory Impact Statement	• particle • "plastic" • solubility (water) • biodegradable • 5 mm (largest dimension)
Australia	Microbeads are small, solid manufactured plastic particles with an upper size limit of 5 mm in diameter that are water insoluble and non-degradable, with typical diameters of around 100–300 µm.		Assessment of the sale of microbeads in personal care and cosmetic products Assessment of the voluntary phase-out of microbeads - report	• particles • solid • "plastic" • solubility (water) • degradable • 5 mm
South Korea	Ban the use of microbeads in cosmetics (less than or equal to 5mm in size) [Annex 1]		Proposed amendments to the "Regulation on Safety Standards etc of Cosmetics" (4 pages, in Korean).	• 5 mm

Example	Definition	Scope	Reference/further information	Definition elements
			Reference: G/TBT/N/KOR/672	
Japan	description from media: The bill is calling for manufacturers to reduce emissions of the plastic particles that reach up to five millimetres across. According to The Environment Ministry, it is thought to be the first legislation that includes measures to reduce microplastics.			• 5 mm

A.2. Other legislations on intentionally added microplastics

A.2.1. EU Member State legislation on intentionally added microplastics

Several EU Member States have banned products, or certain types of products, that contain microplastics, typically 'microbeads' in wash-off cosmetic products. Relevant details are summarised below.

Belgium

In 2015 the Belgian federal government (Belgian DG Environment, FPS Health, Food Chain Safety and Environment) ordered the design of a test - *to assess and prevent the emission of primary synthetic micro particles (primary microplastics)*[1] to assist companies in assessing their use of synthetic micro particles and in taking measures to prevent the emission of synthetic micro particles to the environment.

In October 2017 Belgium announced a plan to phase out microplastics from all consumer products by 2019, through a sector agreement[2]. It also notified the Commission of this intention[3].

France

On 6 March 2017, a French decree was published, aiming at banning the use of solid plastic particles in rinse-off exfoliating and cleaning cosmetics from 1 January 2018. This decree also affects plastic cotton buds, which will be banned from 1 January 2020.

Notification to the Commission (2016/0543/F - S00EC) available at: http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2016&num=543

Ireland

The Irish Ministry for Housing, Planning, Community and Local Government, launched in 2017 a public consultation process in relation to a proposed legislative ban on certain products containing plastic microbeads. Ireland intends to sign a law to ban microbeads in products by the end of 2018.

Italy

Italy will ban microplastics in exfoliating rinse-off cosmetic products or detergents as well as non-biodegradable cotton bud sticks (ban to come into force from 1 January 2019) ("*cosmetici da risciacquo ad azione esfoliante o detergente contenenti microplastiche*", from 2020).

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[1] https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/microplastics_manual_voor_de_website_env2.pdf

[2] http://www.brusselstimes.com/belgium/9991/cosmetic-sector-determined-to-do-without-microplastics-by-2020

[3] http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2017&num=465

The draft technical regulation intends to ban the marketing of non-biodegradable and non-compostable cotton buds and exfoliating rinse-off cosmetic products or detergents containing microplastics.

Notification to the Commission (2018/0258/I) on 6 June 2018 is available at:

http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2018&num=258

Sweden

A Swedish ban on rinse-off cosmetics containing microbeads enters into force at the beginning of July 2018. Sweden announced the proposed ban in 2017 and notified the World Trade Organization (WTO). The ban will apply to cosmetic products that are "rinsed or spotted (sic) and which contain plastic particles with a cleaning, scrubbing or polishing function". It includes, for example, toothpastes, body scrubs, shower gels, shampoos and conditioners with added microbeads. Products consisting solely of "natural polymers, long molecules that have not been synthesised, and which have not been modified chemically" are excluded from the ban. There is also a provision for the Swedish Chemicals Agency to decide on additional derogations or exemptions on case-by-case basis, for cosmetic products that contain plastic particles which are manufactured with naturally occurring polymers as raw material and which are quickly broken down to monomers in aquatic environments and do not constitute any risk for adverse effects on water living organisms. There will be a six-month transition period - products purchased in stock before July may continue to be sold in stores until January 2019.

Sweden is considering extending the ban to all remaining cosmetic products which are not already covered by the Swedish ban, and other chemical products that release microplastics to waste water systems. In March 2018, the Swedish Chemicals Agency (Kemi) produced a report on a broader proposal[4]. The report concludes that action on microplastics in cosmetic and chemical products firstly should take place at EU level.

The Kemi assessment uses the following definition of microplastics: solid plastic particles that are smaller than 5 mm in any dimension and insoluble in water.

Notification to the Commission (2017/0284/S) on 30 June 2017 is available at:

http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2017&num=284

United Kingdom

Legislation has been developed in England, Wales, Northern Ireland and Scotland to ban the manufacture and sale of rinse-off personal care products containing plastic microbeads (defined as any water-insoluble solid plastic particle of less than or equal to 5mm in any dimension) in 2018.

Notifications to the Commission are available:

UK notified on 28 July 2017: http://ec.europa.eu/growth/tools-

[4] https://www.kemi.se/en/global/rapporter/2018/rapport-2-18-mikroplast-i-kosmetiska-produkter-och-andra-kemiska-produkter.pdf in Swedish with a summary in English.

databases/tris/en/search/?trisaction=search.detail&year=2017&num=353

Northern Ireland notified on 10 May 2018: http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2018&num=205

Scotland notified on 01 February 2018: http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2018&num=48

Wales notified on 29 January 2018: http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2018&num=42

A.2.2. Legislation on intentionally added microplastics outside of the European Union

A number countries outside of the EU, like the USA, Canada and New-Zealand, have already introduced bans on intentional use of microplastics, or one kind or another, or have drawn up voluntary agreements with industry for their phase out.

Canada

In 2015, Environment Canada held consultations and reviewed more than 130 scientific studies of microbead pollution. Then, in 2016, after listing microbeads as a 'toxic substance', the federal government announced a ban on the sale, import and production of personal care products containing microbeads as exfoliants or cleansers as of 1 July 2018.

The Microbeads in Toiletries Regulations is available at: https://www.ec.gc.ca/lcpe-cepa/eng/regulations/DetailReg.cfm?intReg=238

USA

In 2014, Illinois became the first state to pass legislation on microbeads. However, this bill fell short of the goals of most environmental groups. The Illinois legislation defined synthetic plastic microbeads as "any intentionally added non-biodegradable solid plastic particle". The bill excluded biodegradable plastics, but did not define that term, creating a loophole. One could argue that a material is "biodegradable" even though it degrades only marginally over several years, for example, modestly changing in shape and form, but persisting in the environment. The definition of "plastic" was also problematic. Plastic was defined as "a synthetic material made from linking monomers through a chemical reaction to create an organic polymer chain that can be moulded or extruded at high heat into various solid forms retaining their defined shapes during life cycle and after disposal" (Illinois Bill SB2727[5]). However, not all polymers in plastics are made by linking monomers. Some are made by modifying existing polymers – e.g. cellulose acetate (which in some forms can be biodegradable) is made by acetylating the natural polymer cellulose, rather than by linking monomers. Also, this definition would not cover plastics that melt at low temperatures. Finally, it might not cover certain plastics depending on the design of the final product.

[5] http://www.ilga.gov/legislation/BillStatus.asp?DocNum=2727&GAID=14&DocTypeID=SB&SessionID=91&GA=100

Californian legislation[6], that came into force in January 2020, omits biodegradation completely. As a consequence, the California bill banned microbeads made from any plastic, with no exceptions. However the legislation applies only to "rinse-off products excluding items such as makeup, lotions, deodorant and industrial and household cleaners".

In general, legislation passed in other states has language modelled on either the Illinois bill, or the California bill (i.e., all plastics banned, irrespective of their environmental impact).

The US federal government *Microbead-Free Waters Act* of 2015[7] will prohibit the formulation and distribution of rinse-off cosmetics (and specifically stated that this included toothpaste) that intentionally contain plastic microbeads. The term microbead means any solid plastic particle that is less than 5mm in size and is intended to be used to exfoliate or cleanse any part of the human body. There are different deadlines for the prohibition of manufacture (July 2017) and placing on the market (July 2018), respectively. The respective deadlines are postponed for a year for 'non-prescription rinse-off cosmetics'.

New Zealand

The New Zealand government regulation banning plastic microbeads[8] came into effect on 7 June 2018. The regulation prohibits, under section 23 of the Waste Minimisation Act 2008, the sale and manufacture of wash-off products that contain plastic microbeads for the purposes of exfoliation, cleaning, abrasive cleaning or visual appearance of the product. A Regulatory Impact Statement[9] was prepared by the Ministry for the Environment (MfE). It provides an analysis of options to prevent the sale and manufacture of "wash-off" products containing plastic microbeads. Microbeads are defined as synthetic, non-biodegradable plastic beads, used in personal care products such as bath products, facial scrubs and cleansers, and toothpastes. The NZ Environment Protection Authority (EPA) has published information[10] on what the ban means for manufacturers, suppliers, retailers and the public.

Australia

After the New Zealand ban on the sale and manufacture of microbeads to cover all 'wash off' products, there is speculation on whether Australia will follow. In December 2016, an official meeting of environment ministers (MEM) from federal, state and territory level across Australia endorsed a voluntary industry phase-out of microbeads by 1 July 2018.

South Korea

In Oct 2016, the Korean Ministry of Food and Drug Safety (MFDS) has notified the World Trade Organization (WTO) of its 'Proposed Amendments to the "Regulation on Safety

[6] Available at http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201520160AB888

[7] Available at https://www.congress.gov/bill/114th-congress/house-bill/1321

[8] http://www.legislation.govt.nz/regulation/public/2017/0291/latest/096be8ed816cddcb.pdf

[9] http://www.mfe.govt.nz/sites/default/files/media/Legislation/RIS/RIS-microbeads-2017.pdf

[10] https://www.epa.govt.nz/news-and-alerts/alerts/microbeads-ban-is-your-product-affected/

Standards etc of Cosmetics"[11]. The proposed amendments have banned the use of microbeads in rinse-off cosmetics from July 2017.

A.2.3. Manufacture

Table 2: Indicative list of polymer materials available in physical forms that would be consistent with a microplastic

Polymer	Trade name, brief product description and manufacturer
Polyamide	**Vestosint** polyamide (PA12) coating and fine powders with d50 from 6 to 100 µm – Evonik (DE) – https://www.vestosint.com
	Orgasol ultrafine industrial polyamide (PA12 and or/PA6) powders from 5 to 60 µm – Arkema (FR) - https://www.orgasolpowders.com/en/
	Organsol cosmetics ultrafine multi-functional polyamide powders 5 to 20 µm (spherical shape) for anhydrous, oil and water-based systems – Arkema (FR) - cosmetics https://www.orgasolcosmetics.com
	Rilsan polyamide (PA11) fine powders – Arkema (FR) - https://www.rilsanfinepowders.com
Polyacrylics (PMMA, acrylate and methacrylate co-polymers) – typically cross-linked	**Spheromers CA** spherical beads 6 to 40 µm – Microbeads AS (NO) - http://www.micro-beads.com
	Techpolymer 0.1 to 200 µm – Sekisui Plastics (JP) - http://www.tech-p.com/en/
	Epostar MA 2 to 12 µm – Nippon Shokubai (JP) - https://www.shokubai.co.jp/en/products/functionality/epokara.html
	Epostar MX 0.01 to 0.40 µm (emulsion) - https://www.shokubai.co.jp/en/products/functionality/epokara.html
	Altuglas BS spherical solid methacrylate beads (between 20 and 300 µm - Arkema (FR) - https://www.altuglas.com/en/resins/acrylics-beads/
	Decosilk ART d50 of 5 to 200 µm – Microchem (CH) - http://www.microchem-online.com/en/microbeads.html
	Caché CA cross-liked PMMA for cosmetics and toiletry applications – Microbeads AS (NO) - http://www.micro-beads.com
Polystyrene	**Spheromers CS** spherical beads 6 to 40 µm – Microbeads AS (NO) - http://www.micro-beads.com
	Dynoseeds TS spherical beads 10 to 500 µm – Microbeads AS (NO) - http://www.micro-beads.com
	Calibre CS calibration standards in aqueous solutions 1 to 160 µm
	Techpolymer 6 to 12 µm – Sekisui (JP) - http://www.tech-p.com/en/
Polyurethane	**Decosoft** d50 of 7 to 60 µm – Microchem (CH) - http://www.microchem-online.com/en/microbeads.html

[11] Available at: http://ec.europa.eu/growth/tools-databases/tbt/en/search/?tbtaction=search.detail&Country_ID=KOR&num=672&dspLang=en&basdatedeb=30/09/2016&basdatefin=12/10/2016&baspays=&basnotifnum=&basnotifnum2=&bastypepays=ANY&baskeywords

Polymer	**Trade name, brief product description and manufacturer**
Melamine-formaldehyde	**Epostar** 0.1 to 2 µm – Nippon Shokubai (JP) - https://www.shokubai.co.jp/en/products/functionality/epokara.html

Annex B. Derivation of a regulatory definition of microplastic

The following Annex considers each of the relevant elements of a fit-for-purpose microplastic definition.

B.1. Substance

In the absence of a definition of 'plastic' in the REACH regulation, the starting point for a regulatory definition of 'microplastics' under REACH can be considered to be the REACH polymer definition.

In accordance with REACH (Article 3(5)), polymer means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

(a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

(b) less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer.

B.1.1. ISO definition of plastic

Multiple respondents proposed that the ISO definition of plastic (ISO 472 (2013)) should be used as the basis for the proposed REACH restriction, rather than the definition proposed by the Dossier Submitter. The definitions are different and have been derived based on different considerations. The regulatory definition proposed by the Dossier Submitter, as is the entire scope of the proposed restriction, is underpinned by physical, chemical and persistence properties that are associated with hazard/risk concerns (the so-called 'microplastic concern'.

In contrast, the ISO definition of plastic is primarily based on process considerations. Although there are some elements of the two definitions in common, the substances/mixtures that will be covered by the different definitions are likely to be different. Therefore, the Dossier Submitter has concluded that the definitions cannot be used interchangeably. The ISO definition of plastic is not sufficiently inclusive to identify all synthetic polymeric substances that are associated with the 'microplastic concern' (i.e. solid minute particles comprised of synthetic polymers that are persistent in the environment). For example, the ISO definition would explicitly exclude elastomeric materials whilst particles from tyres for instance are clearly associated with the microplastics concern. There are further examples of substances/mixtures that would be excluded by the ISO definition of plastic that are associated with the microplastic concern. The Dossier Submitter notes that the proposed restriction does not need to explicitly refer to the term 'microplastic' in the conditions of the restriction if all the elements describing the substances/mixtures of concern are included. The term 'microplastic' is simply a convenient label for a group of substances/mixtures with defined physical, chemical and persistence properties that are consistent with an

identified hazard and risk for the environment.

B.1.2. 'Inorganic' polymers

During the consultation some Stakeholders have requested clarification on the status of 'inorganic polymers'. The definition employed during the call for evidence and in the consultation has consistently included all polymers. The polymer definition given in REACH does not differentiate substances based on the chemical composition, thus all polymers are included in the regulatory definition of 'microplastics' if all other criteria (e.g. size and water solubility) are met.

It should also be noted that while 'inorganic polymer' might be intuitively easy to define, however, in practice this is not so straightforward. For example polymers with silicon backbone (for example polysiloxanes) can be viewed as hybrid materials in which the inorganic backbone is combined with the organic groups attached to the silicon atom (Mazurek, 2007, Blanco, 2018). This type of polymers could be viewed either as inorganic, hybrid or as organic substances. The Dossier Submitter also acknowledges that some polymers such as polyammoniumphosphates do not necessarily include any organic groups(Han et al., 2014). In the consultation some Stakeholders stated that as the physiochemical properties of the inorganic polymers are different from the organic polymers they should not be included in the scope of the restriction proposal. However, it should be noted that while it is possible to give exact examples from different polymers with different physiochemical properties, this can be done also within the group of organic polymers, many of which are distinctly different from each other. More specifically, inorganic polymers may have the same morphology as organic polymers and exhibit similar persistence once released. Therefore, the Dossier Submitter has concluded that there is no justification to make a distinction between different types of polymers within the scope of the restriction proposal from a substance identification perspective.

The Dossier Submitter notes that while citations to 'inorganic polymers' were made during the consultation, no sufficient information (either in the call for evidence or in the consultation) regarding the uses and quantities have been provided. Therefore the Dossier Submitter proposes that information regarding these uses will be specifically requested in the upcoming consultation on the SEAC opinion. Based on this, it could be concluded whether or not a specific use/s of inorganic polymers would merit derogation.

B.1.3. Presence of a particle or 'particle containing solid polymer'

Almost all definitions refer to 'microplastics' as 'particles'. Indeed, it is likely to be one of most critical descriptors of a material consistent with the microplastic concern. There is an ISO definition for particle and there are a range of standard analytical methods available to measure particle size distributions[12].

According to various ISO standards (e.g. CEN ISO/TS 27687:2008 (ISO, 2008)(ISO, 2008)(ISO, 2008)(ISO, 2008)(ISO, 2008) and ISO 14644-6:2007), a particle is defined as a "*minute piece of matter with defined physical boundaries*". This can be further

[12] Several different methods for analysing particle size and particle size distribution of particles and specifically polymer particles are available and are widely used. The standardised methods include for example sieving, laser diffraction and image analysis. The exact methods may be specific for the used polymer type (for example ISO 22498:2005, ISO 17190-3:2001, ISO 13320:2009, ISO 13322-1:2014).

specified such that a *"particle has a physical boundary that can also be described as an interface and that a particle can move as a unit".*

The EU regulatory definition for 'nanomaterial'[13] also refers to particle and the ISO definition, outlined above, was included to ensure a common understanding of this key term. The Joint Research Centre of the EU (JRC) has recently prepared draft guidance on the implementation of the EU definition of nanomaterial covering concepts and terms that are also highly relevant for deriving a fit-for-purpose microplastics definition (JRC, 2018).

JRC (2018) outlines that *'minute piece of matter'* is only called a particle if this piece of matter has defined physical boundaries, i.e. if it can be distinguished from the surrounding matter. In other words: there must be, all around the particle, a continuous boundary that indicates where the particle 'ends'. The term 'interface' can be used to describe this boundary. On the 'other side' of the boundary, there may be a continuous phase (i.e. gas, liquid, solid), or another particle. In this context single polymeric molecules are not considered to be particles even if they have defined physical boundaries. Based on JRC (2018), it appears necessary that an accompanying definition for particle should be included in the regulatory definition of a microplastic.

Stakeholder input on this element has focussed on the size cut-offs, the number of dimensions considered and the state of the particle (solid/liquid).

It also should be noted that, in the context of the regulatory definition, microplastic particle does not refer only to particles consisting solely of polymers. 'Particle containing solid polymer' means a particle of any composition with a (solid) polymer content of ≥ 1% w/w.

B.1.3.1. Coatings on small objects

There are many uses where polymer films are used to coat/encapsulate other materials that would be within the scope of the regulatory definition due to the size of the resulting particle (e.g. seed coatings, controlled release fertilisers, medical products, encapsulated pigments, encapsulated liquids etc.). During reasonably foreseeable conditions of use, the particle may be retained in a matrix or released to the environment (e.g. via wastewater, or from being 'shed' from clothing. Particles that are released under reasonably foreseeable conditions of use are not considered to be adequately controlled and would be within the scope of the restriction. For particles that are permanently embedded in films (e.g. the encapsulated pigments are embedded in a cured paint film), or other solid matrices (e.g. concrete/resin or similar) are considered to have a reduced potential for release. However, releases could occur depending on the conditions of use during the use phase (i.e. disposal of residual product or the cleaning of brushes/tools) or during service life.

The relative weight percentage of the polymer coating versus the material it coats/encapsulates depends on factors like the thickness of the polymer coating, the size of the resulting coated/encapsulated particle, the nature of the encapsulated/coated

[13] 2011/696/EU, Commission Recommendation of 18 October 2011 on the definition of nanomaterial: *"A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm".*

particle and the polymer coating. Based on the information received in the consultation, the (w/w) % of the polymer can be as lower than 0.002 % to as high as 60 %.

As for the threshold for a particular size distribution, using the (w/w) % introduces a bias in the measurement as larger objects weigh more and therefore contribute more to the w/w (%). A thin coating on a larger particle will have a lower (w/w) % contribution to the material mass while a thick coating on a small particle will have a larger (w/w) % contribution, although the amount of polymer in both examples may be the same. For this reason, setting a threshold for the (w/w) % contribution of polymer coating may be both arbitrary and inconsistent.

Therefore, it is proposed not to set a threshold for the (w/w) % of polymer coating for an encapsulated/coated particle. This means that where the polymer coated particle is within the size range specified in the definition, the polymer coating is a "microplastic". Whether it is within the scope of the proposed restriction will depend on the releases that occur under reasonably foreseeable conditions of use.

B.1.3.2. Polymers used for stabilising certain particles or polymers themselves are stabilised in certain "media"

In some uses polymers could be applied to stabilise certain particles such as polymers used for drug delivery systems or stabilisation of colloid metal particles. In other uses polymer particles could be added in a stabilised dispersion to provide a designed functionality e.g. in synthetic latexes. In both uses the polymers could potentially fall under the microplastic definition.

For these applications, it is proposed to set the same threshold as for other applications. If ≥1% w/w of polymer is applied for stabilising particles or if ≥1% w/w of polymer is present in a "media" which the polymer is stabilised in it could be considered as a microplastic[14].

However if the polymer particles coalesce (or similarly react) to form a continuous film during use they would cease to be particles, which will affect how a restriction could apply to their use (see section on film-forming).

B.1.3.3. State of the particle

Many microplastic definitions have included the term "solid" as an inclusion criterion, but without further defining the term. The EU definition for nanomaterial refers to "particles" only and does not have explicit additional qualifiers on "state". In recent draft guidance on the implementation of the EU definition of nanomaterial the JRC (2018) outlines that the term 'particle' is intended to cover only entities with a defined, rigid shape thus in essence solid objects. The report concludes that the EU definition of a nanomaterial covers only particles that are solid at standard temperature and pressure (STP), i.e. 298.15 K and 101325 Pa. In other relevant EU legislation the term 'solid' is understood in

[14] As the matrix of the particle or the "media" in which polymer is stabilised in varies, it is not possible to apply a single analytical method(s) for determining the amount (w/w) of the polymer. However, it is known that several methods which are generally available, can be utilised on case-by-case basis. For example, if colloid metal particle are stabilised with polymers, it is possible to use elemental analysis to determine the amount of carbon in the particles. For organic substances it is possible to use extraction techniques in order to separate the polymer from the matrix which can then be quantified.

relation to liquid and gaseous states. In CLP[15] solid means *'a substance or a mixture that does not meet the definitions of liquid or gas*[16]*'*.

"State of the substance" is also a standard REACH information reporting requirement under the REACH regulation: 7.1. State of the substance at 20 °C and 101.3 kPa

Following the available guidance on preparing robust study summaries, the reporting options are limited to "*physical state (gaseous, liquid or solid*).

Many stakeholders provided input on this element in the call for evidence or in additional information submissions. Some had the view that it was not clear if "semi-solid" would be covered by "solid" or whether particles that were in the liquid state should be included. The reason for this uncertainty is that polymers are generally complex macromolecules and there is an enormous diversity in their chemistry and properties. For this reason, a definition for "solid" would ensure a common understanding.

Based on the considerations in the JRC draft guidance for the implementation of the EU definition for nanomaterial (JRC, 2018), it is likely to be useful to add the qualifier "solid" to the element "particle" to exclude liquids and gases.

In the call for evidence, some stakeholders queried how "wax" will be considered. "wax" is a generic term for the state of a material (i.e. "waxy") and can cover a multitude of very different chemicals (naturally occurring bees waxes, paraffinic waxes, polyethylene waxes, etc.). "Waxes" that are solid in the context of the CLP definition are within scope. However, some "waxes" may form a film on use (see section on film-forming).

In addition to defining the state of the microplastic particle via CLP, the determination of the difference between the solid and the liquid state could be done using melting temperature of the material (T_m). However, this is not straightforward when considering polymeric substances. For some polymeric materials, due to their amorphous nature, it is not possible to define T_m, however, it is possible to define glass transition temperature, T_g, for these substances. T_g describes the temperature or temperature range where a polymer changes from a hard, rigid or "glassy" state into a viscous or rubbery state as the temperature is increased. In principle, this could be used to determine the state of the substance. However, the challenge in using this route to define the state of the microplastic particle is that there would be ambiguity for certain types of materials, such as waxes and potentially additional ambiguity in determining T_g for certain types of materials such as composites.

Based on the comments received from the consultation, there is a need to address more precisely the definition of 'solid' with regard to fully amorphous polymer. As noted above,

[15] The definitions of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) were also considered during the development of the Annex XV report, but it was subsequently decided to apply the Classification, Labelling and Packaging of substances and mixtures (CLP) definitions of Regulation (EC) No 1272/2008 on the basis that this was more consistent with existing EU regulation.

[16] Gas means a substance which: (i) at 50°C has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20 °C at a standard pressure of 101.3 kPa; Liquid means a substance or mixture which: (i) at 50°C has a vapour pressure of not more than 300 kPa (3 bar); (ii) is not completely gaseous at 20°C and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of 20°C or less at a standard pressure of 101.3 kPa; Solid means a substance or mixture which does not meet the definitions of liquid or gas.

fully amorphous, or semi-crystalline, polymers do not exhibit T_m. Therefore, there is a need to address this specifically. One of the commentators suggested that all amorphous polymers should be covered by the restriction proposal by default. However, this would increase the scope to the restriction proposal. Also the option to apply T_g in defining a limit for the purpose of the restriction was suggested. However, as noted above, this was already considered not to be fully applicable in all circumstances. To address this issue the commonly used GHS definition of solid has been used and the CLP definition of 'solid' was supplemented with additional criteria from the GHS definition for a liquid:

"*A viscous substance or mixture for which a specific melting point cannot be determined shall be subjected to:*

ASTM D 4359-90, or

Fluidity test (penetrometer test) described in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)."

B.1.3.4. Solubility considerations

Many definitions have also included water insolubility as an inclusion criterion. However, there is no general agreement for pass/fail cut-off solubility values for "water insolubility" for polymers, in addition questions have been raised for the applicability of the standard methods like OECD 120 for all polymer types. This means that while on a conceptual level "water insoluble" seems clear, on a practical and empirical level it is open to interpretation and is not as straightforward as initially thought.

The relevance of "solubility" was also considered by the SCENIHR in its 2011 Opinion on the "*scientific basis for the definition of the term nanomaterial*" requested by the Commission. The Opinion outlines that while solubility is a relevant property of particles, it is dependent on the interplay between the chemistry of the particle and the environment into which it is placed. The Opinion did not subsequently recommend its inclusion as an element for the EU definition for nanomaterial (SCENIHR, 2010).

Water solubility is a REACH information requirement (Annex 7(7)). There is a definition for water solubility in Regulation (EC) No 440/2008 A.6, section 1.2.

'The solubility of a substance in water is specified by the saturation mass concentration of the substance in water at a given temperature. The solubility in water is specified in units of mass per volume of solution. The SI unit is kg/m^3 (grams per litre may also be used)' (see Regulation (EC) No 440/2008, A.6, section 1.2).

However the REACH Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7a: Endpoint specific guidance on the above definition for solubility of a single substance in water is not "*applicable to substances which are multi-component, such as multi-constituent or UVCB substances, i.e. complex substances*.". In this context, polymers would be generally complex. The practical guide also outlines that

"when a substance has a low water solubility, it is considered to be a 'difficult substance' in relation to some other laboratory testing (especially for environmental endpoints). Special considerations need to be made on how the test is performed and/or the results interpreted."

The revised REACH Annexes for nanomaterials that will come into force in 2019 also highlights that for particulates, test methods used to determine "solubility" can be

confounded by particle dispersion.

"Solubility" may also be open to interpretation for polymers as there is no universal definition that would be applicable to all polymers that would fall under the REACH definition of polymer. Polymers are complex macromolecules and there is enormous diversity in their chemistries. A polymer is generally considered "soluble" in a given medium when it "dissolves" into the medium, in that it forms a solution. The rate at which this dissolution occurs depends on the polymer chemistry, the solvent, temperature and other conditions.

For polymers, many solubility scales are reported e.g. Kaouri-Butanol number, solubility grade, aromatic character, analine cloud point, wax number, heptane number, and Hildebrand solubility parameter. In other literature, the definition of a "water soluble polymer" is context specific – e.g. "Water-Soluble Polymers are organic substances that dissolve, disperse, or swell in water and thus modify the physical properties of aqueous systems undergoing gellation, thickening, or emulsification/stabilisation. These polymers perform a variety of functions in aqueous media, including use as dispersing and suspending agents, stabilisers, thickeners, gellants, flocculants and coagulants, film-formers, humectants, binders, and lubricants".

Due to the considerations above, the Dossier Submitter observed that polymer "solubility" therefore can be understood differently depending on the context in which the term is used. As a consequence of this, the Dossier Submitter initially considered that "solubility" as an element in the definition of "microplastic" may not be useful as the term may be context dependent. The Dossier Submitter therefore originally suggested that the element "solid", "particle" captures well that a polymer has kept its shape in the medium into which it is placed and can move as a unit.

The concept of "solubility" was addressed in number of the comments submitted during the consultation. Based on the comments and further elaboration regarding the rationale, the Dossier submitter concluded that a reasonable argument can be made to include a derogation for polymers with water solubility greater than 2 g/L. The derogation and the justification for the derogation has been provided in Section 2.2.1.1 of the Background Document.

B.1.3.5. Particle size and morphology

RAC and SEAC box

RAC considered that a lower size limit was not necessary to specify in the conditions of the restriction as analytical methods <100 nm are not currently considered to be reliable and enforcement could be based on 'document checks', rather than analytical means.

SEAC considered that a temporary lower limit of 100nm in the conditions of the restriction could appropriate in the event that particles <100nm could not be reliably characterised and enforcement could not be on the basis of 'document checks'.

These details of these changes are reported in the RAC and SEAC opinion, together with the justification for these changes.

Almost all definitions give 5 mm as the upper limit for what is considered a "microplastic". The basis for this was a pragmatic decision based on the premise that it would include a wide range of small particles that could readily be ingested by biota, and

such particles that might be expected to present different kinds of threat than larger plastic items (such as entanglement) (GESAMP, 2015). Many specify the number of dimensions.

Limiting the size cut-off to one dimension means that any "plastic" that is < 5 mm in one dimension would be considered as a microplastic. This would include plastic bags and films with a large surface area (thickness is < 5 mm) as well as thin continuous fibres (diameter < 5 mm). The Dossier Submitter does not consider that it was the intention to consider these polymer entities as intentionally added "microplastics" in the context of a REACH restriction, although we recognise that these materials could be present as environmental litter if they are not appropriately disposed. Some of these entities will be addressed through other measures (e.g. Proposed EU Directive on Single Use Plastics). Consequently, we consider that the size criterion should apply in all dimensions to exclude these types of entities.

An appropriate size cut-off value has been much discussed and a lot of stakeholder input was received on this point, in particular relating to a lower limit size cut-off. The upper size cut-off of 5 mm is almost universal in definitions used in regulatory rulings and reports. Consequently, the upper size limit of 5 mm is proposed although, depending on the scope of the products to which the definition is applied, it could inadvertently include small plastic articles within the scope of any restriction (e.g. small precision parts used in equipment and machinery). Given that the concern stemming from intentionally added "microplastics" for many use applications (e.g. cosmetics) it could be that an upper size limit of 1 mm may be more coherent with "intentional addition". This upper limit would be consistent with the EU Marine Strategy Framework Directive definition of a 'small microplastic'. It would also be consistent with the upper range of the SI *micro* unit (1000 microns = 1 mm).

Many stakeholders have proposed that a lower limit should be specified with values proposed ranging from 1 nm to 5 µm. The arguments given typically stem from observations that sub-micron particles are not microplastics or that without a lower limit single molecules could be affected by a restriction.

A lower limit of 1 nm would include polymer particles that are nanomaterials according to the EU definition for nanomaterial. A lower limit of 100 nm would exclude them. A lower limit of 1 micron would also exclude all sub-micron sized particles. There would not be any scientific reasons for excluding nano and sub-micron sized particles from the scope of the regulatory definition, despite them not occurring within the micro SI unit range. Following the argumentation given in the EU definition for nanomaterial, a lower limit is useful in terms of giving exclusion criteria.

Based on the consideration outlined above, the Dossier Submitter initially considered that the most appropriate lower limit is 1 nm or alternatively no lower limit.

During the consultation on the proposal, stakeholders highlighted several negative implications arising from the use of 1 nm as the lower size limit. The Dossier Submitter considered these comments and concluded that there is merit in revising the lower limit. It was concluded that a revised lower limit of 0.1 µm is a pragmatic solution that balances risk reduction against the obvious analytical constraints and challenges of the initially proposed 1 nm limit.

More detailed elaboration on the reasoning behind the revision on the size limit has been

provided in Section 2.2.1.1 of the Background Document.

B.1.3.6. Fibre considerations

Some stakeholders raised concerns that polymer microparticles that have a fibrous shape may not be adequately covered by the size cut-offs proposed; in particular high aspect ratio particles. Consequently, additional elements may be considered for fibrous particles. The WHO fibre aspect ratio (a fibre is a particle that has length to diameter ratio > 3) is proposed as starting point for what is defined as a fibrous particle. For particles that fulfil the WHO fibre aspect ratio criteria, particles with lengths greater than 5 mm (or 1mm) would also be within the scope of the microplastic regulatory definition. An upper fibre length can be specified to give certainty on what fibres are within scope.

B.1.3.7. Particle size distribution considerations

In relation to the particle size criteria, particle size distribution needs to be considered. In any given test sample, the particle size measured will have a distribution and there may be particles present with sizes both above and below the size cut-off. For all polymer particles in a test sample to be considered microplastics it is logical that a majority of the particles present are within the size range specified. A threshold value for the relative proportion of the particles within the size range can be specified. For example, if the threshold value for inclusion is 50 %, this means that 50 % of the particles must be within the size range for the test sample to be considered as microplastics. The inclusion size range for microplastic is very broad (1 to 5 000 000 nm) meaning that threshold considerations will only be relevant for "large" microplastics close to the limit of 5 mm.

The particles size distribution can be reported using different metrics: weight, volume or number based. A threshold value based on the number metric is the most accurate. The EU definition for 'nanomaterial' has a threshold value of 50 % based on the number size distribution. However, measuring the number-based distribution requires imaging techniques such as transmission electron microscopy.

Based on the stakeholder input and on general considerations, setting a threshold value based on the weight by weight (w/w) % distribution may be more accessible as methods for determining the (w/w) % are available e.g. based on dynamic light scattering. As the mass-based distribution skews that distribution to larger particles as they are 'heavier' and therefore contribute more to the (w/w) %, in this case, it is proposed to give a lower threshold to take this skew into account. To balance the simpler methods available to measure the (w/w) distribution and the skew where a few larger particles (therefore heavier) can shift the measured distribution to larger sizes at the expense of a majority of smaller (and lighter) particles, it is proposed that the threshold be set at 1 % (w/w).

The one-off reporting scheme for nanomaterials under section 8a of TSCA applied a similar logic in the metric and the threshold value used (also 1 % (w/w)). In practice, this means that if more than 1 % w/w of the particles in a sample are within the size range given in the definition for 'microplastics', all particles are considered to be within the scope of the proposed restriction. The proposed threshold allows that the available methods can be applied according to the standards with a good accuracy.

The 1 % threshold is the particle weight-based size distribution. If 1 % or more of the particles of a material in the weight-based size distribution are < 5 mm in all dimensions, the material meets the size criteria for "microplastic". Due to the skew in the metric used

to determine the distribution, the fraction of the material within the scope can be a tiny fraction of the total mass of the material and at the same time be a majority in the total number of particles.

B.1.3.8. Function of the microplastic

The above sections provide elements of the regulatory definition of a microplastic. However, they do not give the context of the uses where the release of the microplastics to the environment is of concern. For many sectors, products include polymer particles that would be considered to be microplastics but where the particles are not released, inevitably or otherwise, to the environment under reasonably foreseeable conditions of use.

Examples include uses where particle coalescence into films i.e. are no longer particulate (which are not solid particles). These polymers do not fulfil the definition of a microplastic. These would also include polymers that lose their particulate form in solution (e.g. at the point of use/disposal).

B.1.3.8.1. Film-forming

Film-forming polymer microparticles are intended to yield a continuous polymer film on use that has properties suitable for the intended application (e.g. long-lasting paint coatings, complete coverage of the skin in sunscreen applications). Although these materials cease to be microplastics at the point of use there could be releases of 'free' particles that have not coalesced through disposal of waste or unused materials e.g. the washing of paint brushes.

B.1.3.8.2. Microplastics permanently contained (entrapped) in a solid matrix (including a film)

Polymer particles that are microplastics in a formulation but are permanently contained in a solid matrix (including a film) in the intended use of the formulation are considered to have inherently limited potential for releases to the environment, although releases could occur during the use phase similarly to film-forming applications, via the inappropriate disposal of residual product to wastewater or the cleaning of tools. Examples would be polymer particles or pigment particles used in architectural paints and coatings, or fibre-based binders used in cement or other construction materials.

B.1.3.8.3. Binders

A binding agent or a "binder" is a term that describes a function of a chemical in the context of an application or use. A "binder" can bind or hold other components together by mechanical, chemical, adhesive means. Depending on the sector, it can refer to thickening agents, film forming agents, coatings, agents to improve the adhesion of coatings, etc.,

Polymers are widely used as "binders" in a diversity of applications (e.g. architectural coatings, cosmetics, inks, coatings on small objects such as seeds, fertiliser particles, medicinal products). For example, polymers used as "binders" can have a film-forming function (e.g. architectural paints), a thickening function in cosmetics (e.g. toothpaste) or be an adhesive to "bind" a coating to a small object (e.g. seed coatings, drug tableting). Some of these polymers will be "microplastics" according to the definition and have potential for release to the environment under reasonably foreseeable conditions of use.

B.1.3.8.4. Hydrogels, 'superabsorbent polymers (SAPs) and other 'swollen polymers'

The superabsorbent polymers are used primarily in absorbent hygiene products (e.g. nappies), cosmetics, agriculture and packaging for their water retention properties. In these cases it is clear that the polymer particles swell (absorbing water or other liquid) at the point of use to form a gel losing their solid particulate form. On this basis these substances no longer fulfil the regulatory definition of a microplastic.

However, certain other polymers also achieve their technical function by swelling during use (e.g. coatings used on pharmaceutical or veterinary products to control the release of an active ingredient after ingestion). Although the physical structure of these materials changes during use they are likely to retain their solid particulate state. In this case they are still considered as microplastics after swelling.

The generic view of the Dossier Submitter on swellable polymers was as mentioned above that these polymers do not fulfil the definition of a microplastic where they form gels in the presence of water (or other solvent) that are not particles. However, if the particulate and solid state is kept after swelling then they are still considered as microplastics as long as the size of the particle does not exceed the relevant dimensions. Therefore, the 'loss of particulate form' was originally considered to be the main parameter to decide on whether the swellable polymer is or is not covered by the regulatory definition.

This concept has been further considered after the submission of the Annex XV report. This elaborated interpretation considers the potential for the reversibility of swelling, and the resultant recurrence of a particle with physical properties consistent with a microplastic, under certain conditions. This is particularly relevant to the interpretation of the derogation described in paragraph 5(b) of the conditions of the restriction that requires the 'permanent modification' of the properties of a polymer at the point of use such that it would no longer be considered to be a microplastic.

During the consultation question arose on the particle definition for swellable polymers with regard to the degree of swelling i.e. how much do they need to swell before they are no longer particles (e.g. minute piece of matter with a defined interface)?

Gels, absorbing gels, water swellable polymer, hydrogel, polyelectrolyte gel, superabsorbents *etc*. all contain polymers (e.g. polyacrylates) that are capable of absorbing significant amounts of liquid (until reaching equilibrium). Liquid is strongly bound and is not released mechanically. During the process the polymer powder usually changes to a gel-like substance. Moreover the original shape of the particles may be kept but their dimension and rheological behaviour are changed (Frank, 2012). This application is used in products such as diapers, personal hygiene products *etc*.

The key to consider if these substances were in the scope of the current regulatory definition of microplastics in the Annex XV report was to assess the change from powder to gel-like structure, as well as the change of particles in terms of their dimensions after reaching equilibrium with liquid. In both cases the assessment should be considered on the particles in terms of change in physical state or dimension.

According to scientific literature described by Mudiyanselage and Neckers (2008) certain swollen SAPs retain their original spherical shape after absorbing water. Furthermore completely swollen polymeric particles will not necessary lose their "particulate form",

they will change density, mass, and the external size but may not change the physical form (Mech et al. JRC, 2019).

After all it is possible that the 'degree of swelling', such that the loss of particle form occurs, cannot be defined sufficiently precisely for all kinds of swellable polymers using reliable quantitative information that it could be used in a regulatory context.

Therefore, a pragmatic approach to determine whether a swellable polymer is in or out of the scope of microplastic restriction could be to assess the physical properties of the polymer before swelling.

In practice this would mean that if the polymer that is intended to be used as superabsorbent, hydrogel etc. is solid before swelling it is considered as microplastic. On the contrary, if the polymer has a liquid state (if such exists) before swelling, it would not be considered as a microplastic. That means the original physical state of the polymer as placed on the market would define if the swellable polymer in question is in or out of the scope of the restriction. This view has also been discussed with JRC and agreed as it can be one of the most appropriate ways for assessing these types of polymers.

In addition to this, during the discussion with experts from the EU JRC there was thought to be another way of looking at the swellable polymers. The concept of reversibility/irreversibility is relevant to consider when assessing these polymers. This means that if the swelling process is reversible (there loss of microplastic form is not permanent) than these polymers as placed on the market are in the scope of the restriction. The reversible swellability might depend on thermal conditions and the environmental compartment in which the particle will appear (water, soil etc.), it may release the solvent and go back to its original size or it may also take totally different size depending on the % of solvent it has released (Mech et al. JRC, 2019). For this reason it might be that the assessment of reswellable polymer particles in terms of a quantitative assessment of the size change to evaluate if such particle is still within the scope of the regulatory definition for microplastics is not feasible. Examples of such reswellable polymers are used in agriculture as water reservoirs. These polymers are designed to function over long time periods in the environment. On the other hand, if the swelling process is irreversible, which means once the liquid is taken up by the polymer (as placed on the market) after swelling it is strongly retained and is not released mechanically, these polymers might be derogated based on paragraph 5(b) as a permanent modification happened at point of use resulting in loss of microplastic form. This is valid provided that all other criteria of the regulatory definition has also been carefully assessed and not met.

According to all these considerations above, the most straightforward way to assess whether a swellable polymer particle is a microplastic would be based on the 'original' physical state of the polymer particle prior to swelling taking place.

Therefore, the Dossier Submitter considers that an assessment of whether a swellable polymer meets the conditions of the proposed restriction should, initially, be based on their original physical state of the polymer particle.

B.1.3.9. Natural polymer

In the initial Annex XV report, in paragraph 3(a) the term "*Polymers that occur in nature that have not been chemically modified (other than by hydrolysis)*" has been proposed.

This term has now been changed to "*Natural polymers (as defined in the REACH Guidance for monomers and polymers) that have not been chemically modified* (as defined in REACH Article 3(40)".

Substances which occur in nature are defined in REACH Article 3(39), which sets stringent requirements for the processes that can be used to obtain them, specifically: manual, mechanical, gravitational, dissolution in water, by floatation, by extraction by water, by steam distillation, or by heating (solely to remove water). By referring to 'occurring in nature' in paragraph 3 the Dossier Submitter have implicitly specified that only the above processes can be used to obtain them.

Whilst this is appropriate from the perspective of determining which substances should be subject, or not, to REACH registration, it may be too stringent for the purposes of the restriction (which is only interested in the nature of the polymer, not necessarily how it was obtained). Equally, a substance occurring in nature is by definition not chemically modified (apart from hydrolysis) as it can only be obtained by physical means or via processing with steam or water. Therefore, the reference to 'not chemically modified' in para 3(a) is redundant.

Alternatively, REACH Guidance on monomers and polymers defines 'natural polymers' as "polymers which are the result of a polymerisation process that has taken place in nature, independently of the extraction process with which they have been extracted". This means that natural polymers are not necessarily 'substances which occur in nature' when assessed according to the criteria set out in Article 3(39) of the REACH Regulation.

The definition of a natural polymer is closer to the original intention of the Dossier Submitter in paragraph 3(a), who had anticipated that any processing of a polymer obtained from nature could be derogated as long as it was 'not chemically modified'. Not chemically modified is set out in REACH Article 3(40) as "a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities".

Therefore, two potential options can be considered for revision:

A. Substances which occur in nature (as defined in REACH Article 3(39).

B. Natural polymers (as defined in REACH Guidance on monomers and polymers) that have not been chemically modified (as defined in REACH Article 3(40) other than by hydrolysis.

During the RAC-50 meeting (held on 11 September 2019) the criteria of "Natural polymers (as defined in REACH Guidance on monomers and polymers) that have not been chemically modified (as defined in REACH Article 3(40) (other than by hydrolysis)" has been proposed and discussed among the Committee members. The element of "other than by hydrolysis" has been questioned by the Commission and asked for clarification why hydrolysis would be allowed to be applied on the natural polymer.

The Dossier Submitter's intention was to allow the hydrolysis of natural polymers since during this process only the polymer chain is broken down (degrades) when the functional groups react with water, but no chemical modification is happening on the polymer chain itself. Such hydrolysis might also happen in nature when the polymer is taking up moisture or comes into contact with water in some ways. Depending on the chemical nature of the polymer (functional group, polymer structure, pH, morphology)

certain types react with water at a different (higher or lower) degree.

It is clear that additional conditions for the hydrolysis would be required to be defined for the hydrolysis which would add another complexity to the derogation therefore it was not further considered.

The derogation in paragraph 3(a) "natural polymers that have not been chemically modified" without the term "other than by hydrolysis" is fully in line with the plastic definition of the SUP Directive (2019/904) and the REACH Guidance on monomers and polymers that do not mention the term "hydrolysis". On top of this industry stakeholders have not commented the withdrawal of term "other than by hydrolysis" from the derogation (paragraph 3(a)). As a conclusion it might be seen by the industry as a positive change in the regulatory context.

Polymers which are the result of a polymerisation process that has taken place in nature can, by default, be considered to be inherently (bio)degradable in the environment and not contribute to the microplastic concern. Therefore, they should not be considered microplastics. This approach is consistent with Article 2(7)(a) and 2(7)(b) of REACH (as elaborated in Annexes IV and V). For the purpose of this restriction proposal the definition of natural polymer is as defined in the REACH Guidance on monomers and polymers (available at ECHA webpage) which defines 'natural polymers' as "polymers which are the result of a polymerisation process that has taken place in nature, independently of the extraction process with which they have been extracted".

Natural polymers that have been chemically modified in some respect (for example cross-linked) should be considered to be microplastics where they also meet the criteria for physical state, morphology and dimensions outlined in the sections below.

The relevance of the chemically modified natural polymers to the scope of the restriction will depend on (i) whether they are released to the environment under reasonably foreseeable conditions of use and (ii) if they are (bio)degradable (see below) provided the chemically modified natural polymer still fulfils the regulatory definition of microplastic.

The derogation in paragraph 3(a) "natural polymers that have not been chemically modified" are also elements of SUP Directive (2019/904). As the guidelines for SUP Directive is aimed at to be published in July 2020, there may be a need to ensure that alignment on the interpretation of these elements is made in both the Microplastic restriction and the SUP Directive.

B.1.4. (Bio)degradation of microplastics

The definition for different biodegradation processes can be found in several standard Test Guidelines. A context relevant definition for "biodegradation" is given for example in CEN/TR 15351 technical report on Plastics. Guide for vocabulary in the field of degradable and biodegradable polymers and plastic items

Biodegradation: degradation of a polymeric item due to cell-mediated phenomena

Aerobic biodegradation: biodegradation under aerobic conditions

Anaerobic biodegradation: biodegradation under anaerobic conditions

Biodegradable: status of a polymeric item that can be biodegraded

Degree of biodegradation: fraction of an original polymeric item that is biodegraded as measured through specified phenomena or techniques sensitive to mineral and biomass formation

Furthermore, EN ISO 14852:2018 and EN 13193 describes **ultimate aerobic degradation** as breakdown of an organic compound by microorganisms in the presence of oxygen into carbon dioxide, water and mineral salts of any other element present (mineralisation) plus new biomass. OECD TG 301 defines **ultimate biodegradation (aerobic)** as "The level of degradation achieved when the test compound is totally utilised by micro-organisms resulting in the production of carbon dioxide, water, mineral salts and new microbial cellular constituents (biomass)" and **primary biodegradation** as "The alteration in the chemical structure of a substance, brought about by biological action, resulting in the loss of a specific property of that substance".

According to OECD TG 301, **ready biodegradability** is an arbitrary classification of chemicals, which have passed certain specified screening tests for ultimate biodegradability. These tests are so stringent that it is assumed that such compounds will rapidly and completely biodegrade in aquatic environments under aerobic conditions. Furthermore, **inherently biodegradable** substances are classified as of chemicals for which there is unequivocal evidence of biodegradation (primary or ultimate) in any test of biodegradability.

In most cases, the regulatory assessment of biodegradability is focusing on aerobic degradation assessed by screening studies and/or higher tier studies measuring degradation rates. In the environment, abiotic degradation processes always accompany biodegradation and biodegradation can be either aerobic or anaerobic or combination of these.

The term "biodegradable" on its own without qualification of the timeframe or the environment where the degradation takes place means very little as, in principle, everything is (bio)degradable over sufficiently long time horizons. Given that one element of the concern is that "microplastics" persist in the environment, a derogation for polymers that demonstrate biodegradability in the relevant environment within a specific timeframe appears to be reasonable and would promote innovation to more sustainable materials in the medium to long-term, which is one of the objectives of the REACH regulation.

Currently there are no microplastics specific PASS/FAIL criteria for the screening of (bio)degradability (ready or inherent biodegradability) or (bio)degradation rates in relevant environmental compartments.

ISO 22403:2020 describes methods and criteria for the intrinsic (i.e. potential) biodegradability in marine environment of virgin plastic materials and polymers. Mineralisation of the whole test material or each individual constituent into carbon dioxide for at least 90 % or for the same extent of the reference material within 2 years is considered a positive results of ISO 18830, ISO 19679, ISO22404, ASTM D6691-17, ISO 23977-1:-, or ISO 23977-2:-.

As for biodegradable plastics, pass or fail criteria for biodegradability are established for compostable plastic (EN 13432:2000) and mulching films (EN 17033:2018). EN 13432 defines biodegradable plastics in the context of the Directive on Packaging and Packaging Waste (94/62/EC) that gives the requirements for packaging to be considered

recoverable. Plastics used in packaging need to fulfil the specifications of the standard EN 13432:2000 "Packaging: Requirements for packaging recoverable through composting and biodegradation". Biodegradable plastic needs to fulfil three criteria to be accepted as compostable;

- Biodegradation under composting conditions (mineralisation) should be 90% of the degradation of a positive control within a maximum of 6 months.
- Disintegration demonstrated as 10 % of material fragments (residues) are allowed to be larger than 2 mm.
- Absence of any negative effect on the composting process.

EN 17033 specifies the requirements for biodegradable films, manufactured from thermoplastic materials, to be used for mulch applications in agriculture and horticulture. It is applicable to films intended to biodegrade in soil without creating any adverse impact on the environment. It also specifies the test methods to assess these requirements as well as requirements for the packaging, identification and marking of films. The material of the mulch film is considered to have demonstrated a satisfactory rate and level of biodegradation in soil if; a) when tested in accordance with EN ISO 17556, it achieves a minimum biodegradation percentage as specified hereunder within a test period no longer than 24 months; and b) 90 % of the organic carbon shall have been converted to CO_2 by the end of the test period (relative to a reference material or [c] in absolute terms). In addition to the degradability, evaluation criteria have been established on ecotoxicity, film properties, and constituents of the biodegradable mulch films.

In addition, the fertilising products Regulation (EU) No 2019/1009 states that "*By 16 July 2024, the Commission shall assess biodegradability criteria for polymers referred to in point 2 of component material category 9 in Part II of Annex II and test methods to verify compliance with those criteria and, where appropriate, shall adopt delegated acts pursuant to paragraph 1 which lay down those criteria.*

Such criteria shall ensure that:

(a) the polymer is capable of undergoing physical and biological decomposition in natural soil conditions and aquatic environments across the Union, so that it ultimately decomposes only into carbon dioxide, biomass and water;

(b) the polymer has at least 90 % of the organic carbon converted into carbon dioxide in a maximum period of 48 months after the end of the claimed functionality period of the EU fertilising product indicated on the label, and as compared to an appropriate standard in the biodegradation test; and

(c) the use of polymers does not lead to accumulation of plastics in the environment."

CMC 9(2): further specifies that "From 16 July 2026, the polymers referred to in point 1(a) and (b) shall comply with the biodegradability criteria established by delegated acts referred to in Article 42(6). In the absence of such criteria, an EU fertilising product placed on the market after that date shall not contain such polymers."

There are also criteria for set biodegradability for different types of organic substances in REACH Regulation 1907/2006, Plant protection products Regulation (EC) No 1107/2009 and Detergents Regulation 648/2004/EC.

Furthermore, there is certification for biodegradability in a "natural freshwater environment", marine, soil and compost are established by TÜV AUSTRIA (http://www.tuv-at.be/home/). For example Biodegradable WATER is with requirement to exhibit a biodegradation rate of 90% within 56 days at temperatures of 20–25°C and for marine environment to exhibit a biodegradation rate of 90% following 6 months exposure.

Table 3 presents in more detail existing criteria for biodegradability/persistence specified under following regulations:

- REACH Regulation 1907/2006;
- Fertilisers Regulation (EC) No 2003/2003 relating to fertilisers;
- Fertilising product Regulation (EU) No 2019/1009;
- Plant protection products Regulation (EC) No 1107/2009 ;
- Packaging and packaging waste Directive 94/62/EC;
- Detergents 648/2004/EC Detergents containing surfactants.

Table 3: Criteria for biodegradability under REACH, Fertiliser regulation, detergents containing surfactants, plant protections products and compostable packaging materials.

Regulation	**Biodegradability criteria**	**Standard / test method**
REACH Regulation 1907/2006 Annexes VII-X Annex XIII	Ready biodegradability, inherent biodegradability, half-live in water (fresh, estuarine and marine), sediment (fresh, estuarine and marine), soil. Ready biodegradability (including modifications allowed in the respective TGs); ≥70% biodegradation measured as DOC removal (OECD TGs 301A, 301E and 306) or ≥60% biodegradation measured as ThCo2 (OECD TG 301B) or ThOD (OECD TGs 301C, 301D, 301F, 306 and 310) Inherent biodegradability; ≥70 % mineralisation (DOC removal) within 7 d; log phase no longer than 3d; removal before degradation occurs below 15%; no pre-adapted inoculum Annex XIII to the REACH Regulation is generally applicable to any substance containing an organic moiety. The PBT/vPvB criteria as set out in Annex XIII to the REACH Regulation. If based on the screening information (e.g. ready biodegradability or other screening tests) there is indication of P and vP properties further information (e.g. simulation tests to derive half-lives) needs to be generated. A substance fulfils the persistence criterion (P) in any of the following situations: (a) the degradation half-life in marine water is higher than 60 days; (b) the degradation half-life in fresh or estuarine water is higher than 40 days; (c) the degradation half-life in marine sediment is higher than 180 days; (d) the degradation half-life in fresh or estuarine water sediment is higher than 120 days; (e) the degradation half-life in soil is higher than 120 days. A substance fulfils the "very persistent" criterion (vP) in any of the following situations: (a) the degradation half-life in marine, fresh or estuarine water is higher than 60 days; (b) the degradation half-life in marine, fresh or estuarine water sediment is higher than 180 days; (c) the degradation half-life in soil is higher than 180 days.	OECD TG 301 A-F OECD TG 302B and 302C OECD 307 OECD 308 OECD 309

Regulation	Biodegradability criteria	Standard / test method
Regulation (EU) No 2019/1009	Preamble (60) An EU fertilising product can contain polymers other than nutrient polymers. However, this should be limited to cases where the purpose of the polymer is that of controlling the release of nutrients or increasing the water retention capacity or wettability of the EU fertilising product. It should be possible for innovative products containing such polymers to access the internal market. In order to minimise risks to human health, to safety or to the environment that may be posed by polymers other than nutrient polymers, the criteria for their biodegradability, so that they are capable of undergoing physical and biological decomposition, should be established. For that purpose, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of defining the criteria for the conversion of polymeric carbon into carbon dioxide and a related testing method. Polymers which do not comply with those criteria should be prohibited after a transitional period. Article 42. Amendment of Annexes By 16 July 2024, the Commission shall assess biodegradability criteria for polymers referred to in point 2 of component material category 9 in Part II of Annex II and test methods to verify compliance with those criteria and, where appropriate, shall adopt delegated acts pursuant to paragraph 1 which lay down those criteria. Such criteria shall ensure that: (a) the polymer is capable of undergoing physical and biological decomposition in natural soil conditions and aquatic environments across the Union, so that it ultimately decomposes only into carbon dioxide, biomass and water; (b) the polymer has at least 90 % of the organic carbon converted into carbon dioxide in a maximum period of 48 months after the end of the claimed functionality period of the EU fertilising product indicated on the label, and as compared to an appropriate standard in the biodegradation test; and (c) the use of polymers does not lead to accumulation of plastics in the environment. Article 50. Biodegradability review By 16 July 2024, the Commission shall carry out a review in order to assess the possibility of determining biodegradability criteria of mulch films, and the possibility of incorporating them into component material category 9 in Part II of Annex II. CMC 9: Polymers other than nutrient polymers. 1. An EU fertilising product may contain polymers other than nutrient polymers only in cases where the purpose of the polymer is: (a) to control the water penetration into nutrient particles and thus the release of nutrients (in which case the polymer is commonly referred to as a 'coating agent'), (b) to increase the water retention capacity or wettability of the EU fertilising product, or (c) to bind material in an EU fertilising product belonging to PFC 4. 2. From 16 July 2026, the polymers referred to in point 1(a) and (b) shall comply with the biodegradability criteria established by delegated acts referred to in Article 42(6). In the absence of such criteria, an EU fertilising product placed on the market after that date shall not contain such polymers. 3. For the polymers referred to in point 1(a) and (b), neither the polymer, nor its degradation by-products, shall show any overall	Methods to be developed

Regulation	Biodegradability criteria	Standard / test method
	adverse effect on animal or plant health, or on the environment, under reasonably foreseeable conditions of use in the EU fertilising product. […]	
Plant protection products Regulation (EC) No 1107/2009	Annex II • Procedure and criteria for the approval of active substances, safeners and synergists pursuant to Chapter II • An active substance, safener or synergist shall only be approved where it is not considered to be a persistent organic pollutant (POP) or PBT/vPvB. CHAPTER II Active substances, safeners, synergists and co-formulants 3.7 Fate and behaviour An active substance, safener or synergist shall only be approved where it is not considered to be a persistent organic pollutant (POP) 3.7.1.1. Persistence (POP) An active substance, safener or synergist fulfils the persistence criterion where there is evidence that the time it takes for a degradation of 50 % (DT50) in water is greater than 2 months, or that its DT50 in soil is greater than 6 months, or that its DT50 in sediment is greater than 6 months. 3.7.2.1. Persistence (P) An active substance, safener or synergist fulfils the persistence criterion where: — the half-life in marine water is higher than 60 days, — the half-life in fresh or estuarine water is higher than 40 days, — the half-life in marine sediment is higher than 180 days, — the half-life in fresh or estuarine water sediment is higher than 120 days, or — the half-life in soil is higher than 120 days. Assessment of persistency in the environment shall be based on available half-life data collected under appropriate conditions, which shall be described by the applicant. 3.7.3.1. Persistence (vP) An active substance, safener or synergist fulfils the 'very persistent' criterion where: — the half-life in marine, fresh- or estuarine water is higher than 60 days, — the half-life in marine, fresh- or estuarine water sediment is higher than 180 days, or — the half-life in soil is higher than 180 days.	OECD TG 301A-F OECD TG 310 OECD TG 307 OECD TG 308 OECD TG 309
Packaging and packaging waste Directive 94/62/EC Composability of plastic used as	Biodegradable and compostable plastic carrier bags EN 13432:2000 – "Packaging: requirements for packaging recoverable through composting and biodegradation" has three criteria for 'compostable' material; Biodegradation, disintegration and safety. Material needs to pass criteria set for these parameters to be 'compostable'. Biodegradability – Biodegradation under composting conditions	Standards for Compostable and biodegradable packaging EN 13432 (2000)

Regulation	Biodegradability criteria	Standard / test method
packaging and labelled as "compostable"	(mineralisation) should be 90% of the degradation of a positive control within a maximum of 6 months. • Disintegration –10 % of material fragments (residues) are allowed to be larger than 2 mm. Absence of any negative effect on the composting process.	
Detergents 648/2004/EC Detergents containing surfactants	Under this Regulation, surfactants and detergents containing surfactants that meet the criteria for ultimate aerobic biodegradation as laid down in Annex III may be placed on the market without further limitations relating to biodegradability. If a detergent contains surfactants for which the level of ultimate aerobic biodegradation is lower than that stipulated in Annex III, manufacturers of industrial or institutional detergents containing surfactants, and/or of surfactants for industrial or institutional detergents, may ask for derogation. Requests for derogation shall be made and decided in accordance with Articles 5, 6 and 9. The level of primary biodegradability shall be measured for all surfactants in detergents failing ultimate aerobic biodegradation tests. Detergent surfactants, for which the level of primary biodegradability is lower than that stipulated in Annex II, shall not be granted derogation. ▼**B** 2004R0648 — EN — 01.06.2015 — 007.001 — 10 Annex II – Primary degradation The pass criterion for primary biodegradability shall be a level of at least 80 %, as measured according to the test methods below. • OECD's technical report of 11 June 1976 on the 'Proposed Method for the Determination of the Biodegradability of Surfactants in Synthetic Detergents'. • The method published in the Journal officiel de la République française of 30 December 1987, p. 15385, and by the standard NF 73-260 of June 1981, published by the Association française de normalisation (AFNOR). • 'Verordnung über die Abbaubarkeit anionischer und nichtionischer grenzflächenaktiver Stoffe in Wasch- und Reinigungsmitteln' of 30 January 1977, published in the Bundesgesetzblatt of 1977, Part I, p. 244, as set out in the Regulation amending that Regulation of 4 June 1986, published in the Bundesgesetzblatt of 1986, Part I, p. 851. • 'Porous Pot Test' and described in Technical Report No 70 (1978) of the Water Research Centre. • The 'Confirmatory test procedure' in the OECD method, described in Annex VIII.1 (including possible changes in operating conditions as proposed in EN ISO 11733). This is also the reference method used for the settlement of litigation. • Analytical methods specified for different type of detergents. Annex III – Ultimate biodegradation Surfactants in detergents shall be considered as biodegradable if the level of biodegradability (mineralisation) measured according to one of the following tests is at least 60 % within 28 days A • EN ISO Standard 14593: 1999. Pre-adaptation is not to be used. The 10-day window principle is not applied (reference method).	Multiple test methods for primary degradation, inherent biodegradation and other additional methods

Regulation	Biodegradability criteria	Standard / test method
	• Directive 67/548/EEC method, Annex V.C.4-C (carbon dioxide (CO2) Evolution modified Sturm test): pre-adaptation is not to be used. The 10- day window principle is not applied. • Directive 67/548/EEC method, Annex V.C.4-E (closed Bottle): pre-adaptation is not to be used. The 10-day window principle is not applied. • Directive 67/548/EEC method, Annex V.C.4-D (manometric respirometry): pre-adaptation is not to be used. The 10-day window principle is not applied. • Directive 67/548/EEC method, Annex V.C.4-F (MITI): pre-adaptation is not to be used. The 10-day window principle is not applied. • ISO 10708:1997. Pre-adaptation is not to be used. The 10-day window principle is not applied. B • Depending on the physical characteristics of the surfactant, one of the methods listed below may be used if appropriately justified (2). It should be noted that the pass criterion of at least 70 % of these methods is to be considered as equivalent to the pass criterion of at least 60 % referred to in methods listed in point A. The adequacy of the choice of the methods listed below shall be decided on a case-by-case confirmation, in accordance with Article 5 of this Regulation. • Directive 67/548/EEC method, Annex V.C.4-A (dissolved organic carbon DOC die-away): pre-adaptation is not to be used. The 10-day window principle is not applied. • Directive 67/548/EEC method, Annex V.C.4-B (modified OECD screening-DOC die-away): pre-adaptation is not to be used. The 10-day window principle is not applied. Additional studies: • Pre-adapted inoculum - Any of the tests described in Annex III, may be run with pre adapted inoculum in order to provide evidence of the relevance of pre-adaptation for the surfactant. • Inherent Biodegradability Tests - At least one of the tests referred to below shall be included: o method of the Directive 67/548/EEC, Annex V.C.12 (Modified SCAS test), o method of the Directive 67/548/EEC, Annex V.C.9 (Zahn-Wellens). Failure to pass the inherent biodegradability test would indicate potential for persistency which may be considered, in general terms, as sufficient to prohibit the placing on the market of such a surfactant except in cases where the criteria set out in Article 6 indicate that there is no justification for refusing a derogation. • Activated Sludge Simulation Biodegradability Tests The following tests referred below shall be included: o method of the Directive 67/548/EEC, Annex V.C.10 (including possible changes in operating conditions as proposed in EN ISO 11733). Failure to pass the activated sludge simulation biodegradability test would indicate potential for the release of the metabolites by sewage treatment, which may be considered, in general terms, as evidence of need for a more complete risk assessment.	

B.1.4.1. Standards for (bio)degradation of plastic

Currently, there are no criteria for (bio)degradability or (bio)degradation rate of microplastics in the environment or standard test methods available targeted on measuring (bio)degradation of microplastics. However, there are several standard methods published for (bio)degradability of plastics and organic chemicals. Existing standards have been developed mainly by American Normative Reference (ASTM), European Normative Reference (EN), Organization for Economic Co-operation and Development (OECD), International Organization for Standardization (ISO) and Association Française de Normalisation (AFNOR).

Applicability of these standards have been extensively discussed by Eubeler et al. (2009), Harrison et al. (2018) and Kyrikou and Briassoulis (2007). Available standards are listed in Table 3 (not exclusive). These standard test guidelines provide methods to measure ready biodegradation, inherent biodegradation, and simulate degradation in different environmental compartments (water, sediment, seawater/sandy sediment interface, and soil) and process environments (sewage treatment plant, digester and compost). Methods cover ultimate and primary degradation both in aerobic and anaerobic conditions.

There are no international standardised higher tier test targeted for determining the half-life of plastics in different environmental compartments (freshwater, marine environment, soil or sediment). Methods available for plastics can be considered to provide screening level information for the assessment of ready biodegradability (ultimate degradation) and inherent biodegradation. Existing test methods for biodegradability of plastics primarily aim at assessing ultimate degradation. The test duration of these tests varies from 28 days to six months or even two years and in general aim to reach the maximum amount biodegradation until a plateau phase is reached.

Most of the methods targeted for plastic materials are applicable for wide variety of test material forms such as powdered plastic, films, pieces and fragments. Some protocols recommend to use plastic without any additives as a test material but most of the guidelines allow a broad range of test materials, including additive containing plastics, copolymers and polymer mixtures.

In general, the recommended range for the test temperature (15-28 °C) is limited to higher than average environmental temperature in the EU (9 °C in marine environment and 12 °C in freshwater environment and soil). Using a temperature close to room temperature corresponds to the screening level OECD 301/310 Technical Guidelines assessing ready biodegradability.

Scope of the most relevant standards in assessing the potential for aerobic biodegradation and the applicability for microplastics is discussed below.

B.1.4.2. Standards for organic substances:

OECD TG 301 A-F Ready Biodegradability includes six methods 301 A-F which permit the screening of chemicals for ready biodegradability in an aerobic aqueous medium. Ready biodegradability test based on DOC measurement (A and E) are not applicable for water-insoluble polymers and therefore from OECD TG 301 test series only those measuring evolved CO_2 or consumed O_2 should be used. The pass level for ready

biodegradability is 60% of ThOD (theoretical oxygen demand) or $ThCO_2$ production for respirometric methods within 28 days fulfilling the 10-day window at temperature of 22-25 °C. Tests may also be prolonged beyond 28 days when the curve shows that biodegradation has started but that the plateau has not been reached by day 28, but in such cases the chemical would not be considered to meet the criteria for ready biodegradability.

OECD TG 310 Ready Biodegradability – CO_2 in sealed vessels (Headspace Test) is a screening method for the evaluation of ready biodegradability of chemical substances and provides similar information to the six test methods described in OECD Test Guideline 301 A to F. Chemical substance that shows positive results can be considered readily biodegradable and consequently rapidly degradable in the environment. Ultimate degradation is measured as evolved CO_2, the DOC removal and/or the extent of primary biodegradation of the test substance can also be measured. The test is applicable to water-soluble and insoluble test substances, though good dispersion of the substance should be ensured. The inoculum may be derived from a variety of sources: activated sludge; sewage effluent (non-chlorinated); surface waters and soils; or from a mixture of these. Test is conducted in the dark at 20°C for 28 days. The pass level for ready biodegradability is 60% of $ThCO_2$ production in 28 days fulfilling the 10-day window.

In principle, ready biodegradability tests described above can be applied for microplastics as a screening study. Special attention should be paid on the dispersion of the microplastic to ensure that the test material is well mixed in the test media. Reaching the pass level within 10-day window would be challenging for biodegradable plastics.

Inherent biodegradability tests such as a Zahn-Wellens test (**OECD TG 302B**) or MITI II test (**OECD TG 302C**) may be used under REACH (ECHA Guidance R.11) to confirm that the substance does not fulfil the criteria for persistency provided that certain additional conditions are fulfilled. In the Zahn-Wellens test, a level of 70% mineralisation (DOC removal) must be reached within 7 days, the log phase should be no longer than 3 days, and the percentage removal in the test before degradation occurs should be below 15% (pre-adaptation of the inoculum is not allowed). In the MITI II test, a level of 70% mineralization (O_2 uptake) must be reached within 14 days, and the log phase should be no longer than 3 days (pre-adaptation of the inoculum is not allowed). A lack of degradation in an inherent biodegradation test (≤20%) can provide evidence that degradation in the environment would be slow. It should however be noted that the very low solubility may reduce their availability and hence their degradability in the test. The lack of degradation in an inherent test does not always imply that the substance is intrinsically persistent.

OECD TG 302B is applicable for chemicals which are non-volatile and are soluble in water to at least 50 mg DOC/l. Therefore, the method may not be applicable without any modifications for poorly soluble microplastics. **OECD TG 302C** might be more suitable option as it specifies that "*If the test material is not soluble at the test concentration, special measures, such as the use of ultrasound dispersion may have to be employed to achieve a good dispersion of the test material*".

OECD TG 304A Inherent biodegradability in soil is performed with ^{14}C-labelled test materials and it is applicable to volatile or non-volatile, soluble or insoluble compounds. This test in performed in the dark at 22°C for 32 days and if necessary maximum of 64 days. In principle **OECD 304A** would be applicable for microplastic. However, **ISO**

17556:2012 described below might be more relevant test as it is developed for assessing ultimate aerobic biodegradability of plastics materials in soil.

OECD TG 306 Biodegradability in Seawater provide information on the biodegradability in marine environment but is not to be taken as indicators of ready biodegradability or simulation of biodegradation in marine environment (higher tier). This TG provides two different methods to assess the ultimate biodegradability in sea water; the Shake flash method and Closed bottle test. Acceptable temperature range is 15-20°C and the degradation is followed over 28 days (Closed bottle test) or maximum of 60 days (Shake flask method). If the result is positive (>70% DOC removal; >60% ThOD - theoretical oxygen demand), it may be concluded that there is a potential for biodegradation in the marine environment. Shake flask method is not applicable for poorly soluble substances as solubility in water should be greater than the equivalent of 25-40 mg C/L. In the closed bottle test the solubility of the substance should be at least 2 mg/l, though in principle less soluble compounds could be tested (e.g. using ultra sonication) as could volatile compounds.

OECD TG 307 Aerobic and Anaerobic Transformation in Soil, OECD TG 308 – Aerobic and Anaerobic Transformation in Aquatic Sediment Systems and OECD TG 309 – Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test

Degradation simulation studies performed in appropriate environmental media and at environmentally relevant conditions are the only tests that can provide a definitive degradation half-life. The half-life can be compared directly to the persistence criteria as defined in REACH Annex XIII.

OECD TG 307 and OECD TG 308 evaluate aerobic and anaerobic transformation of chemicals in soil and aquatic sediment systems. These methods are applicable to all chemical substances (non-labelled or radiolabelled) for which an analytical method with sufficient accuracy and sensitivity is available. It is applicable to slightly volatile, non-volatile, water-soluble or water-insoluble compounds. The OECD TG 307 soil test should not exceed 120 days but when necessary the test can be continued for longer periods e.g. 6 or 12 months. OECD TG 308 test should normally not exceed 100 days (6), and should continue until the degradation pathway and water/sediment distribution pattern are established or when 90 % of the test substance has been removed by transformation and/or volatilisation. The appropriate test temperature is 20 ± 2 °C but TGs allow also testing in lower temperatures e.g. 10 °C). OECD TG 309 is not applicable without modification for poorly soluble substances. Low test concentrations in µg/L range are preferred. For the determination of biodegradation kinetics, the concentrations of the test substance must be below its water solubility. If simulation tests are applied for microplastics, poorly soluble particles, the test results should be interpreted with caution and half-life should be estimated with care when the particle size (surface area) is a degradation rate-limiting factor and the degradation is not following the first order kinetics.

B.1.4.3. Standards for biodegradability of plastics

ISO 14851:2019 Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium — Method by measuring the oxygen demand in closed respirometer

This document specifies a method, by measuring the oxygen demand in a closed respirometer, for the determination of the degree of aerobic biodegradability of plastic materials, including those containing formulation additives. The test material is exposed in an aqueous medium under laboratory conditions to an inoculum from activated sludge. If an unadapted activated sludge is used as the inoculum, the test simulates the biodegradation processes which occur in a natural aqueous environment; if a mixed or pre-exposed inoculum is used, the method is used to investigate the potential biodegradability of a test material. Test shall be conducted within a temperature range preferably between 20 °C and 25 °C.

The biodegradation is determined by comparing the BOD with the theoretical amount (ThOD). The result is the maximum level of biodegradation determined from the plateau phase of the biodegradation curve. In addition, a carbon balance may be calculated. The maximum duration of the test is 6 months. At the end of the test, reference material should have been mineralised more than 60%.

The method applies to natural and/or synthetic polymers, copolymers or mixtures thereof; plastic materials which contain additives such as plasticizers, colorants or other compounds; water-soluble polymers; materials which, under the test conditions, do not inhibit the microorganisms present in the inoculum.

The test material should contain sufficient carbon to yield a BOD that can be measured, at least 100 mg/L and preferable be in powder form, but films, pieces, fragments and shaped articles can also be used.

Aniline and/or a well-defined biodegradable polymer (for example microcrystalline cellulose powder, ashless cellulose filters or poly-β-hydroxybutyrate) can be used as a reference material and non-biodegradable polymer (e.g. polyethylene) as negative control. If possible, the TOC, form and size should be comparable to that of the test material.

ISO 14852:2018 Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium — Method by analysis of evolved carbon dioxide

This document specifies a method, by measuring the amount of carbon dioxide evolved, for the determination of the degree of aerobic biodegradability of plastic materials, including those containing formulation additives. The test material is exposed in a synthetic medium to an inoculum from activated sludge, mature compost or soil under aerobic, mesophilic conditions. If an un-adapted activated sludge is used as the inoculum, the test result can be used to assess the aerobic biodegradation processes which occur in a wastewater treatment plant environment. If a mixed or pre-exposed inoculum is used, the method can be used to investigate the potential biodegradability of a test material. Incubation shall take place at the temperature range preferably from 20 °C to 25 °C.

The method enables the assessment of the biodegradation to be improved by calculating a carbon balance. The method applies to natural and/or synthetic polymers, copolymers or mixtures thereof; plastic materials which contain additives such as plasticizers, colorants or other compounds; water-soluble polymers; materials which, under the test conditions, do not inhibit the microorganisms present in the inoculum. The test material should preferable be in powder form but for example pieces and fragments can also be

used. Well-defined biodegradable polymer (microcrystalline- cellulose powder, cellulose filter or poly(β-hydroxybutyrate) are used as used as reference material and non-biodegradable polymer (e.g. polyethylene) as negative control. The form of the test materials should be comparable. When constant level of carbon dioxide is reached, the test can be completed. The maximum duration of the test is 6 months. At the end of the test, reference material should have been mineralised more than 60%.

Both ISO 14851 and ISO 14852, summarised above, describe a biodegradation test conducted in aquatic test media. Both methods may be performed to investigate the potential biodegradability of a plastic material. Inoculum in ISO 14851 is preferable activated sludge as ISO 14852 includes also a possibility to use mixed inocula (activated sludge, mature compost or soil). Standards differ in the method for detection of the biodegradation process, one being based on measuring the oxygen demand and the other analysis of evolved carbon dioxide.

EN 17033:2018 Plastics - Biodegradable mulch films for use in agriculture and horticulture - Requirements and test methods

This document specifies the requirements for biodegradable films, manufactured from thermoplastic materials, to be used for mulch applications in agriculture and horticulture. This document is applicable to films intended to biodegrade in soil without creating any adverse impact on the environment. It also specifies the test methods to assess these requirements as well as requirements for the packaging, identification and marking of films. For information, it defines a classification of biodegradable mulch films according to their service life on soil and gives a good practice guide for the use of the films. NOTE that films intended to be removed after use and not incorporated in the soil are not in the scope of this standard. They are in the scope of EN 13655.

The material of the mulch film is considered to have demonstrated a satisfactory rate and level of biodegradation in soil if:

a) when tested in accordance with EN ISO 17556 (see below), it achieves a minimum biodegradation percentage as specified hereunder within a test period no longer than **24 months;**

b) **90 % of the organic carbon shall have been converted to CO2** by the end of the test period (relative to a reference material). Both the reference material and the test item shall be tested for the same length of time and the results compared at the same point in time after the activity of both has reached a plateau;

c) as an alternative, 90 % (in absolute terms) of the organic carbon shall have been converted to carbon dioxide by the end of the test period.

Test environment: temperature constant to within ± 2 °C in the range between 20 °C and 28 °C, preferably 25 °C.

Use as reference material a well-defined biodegradable polymer [microcrystalline-cellulose powder, ashless cellulose filters or poly(3-hydroxybutyrate)]. If possible, the physical form and size of the reference material should be comparable to that of the test material.

The validity criteria of the results as stated in EN ISO 17556 (Plastics -- Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved) shall be fulfilled.

The ultimate aerobic biodegradability shall be determined for the whole material or for each organic constituent. Organic constituents which are present at concentrations of less than 1 % do not need to demonstrate biodegradability. However, the sum of such constituents shall not exceed 5 %.

From a precautionary perspective the material of the mulch film under investigation shall not contain substances of very high concern (SVHC)

a) that exceed a concentration limit of 0,1 % (by weight) in the material of the mulch film,

and

b) which appear on the Candidate List of substances of very high concern for Authorization

Carbon black is an inert solid. Therefore, it is not considered as an organic constituent and shall not be accounted in the calculation of the degree of biodegradation.

Inorganic carbon coming from black masterbatches, if any, or from mineral fillers, e.g. calcium carbonate, if any, shall not be accounted in the calculation of the degree of biodegradation.

ISO 17556:2012 Plastics-Determination of the ultimate aerobic biodegradability of plastics materials in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved

The scope of this method is to determine the ultimate aerobic biodegradation of plastic materials in soil by measuring the oxygen demand or the amount of evolved carbon dioxide at the temperature range preferably from 20 °C to 28 °C, preferable 25 °C. Non-adapted soil is used as an inoculum. Method is applicable for natural and/or synthetic polymers, co-polymers and mixtures if these, plastic materials with additives and water soluble polymers. Well-defined biodegradable polymer (microcrystalline- cellulose powder, cellulose filter or poly(β-hydroxybutyrate) are used as used as reference material and non-biodegradable polymer (e.g. polyethylene) as negative control. The test should typically not exceed six months but if the plateau phase has not been reached, the test may be extended up to 2 years. In principle, this method can be applied for microplastics as a screening study if the test material and the reference material are in the same form and have corresponding surface area.

EN ISO 19679:2016 Plastics -- Determination of aerobic biodegradation of non-floating plastic materials in a seawater/sediment interface -- Method by analysis of evolved carbon dioxide

The scope of this test is to determine the degree and rate of aerobic biodegradation of plastic materials when settled on marine sandy sediment at the interphase between seawater and the seafloor, by measuring the evolved carbon dioxide at the temperature range preferably from 15 °C to 25 °C, not exceeding 28 °C. Test material is preferably film or sheet but test material may also be introduced as a powder. Cellulose filter is used as reference material and non-biodegradable polymer (e.g. polyethylene) as negative control. The degree of biodegradation of the reference material should be >60% after 180 days. Maximum test duration is 24 months. In principle, this method can be applied for microplastics as a screening study if the test material can be settled on top of the sediment, floating of the material can be avoided and if the test material and the

reference material are in the same form and corresponding surface area.

ISO 22404:2019 Plastics - Determination of the aerobic biodegradation of non-floating materials exposed to marine sediment.

The scope of this test is to determine the degree and rate of aerobic biodegradation of plastic materials when exposed to marine sediment, by measuring the evolved carbon dioxide at the temperature range preferably from 15 °C to 25 °C, not exceeding 28 °C. Test material is preferably powder, but test material may also be introduced as a film or sheet. Microcrystalline cellulose or ashless cellulose filter is used as reference material and non-biodegradable polymer (e.g. polyethylene) as negative control. The degree of biodegradation of the reference material should be >60% after 180 days. Maximum test duration is 24 months. In principle, this method can be applied for microplastics.

ISO 22403:2020 Plastics — Assessment of the intrinsic biodegradability of materials exposed to marine inocula under mesophilic aerobic laboratory conditions — Test methods and requirements

This document describes testing scheme with test methods and criteria for showing intrinsic biodegradability in marine environments of virgin plastic materials and polymers without any preliminary environmental exposure or pre-treatment. All listed test methods are based on measuring ultimate biodegradation in mesophilic and aerobic conditions; ISO 18830, ISO 19679, ISO22404, ASTM D6691-17, ISO 23977-1, or ISO 23977-2. Standard defines criteria for reaching a positive biodegradation result but tests do not provide sufficient information for determining the specific biodegradation rate. To be considered susceptible to biodegradation by marine microorganisms test item or each individual constituent should mineralize into carbon dioxide for at least 90 % or for the same extent of the reference material within 2 years. Biodegradability of organic constituents at a concentration between 1% and 15 % should be tested separately.

Table 4: Biodegradability standards for plastics and organic chemicals (not exclusive).

STANDARD	TITLE	CONDITION	ENVIRONMENTAL COMPARTMENT
PLASTICS			
ISO 10210:2012	Plastics — Methods for the preparation of samples for biodegradation testing of plastic materials		General
ISO 13975:2012	Plastics — Determination of the ultimate anaerobic biodegradation of plastic materials in controlled slurry digestion systems — Method by measurement of biogas production	Anaerobic	Digestion
ISO 14851:2019	Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium — Method by measuring the oxygen demand in a closed respirometer	Aerobic	Aqueous
ISO 14852:2018	Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium — Method by analysis of evolved carbon dioxide	Aerobic	Aqueous
ISO 14853:2016	Plastics — Determination of the ultimate anaerobic biodegradation of plastic materials in an aqueous system — Method by measurement of biogas production	Anaerobic	Aqueous
ISO 14855-1:2012	Determination of the ultimate aerobic biodegradability of plastic materials under controlled composting conditions — Method by analysis of evolved carbon dioxide — Part 1: General method	Aerobic	Compost
ISO 14855-2:2018	Determination of the ultimate aerobic biodegradability of plastic materials under controlled composting conditions — Method by analysis of evolved carbon dioxide — Part 2: Gravimetric measurement of carbon dioxide evolved in a laboratory-scale test	Aerobic	Compost
ISO 14987	Plastics — Determination of the ultimate anaerobic biodegradation of plastic materials in an aqueous system — Method by measurement of biogas production	Anaerobic	Aqueous
ISO 15985	Plastics — Determination of the ultimate anaerobic biodegradation and disintegration under high-solids anaerobic-digestion conditions — Method by analysis of released biogas	Anaerobic	Digestion
ISO 16929:2013 **ISO/DIS 16929**	Plastics — Determination of the degree of disintegration of plastic materials under defined composting conditions in a pilot-scale test	Disintegration	Compost

STANDARD	TITLE	CONDITION	ENVIRONMENTAL COMPARTMENT
ISO 17088	Specifications for compostable plastics	-	General
ISO 17556:2012 **ISO/DIS 17556**	Plastics-Determination of the ultimate aerobic biodegradability of plastics materials in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved	Aerobic	Soil
ISO 18830:2016	Plastics — Determination of aerobic biodegradation of non-floating plastic materials in a seawater/sandy sediment interface — Method by measuring the oxygen demand in closed respirometer	Aerobic	Seawater/ sediment interface
ISO 19679:2017	Plastics -- Determination of aerobic biodegradation of non-floating plastic materials in a seawater/sediment interface -- Method by analysis of evolved carbon dioxide	Aerobic	Seawater/ sediment interface
ISO 22403:2020	Plastics — Assessment of the intrinsic biodegradability of materials exposed to marine inocula under mesophilic aerobic laboratory conditions — Test methods and requirements	Aerobic	Umbrella document for intrinsic biodegradation in marine environment
ISO 22404:2019	Plastics - Determination of the aerobic biodegradation of non-floating materials exposed to marine sediment - Method by analysis of evolved carbon dioxide	Aerobic	Marine sediment
ISO/CD 23977 **DRAFT**	Plastics - Determination of the aerobic biodegradation of plastic materials exposed to seawater Part 1: Method by analysis of evolved carbon dioxide Part 2: Method by measuring the oxygen demand in closed respirometer;	Aerobic	Seawater
ASTM			
ASTM D5511 - 18	Standard Test Method for Determining Anaerobic Biodegradation of Plastic Materials Under High-Solids Anaerobic-Digestion Conditions	Anaerobic	Digestion
ASTM D5338 - 15	Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials Under Controlled Composting Conditions, Incorporating Thermophilic Temperatures	Aerobic	Compost
ASTM D5526 - 18	Standard Test Method for Determining Anaerobic Biodegradation of Plastic Materials Under Accelerated Landfill Conditions	Anaerobic	Landfill

STANDARD	TITLE	CONDITION	ENVIRONMENTAL COMPARTMENT
ASTM D5988 - 18	Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials in Soil	Aerobic	Soil
ASTM D6691-17	Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials in the Marine Environment by a Defined Microbial Consortium or Natural Sea Water Inoculum	Aerobic	Pre-selected strains or seawater Max 3 months, 30 °C
ASTM D7473-12	Standard Test Method for Weight Attrition of Plastic Materials in the Marine Environment by Open System Aquarium Incubations	Aerobic	Seawater or a Seawater/sediment Max 6 months, variable temp in situ
ASTM D7991-15	Standard Test Method for Determining Aerobic Biodegradation of Plastics Buried in Sandy Marine Sediment under Controlled Laboratory Conditions	Aerobic	Sediment and seawater Max 24 months, 15-28 °C
EN 14987:2006	Plastics. Evaluation of disposability in waste water treatment plants. Test scheme for final acceptance and specifications	Aerobic	Waste water treatment plant
MULCHING FILMS			
EN 17033:2018	Plastics - Biodegradable mulch films for use in agriculture and horticulture - Requirements and test methods **EN ISO 17556** Plastics -- Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved	Aerobic	Soil
AFNOR NF U 52-001	Biodegradable mulching film: Test Methods and Criteria	Aerobic Ecotoxicity	Soil or Aqueous
PACKAGING MATERIALS			
EN 13432:2000	"Packaging: requirements for packaging recoverable through composting and biodegradation"	Aerobic, Disintegration	Compost

STANDARD	TITLE	CONDITION	ENVIRONMENTAL COMPARTMENT
	Includes three criteria for 'compostable' material; Biodegradation, disintegration and safety. Material needs to pass criteria set for these parameters to be 'compostable'.		
ORGANIC CHEMICALS			
OECD 301 A-F	Ready biodegradability	Aerobic	Aquatic
OECD TG 310	Ready Biodegradability – CO2 in sealed vessels (Headspace Test)	Aerobic	Aquatic
OECD TG 302B	Zahn-Wellens/EMPA Test	Aerobic	Aquatic
OECD TG 302C	Inherent Biodegradability: Modified MITI Test (II)	Aerobic	Aquatic
OECD TG 304A	Inherent biodegradability in soil	Aerobic	Soil
OECD TG 306	Biodegradability in sea water Shake flask and Closed bottle	Aerobic	Aquatic (sea water)
OECD TG 314	Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater A Biodegradation in a sewer system test B Biodegradation in activated sludge test C Biodegradation in anaerobic digested sludge test D Biodegradation in treated effluent-surface water mixing zone test E Biodegradation in untreated effluent-surface water mixing zone test	Aerobic Anaerobic	WWTP and mixing zone
OECD TG 307	Aerobic and anaerobic transformation in soil	Aerobic	Soil
OECD TG 308	Aerobic and Anaerobic Transformation in Aquatic Sediment Systems	Aerobic and anaerobic	Sediment
OECD TG 309	Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test	Aerobic	Aquatic

STANDARD	TITLE	CONDITION	ENVIRONMENTAL COMPARTMENT
MARINE BODIS	Biodegradability of Insoluble Substances (BODIS) in Seawater	Aerobic	Aquatic (sea water)

B.1.4.4. Evaluation of Dossier Submitter's proposal for biodegradation by RAC

RAC Box:

This section summaries further details of the RAC evaluation of the Dossier Submitter's approach for the derogation of biodegradable polymers.

Table 5: RAC biodegradability scenario 1 - Dossier Submitter's proposal

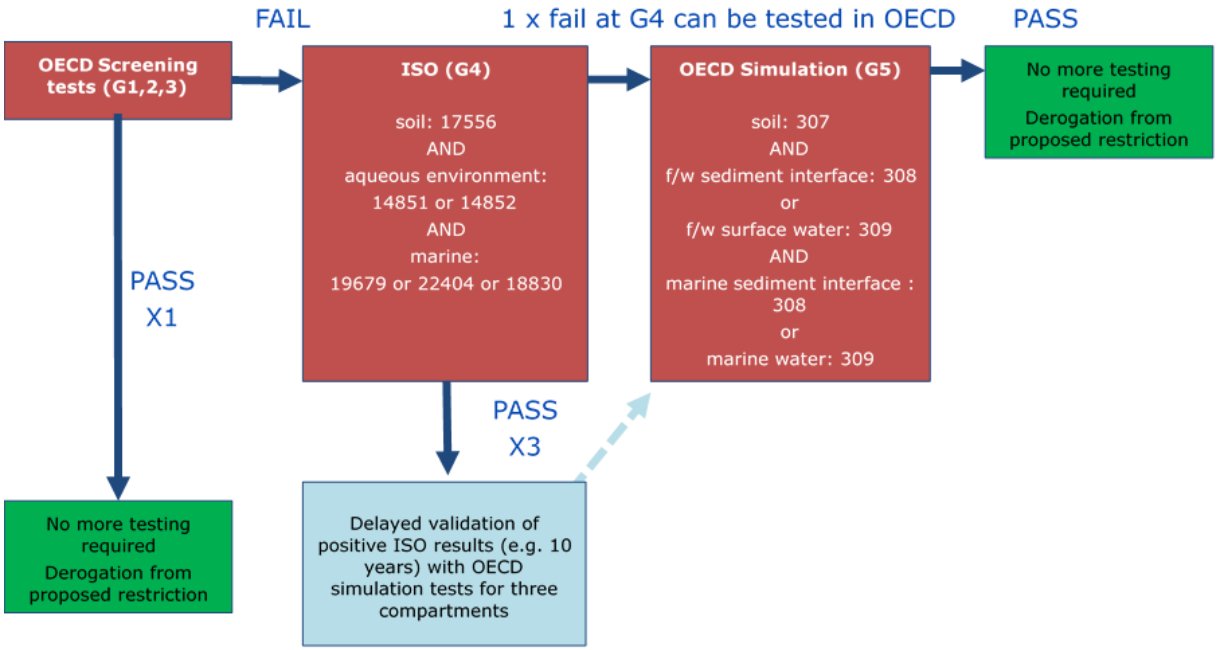
Element to evaluate	1. Dossier Submitter's proposal
Summary of scenario	The Dossier Submitter's proposal (detailed in Table 22 of the Background Document) requires that a microplastic achieve the pass criteria in one of the listed test methods to be derogated from the proposed restriction. Where microplastics are deliberately applied to soil or foliage (e.g. controlled-release fertilising products) test methods applicable to this compartment shall be used. The test material (including additives and other substances were relevant) should be comparable to either (i) the particles produced, or if not technically feasible, (ii) the particles released at the point of use. Where the test material consist of more than one polymeric component (i.e. it is a blend), in addition to demonstrating the (bio)degradation of the microplastic, the biodegradation potential of each of the polymeric components in the blend must also be demonstrated. Tests shall be conducted by laboratories accredited to ISO 17025 or certified to GLP.
Advantages	The proposal is straightforward with clear 'exit' criteria; achieving the pass criteria in any of the permitted test methods specified in groups 1 to 5 is sufficient to demonstrate that a test material should be derogated from the restriction. G1,2,3 and 5 contain the tests already used for assessing biodegradability under REACH and CLP regulations and, therefore, there is extensive experience of their performance (for soluble substances at least). G4 contains a group of tests specifically developed for plastics, which are assumed to be well suited for testing the biodegradation behaviour microplastics. The producer of the microplastic can choose from a range of different test methods based on the properties of the microplastic and how (and where) they are used (a soil-specific test in groups 4/5 is required if the microplastic is intended to be directly applied to soil or foliage). The inclusion of relatively conservative, but simple/rapid, screening tests in groups 1 to 3 of the scheme means that longer term testing will not be needed in all cases if a test material can achieve the pass criteria for these tests (but it is acknowledged that the pass criteria for these tests will be too stringent for many microplastic test materials). Therefore, the time and resources necessary to demonstrate that a polymer is derogated from the proposed restriction can be limited in some cases. The simplicity of the proposal provides certainty and at least some predictability for manufacturers and users of microplastics, therefore presumably supporting innovation to biodegradable alternatives to persistent microplastics. The requirement for ISO 17025 or GLP quality assurance ensures that the data generated will be reliable and reported in sufficient clarity for enforcement to take place.

Element to evaluate	1. Dossier Submitter's proposal
Disadvantages	The disadvantages of the Dossier Submitter's proposal can be grouped as follows: 1. Comparability, in terms of underlying rationale, of the different test methods 2. Adequate consideration of relevant environmental compartments and conditions 3. Requirement for case-by-case testing *Comparability, in terms of underlying rationale, of the different test methods* With the exception of the group 5 (OECD simulation) tests, the pass criteria of the different tests are not directly related to the environmental half life values used to define environmental persistence of concern under REACH (i.e. P and vP criteria included in Annex XIII of REACH). Instead, the test methods are used to demonstrate that test materials are either (i) sufficiently rapidly biodegradable that they can be assumed to not be persistent in the environment under any conditions (G1,2,3 screening tests) or (ii) that they have inherent biodegradation potential similar to reference materials that are 'generally regarded as biodegradable' e.g. cellulose (G4 ISO tests) . Therefore, it is clear that the different test methods do not provide equivalent information and are not directly comparable to one another, despite all being used to justify derogation. Whilst the pass criteria associated with the indirect assessments performed in the screening tests included in G1,2,3 are generally accepted to mean that a test material would not be persistent in the environment (as measured against the criteria in Annex XIII of REACH), the relevance of the indirect assessment of biodegradation performance relative to a reference material, at least in relation to the P and vP criteria in Annex XIII of REACH, in the group 4 tests is not known. Although G4 tests provide relevant information, the comparability of the results of the G4 tests with the results of other tests is challenging as there is no common reference point between them and the other tests. Achieving the pass criteria in an ISO test would mean that a material has similar biodegradation behaviour as a biodegradable reference substance (under the conditions of the test) but its degradation half-life in the environment would not be known. The implications of this, from the perspective of ensuring that derogated materials do not persist over the long-term in the environment (one of the key microplastic concerns), is not fully clear. Although relatively standard for the assessment of soluble substances, there is limited practical experience of performing G5 tests with microplastics. It is also pertinent to note that the availability and practicality of undertaking G5 tests with microplastics (non-soluble particulate test materials) should not be assumed. *Adequate consideration of relevant environmental compartments* Where G4 and G5 tests are used to demonstrate biodegradability (i.e. the pass criteria in G1,2 and 3 tests cannot be achieved), and with the exception of the requirements for microplastics applied to soil or foliage, as only a single passing test is required it is possible that a producer would choose the test where the MP is most likely to pass, without due consideration of the compartment's relevance (e.g., a material may be more likely to pass a terrestrial compartment test but is released to the environment via the aquatic compartment). Equally, as the fate and behaviour of microplastics in the environment are likely to result in them being transferred between compartments after they are released, the appropriateness of requiring testing G4 or G5 tests for only a single compartment can be considered to have questionable effectiveness (in terms of the objective of the derogation) as microplastics may not achieve pass criteria (and could therefore be very persistent) in other relevant compartments.

Element to evaluate		1. Dossier Submitter's proposal
		Requirement for case-by-case testing The Dossier Submitter's proposed requires case-by-case assessment of all of the different microplastics that are placed on the market. Given the large number of potential microplastic formulations (polymers + additives) this could require large amounts of testing to be undertaken.
Uncertainties		MPs derogated using ISO tests are inherently biodegradable, but the tests do not give an indication of environmental half life. Furthermore, by passing only a single test from groups 4 and 5 (representing one environmental compartment), the microplastic may be derogated, but it may not degrade sufficiently quickly across all relevant compartments. In addition, the applicability of P and vP criteria to particulate materials is subject to uncertainty (P and vP criteria were calibrated for soluble chemicals) and will, in all likelihood, be challenging to achieve for particulate materials, even particulate materials of reference materials such as cellulose (depending on particle size).
REACH Action 10 uncertainties	**(i) what information is needed to address the uncertainties**	There is a need for a comparative study or studies on the relationship between testing approaches underpinned by using a reference material and those using radiolabelled material to establish environmental half lives. The results of the comparison will shed light on the environmental relevance of both ISO-tests and G5 tests undertaken using particulate test materials. Information on the performance of particulate reference materials in G5 testing (relative to Annex XIII P and vP criteria).
	(ii) the timeline for generating such information, who could generate the data	As both ISO and OECD simulation tests are relatively long to perform (6 months to two years), it may take 5-10 years (assuming funding) to get sufficient data. Industry is most likely to be able to design such a project considering their access to relevant microplastic test materials. However, in this scenario, Industry is not under obligation to produce these data.
Relevance to the environment (level of protection / effectiveness / probability that persistent MPs used/released)		Passing this scenario will ensure that the microplastic has an inherent possibility to be biodegrade. However, the rate of biodegradation in the environment is unclear if the derogation is based on passing a G4 test (the test compares biodegradation with that of a reference substance), and if derogated based on G4 or G5 tests in one compartment, the overall biodegradation across different environmental compartments (the overall environment) is unclear. Thus, although ensuring biodegradation would be likely to occur in at least some environmental compartments, the proposal **may not ensure that all derogated materials would biodegrade in all relevant environmental compartments**.
Practicality, including enforceability		The tests are already performed, so the main practical problem concerns the long testing duration of the group 4 and 5 tests and the lack of experience of testing microplastic test materials in G5 simulation tests, including the feasibility of synthesising radio-labelled polymers/microplastics**.** The scenario is enforceable, but it requires experience in assessing the outcome of the biodegradation tests that the derogation is based on.

Element to evaluate	1. Dossier Submitter's proposal
Stringency	**Not very stringent.** As only a single test needs to be passed (including at G4/G5).
Conclusion	**The proposal provides clarity to industry and enforcement authorities, but may not fully prevent derogated materials contributing to the microplastic concern as although derogated materials are demonstrated to biodegrade in one compartment they may not degrade sufficiently rapidly in all environmental compartments.**

Table 6: RAC biodegradability scenario 2 – RAC-52 proposal

Element to evaluate	2. RAC-52 proposal
Summary of scenario	Modified Dossier Submitter proposal: - Tests included in G1,2,3 and Dossier Submitter's proposal - G4 testing modified to require a pass in three ISO tests with derogation conditional on also achieving a pass in three (G5) OECD simulation studies against P half-life (within 10 years from placing MP on the market). - Intended to be time limited (could be reviewed if sufficient information/understanding is achieved or if sufficient information/understating is available from another source). 
Advantages	- This scheme offers high level of environmental protection by explicitly addressing relevant identified uncertainties within the scheme itself: - Comprehensive testing requirement ensures protection of all environmental compartments - Uncertainties are addressed by those undertaking to place biodegradable polymers on the market (consistent with the principle of the reversal of the burden of proof under REACH)-

Element to evaluate		2. RAC-52 proposal
		- The specificity of microplastics acknowledged with the integration of G4 tests - Addresses ISO tests uncertainties and the transferability of their results to the environment with the inclusion of OECD simulation testing and a requirement to test all compartments. - Relevant for either P or vP evaluation (or other pass/fail criterion) since DT50 is obtained - Would avoid the placing on the market of materials that may achieve the pass criteria in G4 (ISO tests) but would not degrade sufficiently rapidly in the environment to avoid a microplastic stock in the environment - Allows sufficient time for the development of technical expertise and capacity to perform the G5 tests with microplastics by only requiring these tests to be performed after an extended period after placing a G4 derogated microplastic on the market.
Disadvantages		- Assumes that G5 tests and pass criteria based on P/vP are appropriate to address the microplastic concern and will be technically possible to perform as they are mandatory if G1,2,3 tests pass criteria are not met (i.e. feasibility to radiolabel polymers/microplastics), whilst this is subject to considerable uncertainty. - Many (at least 6) relatively long tests are required if G1,2,3 pass criteria cannot be achieved and thus a long time period is necessary to perform them. - Testing will be time, resource and economically intensive – considerable adverse predictability and certainty for industry if G4 is used as the basis for a derogation (at least until G5 testing is performed and passed). Industry may choose to skip G4 tests completely to mitigate these uncertainties and proceed directly to G5 testing, despite inherent uncertainties. - To carry out these tests, MPs should be radiolabelled. To use the simulation tests and their results, the DT50, setting the thresholds to obtain the derogation is necessary.
Uncertainties		Although the aim of this scheme is to minimise the uncertainties linked to the transferability of the ISO tests to the environment there are some key remaining uncertainties. The principle uncertainty being the technical feasibility of performing G5 testing with microplastics. G5 testing is optional under the Dossier Submitter's proposal, but becomes mandatory under this revised proposal if G1,2,3 test pass criteria are not achieved. Should G5 testing prove to be impossible then only microplastics that pass G1,2,3 test pass criteria can be derogated from the proposed restriction. In addition, the applicability of P and vP criteria to particulate materials is subject to uncertainty (P and vP criteria were calibrated for soluble chemicals) are will, in all likelihood, be challenging to achieve for particulate materials, even particulate materials of reference materials such as cellulose (depending on particle size)..
REACH Action 10	**(i) what information is needed to address the uncertainties**	- Information on the practical application of G5 testing methods to microplastics. Information on the performance of particulate reference materials in G5 testing (relative to Annex XIII P and vP criteria). - Only ISO tests seem tailored for MPs, but there are uncertainties in relation to their representativeness to the environmental conditions. OECD simulation tests are more environmentally representative. There is a lack of correlation between the results of ISO and OECD tests. Testing with both G4 and G5 tests, as proposed in this scheme, deals with this uncertainty.

Element to evaluate		2. RAC-52 proposal
	(ii) the timeline for generating such information, who could generate the data	- 10 years would be a sufficient time to perform the tests and fulfil the uncertainty linked to the ISO tests
Relevance to the environment (level of protection / effectiveness / probability that persistent MPs used/released)		- Passing this scenario will ensure that derogated microplastic are not persistent across various different environmental compartments.
Practicality, including enforceability		- Testing will be time, resource and economically intensive. - Technical feasibility of undertaking G5 testing with microplastics is currently unknown; scenario assumes that technical progress will occur before G5 testing results are required.
Stringency		**Very stringent.** Scheme intended to provide a high level of protection to the environment. Assumes that confirmatory testing with G5 with P or vP criteria is fit-for-purpose for assessing the persistence of particulate materials, but these criteria could prove to be very difficult to achieve, even for particulate reference materials. On this basis the scheme could be overly stringent by failing to derogate materials that would not contribute to the microplastic concern.
Conclusion		**This scheme is environmentally relevant and will ensure that derogated materials will not contribute to the microplastic concern but it is time and resource intensive for industry and, at present, its technical feasibility (because of G5 testing experience with microplastics) is unknown. There are also uncertainties regarding the appropriateness of using the P and vP half-life criteria as G5 pass criteria and considerable challenges for industry in relation to certainty and predictability until G5 testing is completed.**

Table 7: RAC biodegradability scenario 3 – All compartments at G4/G5

Element to evaluate		3. 'All compartments' at G4/G5
Summary of scenario		DS scheme modified such that, if G1,2,3 pass criteria are not achieved, three ISO (G4) test passes are required to justify derogation (rather than one as proposed by the DS). G5 testing (against P or vP criteria) is not mandatory but corresponding G5 test(s) may be used to justify derogation should an equivalent G4 level test not achieve the pass criteria. Acknowledges that based on the relative uncertainties G4 and G5 are not part of a hierarchy, but both are equally acceptable means upon which to justify a derogation – note: on this basis, and for the purposes of this scenario, it is assumed that a corresponding G4 test could equally be used justify a derogation where G5 pass criteria are not met.
Advantages		- Having a requirement to pass 3 ISO-tests that represent different environmental compartments (soil, aqueous environment, marine water/sediment) will increase the likelihood that microplastic particles will biodegrade in the environment (after taking into account relevant fate and transport processes). - Differently from OECD tests, ISO tests are specifically developed for microplastics. - The testing strategy is simpler to perform and less time consuming with respect to scenario 2 (above). No OECD simulation tests are needed to confirm ISO test results. ISO tests and OECD G5 tests are on the same level in the strategy
Disadvantages		- ISO tests are performed in different environmental compartments, but there is incomplete understanding of their relevance to actual environmental conditions, specifically in relation to DT50. - ISO-tests can take a long time to perform (up to 2 years). - G5 tests will need to be performed for any compartment that fails corresponding G4 tests. If these tests are run sequentially then could be a long process.
Uncertainties		Environmental relevance of the ISO-tests, but also the technical feasibility of G5 tests (radiolabelling of polymers/microplastics) and appropriateness of vP/P criteria for particulate materials.
REACH Action 10 uncertainties	**(i) what information is needed to address the uncertainties**	Same as scenario 1: Technical feasibility of undertaking G5 tests with microplastics, including feasibility of radiolabelling polymers/microplastics. There is a need for a comparative study or studies on the relationship between testing approaches underpinned by using a reference material and those using radiolabelled material to establish environmental half lives. The results of the comparison will shed light on the environmental relevance of both ISO-tests and G5 tests undertaken using particulate test materials. Information on the performance of particulate reference materials in G5 testing (relative to Annex XIII P and vP criteria).
	(ii) the timeline for generating such information, who could generate the	As the ISO-and OECD tests are rather long, it may take 5-10 years (assuming funding) to get sufficient data to enable a firm conclusion on the environmental relevance of the ISO-tests. Data could be generated by industry or academia.

Element to evaluate		3. 'All compartments' at G4/G5
	data	
Relevance to the environment (level of protection / effectiveness / probability that persistent MPs used/released)		As described above, the environmental relevance of the ISO-tests is not clear, but OECD simulation tests, mandatory for a G4 fail, are more representative of actual environmental conditions, but there are uncertainties in relation to the appropriateness of P and vP criteria for particulate substances, such as microplastics.
Practicality, including enforcability		Unless pass criteria are achieved in G1,2,3 screening tests, G4/G5 testing will be time and resource intensive. Technical feasibility of undertaking G5 testing with microplastics is currently unknown.
Stringency		**Stringent**. Scheme requires a test material to pass either a conservative screening test or achieve pass criteria in multiple ISO or OECD simulation studies.
Conclusion		**The scheme is implementable. Comprehensive testing requirements for different environmental compartments is likely to ensure derogated materials do not contribute to the microplastic concern, but there will be some remaining uncertainty with respect to environmental half-lives of degraded microplastics if G5 testing is not performed. Similar timeline as Dossier Submitter proposal, but greater resources as more testing at G4 and G5 is needed. Nevertheless, this scheme does not solve the ISO tests uncertainties by itself and research into the relationship between reference substance and simulation testing biodegradation tests would be a high priority.**

Table 8: RAC biodegradability scenario 4a - OECD test methods only (G1, 2, 3 and/or 3 x G5)

Element to evaluate		4a.OECD test methods only (G1, 2, 3 and 5)
Summary of scenario		Scheme based on OECD test methods only (G1,2,3,5)
Advantages		- OECD tests are required in REACH and/or CLP regulations and used widely for all substances. In this case microplastics will be assessed according to the standard methods. The testing strategy will be consistent among substances in REACH regulation There is a lot of experience with the OECD tests, making interpretation of data easier, e.g. with respect to environmental relevance of the data. Due to the specificity of microplastics, the standards with an extended test duration are accepted (similar to P, vP criteria). - This scheme permit to capture the biodegradable and the not persistent alternatives. - Passing the screening tests is considered enough to demonstrate that the polymer is not persistent in the environment. - Lack of degradation in an inherent biodegradability test equivalent to the OECD TG 302 series would provide sufficient information to confirm persistence without the need for further simulation testing. - Testing scheme requires to test microplastics in all three compartments in OECD simulation tests and would thus provide ideally information on the persistency of the particles in the real environment conditions as well as handle the concern of microplastics best possible way.
Disadvantages		- The OECD screening tests are considered as stringent for polymers and not tailored for microplastics. - No enough experience that OECD simulation tests are easy to apply to microplastic. A critical point is the interaction between bacteria (normally in liquid phase) and microplastics in solid phase. - A long time period is necessary to perform the OECD simulation tests and to derogate definitely to the restriction. To use the simulation tests and their results, the DT50, setting the thresholds to obtain the derogation is necessary. - The amounts of test item introduced in the test vessels may lead to limitations on the shape and the size of the item to be tested
Uncertainties		Group1 to 3 are OECD tests designed for soluble substances and not for microplastics. OECD screening tests are conservative leading to a possibility to return negative results (materials that will not pass the screening tests but would not be persistent in the environment). In this case, OECD simulation tests could be useful to perform. Group 5 tests are not designed for microplastics and it is also unknown how feasible it will be to produce radiolabelled polymers/microplastics. Particulate test material could fail P or vP, but not be persistent over the long-term in the environment (particulate cellulose may not pass P/vP criteria (depending on particle size). Furthermore, the pass levels required for the tests (60 or 70%) do not allow to assess biodegradation of components present in small amounts. Care should be taken in the interpretation of OECD data as they are not designed for microplastics, for example a very low solubility of a test substance in the inherent biodegradability tests may reduce the availability of the substance for the inoculum.
REACH Action 10	**(i) what information is needed to**	Studies on how different microplastic particles behave in the OECD tests provide information to address the uncertainties as it would be possible to compare the biodegradability behaviour to the microplastics in different compartments and representing real environmental conditions (e.g. OECD

Element to evaluate		4a.OECD test methods only (G1, 2, 3 and 5)
	address the uncertainties	simulation tests). Biodegradation data for individual components present at concentrations below 10 %. A critical review of the available information.
	(ii) the timeline for generating such information	OECD screening tests take long time. It will most likely take many years to generate sufficient data to fully understand how the OECD tests can be used to fully predict the biodegradation of microparticles.
Relevance to the environment (level of protection / effectiveness / probability that persistent MPs used/released)		OECD screening tests are considered stringent as passing the threshold is considered to indicate that the substance will not be persistent in the environment. OECD simulation tests are environmentally relevant and will provide information on the rate and transformation pathway of microplastics. Passing this scenario will ensure that the microplastics most likely biodegrade in the environment, thus provide high level of protection.
Practicality, enforceability		The tests are already performed, so the main practical problem concerns the long testing duration of the OECD simulation tests, availability of radio-labelled microplastics for the simulation tests as well as lack of experience of testing microplastics in G5 tests. Preparation of the sample to be tested is also challenging. The scenario is enforceable, but it requires experience in assessing the outcome of the biodegradation tests that the derogation is based on.
Stringency		**Stringent**. OECD simulation tests provide information on the possible degradation potential of the microplastic in the environment and with the DT50 it is possible to obtain degradation half-life values.
Conclusions		**This scenario provides the possibility to a apply standard testing scheme and to work in the longer term to build up information regarding the applicability of the OECD test methods to microplastics as well as to the real environmental conditions also to be able to decide whether the concern of microplastics can be eliminated with the described derogation criteria.**

Table 9: RAC biodegradability scenario 4b – ISO test methods only (3 x G4)

Element to evaluate		4b.ISO test methods only
Summary of scenario		Scheme based on ISO test methods only (3 x G4)
Advantages		- Straightforward derogation – easy to understand - Standard ISO test methods have been specifically developed for assessing the biodegradability of plastic materials and could be suitable for microplastic particles.
Disadvantages		The ISO tests are performed in different environmental compartments, but there is lack of knowledge on the environmental relevance of the test conditions (the size of the inoculum, the longer test period, the difference of kinetic between the reference and the tested item) and results with regards to microplastic particles. Thus, even though a test material may achieve the pass criteria e.g. a 'soil ISO-test', there is some uncertainty whether the derogated material would still contribute to the microplastic concern under real environmental conditions. No pass level is given in the ISO standards to conclude on the biodegradability of the test item. It has been proposed in the restriction to apply, for all tests developed by ISO/TC 61, the criteria described in EN 13432: 2000 (Packaging — Requirements for packaging recoverable through composting and biodegradation — Test scheme and evaluation criteria for the final acceptance of packaging), i.e. at least 90 % in total or 90 % of the maximum degradation of a suitable reference substance after a plateau has been reached for both test material and reference substance. One should be kept in mind that EN 13432 specifies the requirements and procedures to determine the compostability and anaerobic treatability of packaging and packaging materials. In any case, EN 13432 has been developed for assessing the ultimate biodegradation of packaging materials. The ISO-tests take a long time to perform (<2 years).
Uncertainties		Microplastics derogated using only ISO tests are inherently biodegradable, but as the tests do not give an indication of environmental half-life the environmental relevance of the test conditions and pass criteria (inoculum amount, temperature conditions) is unknown. Degradation will be very much affected by the particle size, so the results of any tests will be greatly affected by mean particle size and size distribution.
REACH Action 10 uncertainties	**(i) what information is needed to address the uncertainties**	Same as 1 and 3. There is a need for comparative studies, where preferably the degradation of microplastic particles (or possibly natural fibres) are studied both in ISO-tests and tests representing real environmental conditions (e.g. OECD simulation tests). This comparison will shed light on the environmental relevance of the ISO-tests. A faster, but uncertain, option both be to review all ISO-tests that have been conducted so far, to see if some ideas of the environmental relevance can come out of that review.
	(ii) the timeline for generating such information	ISO-tests are rather long, it may take 5-10 years (assuming funding) to get sufficient data to enable a firm conclusion on the environmental relevance of the ISO-tests.

Element to evaluate	4b.ISO test methods only
Relevance to the environment (level of protection / effectiveness / probability that persistent MPs used/released)	ISO tests alone are not suitable for assessing the biodegradability of microplastic particles in the real life environmental conditions, thus passing this scenario would have remaining uncertainties.
Practicality, enforceability	- Practicable, laboratories able to perform ISO tests but there is limited experience from testing microplastics. - Long duration - The scenario is enforceable.
Stringency	**Stringent.** Derogated materials are inherently biodegradable, may continue to contribute to the microplastic concern if they do not degrade sufficiently rapidly under environmental conditions. Pass must be achieved in multiple compartments.
Conclusions	**Although demonstrating inherent biodegradability ISO tests are not considered to be as stringent as OECD screening or simulation tests and may have limited environmental relevance (until proven otherwise).**

Table 10: RAC biodegradability scenario 5 – Polymer only

Element to evaluate	5. polymers only
Summary of scenario	Testing scheme modified such that only data on polymer(s) present in microplastics is needed. Testing of the microplastic placed on the market is not necessary.
Advantages	The polymer only scenario significantly reduces the numbers of necessary tests and consequently the necessary resources and time for completing the required testing. Currently more scientific knowledge exists on the biodegradation of polymers compared to the high number of different microplastics. Especially the representativeness of laboratory test systems on the degradability in the environment is easier for polymers than for microplastics as there is less potential for interferences from other substances in the polymer matrix. . Testing only the polymers separately and in a standard particle size would allow to demonstrate that the main contributors to the persistence concern are biodegradable. The microplastic which falls in the derogation would be composed only from polymers which proved to be degradable. Consequently, it would not be possible, that very persistent polymers are part of a microplastic blend. The Dossier Submitter's proposal ensures that microplastics cannot contain additives (or other substances) that meet PBT/vPvB criteria. Overall the largest advantage of the polymer only scenario is the easy and cost-effective enforcement.
Disadvantages	Testing only the polymers separately and in a standard particle size does not consider that microplastic as it is placed on the market including the blend, additives and the form, size and the surface area of the microplastic. Consequently, we do not gain scientific understanding on the biodegradation of the different microplastics as they are placed on the market or released to the environment. In addition to test standard particle size it could be necessary to also test the particle as it is placed on the market, as size and shape are key parameters for polymer biodegradation. In addition to testing the polymer only it could be necessary to evaluate the effect of any relevant additives. Many of these have the technical function to provide durability and consequently make the microplastic as it is placed on the market less biodegradable. Consequently, testing the polymers only may underestimate the fate and behaviour of the microplastic under relevant environmental conditions.
Uncertainties	Testing only the polymers separately and in a standard particle size gives a transparent and comparable test results but would not address uncertainties related to the effect of additives/other substances in the polymer matrix on biodegradability. The representativeness of the degradability of each polymer in the different environmental compartments under relevant environmental conditions is scientifically much easier. The surface area is significantly correlated with biodegradation. If the standard size tested is significantly smaller than the microplastic placed on the market there is uncertainty as to the environmental relevance of the standard test data. If on the other hand the polymer is only tested as 5 mm particles an important parameter specific for each microplastic would be missed in the derogation scheme. The polymer only scenario does not consider the variety of size of the microplastic placed on the market Standard particle size (or a range of standard particle sizes) needs to be defined.

Element to evaluate		5. polymers only
REACH Action 10 uncertainties	**(i) what information is needed to address the uncertainties**	In addition to testing only the polymers separate and in a standard particle size it might be necessary to address the uncertainties resulting from the microplastics as it is placed on the market, including the blend and the form, size and the surface area of the microplastic.
	(ii) the timeline for generating such information	For many polymers the test results are already available. It might be necessary to perform new test with a standard size or with a lower test temperature more relevant for environmental conditions. New testing requires the same timeline as in the other scenarios.
Relevance to the environment (level of protection / effectiveness / probability that persistent MPs used/released)		The environmental relevance is unclear of testing polymers in separate and in a standard particle size as it is different from the forms that are released on the market. Testing of the polymers only without additives might not be protective for the environment. Additives might significantly decrease the biodegradation of microplastics.
Practicality, including enforceability		The polymer only scenario requires testing of the polymers separately and in a standard particle size. Since the derogation would only apply to microplastic which is composed from only degradable polymer it is fully applicable. Other microplastic would be outside the derogation. The polymer only scenario cause the lowest number of necessary tests, is resource effective and relatively easy to implement and to enforce. It will be straightforward to set transparent and well justified criteria for the standard size to test. Overall, to justify the derogation with the polymer only scenario is very practicable. The necessary effort for the enforcement seems to be significant lower with this polymer only scenario.
Stringency		If small particle sizes are testing then then derogation **may not be very stringent as**, although efficient, additives and other substances in the polymer matrix may significantly decrease the biodegradability of microplastics as placed on the market, which would not been considered by this derogation. If relatively large particles are tested the derogation could be considered to be **very stringent** as biodegradation is acknowledged to be a surface-limited process.
Conclusions		**Derogation based on testing only polymers separately and in a large e.g. (5 mm) standard particle size would have significant advantage. This derogation would cause the lowest number of necessary tests, would be practicable and easy to enforce. The derogation would be stringent, since the microplastic as it is placed on the market only contains polymers for which it has been proven that they are degradable in the different environmental compartments under relevant environmental conditions. However, an effect of the composition (e.g. additives) on the biodegradability is not taken into account so the fate and behaviour of the microplastics in the environment under relevant environmental conditions may be underestimated.**

Table 11: RAC biodegradability scenario 7 – Confirmatory polymer data

Element to evaluate		**7. Confirmatory polymer data** "Testing scheme modified such that additional information on the polymer itself is needed where there is some potential for the interpretation of screening test results to be confounded by another (biodegradable) constituent (e.g. additive).
Summary of scenario		Testing scheme modified such that where a derogation for a MP comprising a single polymer is justified on the basis of the results screening tests (G1 to 3) additional data demonstrating the biodegradation of the polymer itself (without additives) in the same tests is also needed (this could be additional testing or analytical data demonstrating the degradation of the polymer). The Dossier Submitter approach already requires data on polymer degradation where there is a blend comprising >1 polymer in the test material. This modification would apply where there is a single polymer in the test material and would address the concern that pass criteria are achieved in screening tests because of the degradation of other constituents in the test material (e.g. additives) rather than the polymer itself. Most relevant to G1 to G3 test methods (because it is acknowledged that they have limitations when testing mixtures). G4 tests are designed for plastics, which are typically mixtures of polymers and additives, and have more conservative pass criteria.
Advantages		The screening tests are not designed for mixtures, such as a MP containing polymers and different additives, and requiring additional information on the polymer itself will rule out that additives are interfering with the tests and therefore provide clarity as to the biodegradation of the polymer.
Disadvantages		Additional data requirements may delay testing and, consequently, innovation. It may be difficult to predict if other components of the microplastic (than the polymer) affect the tests. And the content of other components (e.g. additives) may not be fully known. The amount of other constituents in a test material may be so low in relation to the content of polymers that it could not affect the result of testing, and a requirement to test the polymer as such may complicate testing while not really being needed.
Uncertainties		Will the content of additives be so high that it affects the outcome of testing[17].
REACH Action 10 uncertainties	**(i) what information is needed to address the uncertainties**	Information in needed on what 'other constituents (and the concentration) are used in MPs to get an indication whether they may affect the outcome of testing. Data from testing MPs with and without other constituents is needed for a firm conclusion as to the possibilities of other constituents to affect the results of testing MPs. Information from the MP producers may become available within a few years, but it will most likely take many years to get test data allowing a firm conclusion.

[17] Colwell, J. M. et al. Lifetime prediction of biodegradable polymers. Prog. Polym. Sci. 71, 144–189 (2017); Kjeldsen A., Price, M., Lilley C, Guzniczak, E. 2019. A Review of Standards for Biodegradable Plastics. Industrial Biodetechnology Innovation Centre (IBIOIC)

Element to evaluate		7. Confirmatory polymer data "Testing scheme modified such that additional information on the polymer itself is needed where there is some potential for the interpretation of screening test results to be confounded by another (biodegradable) constituent (e.g. additive).
	(ii) the timeline for generating such information	Information from the MP producers may become available within a few years, but it will most likely take many years to get test data allowing a firm conclusion.
Relevance to the environment		Depending on the concentrations of other constituents used in microplastics, the environmental relevance of test data for MPs may be questioned.
Practicality, including enforceability		It will be an industry task to decide to perform additional polymer testing and to provide a rationale for why other constituents may affect the testing of the microplastic as released on the market. It may be difficult to enforce if dependent on expert judgement (i.e. interpretation of analytical data).
Stringency		If other constituents decrease the biodegradation of microplastics in laboratory tests, they will also decrease biodegradation of the microplastics in the environment.
Conclusions		The need for such a testing regime is unclear to RAC. If allowing derogations based on additional testing of the polymer itself, the consequences as the environmental protection is unclear and may lead to build up of the microplastic in the environment.

Table 12: RAC biodegradability scenario 9 – weight of evidence approaches

Element to evaluate	9. Weight of evidence
Summary of scenario	Testing Scheme modified to allow the use of (i) non-testing or (ii) 'non-standard' test method data to waive Appendix X testing requirements e.g. based on QSAR, read-across (including between different sizes of the same MP), use pattern or environmental fate information (to justify lack of exposure in a particular compartment)
Advantages	A weight of evidence (WoE) approach is a case-by-case decision and consequently allows flexibility to prove that a microplastic would biodegrade in the environment. The use of non-testing or 'non-standard' test data to waive standard testing would reduce the burden of laboratory testing.
Disadvantages	A weight of evidence (WoE) approach is impossible to compare between different types of microplastics. The robustness and the confirmability of the WoE is extremely low. Furthermore, the WoE only depends on expert judgement, which is legally difficult to prove, to challenge and to enforce. MS enforcement authorities would need access to all information which was considered during the WoE. On the one hand this causes for industry a huge burden of preparing a detailed documentation of the WoE. On the other hand, the evaluation of this would causes extremely high effort for enforcement. For each single waiving of standard tests with non-testing or 'non-standard' test data the scientific validity must be proven and must be established. This causes huge effort and has not been established yet for e.g. QSAR-models or simulation studies. The level of quality and reliability of each information used might be extremely different and is very difficult to assess. In case of monitoring data or simulation studies the result must be representative and should not be specific for a use or a site. It is difficult to correlate monitoring data with a source or use over time and space compromising the possibility of reaching reliable conclusions on persistency. The lack of adequate analytical methods for field studies in comparison to standard test systems must be considered.
Uncertainties	A weight of evidence (WoE) approach results in a high degree of uncertainty in every single aspect of the decision. It depends mainly on combining uncertain aspect using expert judgement, which can result in an uncertain overall conclusion. In consequence different experts will come to different WoE even if the available information is the same. Also, a WoE does not depend on transparent criteria and the expert judgement used in the WoE is usually not transparently justified. A WoE approach can only be implemented in a scientific area where a lot of scientific experiences and well documented investigations is available. In the case for assessing the degradability of microplastic in the different environmental compartments under relevant environmental conditions (e.g. temperature, microorganisms, fungi etc.) the available different sources for information are low (lack of knowledge) and consequently the implementation of a weight of evidence (WoE) approach is difficult or even impossible. In general uncertainties are higher if standard tests are waived. Although monitoring data could be more illustrative for relevant environmental conditions, uncertainties may remain from quality of the sampling and analytical techniques as well as about its representativeness (geographic and time scales) across Europe. The general lack of understanding of the fate and behaviour of a particular microplastics in the environment causes a lack of adequate simulation models

Element to evaluate		9. Weight of evidence
		to predict the fate and transport of microplastics in the environment. The relevance of size and surface area for the degradation of microplastic can hinder the implementation of a read across. On the other hand, it may be justified to read across from larger particle sizes of identical microplastics to smaller particle sizes. QSAR models and simulation models to assess the degradability of polymers and microplastics in different environmental compartments under relevant environmental conditions do not exist. However, if they become available the uncertainty is expected to be extremely high, because of the low number of standard test results available.
it' s extremely difficult to correlate monitoring data with a source (in time and in space) so, this undermine the possibility to REACH Action 10 uncertainties	(i) what information is needed to address the uncertainties	To decrease the uncertainty and increase the transparency, there would be a need to establish criteria for how to weight different types of information and criteria for how to combine them into an overall WoE conclusion. Before it is scientifically justified to waive standard tests more standard test results and a better understanding of the fate and transport of microplastics in the environment, including better methods for microplastics sampling and quantification in the environment as well as better simulation models need to become available.
	(ii) the timeline for generating such information	To implement the weight of evidence (WoE) approach, there is a need for a common view on how to weight and combine different types of information. This is not available and it is likely to take a long time to get this experience. The WoE itself needs to consider all available relevant information and does not request a specific type of information. However, it is extreme likely that a WoE would require new testing with standard test system just like in the other approaches.
Relevance to the environment((level of protection / effectiveness / probability that persistent MPs used/released)		The weight of evidence (WoE) approach would allow to consider all relevant information for assessing biodegradability and fate of microplastics in the environment and therefore could be protective for the environment. However, the disadvantages and uncertainties are much more significant than the advantages and consequently a WoE is very likely not protective for the environment. However, it is crucial, that the WoE is protective and conservative enough that the outcome must not be overruled in future by standard testing-data, if they become available. A WoE depends strongly on the individual expert judgement and does not follow transparent criteria which have been agreed by the society to define the level of protection for the environment.
Practicality, including enforceability		The scientific complexity to allow non-testing or non-standard testing in a WoE is very high. To set up QSAR models, simulation models or field monitoring studies causes a much higher effort than to perform standard tests in the laboratory. Overall, the practicality and enforceability of the weight of evidence (WoE) approach is considered low.
Stringency		The weight of evidence (WoE) approach would be quite flexible and would allow all relevant information. This would include low quality data. It can be

Element to evaluate	9. Weight of evidence
	expected that for many microplastics the derogation could be justified with a WoE and consequently the level of stringency is low.
Conclusion	A weight of evidence (WoE) approach including the use of (i) non-testing or (ii) 'non-standard' test method data to waive Appendix X testing requirements e.g. based on QSAR, read-across (including between different sizes of the same MP), use pattern or environmental fate information (to justify lack of exposure in a particular compartment) would not protective for the environment and would be extremely difficult to enforce. While reducing the burden of standard testing it would significantly increase the uncertainty of the derogation.

Annex C. Hazard, releases, exposure and risk

C.1. Summary of review articles

Table 13: Summary of review articles

Journal reference	Key components	Summary/Overview
Andrady (2011) *Microplastics in the marine environment*	Early review in the topic area to cover the fate of plastics in the marine environment, the mechanisms by which microplastics arise from larger plastics debris and the potential ecological impacts. Keywords: Microplastics, Nanoplastics, POPs, Plastics, Food web	Part one of the Andrady review gives an extensive summary on the weathering of larger plastic debris to smaller plastics fragments. However, they also document the most commonly produced and therefore encountered polymers being polypropylene (PP), polyethylene (PE) and polyvinylchloride (PVC) composing 24%, 21% and 19% of global plastic production in 2007, respectively. Andrady discusses the toxicity of ingested microplastics in relation to their role as transport mechanisms for POPs derived from seawater. Here they suggest that toxicity can be attributed to any of the three factors (or in combination): residual monomers from manufacture (BPA; Vandenberg et al. 2007); toxicity of intermediates from partial degradation; or adsorbed POPs from seawater. Andrady reports evidence on the uptake of chemicals from seawater to plastic documenting distribution coefficients for types PE=PP>PVC from a previous study by Teuten et al. 2007. Additional studies are listed suggesting high distribution coefficients for the common polymers found in microplastics and Andrady concludes that plastic particles in the ocean could yield a highly concentrated source of POPs. Additional environmental studies are cited which provide evidence of high PAH, PCB and DDT concentrations in plastic pellets globally. However, Andrady comments that desorption of the contaminants also appears to be a very slow process and additional leaching of residual monomers is possible but estimates are not available. In conclusion he comments that '*total plastics debris-mediated pollutant load introduced into seawater is likely to be at least several orders of magnitude smaller than that introduced from air and waste water influx into oceans. The critical ecological risk is not due to low-levels of POPs in water but from the bioavailability of highly concentrated pools of POPs in microplastics that can potentially enter the food web'*. Andrady conveys little doubt that the particles (PE beads) can be ingested as part of the staple diet of plankton and other marine species such as echinioderms, molluscs and polychaetes. (Brown and Thompson 2009 and Andrady 2009). Yet, when the review was published, no studies had been conducted with POPs loaded particles and data on bioavailability post ingestion was sparse. A study on marine lugworms (Voparil et al. 2004) demonstrated the bioavailability of PAHs from tyre tread when placed in gut fluid *(in silico*) and small organisms that consume contaminated particles could have significant toxicological impacts. However, the dose delivered is dependent on the volume consumed, residence time of the POP and the kinetics of repartition. When written, Andrady concludes that no *data is available on the transfer coefficients across marine trophic levels for POPS introduced via ingested microplastics yet delivery via this mechanism is 'very likely'.*

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		Engineered or secondary nanoparticles in the oceans are also highlighted as a significant challenge to the marine ecosystem yet the impacts and effects of polymer nanoparticles are not yet known. Nanoparticles have the potential to enter organism cells by endocytosis (such as in drug delivery using engineered nanoparticles; references are detailed in the paper) therefore Andrady speculates that a polymer nanoparticle laden with POPs could also follow the same pathway to deposit contaminants internally to marine organisms. Yet Andrady states that data on the effects of plastic nanoparticles on marine flora and fauna (Bhattacharya et al., 2010; Brown et al., 2001) at present are limited.
Cole et al. (2011) *Microplastics as contaminants in the marine environment: A review*	Main objectives of the review are (1) to summarise the properties, nomenclature and sources of microplastics; (2) to discuss the routes by which microplastics enter the marine environment; (3) to evaluate the methods by which microplastics are detected in the marine environment; (4) to assess spatial and temporal trends of micro- plastic abundance; and (5) to discuss the environmental impact of microplastics. They conclude by highlighting key future research areas for scientists and policymakers. Keywords: Microplastics, Marine litter, Plastic debris, Priority pollutant	Cole et al. note the early inconsistency in microplastics definition and size ranges which makes comparing early works difficult and highlights the importance of creating a scientific standard (Claessens et al., 2011; Costa et al., 2010). Cole et al. discuss key uses of primary microplastics and the replacement of traditionally used natural ingredients, including ground almonds, oatmeal and pumice (Derraik, 2002; Fendall and Sewell, 2009) with microplastic "scrubbers" in cosmetics in the 1980s and their use in air-blasting technology (where they can become contaminated with heavy metals such as cadmium, chromium, and lead; Derraik, 2002; Gregory, 1996). The review also discusses the potential inappropriateness of biodegradable plastics as a viable replacement, as they are often composed of synthetic polymers and decomposition can be partial. *Decomposition times of even the degradable components of bio-plastics will be prolonged, increasing the probability of the plastic being fouled and subsequently reducing UV permeation on which the degradation process relies (Andrady, 2011; Moore, 2008; O'Brine and Thompson, 2010). Once decomposition does finally occur, microplastics will be released into the marine environment (Roy et al., 2011).* Cole et al. conclude that meta-studies on microplastics are difficult to develop due to varieties of sampling methodologies, huge spatial variations in microplastic abundance, and lack of standardised size definitions of microplastics (Ryan et al., 2009; Barnes et al., 2009). Cole note the possibility of consumption of microplastics across a large number of marine organisms and the potential for those plastics to leach inherent or extraneous pollutants, which (via ingestion) may be introducing toxins to the base of the food chain, from where there is potential for bioaccumulation (Teuten et al., 2009). Indeed ingestion is demonstrated in the paper for a number of organisms (see table in article; including particles as small as 2 microns) including lower trophic organisms that feed indiscriminately (Moore, 2008). Cole note that the affected animals could have ingested microplastics voluntarily or potentially transferred through the food chain, however only one example of the latter is referenced, that of Murray and Cowie (2011) who fed plastic (fibre) contaminated fish to *Nephrops* sp. Overall, Cole notes that, at the time of writing, the establishment of significant adverse health effects (morbidity, mortality, reproductive failure) have not yet been demonstrated despite evidence of ingestion, blocking of filter feeding appendages, pseudo-satiation and the potential translocation of microplastics from the digestive tract into circulation. The authors mention that this may be due to the ability of marine

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		organisms to remove unwanted materials without harm (Thompson 2006 (polychaete worms) and Andrady 2011). Finally, Cole et al. discuss plasticiser leachates that provide resistance to heat (e.g. polybrominated diphenyl ethers), oxidative damage (e.g. nonylphenol) and microbial degradation (e.g. triclosan) (Browne et al., 2007; Thompson et al., 2009b). Cole et al. state that these additives may extend the degradation times of plastics but many are also known to be EDCs that are known to induce biological effects in the ng-mg/l range. However, Cole cites Oehlmann et al. (2009) who suggest that there has been relatively little research into the chronic effects of these additives in long-term exposures to aquatic species. Hydrophobic contaminants can dissociate/desorb to biota (such as polychaetes, Teuten et al. 2007, 2009) and transfer from plastics to biota which has been demonstrated with PCBs in birds (Betts, 2008; Teuten et al. 2009). Finally, Cole et al. conclude that despite concerns surrounding microplastic ingestion and the potential leaching of contaminants, evidence remains inconclusive regarding adverse health effects, bioaccumulation of contaminants up the food chain and few toxicity studies using microplastic vectors have been conducted. Key requirements are suggested by Cole to address research gaps (largely the same gaps that still exist today; definition, methods, fate and behaviour, uptake, impact, and the effect of leachates).
Wright et al. (2013b) *The physical impacts of microplastics on marine organisms: A review*	The review aims to: (1) summarise the factors contributing to the bioavailability of microplastics; (2) outline the susceptibility of different feeding guilds to microplastic ingestion; (3) determine the factors likely to influence the physical impacts of microplastics; and (4) discuss microplastic transfer through the food chain. Keywords: Microplastics, Plastic debris, Marine litter, Marine invertebrates, Food web	Fibrous microplastics are considered to be most abundant in the marine environment and Wright et al. discuss and present an overview of the concentrations of plastic particles found in a selection of studies globally but do not comment further on the reliability of these results. These include sediment and coastal waters with some values exceeding the 'safe' concentrations reported by Everaert (2018). Overall, Wright et al. present evidence to suggest that particle concentrations are increasing, based on historical samples collected in the Pacific and Atlantic (Goldstein et al., 2012; Thompson et al., 2004) and the average size of plastic fragments is decreasing, for example 69% of fragments in the west North Atlantic over 24 years were 2-6mm (Morét- Ferguson et al., 2010). Wright et al. reaffirm that ingestion of microplastics in a whole range of marine organisms is not disputed however organism and population effects have not yet been demonstrated. Wright et al. further discuss the potential bioavailability of microplastics to marine organisms in the context of factors such as size, density, abundance and colour. Size primarily effects the availability of microplastics to ingestion by lower trophic organisms and the density will influence the position within the water column and therefore the organisms (occupying different depths) consuming microplastics. Wright et al. also state that the process of biofouling can lead to particles sinking and becoming available to benthic/deposit feeders, which would be the case for high density plastics such as PVC. Colour and resemblance of microplastics to prey items may also increase the likelihood of ingestion, with early work by Carpenter et al., (1972) finding that fish from the Niantic Bay area, New England had ingested only opaque, white polystyrene spherules in equal proportion with clear polystyrene spherules, indicating selectivity. Wright et al. further suggest that the potential for microplastics to become incorporated into marine aggregates may present a further mode of

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		entry into the food chain. Further discussion of susceptibility of organisms (to ingestion) is broken down by feeding guilds. Global impacts include internal and/or external abrasions and ulcers; and blockages of the digestive tract, which can result in satiation, starvation and physical deterioration. In turn this can lead to reduced reproductive fitness, drowning, diminished predator avoidance, impairment of feeding ability, the potential transfer of damaging toxicants from seawater and ultimately death (Gregory, 2009). Other feasible impacts have been suggested by the Marine Strategy Framework Directive Task Group 10 (Galgani et al., 2010) and include: blockage of enzyme production; diminished feeding stimulus; nutrient dilution; reduced growth rates; lowered steroid hormone levels; delayed ovulation and reproductive failure; and absorption of toxins. In addition, Wright et al. present a summary of the direct impacts of microplastics. This includes studies on accumulation in plankton and bivalve molluscs in a laboratory setting, which could potentially cause blockages in the digestive system, suppression of feeding (through satiation) and possible trophic transfer (although no studies documenting this are quoted). External adsorption of microplastics may also inhibit photosynthesis in algal species (*Chlorella* and *Scenedesmus*) potentially due to the physical blockage of light and air and microplastics also increased reactive oxygen species production, indicating a state of oxidative stress (Bhattacharya et al., 2010). It was noted, however, that this study used extremely high concentrations of 1.4-40 mg/ml relative to environmental levels. Both Browne et al. (2008) and later Hussain et al. (2001) document translocation of microplastics for bivalves and rats respectively in laboratory studies, however toxicological effects are inconsistent, and the studies do not reflect the sub-lethal chronic exposure organisms are exposed to in the environment. Wright et al. states that egestion of ingested or translocated microplastics is also poorly studied, therefore detrimental effects and food chain transfer remain unquantified. Wright et al. conclude that toxicological effects remain to be identified despite the presence of microplastics in various compartments of the marine food web and the potential of POPs associated with microplastics to accumulate/transfer and biomagnify. The use of phthalates and plastics additives such as antimicrobials, dyes or stabilisers as tracers for microplastic ingestion and bioaccumulation is named as a promising avenue for future research (Fossi et al., 2012).
Eerkes-Medrano et al. (2015) *Microplastics in freshwater systems: A*	Microplastic, Plastic contamination, Freshwater systems, Riverine litter, Lake litter, Marine debris Comprehensive table on estimates of microplastic	Evidence suggests that freshwater systems may share similarities to marine systems in the types of forces that transport microplastics (e.g. surface currents); the prevalence of microplastics (e.g. numerically abundant and ubiquitous); the approaches used for detection, identification and quantification (e.g. density separation, filtration, sieving and infrared spectroscopy); and the potential impacts (e.g. physical damage to organisms that ingest them, chemical transfer of toxicants). The review paper defines that 'primary microplastic sources include manufactured plastic products such as

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review of the emerging threats, identification of knowledge gaps and prioritisation of research needs	concentrations across a range of FW environments/geographies Table 3 offers an excellent summary of effects in FW and marine biota	scrubbers in cleaning and cosmetic products, as well as manufactured pellets used in feedstock or plastic production (Gregory, 1996; Fendall and Sewell, 2009; Cole et al., 2011). Manufactured pellets may be especially common in the environment near plastic processing plants whereas scrubbers or microbeads may be present in industrial and domestic wastewater discharge, where they enter the system via rivers and estuaries (Colton, 1974; Hidalgo-Ruz et al., 2012). Eerkes-Medrano et al. note one study from Eriksen et al. 2013 that confirmed the presence of primary microplastics, likely from microbeads, in samples from North American Great Lakes derived from combined sewer overflows (in the densely populated industrial lake Erie). Ingestion has been documented in a number of freshwater species. According to Eerkes-Medrano et al., the only fresh-water river field study to date shows that gobies collected from 7 out of 11 French streams contained microplastics (Sanchez et al., 2014). Higher trophic level organisms have been found to contain microplastics (with examples referenced) and Eerkes-Medrano et al. suggest these may arise from both direct and indirect transfer (through consumption of prey items). Marine estimates presented in the paper indicate that *microplastics can have average densities of 1-1.9 pieces per fish (Carpenter et al., 1972; Lusher et al., 2013), but magnification through the food web suggests a concentration factor of between 22 and 160 times in seals (Eriksson and Burton, 2003).* Literature evidence indicates few freshwater studies examining impacts have been conducted to date, however, those that exist suggest physical impacts being similar to those in marine studies. Differential retention in sea scallops (Brilliant and MacDonald 2000) or false satiation in the marine lugworm (Wright et al. 2013) and field collected estuarine fish (Ramos et al. 2012) are a few of the examples presented on direct impacts in biota in Eerkes-Medrano et al. Eerkes-Medrano et al. note that Rochman et al. 2013b published one of the few laboratory studies documenting bioaccumulation of microplastics and liver toxicity in Japanese medaka (that inhabit marine, FW and estuarine environments) suggesting stress induced responses following microplastic ingestion. Indirect effects of microplastics in freshwater environments include the transfer of contaminants (Teuten et al., 2007, 2009; Engler, 2012; Browne et al., 2013). The transfer of contaminants has been shown to be facilitated by the presence of microplastics in organisms such as the sediment-dwelling lugworm, *A. marina* and to the amphidromous Medaka fish, *O. latipes* (Teuten et al., 2007; Rochman et al., 2013b). In other experiments with *A. marina*, accumulated nonylphenol and triclosan from polyvinyl chloride (PVC) led to impaired immune functions and physiological stress and mortality, however the quantity of plastic used was relatively high (Browne et al., 2013). Experiments also show evidence that microplastics modulate contaminant toxicity, inducing stress and altering mortality in fish exposed to microplastics in the laboratory (Rochman et al., 2013b and Oliveira et al., 2013). Limited information exists regarding contaminant transfer to high trophic levels such as birds. Eerkes-Medrano et al. highlight the importance of testing these impacts in the field and in the absence of such data, it is difficult to infer the extent of effects of microplastics in the natural environment.

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		Eerkes-Medrano et al. suggest that we do not know how microplastics might transfer from freshwater to terrestrial ecosystems, and we do not know if and how they may affect human health (Hollman et al. 2013). Such interactions are complex and not yet fully predictable- depending on the plastic, the temperature, the contaminant and the organism that ingests the plastic. Similarly, potential effects during more vulnerable early life stages (environmental impacts on early life stages can transfer to later life stages, leading to reduced developmental potential, fitness, and survivorship (Pechenik, 2006)) remains largely unknown and it would be beneficial to understand possible differential impacts on organisms exposed during development. Such scenarios are observed for other contaminants; exposure of pink salmon, *Oncorhynchus gorbuscha*, embryos to crude oil led to carry-over effects in growth of juveniles and in survival of the marine stages (Heintz et al., 2000). Eerkes-Medrano et al. also state that as it is not viable to remove microplastics once in the environment, measures focussed on reducing inputs initially are recognised as being the most effective. However, their relative contribution to water treatment problems may be small in comparison to natural particulates for example but removal estimates or comparisons are not presented in the article.
Ivar Do Sul and Costa (2014) *The present and future of microplastic pollution in the marine environment*	This paper provides the first in-depth exploration of the effects of microplastics on the marine environment and biota. Marine debris Risk to marine life Priority pollutants Coastal environments POPs Literature review	Within this article specifically they adopt the Arthur et al. (2009) definition of microplastics (fragments and primary-sourced plastics that are smaller than 5 mm) as the main criteria for discerning a specific size class of plastic pollution. No long-term studies have been undertaken to estimate the actual residence time of these fragments (Roy et al., 2011; Hidalgo-Ruz et al., 2012). In the laboratory, experiments confirmed they are able to ingest microplastics when feeding and expel the plastic within one week (Ugolini et al., 2013). Among copepods, the presence of microplastics significantly reduced feeding, which illustrates the negative impacts of microplastics on zooplankton communities (Cole et al., 2013). *Arenicola marina* ingested polystyrene (PS) microplastics; the authors established a positive relationship between the microplastic concentration in the sediment and the ingestion of plastics and the weight loss by the lugworm (Besseling et al., 2013). Feeding activity was also reduced. Despite these physical impacts, the microplastics did not accumulate in their digestive tracts during the experiment (28 days). The ingestion of PS (small doses) by *A. marina* was associated with higher concentrations of PCBs in their tissues (Besseling et al., 2013). Furthermore, because fish excrete ingested plastics (Hoss and Settle, 1990), sub-lethal effects are a very likely hypothesis. Therefore, population level effects, including the mechanisms to explain the transference of ingested plastics and their adsorbed contaminants along marine food webs, are merely speculative. Ivar Do Sul and Costa reiterate that in estuaries, which are potential sources of these contaminants, studies are nearly non-existent. Moreover, the presence of microplastics in terrestrial ecosystems and the

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		soil are completely absent from the literature (Rillig, 2012).
Duis and Coors (2016) *Microplastics in the aquatic and terrestrial environment: sources (with a specific focus on personal care products), fate and effects*	In the present work, information on sources and fate of microplastic particles in the aquatic and terrestrial environment, and on their uptake and effects, mainly in aquatic organisms, is reviewed. Plastic debris, Environmental concern, Persistence, Personal care products, Cosmetic products, Microplastic Includes summary of methods	Microplastics are now an emerging area of research and most often been defined as synthetic organic polymer particles with a size (or, more specifically largest dimension) of less than 5 mm with few definitions including a lower size limit. In view of the definition of nanoscale (1–100 nm [12]), the term microplastics is used in this review for solid synthetic organic polymer particles with a size between 100 nm and 5 mm produced specifically in the micro-size range. Duis and Coors focus on the contribution of microplastics from PCPs to the overall pollution of the environment. Additives in these primary microplastics is discussed elsewhere in Oehlmann et al. 2009. Gouin et al. estimated that in 2012, approx. 6 % of the liquid skin cleaning products marketed in the European Union, Norway and Switzerland contained microplastics. Based on a survey conducted by Cosmetics Europe, PE accounted for 93 % of the microplastics used in skin cleaning products in these countries in 2012. The products typically contained between 0.05 and 12 % of microplastic particles, with the size of most particles ranging from 450 to 800 µm. microplastics are also used in dentist tooth polish, as carriers for APIs, in drilling fluids and as industrial abrasives. These can end up in the environment via wastewaters or directly if not disposed of properly. Only a few studies are available on the removal and efficiency of wastewater treatment processes. Coarse screens have openings of approx. 20–50 mm, intermediate screens of approx. 10–20 mm and fine screens of approx. 2–10 mm. Such screens are suitable for removing macroplastics from wastewater, while they will—based on the opening sizes mentioned above—not be able to capture smaller microplastics. No studies on removal efficiency unambiguously identified personal care products as source of the detected microplastics, as they are not unique in shape or chemical composition compared to other microplastics. Leslie et al. 2012 suggest removal efficiencies of ~90% and 95% in Russian wastewater treatment plants (WWTPs). Sewage sludge however can represent a source of microplastics to the terrestrial environment. Gouin et al. estimate a mean annual amount of 4 130 t of microplastic particles was derived for the European Union, Norway and Switzerland for 2012. This value is consistent with the result of the previously mentioned survey of Cosmetics Europe (4 360 t for the same region and year). For the countries in the watershed of the North Sea annual use of microplastics in personal care products was estimated to be 2 300 t. Assuming removal of 90 % of the microplastics in WWTPs and discharge of all water from these countries to the North Sea, microplastics from personal care products would constitute approximately 1 % of the overall amount of marine debris that has been estimated to enter the North Sea each year (20,000 t). According to Sundt et al. microplastics from personal care products account for approx. 0.5 % of all direct emissions of microplastics in Norway. For Denmark, emissions of microplastics from personal care products to the aquatic environment were estimated to account for 0.1 % of the overall emissions to the aquatic environment.

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		Microplastics are ingested and, mostly, excreted rapidly (within a few hours or days) by numerous aquatic organisms such as copepods, amphipods, shore crabs and mussels. In laboratory studies, the ingestion of large amounts of microplastics mainly led to a lower food uptake and, consequently, reduced energy reserves and effects on other physiological functions. Based on the results of laboratory experiments, translocation from the intestinal tract to the circulatory system or surrounding tissue depends on the size of the microplastics with an upper size limit for translocation that appears to be specific for the species or taxonomic group. So far, there is no clear evidence of bioaccumulation or biomagnification but several laboratory studies have demonstrated trophic transfer such as Setala et al. (2014) and Farrell and Nelson (2013). Based on the evaluated data, the lowest microplastic concentrations affecting marine organisms exposed via water are much higher than levels measured in marine water. Studies on possible toxic effects of microplastics on freshwater organisms are scarce, effects on terrestrial biota have so far not been investigated. Hydrophobic contaminants are enriched on microplastics, but the available experimental results and modelling approaches indicate that the transfer of sorbed pollutants by microplastics is not likely to contribute significantly to bioaccumulation of these pollutants. The relevance of marine plastics (including both micro- and macroplastics) as transport vectors for PCBs, PBDEs and perfluorooctanoic acid (PFOA) to the Arctic was evaluated by Zarfl and Matthies. Based on estimated amounts of plastics and pollutants in the oceans, sorption of the pollutants to plastics, and ocean current velocities they derived a rough estimate of plastic-mediated mass fluxes of PCBs, PBDEs and PFOA. These mass fluxes were by factors of 10^3–10^6 lower than mass fluxes via atmospheric transport and transport with water. Therefore, it was concluded that for most sub- stances, plastics are no relevant vectors for transport to the Arctic. Besseling et al. exposed *A. marina* for 28 d to sediment contaminated with low PCB concentrations (5.28 µg PCBs/kg dw)—either alone or in combination with pre-production PS particles (400–1300 µm; 0.074, 0.74 and 7.4 % of sediment dw). The authors concluded that PS microparticles had a relatively limited effect on uptake of PCBs by *A. marina*. It was suggested that ingestion of the relatively large microplastic particles might have led to physical stress. Rochman et al. 2013 performed a two-month experiment with adult medaka (*O. latipes*) marine microplastics caused more pronounced histopathological changes in the liver than virgin microplastics: 74 % of the fish exposed to marine microplastics exhibited severe glycogen depletion (virgin microplastics: 46 %), 47 % fatty vacuolar degeneration (virgin microplastics: 29 %) and 11 % single cell necrosis (virgin microplastics: 0 %). These effects were considered as indicators of endocrine disruption, but are most likely related to depletion. Modelling approaches have been used to assess the relative contribution of microplastics as vectors to the overall uptake of hydrophobic organic pollutants. Based on these results, Koelmans et al. 2016 concluded that the contribution of microplastics to bioaccumulation can be assumed to be not very relevant. Similar results were obtained by Gouin et al. 2011 with two modelling approaches, concluded that microplastics

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		have a limited relevance as vector for the transfer of hydrophobic pollutants to fish. From a risk assessment perspective, the highest measured levels of microplastics in the environment were identified based on Hidalgo-Ruz et al. In the surface layer and the water column of the oceans, maximum concentrations of 9 and 10 items/L, respectively, were found. These concentrations are by a factor of approx. 10^4 lower than the acute LOEC of 3×10^5 items/L and the chronic LOEC of $\leq 2.6 \times 10^5$ items/L obtained for marine invertebrates exposed via the water phase. The highest microplastic concentrations measured in subtidal sediments, 2 175 items/ kg dw in the lagoon of Venice and 3 600 items/kg dw in the Rhine estuary, are lower than the LOEC of 10 g/kg sediment ww (1 % w/w) derived in a water/sediment test with marine polychaetes. Based on the evaluated data, the lowest concentrations eliciting adverse effects in aquatic organisms exposed via the water are by a factor of approximately 10^4 higher than maximum microplastic concentrations found in marine waters. The effect concentration in a water/sediment test with lugworms is higher than microplastic levels measured in subtidal sediments but in the same range as highest levels recorded in beach sediments. It should be noted that to date only relatively few studies are available on the effects of microplastics in marine organisms and even fewer on those in freshwater organisms. In several cases, only single concentrations were tested and threshold concentrations, below which no significant effects are observed in the respective test organisms, were not determined. Terrestrial effects have not been studied at all and freshwater systems are limited. However, in view of the persistence of microplastics in the environment, the high concentrations measured at some environmental sites (high concentrations in coastal sediments, which have been recorded at some sites) are of specific concern. With the prospect of further increasing concentrations, the release of plastics into the environment should be reduced in a broad and global effort regardless of a proof of an environmental risk (in order to avoid exceeding critical environmental threshold concentrations). Assessment factors, which have been derived for the environmental risk assessment of chemicals, may not be appropriate for microplastics. As suggested by Syberg et al., such an approach should build on frame-works, which have been developed for assessing environmental risks of nanomaterials and mixtures. Contribution of PCPs to overall amount of microplastics in the environment is of minor relevance
Horton et al. (2017) *Microplastics in freshwater and terrestrial environments:*	This review critically evaluates the current literature on the presence, behaviour and fate of microplastics in freshwater and terrestrial environments and, where appropriate, also draws on relevant studies from other	In this review, Horton et al. focus on microplastics defined as being any polymer within the size range 1 µm to 5 mm as this is the size range which has been the major focus of reported microplastics research to date. They note that microplastics in environmental samples can currently be detected down to a size of 1 µm, however few environmental studies identify particles <50 µm due to methodological limitations (Hidalgo-Ruz et al., 2012; Imhof et al., 2016). Horton et al. note that despite the capability of some WWTPs to remove up to 99.9% microplastic particles

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Evaluating the current understanding to identify the knowledge gaps and future research priorities	fields including nanotechnology, agriculture and waste management. Plastic pollution Nanoplastics Litter Rivers Soil Hazard	from wastewater (dependent on the processes employed by the treatment plant), the sheer number of particles entering the system may still allow a significant number to bypass filtration systems and be released into the freshwater environment with effluent (Carr et al., 2016; Murphy et al., 2016). Major routes of release are therefore the same for primary and secondary microplastics. Given that microplastics are not yet considered by sludge regulations it is anticipated that the mass of microplastics inadvertently applied to land annually may exceed 400,000 tonnes – higher than the mass currently estimated to be present in oceanic surface waters worldwide (Nizzetto et al., 2016b). This is demonstrated by Zubris and Richards (2005) who found that soils with a known history of sewage sludge application contained significantly higher concentrations of synthetic microfibres than soils which had not received sewage sludge. In some field sites, synthetic microfibres were found 15 years after the last sludge application (Zubris and Richards, 2005). Horton suggests that microplastics and synthetic fibres are therefore likely to accumulate in soils after repeated sludge applications. Primary microbeads from personal care products also likely to be a significant contributor to microplastic pollution (Castañeda et al., 2014; Murphy et al., 2016; Napper et al., 2015). The treatment processes at seven wastewater reclamation plants in California resulted in the complete removal of microparticles (45–400 µm) from water outputs, as a result of tertiary treatment including surface skimming, sludge settling and microfiltration processes (Carr et al., 2016). After secondary treatment only (elimination microfiltration), effluents contained on average one plastic particle per 1 140 L of effluent, compared to an estimated one particle per litre in the influent (Carr et al., 2016). Horton also emphasise that where treatment is not advanced, these estimates could fall short by up to 100-fold in places. Horton et al. quote one of the few soil studies that exists, by Huerta Lwanga et al. (2016) where they observed mortality in *Lumbricus terrestris* earthworms exposed to polyethylene particles; mortality was increased by 8% at a concentration of 450 g kg^{-1} polyethylene (in overlying leaf litter) and 25% mortality at 600 g kg^{-1}. Reduced growth and negative effects on burrow construction were also observed. However, Horton indicates that the concentrations used seem high compared to expected microplastic levels resulting from diffuse pollution. Contrary to the above study, Lee et al. (2013) found that although acute exposure (96 h) to three different particle sizes (0.05, 0.5 and 6 µm) of polystyrene microbeads, had no impact on the survival rate of adult marine copepod, *Tigriopus japonicas*, in a two generation chronic exposure experiment mortality was observed at concentrations above 12.5 µg mL^{-1}, with the second generation observed to be much more sensitive than the first generation, especially when exposed to the nano-scale particles (0.05 µm). Larger particles in contrast (6 µm) had no effect on survival even over two generations, although fecundity was affected at concentrations above 25 µg mL^{-1}. Horton et al. introduce other studies which highlight possible size dependent influences on toxicity for both acute survival effects (Besseling et al., 2014; Nasser and Lynch, 2016) and different reproductive effects observed in response to smaller particle fractions (Lee et al., 2013). Additionally, exposure to artificially

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		aged (nano)polystyrene has been found to cause mortality, growth and reproduction effects to the standard test species *Daphnia magna* over a 21 day period, whereas pristine nano-polystyrene particles caused no significant effects on mortality. Mixtures of nano-polystyrene and fish kairomones (known to cause stress in *D. magna*) produced an additive effect on body size and reproductive endpoints, indicating that exposure to plastic particles can exacerbate existing environmental stress responses (Besseling et al., 2014). Horton et al. therefore suggest that the use of pristine particles could thus lead to a potential underestimation of the toxicological impacts of microplastic exposure under more realistic environmental exposure scenarios. They note that the nanotoxicology research community have recognised the need to conduct experiments with environmentally 'aged' nanomaterial forms (Christian et al., 2008; Judy et al., 2015; Lahive et al., 2017). Final mention is given to the chemicals associated with plastics, that have been identified as either toxic or endocrine disruptors including bisphenol-A, phthalates such as di-n-butyl phthalate and di-(2-ethylhexyl) phthalate, polybrominated diphenyl ethers (PBDEs) and metals used as colourings (Hua et al., 2005; Kim et al., 2006; Lithner et al., 2009; Oehlmann et al., 2009; Rochman et al., 2013b; Teuten et al., 2009). Additional studies cited suggest that plastic materials release chemicals to soil via a number of the pathways and are a potential source of plasticisers to soils. Horton suggest that this may have significant implications for terrestrial locations where microplastic concentrations are high, although further studies are needed to confirm this early evidence.
Koelmans et al. (2016) *Microplastic as a Vector for Chemicals in the Aquatic Environment: Critical Review and Model-Supported Reinterpretation of Empirical Studies*	The hypothesis that 'microplastic will transfer hazardous hydrophobic organic chemicals (HOC) to marine animals' has been central to the perceived hazard and risk of plastic in the marine environment. We provide a critical evaluation of the scientific literature regarding this hypothesis.	Koelmans et al. mention 13 studies (excluding seabirds) that somehow addressed the role of plastic in the bioaccumulation of hydrophobic organic contaminants (HOCs) in the context of pollution with marine debris. Several studies conducted in the laboratory demonstrate the ability of plastics to act as a vector for administering contaminants (using high quantities of HOC spiked microplastics), with only one study performed by Besseling et al. (2013) under environmentally relevant conditions with all exposure pathways accounted for, and reported an increase in accumulation of ∑PCBs in lugworms of 29%. However, the authors could not clearly show that plastic acted as a carrier for HOCs. The increase was ascribed to physical effects of the plastic ingestion and not to transfer of the chemicals from the plastic. Similarly, Koelmans et al. mention the laboratory study of Rochman et al. who exposed Medaka to a diet with 10% plastic, and observed increased uptake of HOCs (∑PAH) up to a factor 2.4. Koelmans et al. note that the 10% of plastic in the diet as used in the studies by Gouin and Rochman is quite high compared to conditions in many aquatic habitats and thus can be considered to represent a worst case scenario. Koelmans et al. also present studies using empirically validated models for bioaccumulation from regular prey and compare this to bioaccumulation from ingested plastic. Comparison of the HOC fluxes bioaccumulated from ingested prey with those of ingested plastic, generally showed small to negligible

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		contributions of plastic to bioaccumulation by the various marine species like lugworm, fish, and seabirds. Koelmans et al. indicate that they are aware of only two studies that compared model calculations with empirical data, which implies that further validation is recommended. Koelmans et al. note that the relative importance of plastic ingestion is hard to disentangle. However, there is no reason to deny that bioaccumulation of some HOCs can be linked to a high abundance of plastics that may act as a source of these HOCs (Rochman et al. 2014). They summarise that laboratory studies that use high doses of only plastic tend to find an effect of ingestion on HOC accumulation. Yet, studies aiming at environmentally realism (either lab or model) by accounting for parallel uptake pathways tend to conclude that there is no (or a negligible) effect. Koelmans et al. indicate that field studies undertaken also struggle with the problems of multiple causation, lack of gradient and environmental variability, which limits their use to detect the contribution of plastic ingestion to bioaccumulation. Based on the synthesis they provide, Koelmans et al. suggest that the scientific evidence is consistent, yet that the dichotomy in study outcomes is perceived and probably reflects and is related to different exposure scenarios used in these different studies Koelmans et al. argue that these empirical laboratory studies and model studies agree that up to realistic as well as at very high concentrations of about 1 to 10% of plastic in the sediment or in the diet, about a factor two change of bioaccumulation in either direction may occur. Under such more realistic environmental conditions, organisms may simply ingest not enough micro- plastic particles compared to natural prey, rendering the effect on bioaccumulation to be even below a 10−20% difference in either direction. Koelmans et al. conclude that effects of plastic ingestion can be smaller than the biological variability in bioaccumulation data (Selck et al. 2012) This implies that small effects of microplastic on bioaccumulation of HOCs can be observed under artificial laboratory conditions, but in nature will be overwhelmed by natural variability and by bioaccumulation from natural exposure routes. Based on the data presented, Koelmans et al. state that the fraction held by plastic is so small that even if we would underestimate the abundance of plastic by orders of magnitude, plastic still would be unimportant as a transfer pathway for HOCs. They conclude that overall the flux of HOCs bioaccumulated from natural prey overwhelms the flux from ingested microplastic for most habitats, which implies that microplastic ingestion is not likely to increase the exposure to and thus risks of HOCs in the marine environment.
Galloway (2015)	This review considers the kinds of plastics in widespread,	Galloway states that biomonitoring - considered a gold standard in assessing the health risks of environmental exposures because it can provide an integrated measure of an individual’s exposure to

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Micro- and nano-plastics and human health	everyday use and the potential hazards they may cause. It reviews the routes of uptake of micro and nanoplastics into humans through the food chain and the potential consequences for human health. Health risks associated with microplastics and plastic-associated chemicals are discussed.	contaminants from multiple sources - has shown that chemicals used in the manufacture of plastics are present in the human population. Indeed for some chemicals, Galloway notes that their widespread presence in the general population at concentrations capable of causing harm in animal models has raised public health concerns (Talsness et al. 2009; Melzer and Galloway 2010). The general consensus surrounding microplastics considers their presence in the guts of organisms, an organ that is not generally consumed directly by humans, however uptake (specifically of nanoparticles) has been demonstrated in mice through the gut and via villi, before recirculation and eventual elimination through faecal matter and urine (Garrett et al. 2012). However, Galloway indicates that leaching from plastic particles could present a long- term source of chemicals into tissues and body fluids, despite the fact that many of these chemicals are not persistent and have short half lives in the body (Engler 2012). Plastics additives of concern to human health include phthalates, bisphenol A, brominated flame retardants, triclosan, bisphenone and organotins. Galloway discusses that the European Food Standards Agency has a total migration limit of 10 mg/dm^2 for additives within plastics intended for packaging use, with a more stringent migration limit of 0.01 mg/kg for certain chemicals of concern (Commission Directive 2007/19/CE that modifies Directive 2002/72/CE). This means that for an average 60 kg adult who consumes 3 kg of foods and liquids per day, exposures to individual substances from food packaging could be up to 250 µg/kg body weight per day (Muncke 2011). BPA is known to exert its activity through interaction with steroid hormone receptors, showing both estrogenic and antiandrogenic activity and suppressing aromatase activity (Bonefeld-Jørgensen et al. 2007, Lee et al 2003). However, Galloway indicates that whether the release of BPA from ingested micro- or nanoplastics directly into the body contributes to human exposure remains unknown. The current tolerable daily intake is 0.05 mg/kg/day (EFSA 2006) and compared with this, the median exposure of the general adult population globally has been estimated from human biomonitoring or urinary BPA to be 0.01–0.12 µg/kg/day (EFSA 2015). The concentrations of BPA in plasma are higher than would be predicted only from this level of exposure to BPA through food and drink (Mielke and Gundert-Remy 2009), and it is therefore plausible that other routes of exposure could occur, e.g. from ingestion of plastic particles containing BPA, which subsequently leaches into tissues. Galloway mentions that BPA can also certainly be absorbed across body surfaces other than the gut. Galloway mentions that there are currently no studies in humans of the transfer of BPA from plastic directly into tissues, but the potential for BPA to leach from ingested polycarbonate into aquatic species was explored by Koelmans et al. (2014) who used biodynamic modelling to calculate the relative contribution of plastic ingestion to total exposure to chemicals residing in the ingested plastic. They proposed that a continuous ingestion of plastic containing 100 mg/kg BPA would lead to a very low steady-state concentration of 0.044 ng/kg BPA in fish and 60 µg/kg (normalized to lipid) in worms. Whilst this represents a substantial exposure pathway, the risk of exposure through this route was considered low in

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		comparison with other pathways of exposure, based on the reported abundance of microplastics. Galloway finally concludes that detailed information on migration rates of nanoparticles into food or food stimulants is sparse. It is clear that our understanding of the potential contamination of the human population by micro- or nanoplastics sourced from the environment is in its infancy, leaving many questions unanswered • Does significant bioaccumulation and trophic transfer for micro- and nanoplastics occur in the environment? If so, what species are most at risk? • How does ageing of plastics affect their physico-chemical properties and subsequent toxicity? • Following ingestion, does uptake of micro- and nanoplastics occur? Do proteins bind to the surface of the particles to form a protein corona? How does this vary for different plastic litter types and what cell types are most vulnerable to toxicity? • What methods should we be using for locating, identifying and quantifying micro- and nanoplastics in complex matrices including biological tissues?
Lusher et al. (2017) *Microplastics in fisheries and aquaculture: status of knowledge on their occurrence and implications for aquatic organisms and food safety (UN FAO)*	Global trends, types, production, use, contribution, definition, sources, distribution, interactions, microplastics in foods, risk profiling for humans and analytical techniques, Very comprehensive table on estimates of microplastic concentrations across a range of environments/geographies and interactions with aquatic organisms.	This FAO report states that microplastics have been reported in all environmental matrices and are usually defined as plastic items which measure less than 5 mm in their longest dimension (Accepted by NOAA and the MSFD), this definition also includes nanoplastics which are particles less than 100 nanometres (nm) in their longest dimension (nanoplastics are defined as plastic particles ranging from 0.001 µm to 0.1 µm (Klaine et al., 2012)). Lusher et al. note that the size range defined has been adopted in practical terms as it is considered the size under which ingestion by many species of biota occurs (GESAMP 2015). Ingestion has been documented by multiple species (~220; see paper for list) *in vitro* and *in vivo* (GESAMP 2016; reviewed in Lusher 2015) although quantities observed in wild fish guts, for example, are generally very low (1-2 particles per individual). Lusher et al. note that field studies on wild populations document only the ingestion of microplastics and no evidence of negative health effects in aquatic organisms or at the population/community level. Environmentally relevant concentrations of microplastics have been used in two studies with fish (Japanese medaka; Rochman et al. 2013, 2014 and rainbow trout; Rummel et al. 2016) which report varied outcomes – microplastic exposure induced liver toxicity, hepatic stress and changed endocrine function and gene expression in Japanese medaka, yet no effects were observed in rainbow trout. Lusher et al. report that microplastics may be egested along with faecal material or retained within the digestive tract and in addition, translocation to other tissues does not occur or is very low for the smaller microplastics (< 600 µm).

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		Central to the perceived hazard is the subsequent risk of desorption of contaminants (PBTs) sourced from plastic manufacture or from pollutants adsorbed from the environment. Overall, Lusher et al. note that ingestion of contaminated microplastics are not likely to increase exposure to PBTs in marine organisms and experimental evidence is lacking (Koelmans et al. 2016). Lusher et al. emphasise that it should also be borne in mind that with fresh microplastics having a low level of contamination, the net movement of chemicals may be reversed: from an organism into the microplastic (Koelmans, Besseling and Foekema, 2014). Trophic transfer has been observed in the laboratory (not in the wild) however Lusher et al. indicate this is unlikely to lead to accumulation or translocation into the hosts tissues. Additionally, negative physiological effects have only been observed in laboratory exposure assessments where high levels of microplastics (uncommon in the natural environment) have been used. Often at high concentrations, detrimental effects can be associated with the physical entanglement and adherence to external appendages, setae and swimming legs of microplastics in copepods, crabs and mussels. Top predators, such a baleen whales can be considered a sentinel for ocean health and may provide an indication of adverse health effects in mammals, although effects would need to be directly attributable to microplastics alone. Lusher et al. conclude that in principle, microplastic ingestion by bivalves and fish may affect individual physiology, metabolism, body condition, growth, contaminant body burden and reproductive success, but the evidence has to be considered currently to be weak (inc. no population level studies) (Ziccardi et al., 2016). Lusher et al. state that the majority of reports state the occurrence of microplastics in seafood (EFSA, 2016) but evidence on incidence of nanoplastics in food items is still lacking. Human intake of microplastics from seafood (i.e. mussels) has been estimated to equal anywhere from 1 particle per day to 30 particles per day depending on seafood consumption habits and exposure of organisms to microplastics. Lusher et al. develop a worst case scenario risk of microplastics to human health following consumption of a portion of mussels (225 g). This would lead to ingestion of 7 micrograms (~900 particles) of plastic, which would have a negligible effect (less than 0.1 percent of total dietary intake exposure) on chemical exposure to certain PBTs and plastic additives. In addition, Lusher et al. quote EFSA (2016) who state that >90% of ingested microplastics and NPs will be excreted via faeces following consumption. A paucity of literature on the impacts of oral uptake of microplastic particles to humans means that the risk cannot be evaluated.
GESAMP (2016) *Sources, fate and effects of microplastics in the marine environment: part two*	Provide a more robust evidence base to focus and support the development and implementation of potential solutions to reduce the impact of marine microplastics	GESAMP begin by raising the issue of methods of defining microplastics, stating that sampling and measurement vary considerably among studies, source sectors and geographical regions making it difficult to synthetize data across studies. It is important to come to an agreement on the categorisation of different types of debris. GESAMP state that it has become common to use the definition of any plastic particle <5 mm in diameter, which includes particles in the nano-size range. However nano-plastics have not yet been detected in the marine environment, due to analytical constraints, and the range of marine organisms exposed to them is currently unknown (GESAMP 2015; Koelmans et al. 2015).

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of a global assessment		GESAMP then elaborate in detail on the sources of microplastics, noting the source sector. Following this GESAMP refers to the entry points microplastics take to reach the ocean. The first mentioned entry point is rivers and an example is given; granulated polyethylene (PE), polypropylene (PP) or polystyrene (PS) particles, used for example in skin cleaners, can be introduced into wastewater (Gregory 1996). Some studies report not only the presence of microplastics in freshwater ecosystems but show that contamination is as severe as in the oceans (Dris et al. 2015). GESAMP continues to state that a study by McCormick et al (2014), demonstrated increases in the concentrations of primary microplastics downstream from a wastewater treatment plant, by between 9.2 to 17.93 times. To simulate the movement of particles from source to the ocean Lebreton et al. (2012) used an ocean circulation model coupled to a Lagangian particle-tracking model to simulate the input, transport and accumulation of marine debris over a 30-year period. GESAMP note that the model estimates >60 billion particles enter the ocean from rivers every day. Coastline is then discussed as an entry point for microplastics. According to the US National Academy of Science (1975) 5.8 million tonnes (6.4 million short tons) of waste are released into the ocean every year and of this 0.7% is plastic, roughly 41,000 metric tons. More recently, a study calculating the amount of mismanaged plastic waste generated by coastal populations worldwide estimated that 4.8 to 12.7 million tonnes can potentially enter the ocean as marine debris (Jambeck et al. 2015). Atmosphere is the final entry point discussed. Aerosol particles, defined as natural and anthropogenic solid or liquid droplets suspended in the atmosphere, may have sizes ranging from a few nanometres in diameter to several tens of micrometres (Pryor et al. 2015) and include primary anthropogenic aerosol particles derived principally from fuel combustion and industrial processes, as well as synthetic fibres (Dris et al. 2015). Also discussed within this section is the release of microplastic through marine entry points such as boats, ships and offshore platforms. Numerical modelling assessment of marine debris dispersal originating from shipping activity is reviewed in Lebreton et al. (2012). GESAMP then review the ecological impacts of microplastics. As a result of widespread contamination, a diverse array of wildlife is exposed to microplastics. Ingestion has been recorded in tens of thousands of individual organisms and, at the time of writing, over 100 species (Gall and Thompson 2015; Lusher et al. 2013, 2015). Exposure pathways are discussed, including adherence to the body (i.e. attached to external appendages; Cole et al. 2013) and/or absorbed (i.e. taken up by the organisms into the body through cell membranes). Absorption of microplastics has been demonstrated in phytoplankton (Bhattacharya et al. 2010; Long et al. 2015). Alternatively, microplastics can be taken up across the gills through ventilation, which has been demonstrated in crabs (Watts et al. 2014).Organisms can also ingest microplastics directly or indirectly. GESAMP mention that past studies with microplastics monitored ingestion rates and retention time of

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		particles to understand feeding behaviour (Hart 1991; Ward et al. 1998; Bolton and Havenhand 1998; Greiller and Hammond 2006). Whilst more recently, studies have been used to demonstrate uptake of debris (e.g. Thompson et al. 2004; Browne et al. 2008; Cole et al. 2013; Watts et al. 2014) and begin to learn about the impacts of microplastics (e.g. Browne et al. 2008; Teuten et al. 2009; Wright et al. 2013; Rochman et al. 2013a). The authors then list the laboratory studies in table format; noting the species examined, the exposure concentrations, exposure duration and the interaction with the microplastics. In addition to the laboratory studies, a table of field studies is included. This includes the species, the method and the reference of the study. Beginning at the bottom of the food chain GESAMP discuss the effect on plankton. One study found that the exposure of phytoplankton to microplastic did not produce adverse effects (Long et al. 2015). Another study demonstrated that charged PS nano-sized plastics (0.02 µm) can sorb to microalgae, inhibiting microalgal photosynthesis and consequently reducing population growth and chlorophyll concentrations in the green alga *Scenedesmus obliquu*s (Bhattachyra et al. 2010). For zooplankton, microplastic can adhere to external and internal body parts, including the alimentary canal, furca and urosome, and swimming legs of copepods (Cole et al. 2013). Then GESAMP follows on with other invertebrate taxa. In echinoderms, a toxic effect on the embryonic development of the green sea urchin (*Lytechinus variegatus*) was observed as a result of exposure to PE microplastic particles (Nobre et al. 2015). However, Kaposi et al. (2014) reported only a limited threat to the sea urchin *Tripneustes gratilla* using more environmentally relevant concentrations of microplastic. For *crustacea*, no negative effects have been observed, but translocation between tissues was demonstrated. A 2-month exposure resulted in PS microplastic (180 to 240 µm) in the gills stomach, and hepatopancreas of crabs (*Uca rapax*; Brennecke et al. 2015). Molluscs have been studied in depth, with a number of lab experiments assessing the potential adverse effects of microplastics on *Mytilus edulis.* Wegner et al (2012) demonstrated increased production of pseudofaeces and reduced filter-feeding activity after exposure to 30 nm polystyrene nanosized plastic particles (0.1, 0.2 and 0.3 g/L). Whilst other studies have shown no impact on feeding activity or energy reserves (Browne et al. 2008; Van Cauwenberghe et al. 2015). Von Moos et al. (2012) observed significant effects from exposure to microplastic of a larger size range (>0 to 80 µm; 2.5 g/L). The microplastic accumulated in epithelial cells of the digestive system (more specifically the digestive tubules), where they induced a strong inflammatory response accompanied by notable histological changes after only 3 hours of exposure. With increasing exposure times, the measured biological effects became more severe. Continuing to vertebrates, GESAMP note that the laboratory studies assess the effect of microplastics on fish species, for example a significant decrease in the predatory performance of *P. microps* (common goby) after exposure to microplastics. (de Sá et al, 2015). Other affects observed include increased AChE activity, weight loss, altered metabolism and liver toxicity.

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		GESAMP state that there is very little direct evidence for physical impacts of microplastic in nature. However, there are results from the field studies that suggest there are some implications. An example is in the North Pacific Subtropical Gyre, the increasing population of *Halobates sericeus*, a marine insect, was linked to the increasing concentrations of microplastics in the region (Goldstein et al. 2012). GESAMP conclude the section by stating there remains, as yet, little demonstrated evidence of ecological impacts of microplastic debris in the natural environment. GESAMP discuss the effect of plastic-related chemicals. Two recent non-targeted screening analyses looking at the chemicals associated with plastic debris, detected a total of 231 to 251 organic compounds on plastics, including hydrocarbons, UV-stabilizers, anti-oxidants, plasticisers, flame retardants, lubricants, intermediates and compounds for dyes and inks (Gauquie et al. 2015; Rani et al. 2015). GESAMP examine the pathway by which the chemicals may interact with organisms, via microplastics, including uptake from surrounding water, air or sediment and ingestion of particles in the water and/or their diet (Van der Oost et al. 2003). One study found that the combination of PVC with sorbed triclosan altered feeding behaviour and caused mortality in lugworms (Browne et al. 2013). Another study demonstrated that polyethylene deployed in San Diego Bay, CA (i.e. allowing the plastic to accumulate environmentally relevant concentrations of priority pollutants) caused hepatic stress, including glycogen depletion, lipidosis, cellular death and tumour development, in fish exposed to microplastic for a 2-month period (Rochman et al. 2013a). Moreover, fish exposed to the combination of polyethylene and priority pollutants showed signs of endocrine disruption via changes in gene expression and abnormal growth of germ cells in the gonads (Rochman et al. 2014a). In terms of nanoplastics and their potential impacts. GESAMP discuss a study on blue mussels which were exposed to HDPE powder >0 to 80 µm, then analysed for translocation of the particles into their tissue. GESAMP refer back to the studies previously discussed that include the analysis of nanoplastics. Several of these studies have shown that uptake and toxicity depend on the intrinsic properties of the particles, such as size and surface charges that affect their interaction with exposure media (Della Torre et al. 2014). In addition, a number of recent studies have demonstrated effects of PS nanoparticles on feeding, behaviour and physiology of early life stages, such as brine shrimp (Bergami et al. 2015) and sea urchins (Della Torre et al. 2014; Canesi et al. 2015). Transport of indigenous species is another aspect mentioned by GESAMP. In the discussion the authors compare the difference between transference by natural floating substrata and plastics. The distribution of plastic is different from that of natural substrata, and plastic has substantially increased the available substratum in oligotrophic open ocean regions, potentially altering the distributions of marine organisms (Goldstein et al. 2012). GESAMP describe some examples, plastic pellets act as an oviposition site for marine insects such as *Halobates micans* and *Halobates sericeus* (Goldstein et al. 2012; Majer et al. 2012), having a positive effect on the population size and dispersal of this species. Duarte et al. (2012) pointed out that the increase in human structures in the ocean may be contributing to the increase in jellyfish blooms. The proliferation of microplastic particles provides substratum for attachment and development of

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		jellyfish hydroid life stages. GESAMP list the species of commercial fish that have been documented with microplastics in their guts; including the pelagic bluefin, swordfish, albacore, Atlantic herring, sardine, European and Pacific anchovies, Indian mackerel, benthic/demersal hake, blue whiting, red mullet, small scale and common dolphin fish (Foekema et al. 2013; Kripa et al. 2014; Rochman et al. 2015a; Romeo et al. 2015; Lusher et al. 2013; Avio et al. 2015; Deudero and Alomar 2015). According to GESAMP, little is known about the impact of microplastics to fish health. Concern is mentioned over the translocation of microplastics into the tissues of organisms, as well as the tendency of microplastics to accumulate chemical contaminants. In terms of shellfish, GESAMP reports that microplastics identified in shellfish range in size from5 µm to 5 mm and are composed of fragments, pellets and fibres and are found in both wild and cultured shellfish. One study showed that microplastics (2 to 16 µm) can be retained by *Mytilus edulis* following ingestion (Browne et al. 2008) and that the particles in the size range 3 to 9.6 µm can be translocated outside the gut and into the hemolymph. GESAMP also mention studies on green crab, which were found to ingest microplastics under controlled conditions (Farrell and Nelson, 2013; Watts et al. 2014). Natural populations of brown shrimp (*Crangon crangon*), sampled across the English Channel area and Southern part of the North Sea (between France, Belgium, the Netherlands and the UK) have also been found to be contaminated with microplastics. In addition, studies on gastropods are mentioned; which reported the presence or absence of microplastics in edible snails collected from the Dutch coast: 30 microplastics per gram d.w. in periwinkles (Leslie et al. 2013) while microplastic could not be detected in common limpet (*Patella vulgaris*) (Karlsson 2015). Echinoderms are mentioned by GESAMP, however the effects of microplastics are not included in the text.
Foley et al. (2018) *A meta-analysis of the effects of exposure to microplastics on fish and aquatic invertebrates*	In the current study, we conducted a meta-analysis of published literature to examine impacts of exposure to microplastics on consumption (and feeding), growth, reproduction, and survival of fish and aquatic invertebrates. Plastics Hazard assessment	Foley et al. indicate that microplastic can also be incidentally ingested by adhering to natural prey items, e.g. seaweed or fish eggs, (e.g., Kashiwada, 2006; Gutow et al., 2016), or via absorption through gills (e.g., Kashiwada, 2006; Watts et al., 2014). Further, plastic particles that have been ingested could be absorbed through gut walls (Browne et al., 2008; Snell and Hicks, 2011). The evidence presented in the review suggests that exposure of individual aquatic organisms to microplastics may negatively impact feeding (e.g., Wegner et al., 2012; Ogonowski et al., 2016), growth (e.g., Au et al., 2015; Jeong et al., 2016), reproductive capabilities (e.g., Della Torre et al., 2014; Ogonowski et al., 2016), and survival (e.g., Booth et al., 2016; Luís et al., 2015), due to, for example, blockage of feeding structures or reduced consumption of prey (e.g., as reviewed by Wright et al., 2013b, Eerkes-Medrano et al., 2015). However, Foley et al. conclude that the effects of microplastic exposure do not appear to be consistent across studies. Some organisms may be resilient to stresses induced by microplastic exposure (e.g., Nasser and Lynch, 2016; Watts et al., 2016), and the fact that microplastics

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	Microbeads Microfibers Review Good table 1 summarising effects literature	can be egested suggests that cumulative impacts may not occur. Foley et al. state that the overall potential impact of microplastic pollution in aquatic systems remains difficult to predict. Foley et al. include a number of scientific studies assessing the impacts of microplastics on the vital rates of fish and aquatic invertebrates (e.g., Eerkes-Medrano et al., 2015; Phuong et al., 2016; Wright et al., 2013b, among others) and suggest that their results most strongly support the notion that exposure to microplastics leads to negative effects on consumption of aquatic organisms, with less compelling and consistent evidence that growth, reproduction, or survival of aquatic organisms is negatively affected by exposure to microplastics. Foley et al. suggest that zooplankton are among the most susceptible biota to microplastic exposure, which could have broader ramifications for aquatic food webs. The tendency of these taxa to consume microplastics may promote the accumulation and transfer of plastics up the food web (e.g., Setälä et al., 2014; Farrell and Nelson, 2013). In addition, Foley et al. support the notion that plastics interfere directly with feeding by larval or juvenile fishes, potentially blocking digestive tracts or otherwise not allowing for proper digestive function (reviewed in Cole et al., 2011). Therefore any factor that negatively influences an animal's ability to feed may have impacts on long-term growth and survival. Interestingly, their findings do not provide strong evidence that growth was negatively impacted by plastic exposure. Although Foley et al. note that it is possible that many studies did not extend long enough for strong growth effects to be observed, given that most exposures were limited to <30 days. In their meta-analysis Foley et al. did observe within-taxa negative effects for all four categories of responses, however many of the effects summarized in the study were neutral, indicating that the effects of exposure to microplastics are highly variable across taxa. The most consistent effect was a reduction in consumption of natural prey when microplastics were present. For some taxa, negative effects on growth, reproduction and even survival were also evident. As opposed to the relatively direct responses that were assessed, Foley et al. suggest that it is possible that effects of exposure to microplastics are more indirect (e.g., alteration of microbial communities in the environment or guts; Oberbeckmann et al., 2015) or have more direct and apparent impacts on responses other than the four assessed herein (e.g., endocrine disruptor effects that negatively impact reproduction; Sussarellu et al., 2016). The biochemical effects of microplastics have potentially important implications for the fitness of organisms (e.g., Rochman et al., 2013). For example, Foley et al. give the example of PCB concentrations in fish tissue decreasing after fish were fed PCB-spiked food followed by clean plastic (Rummel et al., 2016), and exposing organisms to silver or fluoranthene alongside microplastics may have helped decrease the amount of contaminant that was ultimately transferred to organisms (Khan et al., 2015; Paul-Pont et al., 2016). All of these authors noted, however, that any decreases in contaminant level could also have been

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		attributed to other sources, and transfer of contaminants to organisms did still happen (Khan et al., 2015; Paul-Pont et al., 2016; Rummel et al., 2016). Foley et al. suggest that future work should focus on whether microplastics may be affecting aquatic organisms in more subtle ways, e.g., by influencing exposure to contaminants and pathogens, or by acting at a molecular level. Future authors should consider reporting both the size and weight of individual plastic particles, if possible, and a weight or density per unit of volume (as described in Phuong et al., 2016). Their findings support the scientific and public concern over plastic pollution of aquatic ecosystems: effects of microplastics were generally negative or neutral across taxa (never positive), with the strongest effects observed on lower trophic level organisms that serve as important linchpins for food web structure (Pace et al., 1999). Importantly, Foley et al. notes that the results included in the analyses were potentially affected by publication bias. This remains a challenge to meta-analyses, and even the studies that we included had bias-related issues.
Auta et al. (2017) *Distribution and importance of microplastics in the marine environment: A review of the sources, fate, effects, and potential solutions*	This review describes the sources and global distribution of microplastics in the environment, the fate and impact on marine biota, especially the food chain. Microplastics Pollution Ingestion Marine environment Sediments Bio-uptake	Auta et al. begin by stating the level of the problem, suggesting that only <5% of plastic material used has been recovered and this has led to the accumulation of plastics in the marine environment (Sutherland et al., 2010). Auta et al. use the definition that 'microplastics are tiny ubiquitous plastic particles smaller than five millimetres (5 mm)' and confirm that microplastics have the potential to cause many adverse effects such as cancer, impaired reproductive activity, decreased immune response, and malformation in animals and humans. Auta et al. quote the study Gouin et al. (2011) that reported that the US population releases about 263 tonnes yr^{-1} polyethylene microplastics, mainly from the usage of personal care products. Auta et al. note that sewage sludge is also a source of microplastic pollution as it contains more microplastics than effluent (Leslie et al., 2012; Alomar et al., 2016). The consumption of microplastics by marine organisms is noted to cause mechanical effects such as attachment of the polymer to the external surfaces thereby, hindering mobility and clogging of the digestive tract, or the effect could be chemical such as inflammation, hepatic stress, decreased growth (Setala et al., 2016). In addition to the physical/mechanical effects, Auta et al. indicate that the large surface area to volume ratio of microplastics makes them liable to contamination by water borne-contaminants such as persistent organic pollutants (POPs), metals (Ashton et al., 2010; Cole et al., 2011), and endocrine disrupting chemicals (Ng and Obbard, 2006). Chua et al. (2014) demonstrate the assimilation of polybrominated diphenyl ethers from microplastics by *Allorchestes compresa*. Auta et al. also note the study of Wardrop et al. (2016), who reported the assimilation of polybrominated diphenyl ethers by fish into the tissues. This experiment investigated the transfer of persistent organic pollutants sorbed unto microplastics from

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		personal care products, the rainbow fish (*Melanotaenia fluviatilis*) were exposed to microbeads that had been sorbed with polybrominated diphenyl ethers (PBDEs) and monitored at 0, 21, 42, and 63 days. Exposed fish were found to have accumulated high concentrations of PBDEs (ca.115pg.g^{-1} ww.d^{-1}) in the tissue after ingestion (Wardrop et al., 2016). Marine studies focussed on ingestion and subsequent toxic implications are listed in the article by Auta et al. including effects on *Pomatoschistus microps* (Oliveira et al., 2013; Luís et al., 2015; Ferreira et al., 2016), zebra fish (*Danio rerio*)(Khan et al., 2015), whales (Fossi et al., 2016; Lusher et al., 2015a,b), microalgae (Sjollema et al., 2015), and on cod, dab, flounder, and the pelagic fish species (mackerel and herring) from the North and Baltic Sea (Rummel et al., 2016). Again the study of Rochman et al. (2013) is noted by Auta et al., where they investigated the effect of toxic chemicals that had been sorbed on microplastics in marine fish (*Oryzias latipes*). From the study, the fish ingested and bioaccumulated the harmful chemical substances which resulted in pathological and oxidative stress, and the inflammation of the liver. Few studies have demonstrated trophic transfer of microplastics and adhered contaminants, other than Batel et al. (2016) who investigated the transfer of microplastics and potential harmful substances between different trophic levels in the marine environment. The study concluded that the microplastic particles acted as a vector for the transfer of associated persistent organic pollutant benzo [a] pyrene (BaP) from the nauplii to the zebra fish, and the substance was retained in the intestinal tract. However, no physical harm was observed in either nauplii and zebrafish. Auta et al. do mention one population level study using European perch (*Perca fluviatilis*), exposed to 90µm polystyrene microplastic particles. Fish ingested and accumulated the polystyrene microplastics which resulted in decreased growth, hindered hatching, and altered the feeding and behaviour, and even affected the olfactory senses that enhanced susceptibility to predation. There was a steep decline in the European perch population which the study attributed to the high pollution of the sea with microplastics (Lönnstedt and Eklöv, 2016). Auta et al. note a study on the effects of microplastics on trophic/ assemblage structure in marine organisms. Green (2016) subjected European flat oyster (*Ostrea edulis*) to low and high doses (0.8 µgL^{-1} and 80 µgL^{-1}) of biodegradable and conventional microplastics for a 60 day period. After exposure, it was observed that the respiration rates of *Ostrea edulis* were elevated in response to high doses of polylactic acid (PLA) microplastics which indicated that the oysters were under stress. Similarly, the abundance and biomass of associated benthic organisms which included periwinkles (Littorina sp.), isopod (*Idotea balthica*), and the peppery furrow shell clam (*Scrobicularia plana*) reduced. The reduction was attributed to reduced reproductive output and mortality due to microplastic ingestion and reduced feeding (Green, 2016).

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		A number of further studies are referenced by Auta et al. that focus on effects on marine plankton. For example, Cole et al. (2016), demonstrated the effect of polystyrene microbeads on the feeding, function and fertility of the marine copepod; *Calanus helgolandicus*. Prolonged exposure resulted in death of some of the copepods, fewer egg productions, and decreased reproductive output which affected hatching. The results were comparable with Kaposi et al. (2014) and Lee et al. (2013) that also demonstrated that the survival of zooplankton may be impacted by exposure to high concentrations of microplastics. Auta et al. discuss a single study on the contamination of microplastics in human food. The presence of microplastics in sea salt has recently been demonstrated by Yang et al. (2015) who report 7–204 particles kg^{-1}, 550–681 particles kg^{-1} and 43– 364 particles kg^{-1} of microplastics in 15 brands of rock/well salts, sea salt and lake salt, respectively. The microplastics found were polyethylene, cellophane and polyethylene terephthalate. In summary, Auta et al. list a number of studies that demonstrate effects of microplastics in wildlife including: increased toxicological stress in fin whales (Fossi et al., 2016) and affected algal growth (Sjollema et al., 2015). Microplastics are known to cause liver toxicity and inflammation, and cause the accumulation of lipids in the liver of fish (Lu et al., 2016). Microplastics can also serve as a vector for the assimilation of persistent organic pollutants (POPs) and heavy metals by marine organisms and the environment (Chua et al., 2014; Brennecke et al., 2016), and reduce the feeding activity of invertebrates (Besseling et al., 2012). Auta et al. suggest that a more promising and environmentally safe approach could be provided by exploiting the potentials of microorganisms, especially those of marine origin that can degrade microplastics.
Phuong et al. (2016) *Is there any consistency between the microplastics found in the field and those used in laboratory experiments?*	Microplastics Field samples Laboratory exposures Ingestion Biological effects	Phuong et al. state that among the different biological effects, mortality rate, energy budget, loss of weight, feeding activity, embryonic development, predation, biomarker responses and alteration of gene expression have been the most investigated in relation to microplastics. The hypothesis that microplastics are taken up into cells and can cause significant effects on tissue and at the cellular level was corroborated by Von Moos et al. (2012) in mussels (M. edulis). Browne et al. (2008) showed in mussels (M. edulis) that ingestion and translocation of microplastics did not change the phagocytic activity, but increased immune response. Phuong et al. discuss a fish study concerning *Pomatoschistus microps* that were exposed to PE microspheres at concentrations ranging from 18.4 to 184 mg/L (Oliveira et al., 2013). After 96 h of exposure, a reduction of acetylcholinesterase (AChE) activity had been shown to occur. In contrast, no significant effect of PE was found for glutathione S-transferase activity and lipid per- oxidation. Again, Phuong et al. note that they study of Rochman et al. (2014) mixed low-density PE with the food of

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		another fish species (*Oryzias latipes*) at a high proportion (up to 10% of the prey species) over a two month exposure. Several negative effects were identified: down-regulation of choriogenin, vitellogenin and estrogen receptor (ERa) mRNA gene expression and abnormal germ cell proliferation. Severe glycogen depletion and fatty vacuolation were also observed. In the long term, a potential increase of mortality due to the effects observed at molecular level is still under debate. Contrasting effects are demonstrated by Phuong et al. using Rochman et al. (2013, 2014) who reported a mortality rate reaching 6%. In contrast, Browne et al. (2008) showed that in mussel (*M. edulis*), exposure to PS microspheres did not affect their viability. Again, Phuong et al. give examples of contrasting study outcomes including at high concentrations of exposure (up to 5% by weight, in sediment), where Wright et al. (2013) showed a depletion of energy reserves (up to 50%) in lugworms (*Arenicola marina*), after 10 days of exposure, whereas despite longer exposure time (up to 14 days), Van Cauwenberghe et al. (2015) showed no depletion of energy reserves for this species at low concentrations. The impact of microplastics on copepod (*Centropages typicus*) feeding activity was also investigated by Cole et al. (2013, 2015). A significant decrease of algal feeding was shown under different conditions of microplastic exposure (>4000 beads of PS 7.3 mm/24 h and 75 beads of PS 20 mm/ 24 h, Cole et al., 2013, 2015 respectively). For lugworms (*Arenicola marina*) exposed to microplastics, a reduced feeding activity was likewise shown in two different studies (Besseling et al., 2013; Wright et al., 2013). A loss of weight in *A. marina* was indeed observed when microplastic concentration increased in exposure media (Besseling et al., 2013). Phuong et al. note that predation effects as a result of microplastics exposure has also been studied. De Sa et al. (2015) showed that predation of a fish species (*Pomatoschistus microps*) and its efficiency were reduced by 65% and 50% respectively in the presence of PE microspheres. At the ecological level, Phuong et al. give examples of studies examining population survival. Although there was no significant effect of microplastic exposure on production rates and egg size of the copepod (*Centropages typicus*), following exposure to microplastics the hatching of eggs seemed depleted (Cole et al., 2013, 2015). The toxicity of PE on the embryonic development of an Echinodermata (*Lytechinus variegatus*) was also demonstrated by Nobre et al. (2015). After 24 h of exposure, PE pellets had negative effects on embryonic development, which was assessed in terms of the presence of abnormal embryos. Phuong et al. also highlight that trophic transfer has been studied at different levels of the food web. Farrell and Nelson (2013) observed microplastic trophic transfer from mussels to crabs. *M. edulis* were exposed to 0.5 mm fluorescent PS microspheres (411 million particles) during 1 h. Microspheres were subsequently detected in the stomach, hepatopancreas, ovary, gills and haemolymph of the exposed crabs. Another study by Desforges et al. (2015) is discussed, who estimated that consumption of the microplastics contained in zooplankton led to the ingestion of 2-7 microplastic particles/day by members of

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		the juvenile salmon species (*Oncorhynchus spp*.) from coastal British Columbia, and 91 microplastic particles/day in returning adults. Finally, Van Cauwenberghe and Janssen (2014) estimated that annual dietary exposure for European shellfish consumers can reach 11,000 microplastics per year. Phuong conclude that these results pose a challenge about consequences on human health. Phuong et al. then compare field and laboratory studies, stating that the range found in the field was 0.004-9200 particles/m^3. In laboratory exposure studies, the contamination range expressed in particles/mL was 42 to 10 000 corresponding to 42 million to 10 billion particles/m^3. Comparing these values, it is obvious that the concentrations were not of the same order of magnitude, the lowest concentration of exposure being about 4 500 times greater than the highest field concentration. For sediment studies, Phuong et al. quote field microplastic concentrations in particle number/ kg of sediment with values ranging from 0.3 to 8 000 corresponding to 0.0003 to 8 particles/g. This value is more than 10 times below the concentration employed by Van Cauwenberghe et al. (2015). Only one study on natural sediments from the Indian Ocean (Reddy et al., 2006) has expressed the concentration as 81.43 mg/kg, corresponding to 0.0081%, which was about 600 times lower than the concentrations used by Browne et al. (2013) and Wright et al. (2013) in laboratory exposures. Phuong et al. state that it therefore remains difficult to conclude that experimental exposures are likely to mimic environmental conditions in terms of microplastic contamination. Only Rochman et al. (2014) deployed PE pellets in marine areas during a three month period to obtain microplastics more similar to those found in the environment. Otherwise, all the laboratory experiments reviewed were performed with microplastic concentrations at greater concentrations than those found in the field. Consequently, the ingestion and associated effects observed in organisms in laboratory studies corresponded to highly contaminated conditions. Studies employing concentrations comparable to environmental microplastic levels are challenging since the available analytical tools do not yet permit identification of the biological effects occurring at low concentrations of exposure. In addition to the problems associated with highly variable microplastic concentrations, Phuong note the difficulty to differentiate and separately measure the mechanical and the chemical effects of microplastics on organisms. The organic compounds include nonylphenol, triclosan, pyrene, polybromodiphenylethers (PBDEs), PAHs, PCBs (Browne et al., 2013; Oliveira et al., 2013; Chua et al., 2014; Avio et al., 2015) which are known to cause toxic effects by themselves (Meeker et al., 2009; Oehlmann et al., 2009; Talsness et al., 2009; Vidal-Linan et al., 2015). Consequently, the presence of these compounds in microplastics generated an additional effect, rendering it difficult to determine from where the toxicity arises.
EFSA (2016)	Microplastic	EFSA discuss the occurrence of microplastics in food, commenting that studies and data on the subject are scarce. EFSA states that in terms of fish (as food) studies only provide data on microplastics in the

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Statement on the presence of microplastics and nanoplastics in food, with particular focus on seafood	Nanoplastic Food Seafood Occurrence Risk assessment	digestive tract. This part of the fish is usually discarded and are rarely consumed, so EFSA assume that the consumption of microplastics from this source is negligible. In comparison Bivalves are more likely to accumulate microplastics and their digestive tract is consumed rather than thrown away. Therefore, ingestion by humans from this source is likely to be significantly higher. According to EFSA, Chinese mussels contained the highest number of microplastics: median value 4 particles/g (Li et al., 2015). Following calculation, EFSA conclude that consumption of such a portion of Chinese mussels (225 g) would lead to ingestion of about 900 plastic particles. There are no studies regarding the effects of microplastics once ingested by humans according to the EFSA article. A chicken model was used by Mahler et al (2012) to study the effects of iron uptake with nanoparticles. A single dose of 2 mg/kg body weight (bw) of 50 nm carboxylated polystyrene particles resulted in a threefold suppression of iron absorption. Following on from this study, EFSA mention a second in vitro study that used human cell lines, it suggested that positively charged polystyrene nanoplastic particles can disrupt intestinal iron uptake. A chronic 2-month dietary exposure in Japanese medaka, using plastic pellets, resulted in female fish expressing significantly less Chg H when compared to the control (Rochman et al. 2014b). In another study disposition and toxicity of two different polystyrene nanoparticles in the early development of sea urchin embryos were investigated (Della Torre et al. 2014). Embryos were exposed to either carboxylated polystyrene nanoparticles (PS-COOH) (40 nm) or amino-modified polystyrene nanoparticles (PS-NH2; 50 nm) (Della Torre et al. 2014). Findings included thickening and abnormal proliferation of the ectodermal membrane, incorrect location, incomplete or broken skeletal rods and fractured ectoderm (Della Torre et al. 2014). In addition to these effects studied, it may be expected that micro- and nanoplastics will most likely interact with the immune system, not in the least because they can be taken up by phagocytic cells. In a study in mussels (*M. galloprovincialis*), decreased phagocytic activity caused by nanoplastics has been described (Canesi et al., 2015), but studies in other species are lacking. Based on a conservative estimate the presence of microplastics in seafood would have a small effect on the overall exposure to additives or contaminants. Toxicity and toxicokinetic data are lacking for both microplastics and nanoplastics for a human risk assessment. It is recommended that analytical methods should be further developed for microplastics and developed for nanoplastics and standardised, in order to assess their presence, identity and to quantify their amount in food.
Anbumani and Kakkar (2018)	The present review focused on the ecological impact of microplastics on biota at different trophic levels, its	Anbumani and Kakkar begin by giving and overview of the scientific evidence around microplastics which shows that exposure triggers a wide variety of toxic insult from feeding disruption to reproductive performance, physical ingestion, disturbances in energy metabolism, changes in liver physiology, synergistic and/ or antagonistic action of other hydrophobic organic contaminants etc. from lower to higher

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Ecotoxicological effects of microplastics on biota: a review	uptake, accumulation, and excretion etc., and its plausible mechanistic toxicity with risk assessment approaches. Microplastics Ecological impacts Risk assessment Regulatory ecotoxicology Table 2 has good summary of effects literature. Key diagrams of proposed impact pathways are also given in the article.	trophics. Anbumani and Kakkar conclude that microplastic accumulation and its associated adverse effects make it mandatory to go in for risk assessment and legislative action. Anbumani and Kakkar do note that evidence for microplastics impact on freshwater biota is limited both in terms of studies and species exposed. As stated by Duis and Coors (2016), microplastics uptake by freshwater organisms has so far only been addressed in relatively few studies. Effects are presented in the paper by trophic level, starting with producers. Anbumani and Kakkar introduce the following studies (sometimes contrasting) on producers: Nano-polystyrene particles (0.22 and 103 mg/l) exposure to *Scenedesmus obliquus* affects the growth and photosynthesis in terms of reduced chlorophyll content (Besseling et al. 2013). On the other hand, Sjollema et al. (2016) observed no changes in algal growth rate but a significant reduction in photosynthesis from 2.5 to 45% upon 72-h exposure to polystyrene particles of size between 0.05 and 6 µ min *Dunaliella tertiolecta*, *Thalassiosira pseudonana*, and *Chlorella vulgaris*. Lagarde et al. (2016) presented the first evidence on microplastic-induced molecular toxicity in freshwater microalgae, *Chlamydomonas reinhardtii*. Exposure to high density polyethylene (HDPE) and polypropylene (PP) particles to *C. reinhardtii* induced hetero aggregates consisted of 50% microplastics, 50% microalgae, and exopolysaccharides during 20 days post-exposure period. For consumers: Information on the accumulation and ecotoxicity of microplastics in freshwater biota is limited, except a few from laboratory studies (Rosenkranz et al. 2009; Holmetal. 2013; Jemec et al. 2016; Maetal. 2016; Ogonowski et al. 2016; Rehse et al. 2016; Rist et al. 2017; Lei et al. 2018; Murphy and Quinn 2018) conducted on crustaceans and cnidarians whereas Imhof et al. (2013) observed the uptake of microplastic in different taxa like annelids(*Lumbriculus variegatus*), crustaceans (*Daphnia magna* and *Gammarus pulex*), ostracods (*Notodromas monacha*), and gastropods (*Potamopyrgus antipodarum*) under field conditions. Rosenkranz et al. (2009) noticed that the water flea, *Daphnia magna*, is capable of rapidly ingesting the microplastics of size 0.01 and 1 mm in the gut epithelia and accumulate in lipid storage droplets. The findings revealed that the observed mortality is not due to the release of chemicals from the fibres but merely a clogging effect in the gut portion might be the possible reason for daphnid mortality. Ogonowski et al. (2016) noted lower feeding and reproductive performance in *Daphnia magna* exposed to primary and secondary microplastics and accumulation in the digestive tract with increased gut passage time. Rehse et al. (2016) showed that daphnids are sensitive enough to ingest 1 µm microplastic particles in a concentration-time dependent manner that results in immobilization suggesting that particle size plays a crucial role. Anbumani and Kakkar mention a more recent study by Rist et al. (2017) that looked at quantifying body burden by fluorescent intensity measurement, feeding rate assessment, and reproduction in *D. magna* after fluorescent polystyrene beads (2 µm and 100 nm) exposure. Despite the high body burdens and 21% decreased feeding rate, no significant effects on reproduction is noted for 100 nm particles at the end of

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		21-day exposure. These findings of Rist et al. (2017) show that measurement of the fluorescence intensity provides valuable data for quantification of animal body burden of microplastic particles that are analytically challenging till date. Effects of microplastics on freshwater pelagic (water column) and benthic (sediment) ecosystems were studied by Lei et al. (2018). Significant inhibition of survival rate, body length, and reproduction has been noted in the sediment- dwelling organism, *C. elegans* along with increased GST enzyme levels. Anbumani and Kakkar also give some examples of studies for vertebrates: Microplastics between 1 and 5 µm (polyethylene) modulate the toxicity of pyrene in the estuarine goby, *Pomatoschistus microps* with increased pyrene metabolites (Oliveira et al. 2013) whereas microplastic-induced hepatotoxicity was observed in Japanese medaka, *Oryzias latipes* exposed to 3- mm low-density polyethylene (LDPE). Interestingly, female fish exposed to dietary microplastics showed a significant reduction in the expression of choriogenin H, an early warning signal for endocrine disruption (Rochman et al. 2013). In addition, Anbumani and Kakkar state that it has also been shown that plastic facilitates the transport of contaminant to the sediment dwelling lugworm, *Arenicola marina* and amphidromous Medaka fish, *Oryzias latipes* (Teuten et al. 2007; Rochman et al. 2013). Besides, microplastics can also act as vectors in modulating the toxicity in organisms exposed, and it is proven experimentally that microplastics attenuated the effects of organic contaminants such as POPs, PAHs, PCBs, and PBDEs in fishes (Rochman et al. 2013; Oliveira et al. 2013). Trophic transfer of contaminants is discussed in Anbumani and Kakkar using the study of Batel et al. (2016) who studied the extent microplastics aid in the transfer of persistent organic pollutants like benzo(a)pyrene (BaP) through an artificial food chain. Zebrafish were fed with *Artemia* nauplii loaded polyethylene microplastics of 1–5 and 10–20 µm size with pre-conditioned BaP (252 µg/L) results in efficient transfer of chemicals on natural food chains across various trophic levels. Polystyrene microplastic particles induced systemic toxicity is reported by Veneman et al. (2017) in zebrafish larvae. Anbumani and Kakkar also give the following studies demonstrating effects in marine species. From the level of producer: Exposure of polyvinyl chloride (PVC) microplastics of 1 µm size on marine microalgae, *Skeletonema costatum*, effectively inhibits 39.7% growth ratio after 96-h exposure whereas 1mm particle size of PVC had no effects on algal growth (Zhang et al. 2017b). Contrary to this, no significant growth rate inhibition is noted in *Tetraselmis chuii* after fluorescent red polyethylene micro- spheres (1–5 µm) exposure in the presence and absence of copper suggesting that the smaller the particle size, the greater the microplastic toxicity (Davarpanah and Guilhermino 2015). Farrell and Nelson (2013) observed the trophic level transfer of microplastics from mussels to crabs. This is the first report that shows the 'natural' trophic transfer of microplastics on marine biota. Additional highly cited studies are also referenced by Anbumani and Kakkar, such as Cole et al. (2013, 2015) who identified a downward shift towards feed intake, fecundity, and survival of *Calanus helgolandicus*. Findings suggest that chronic exposure to PS particles has an untoward effect on

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		reproductive output with no differences in egg production rate, respiration, or survival. This important finding is of particular ecological relevance, that copepods with reduced growth might impact higher trophic organisms which rely on the high lipid content of copepods for their own survival. From the population-level perspective Anbumani and Kakkar note one study where microplastics exert negative effects on reproduction at the higher hierarchy. Here, oysters exposed to polystyrene microplastics (2 and 6 μm size) showed decreased oocyte number (− 38%) and sperm velocity (− 23%) (Sussarellu et al. 2016). Anbumani and Kakkar state that the first evidence on the adverse effects of microplastics on diversity and benthic communities' growth abundance was shown by Green et al. (2015) and Green (2016). Repeated exposure of biodegradable and conventional microplastics resulted in altered benthic assemblage structures and species richness with primary productivity. From the perspective of contaminants, Anbumani and Kakkar also note the popular study of Browne et al. (2013) who observed increased accumulation of nonylphenol and triclosan in the presence of polyvinyl chloride (PVC) leading to impaired immune functions, physiological stress, and mortality in the lugworm, *A. marina*. Paul-Pont et al. (2016) observed accumulation of higher concentrations of fluoranthene in *Mytilus* spp. exposed to both PS microbeads and fluoranthene owing to the higher partition coefficient of PS particles. The study by Martínez Gomez et al. (2017) is also noted, as they evaluated the effects of virgin, aged and leachate of PS and HDPE fluff particles in the sea urchin, *Paracentrotus lividus*. During the 48-h incubation period, fertilization and larval development are impaired to a significant extent. Rist et al. (2017) also evaluated the ecotoxicity of micro-sized PVC particles (1–50 μm) in Asian mussel, *Perna viridis*. Microplastics suspensions from the sediment were exposed to *P. viridis* for 2 h/day for a total of 91 days. After 44 days of exposure, filtration behaviour, respiration rate, and byssus production were greatly reduced. Anbumani and Kakkar conclude that studies in fish have observed that microplastics effects are inconsistent and depend on species. Peda et al. (2016) report incidences where PVC fragments tend to induce severe effects on distal part of the intestine. Whereas Tosetto et al. (2017) were unable to find any prominent effects of microplastics on fish personality occupying intertidal zone and Alomara et al. (2017) analyzed the effects of polyethylene terephthalate (PET) microplastics on striped red mullet, *Mullus surmuletus*. One-third of the individuals exposed shows microplastics ingestion and no further evidence of oxidative stress induction. Jovanovic (2017) summarizes recent discoveries regarding the potential negative effects of micro- and nanoplastic ingestion by fish. Anbumani and Kakkar note that the occurrence of microplastics in the gastrointestinal tract of fish is ephemeral, with low accumulation potential in the gastrointestinal tract, although translocation to the liver may occur. Overall, Anbumani and Kakkar suggest that the findings highlight the need for further investigations on the interaction of multiple stressors (chemical contaminants and abiotic factors like temperature) on higher

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		organisms during marine microplastics risk assessment. Only Fonte et al. (2016) investigated the multiple stressor toxicity (microplastics, cefalexin, and temperature) to *Pomatoschistus microps* juveniles. As the temperature increases from 20 to 25 °C, microplastics-induced mortality is noted with predatory performance inhibition whereas co- exposure of microplastics and cefalexin results in reduced predatory performance and acetylcholine esterase inhibition. Anbumani and Kakkar conclude by listing the following data gaps in the literature: • Information on the impact of microplastics on human health via sea food ingestion is currently not available. • Information on the transfer of microplastics across the gut into tissues and transfer of associated chemical moieties is unavailable. • Detailed global protocol for isolation, characterization, and validated instrumental analysis to determine microplastics in various freshwater matrices are lacking. • Moreover, data from field studies are required adjudicate the probability of one-to-one interaction between microplastics and organism to shed light on expected biological effects and its relevance to ecosystem dynamics • Systematic comparative studies should be undertaken on physical and/or chemical components of microplastics to discern whether the observed effects are due to particle induced (physical ingestion) or chemically released hazards. • Occurrence and effects of microplastics on invertebrates is not fully understood. • Research should be prioritized on suitable alternatives to microbeads in the cosmetic products that are likely to biodegrade.
Burns and Boxall (2018) *Microplastics in the aquatic environment: Evidence for or against adverse impacts and major knowledge gaps*	We present the results from a systematic review of the published literature to attempt to answer the following question: do existing data on the occurrence and effects of microplastics in the environment indicate that these materials are causing harm?	Burns and Boxall begin by discussion the definition of microplastics, stating that 'a microplastic is any solid plastic particle <5mm in size (Eerkes-Medrano et al. 2015). Agreement on the higher end of the microplastic range (5 mm) is consistent in the literature; however, various authors have proposed differing lower limits (Hidalgo-Ruz et al. 2013; Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection 2015; Lassen et al. 2015). The Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (2015) set the lower limit of the microplastic size range to 1nm, whereas Lassen et al. (2015) limited the lower end of the range to 1mm. Burns and Boxall give some examples quantifying releases from primary microplastics, one by Sundt et al. (2014), who concluded that consumer products were expected to have the smallest contribution. The other was focussed on Denmark: 0.9% of the total microplastic emission to the aquatic environment was

Journal reference	Key components	Summary/Overview
	Microplastics; Species sensitivity distribution; Risk; Persistent organic pollutants	expected to be primary microplastics (0.1% cosmetic products) (Lassen et al. 2015). Burns and Boxall comment that a great deal of regulatory focus has been placed on primary microplastics, which, in terms of occurrence, appear to be less significant based on the present results. Burns and Boxall conclude that reducing or banning (e.g., cosmetic microbeads) may only have a limited impact on reducing environmental microplastic loads, a conclusion also drawn by Gouin et al. (2015). Burns and Boxall introduce a number of studies that demonstrate ingestion/egestion rates of microplastics on a number of trophic levels. For example, Scherer et al. (2017) found that microplastics co-exposed with algae significantly reduced microplastic ingestion by *Daphnia magna*. Weber et al. (2018) found that the microplastic body burden of *Gammarus pulex* depended on dose and age. There is evidence of efficient gut clearance in goldfish of both bead-shaped microplastics and fibres (Grigorakis et al. 2017). Furthermore, Mazurais et al. (2015) observed complete egestion of bead-shaped microplastics (10–45mm) from *Dicentrarchus labrax* larvae after a 48-h depuration period. Lu et al. (2016) exposed zebra fish to 20- and 5-mm as well as 70-nm microplastics and found 5-mm and 70-nm particles in the gills, liver, and gut, whereas 20-mm particles were found only in the gills and gut. Burns and Boxall note that the trophic transfer of microplastics has been demonstrated in the laboratory (Farrell and Nelson 2013; Setala et al. 2014; Tosetto et al. 2017) but the circumstances of these conclusions are important to consider. Burns and Boxall state that these artificial conditions are poorly representative of environmental conditions and thus results should be interpreted with caution. They also conclude that trophic transfer of microplastics has yet to be shown in the field, although a recent study reported that neither fish mass nor trophic level was related to microplastic ingestion, leading the authors to conclude that observed microplastic presence is ephemeral, suggesting low biomagnification potential because of significant gut clearance (Guven et al. 2017). Burns and Boxall indicate that the above studies agree with laboratory studies demonstrating low microplastic gut retention times in fish (Mazurais et al. 2015; Grigorakis et al. 2017) and invertebrates (Ugolini et al. 2013; Hamer et al. 2014; Blarer and Burkhardt-Holm 2016), providing further evidence that accumulation will be minimal. Burns and Boxall suggest that the majority of laboratory tests have resulted in a NOEC; however, in many cases this refers to the highest exposure concentration tested (Browne et al. 2008; Blarer and Burkhardt-Holm 2016; Watts et al. 2016; Chen et al. 2017). This therefore could indicate that the true NOEC may actually be greater. Caveats of some studies are also discussed by Burns and Boxall including, for example, Rochman et al. (2013b). Important biomarker responses related potentially to lack of nutrition were reported. In addition, the study, similar to others (Paul-Pont et al. 2016), lacked a negative control. Burns and Boxall suggest a more realistic approach would be the addition of plastic to food without replacement (Imhof and Laforsch 2016) or including a negative control (Karami et al. 2016; Watts et al. 2016). Burns and Boxall conclude that data from laboratory-based studies indicate that some microplastics have the potential to adversely affect organisms when exposed at very high concentrations (e.g., EC50 of 8.6 $x10^7$ particles/L; Ogonowski

Journal reference	Key components	Summary/Overview
		et al. 2016). However, Burns and Boxall note that some laboratory studies have reported complete egestion of microplastics (in unrealistically high exposures) in 24 to 48 h (Grigorakis et al. 2017). This, in addition to the low internal concentrations of microplastics in wild animals (Table 2), lead Burns and Boxall to suggest that plastic does not accumulate in the gut long enough to facilitate desorption, even if gut surfactants did slightly enhance the thermodynamic favourability of HOC desorption. In addition, Burns and Boxall were not able to find a study where uptake of HOCs could truly be attributed to transport into the organisms by microplastics. Burns and Boxall indicate that based on these data, there is therefore little evidence that concentrations of microplastics seen thus far in the environment have a negative effect on organisms, particularly given that many of the monitoring studies are thought to have overestimated concentrations because of limitations in the identification methodologies. Overall, Burns and Boxall conclude that the comparison of MECs with effects endpoints does not support the claim of some that microplastics are negatively impacting the health of organisms in the environment. Concentrations of microplastics seen to cause effects on organisms are orders of magnitude higher than concentrations of microplastics measured in the environment. They recommend that to answer the question of whether microplastics negatively impact organisms in the environment: • the size range of microplastics needs to be clearly defined; • monitoring studies need to characterize the complete size range of microplastics that occur in the environment; • and effects studies need to work with test materials (plastic types, sizes, and shapes) that are consistent with those found in the environment. • Only then will we be able to come to any conclusion as to whether microplastics negatively impact the environment or not. Burns and Boxall also demonstrate that significant evidence for microplastics acting as a vector for HOCs into organisms has yet to be proven and that recent laboratory and modelling evidence suggests that the impact of this exposure pathway is minimal. There is currently limited evidence to suggest that adverse environmental impacts are caused by microplastics; however, there are major knowledge gaps that urgently need to be addressed to confirm or disprove this.

Journal reference	Key components	Summary/Overview
Connors et al. (2017) *Advancing the quality of environmental microplastic research*	We performed a thorough review of the quality and focus of environmental microplastic research, to understand the methodologies employed and how this may assist or distract from the ability of environmental risk assessors to evaluate microplastics. Microplastic Risk assessment Quality Relevance Reliability	Connors et al. note that 'Microplastics are generally defined as solid particles smaller than a specified upper size limit (<5mm)' and additionally, primary microplastics are unlikely to be a major component of microplastic pollution. Connors et al. discuss the issue that experimental concentrations frequently range from 10 to above environmentally relevant concentrations. These high experimental concentrations need to be considered when physically mediated hazard effects are proposed or observed. For example, in 2013 Cole et al. noted a decrease in algal uptake by copepods exposed to 4000 to 25 000 microplastic beads/mL. Physical adherence of microplastics to appendages and carapaces was also noted. Both effects are likely correlated to the high experimental concentrations. These modes of toxicity may be irrelevant at environmental concentrations. Connors et al. echo the suggestion of Phuong et al., that there is an urgent need for laboratory exposure conditions to mimic environmental concentrations. From the perspective of risk assessment, Connors et al. note that environmental risk typically focuses on mortality, growth, and reproduction. However, very few studies have examined these endpoints for microplastics. Connors et al. identified 14 toxicity studies that employed standard regulatory approaches to determine lethality from exposure to microplastics (Table 2). The lowest hazard concentration as described by particle abundance was observed in *Hyalella azteca* with 10- to 27-mm polystyrene particles (240-h median lethal concentration of 46 400 particles/mL). Connors et al. state that this concentration is orders of magnitude above currently measured environmental concentrations. When discussing the quality of current microplastic research Connors et al. suggest that despite the flurry of research, we still do not know whether we are focusing on the right particles (primary or secondary microplastics) or if polymer type is important, nor do we understand the importance of particle size on toxicity. To date, Connors et al. indicate that much of the existing hazard literature is unusable in a risk assessment framework because of sparse particle descriptions, limited methodological details, unverified exposure concentrations, inadequate experimental controls, and reliance on non traditional experimental endpoints. In summary, Connors et al. highlight that ecotoxicologists may be overselling their studies for decision-making and that our understanding of microplastic hazard and exposure is still in its infancy. Connors et al. warn that improvements in microplastic research are needed before an accurate and reliable risk assessment can be conducted and more emphasis should be on investigators to assess the relationship between laboratory observations and likely (or even extreme) levels of environmental exposure.
Scherer et al. (2018)	The aim of this chapter is to synthesize and critically revisit these aspects based on the state	Scherer et al. begin by stating that studies on the potential adverse effects caused by microplastic exposures are scarce for freshwater compared to marine species. For the most part, the literature on physical impacts suggests that nonselective filter feeders are especially prone to microplastic exposures.

Journal reference	Key components	Summary/Overview
Interactions of microplastics with freshwater biota	of the science in freshwater research. In this regard, the challenge is to understand the complex interactions of biota and plastic materials and to identify the toxicologically most relevant characteristics of the plethora of microplastics. Autecology, Feeding types, Microplastic-biota interaction, Polymers, Suspended solids, Vector	Scherer et al. note that adverse effects may include blockages, reduced dietary intake, and internal injuries. Discussion of effects literature is then broken down by organism groups. Starting with algae, for instance, 1 µm PVC fragments inhibited the growth and negatively affected photosynthesis (50 mg L^{-1}) of the marine algae *Skeletonema costatum*, while 1 mm PVC fragments did not induce such alterations. Scherer et al. then discuss a freshwater species *Daphnia magna*. The study determined that acute toxicity testing over 96 h resulted in an elevated immobilization at extremely high concentrations of 1 µm polyethylene (PE) particles. In addition, Scherer et al. comment on the chronic exposure to nanoscale PS over 21 days (0.22–150 mg L^{-1}) finding that it was not lethal. However, high concentrations of nano-PS (>30 mg L^{-1}) induced neonatal malformations and slightly decreased the reproductive output. Interestingly, the mortality as well as the amount of malformations increased when the daphnids were fed with nano-PS incubated algae (5 days). A study by Ogonowski et al. was also mentioned within the text, which covers a life-history experiment with *D. magna* with exposure to primary microplastics (spherical beads, 1.3 g cm^{-3}, 4.1 µm), secondary microplastics (PE fragments, 1.0 g cm^{-3}, 2.6 µm), and kaolin (2.6 g cm^{-3}, 4.4 µm) under food- limited conditions. It observed the increased mortality and decreased reproduction of the daphnids. According to Scherer the effects depend on the size, shape, concentration, polymer densities and particle interaction with stressors. In conclusion *D. magna* is resistant to microplastic exposure, as a result of behavioural and morphological adaptations. Scherer et al. also note that null effects were found in the amphipod *Gammarus pulex* exposed to irregular polyethylene terephthalate (PET) fragments (0.4–4,000 P mL^{-1}, size 10–150 µm). After 48 days, microplastics did not induce any effects on behaviour (feeding activity), metabolism (energy reserves), development (moulting), and growth. Scherer et al. mention a study by Au et al, which test the effects of weathered polypropylene and polyethylene on in the amphipod *Hyalella azteca*. In a 10-day acute exposure, PP fibres were more toxic than PE fragments with LC50 values of 71.43 and 46,400 P mL?1, respectively. This might be related to the longer gut retention times of fibres versus fragments and again highlights the importance of particle shape. In the same study, a 42-day chronic exposure to PE fragments significantly decreased growth and reproduction. A recent study by Welden and Cowie is also discussed by Scherer et al. in the chapter. It studies the negative exposure effects of polypropylene on the feeding, body mass, metabolic activity, and energy reserves of *Nephrops norvegicus.* An 8-month exposure of PP resulted in formations of microplastic aggregates in the gut of the langoustines, which may have led to reduced nutrient uptake. The presence of 20 µm PS beads (75 P mL^{-1}) reduced the feeding on algae and provoked a feeding preference for smaller algae prey. Also mentioned is a study by Lee et al. which demonstrated a nonselective ingestion of 0.05, 0.5, and 6

Journal reference	Key components	Summary/Overview
		µm PS beads by the marine *Tigriopus japonicus*. While all individuals survived an acute exposure (96 h), a two-generation chronic exposure to 0.05 (>12.5 µgmL?1) and 0.5 µm beads (25 µgmL-1) induced a concentration- and size-dependent mortality and a significant decrease in fecundity by 0.5 and 6 µm PS beads. Again, the observed effects were mainly interpreted as related to an impaired nutritional uptake. However, other negative effects such as a negative energy budget (Bundy et al) or attachment to external carapace and appendages (Cole et al) have also been mentioned in the Scherer et al. chapter. Additionally, it is discussed how Watts et al. found a significantly decreased oxygen consumption of microplastic-exposed crabs after 1 h and observed some adaptation as oxygen consumption returned to normal after 16 h. Bivalves are the next organism examined by Scherer et al., which discusses the transfer of microplastics to tissues induces cellular injuries as well as inflammatory responses in the marine filter-feeding mussel *M. edulis*. Scherer et al. looks at a study by Browne et al, which observes the translocation of polystyrene beads into the circulatory system following 3 days of exposure. The microplastics remain in the system for up to 48 days, although the pathway is not yet known according to Scherer et al. Also mentioned is the accumulation of particles in the digestive gland and absorption in the lysosomal system; because of particle interaction with tissue or hemolymph cells, marine bivalves express immediate stress. In another study mentioned by Scherer et al., Rist et al. exposed the marine Asian green mussel *Perna viridis* to 1–50 µm polyvinyl chloride (PVC) fragments. microplastic exposure reduced the filtration and respiration rates, byssus production, as well as motility, while mortality was enhanced. Scherer et al. note that the study Sussarella et al, which examines the effect of microplastics on *Crassostrea gigas'* reproductive success, concludes in a negative impact. It is mentioned that polystyrene spheres have no effect on the energy reserves of *M. edulis* following exposure (Cauwenberghe et al). Scherer also comments on the behavioural and physiological responses that have also been shown for bivalves exposed to suspended solids. For instance, particle exposure damaged the cilia of the gill filaments in *P. viridis* (<500 µm) and significantly reduced the algal ingestion of *M. mercenaria* (3–40 µm). Scherer et al. comment on the limited studies that have examined Gastropods. In the only available study it looks at the omnivorous surface grazer *P. antipodarum* which was exposed to a mixture of five different polymers (4.6–603 µm particle size; polyamide (PA), polycarbonate (PC), PET, PS, PVC) mixed with food at a ratio of 30 and 70%. After 8 weeks, microplastics neither affected the growth (shell width, length, body weight) nor the reproduction (number of produced embryos and ratio of embryos with and without shell). Additionally, microplastic had no effect on the development of the consecutive generation of juveniles. The Scherer et al. discussion then moves onto fish, giving an initial example of *Danio rerio*. Polystyrene beads are known to accumulate in the gills, gut and liver according to the chapter, histopathological analysis revealed an inflammatory response and accumulation of lipids in the liver as well as oxidative stress. It is also compared to a study by Karami et al, where far more severe histological alterations in the gills, liver and blood chemistry were observed. Scherer et al. state that the authors point toward ethylene

Journal reference	Key components	Summary/Overview
		monomers (released from HDPE) and internal as well as external abrasions (caused by sharp edges of the fragments) as possible mechanisms for the changes in biomarker responses. In a final statement, Scherer et al. mention that Michel et al. conclude that the uptake of fine particles by gill epithelial cells is a common natural event in aquatic species with the material, size, shape, and concentration determining the impacts. Chemical impacts are also discussed in the Scherer et al. chapter. A study by Fries et al extracted several organic (e.g., phthalates) and inorganic additives (e.g., metals) from microplastic samples in marine sediments highlighting the relevance of these compounds. Besides additives, adsorbed persistent organic pollutants have been found on microplastics. It looks at the tendency of microplastics to adsorb hydrophobic contaminants. Several studies are mentioned within this chapter describing the impact of microplastics via chemical bioavailability. For example, Besseling et al. observed a decreased bioaccumulation of polychlorinated biphenyls in lugworms at higher doses of PS particles; Oliveira et al. confirmed a delayed pyrene- induced mortality of juvenile fishes (*Pomatoschistus microps*) in the presence of PE microplastics. Whilst Karami et al. as well as Paul-Pont et al. detected modulations of adverse effects by an exposure to phenanthrene-loaded LDPE fragments (African catfish) and PS beads and fluoranthene (*Mystilus spp.)* respectively. Alternative studies highlight the minor influence of microplastics as vectors for bioaccumulation of pollutants, suggesting they are outcompeted by organic matter. Scherer et al. comment on Besseling et al. suggesting that microplastics can interfere with intra- and interspecies signalling as an integral component of aquatic biocoenosis regulating predator-prey interactions as well as population and community structures. Although they found significant interactions between kairomones and nano-PS when investigating the growth of the water flea *D. magna*, it remains unclear whether the nano-PS beads increased the bioavailability of kairomones or they observed an additive effect of both stressors. Any disturbance of this inter- and intraspecies communication can lead to maladaptive responses in both signaller and receiver. In the final part of the chapter Scherer et al mention the impacts for freshwater ecosystems. Noting that the understanding of the extent of microplastics in freshwater ecosystems is primitive. microplastics do not represent one stressor, whose impacts can be evaluated relatively easily, but a very large number of stressors that potentially act jointly. The use of copolymers, product-specific mixtures of additives, and source- and pathway-specific sorbed pollutants further complicates the situation. microplastics can affect the aquatic biocoenosis on a large scale, for instance, as vectors for invasive species and pathogens. It is commented that there is a relationship between decreasing particle size and increasing adverse effects. Accordingly, evolutionary adaptations (e.g., peritrophic membrane, mucus, avoidance) might explain the species-dependent resistance to high concentrations of microplastics (e.g., *D. magna, G. pulex*). However, microplastics can infiltrate habitats normally low in suspended solid and thereby affect more sensitive

Journal reference	Key components	Summary/Overview
		species. In summary Scherer et al. discuss the effects of microplastic on different species. To achieve this, Scherer et al. examined the studies that have been completed on algae, daphnia, bivalves, gastropods, crustaceans and fish. Each study investigates the impact of a microplastic in relation to the function of the species body (e.g. gut, mobility, growth…). In some cases, it was found that species can remain unaffected by the microplastics. In addition, the chapter also discussed the impact of chemicals and their bioavailability and bioaccumulation. Scherer et al. looks at the tendency of microplastics to adsorb hydrophobic contaminants. Several studies are mentioned within this chapter describing the impact of microplastics via chemical bioavailability. For example, Besseling et al. observed a decreased bioaccumulation of polychlorinated biphenyls in lugworms at higher doses of PS particles; Oliveira et al. confirmed a delayed pyrene- induced mortality of juvenile fishes (*Pomatoschistus microps*) in the presence of PE microplastics. Whilst Karami et al. as well as Paul-Pont et al. detected modulations of adverse effects by an exposure to phenanthrene-loaded LDPE fragments (African catfish) and PS beads.
Lassen et al. (2015) *Microplastics: Occurrence, effects and sources of releases to the environment in Denmark*	This report contains a review of existing knowledge on issues related to contamination by microplastics with a focus on the use and release of microplastics in Denmark and the presence of microplastics in the surrounding waters. Microplastic Field samples Laboratory exposure Ecological Impact Species Impact Ingestion	Within the text Lassen et al. discuss the observed biological effects of microplastics on several organism categories, including zooplankton, benthic organisms, fish and seabirds. The first discussed is zooplankton is known for mistaking microplastics for pre (Cole et al, 2011). A number of laboratory studies have been published on zooplankton taxa, mainly crustaceans, and it has been reported that there was significantly reduced feeding among copepods in the presence of microplastics (Ivar do Sul and Costa 2014). Additionally, plastic particles can adhere to the organism's surface, effecting the organisms by, for example, affecting algal photosynthesis as Bhattacharya et al. (2010) have reported for plastics in the nano range. At the same time, adsorption can lead to a transfer of plastic particles through the food chain if, for example, these algae are ingested by zooplankton. Benthic organisms are the next discussed organisms. Lassen states that studies focusing on microplastic ingestion by benthic crustaceans are limited. Therefore there is little research available on the biological impact for these species. Besseling et al. (2013) observed a positive relationship between the microplastic concentration in the sediment and the ingestion of plastics on the one hand and the weight loss and reduced feeding activity on the other. Microplastic particles have furthermore been observed to cause an inflammatory response in tissues of blue mussels (*M. edulis*) and reduced membrane stability in cells of the digestive system (Besseling et al. 2013; Ivar do Sul and Costa 2014). Lassen et al. comment on the ingestion of microplastics by fish and the resulting impacts. Bioaccumulation and liver stress response and early tumour formation have been reported in the fish Japanese medaka (*Oryzias latipes*) fed virgin and marine polyethylene fragments of the size <0.5 mm (Rochman et al. 2013b; Eerkes-Medrano et al. 2015). Rochman et al. (2014c) have furthermore found evidence of liver stress and endocrine disruption in Japanese medaka (*Oryzias latipes*) after two months of dietary exposure

Journal reference	Key components	Summary/Overview
		to environmentally relevant concentrations of microplastics (<1 mm) and associated chemicals. Seabirds are commonly known to ingest plastic particles, although the effect of the plastic once ingested is less well explored according to Lassen et al. Lassen et al. comment on how Cole et al. (2011) studied the uptake and accumulation of polychlorinated biphenyls (PCBs) in streaked shearwater chicks. Two groups of chicks were served fish and resin pellets, or only fish and the preen gland oil, was analysed weekly for a duration of 42 days. In both groups, PCB concentrations increased over the test period. The contribution from the resin pellets was determined by a congener PCBs analysis that showed that an increase was found to be significantly larger in the chicks eating the plastic pellets. Although the impact of microplastics on larger mammals in the aquatic environment is mentioned by Lassen et al., the focus of studies has been on ingestion. Minimal research has been executed so far into the effects of the plastic following ingestion.

C.2. Most influential studies

This element reviewed in more detail a subset of 25 scientific papers that were deemed 'most influential' in relation to (eco)toxicological concerns / observed effects of microplastics in environmental receptors, but also in terms of potential effects in humans through the consumption of contaminated food. Articles were selected on the basis of:

- Reporting effects in organisms related to microplastic exposure
- Being the most highly cited articles
- Being consistently mentioned in review articles

Articles are presented in the series of tables below each with a summary of standard information recorded for each article. This includes: author, bibliographic information, material tested, compartment, species (and life-stage or target organ), exposure duration, endpoints assessed. The reliability of each study was also scored using the criteria proposed by Klimisch et al. (1997), as follows:

> ***1 = reliable without restrictions****: "studies or data [...] generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline [...] or in which all parameters described are closely related/comparable to a guideline method."*
>
> ***2 = reliable with restrictions:*** *"studies or data [...] (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable."*
>
> ***3 = not reliable:*** "studies or data [...] *in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g. unphysiological pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment."*
>
> ***4 = not assignable***: *"studies or data [...] which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.)."*

It is important to note that standard ecotoxicity test methods have, as yet, not been explicitly validated for assessing the effects of exposure to microplastics. As such, a study performed according to an internationally accepted test guideline should still be interpreted carefully. Equally a study that is not considered reliable under the Klimisch framework may still provide useful information for risk assessment.

Table 14: Study Summary – Au et al. (2015)

Bibliographic details	**Au, S. Y. et al. (2015) 'Responses of *Hyalella azteca* to acute and chronic microplastic exposures', Environmental Toxicology and Chemistry, 34(11), pp. 2564–2572. doi: 10.1002/etc.3093.**
No. citations Scopus (07/2018)	41
Summary	The present study was conducted to evaluate the effects of microplastic ingestion on the freshwater amphipod, *Hyalella azteca*. *Hyalella azteca* was exposed to fluorescent polyethylene microplastic particles and polypropylene microplastic fibres.
Test material	Polyethylene microplastic and polypropylene microfibres
Particle size	10µm to 27µm in diameter
Compartment	Marine
Species	*Hyalella azteca* (amphipod crustacean)
Life-stage	Juvenile
Target organ	Body tissue and gut
No. of individuals	10 per replicate
No. of replicates	3 replicates for the 10 day and 12 for the 42 day exposure treatment
Exposure duration	10 days and 42 days
Concentration of microplastics	Acute (0, 10, 100, 1 000, 10 000,100 000 microplastics/mL) and chronic (0, 5 000, 10 000, 20 000 microplastics/mL)
Endpoints assessed	Mortality, reproduction, growth, microplastic ingestion, and microplastic egestion were compared with an analysis of variance to determine if there were significant effects of microplastic type and concentration.
Observed outcome/effects	Chronic exposure to polyethylene microplastic particles significantly decreased growth and reproduction at the low and intermediate exposure concentrations. Acute exposures to polyethylene microplastic particles meant that, 1) the egestion times did not significantly differ from the egestion of normal food materials in the control; 2) egestion times for polypropylene microplastic fibres were significantly slower than the egestion of food materials in the control. Amphipods exposed to polypropylene microplastic fibres also had significantly less growth. The greater toxicity of microplastic fibres than microplastic particles corresponded with longer residence times for the fibres in the gut.
Summary of reliability and quality assessment	Toxicity of microplastics to *H. azteca* was determined using revised USEPA methods for conducting 10-d to 42-d water-only toxicity exposures. Reliable and clear reporting of test parameters and methods throughout. Range of concentrations tested.
Klimisch Score	1 (reliable without restrictions)

Table 15: Study Summary – Avio et al. (2015)

Bibliographic details	**Avio, C. G. et al. (2015) 'Pollutants bioavailability and toxicological risk from microplastics to marine mussels', Environmental Pollution, 198, pp. 211–222. doi: 10.1016/j.envpol.2014.12.021.**
No. citations Scopus (07/2018)	117
Summary	In this study polyethylene (PE) and polystyrene (PS) microplastics were shown to adsorb pyrene with a time and dose-dependent relationship. Results also indicated a marked capability of contaminated microplastics to transfer this model PAH to exposed mussels *Mytilus galloprovincialis*; tissue localisation of microplastics occurred in haemolymph, gills and especially digestive tissues where a marked accumulation of pyrene was also observed. Cellular effects included alterations of immunological responses, lysosomal compartment, peroxisomal proliferation, antioxidant system, neurotoxic effects, onset of genotoxicity; changes in gene expression profile was also demonstrated through a new DNA microarray platform. The study provided the evidence that microplastics adsorb PAHs, emphasizing an elevated bioavailability of these chemicals after the ingestion, and the toxicological implications due to responsiveness of several molecular and cellular pathways to microplastics.
Test material	Polystyrene and polyethylene (virgin or pyrene-contaminated plastics)
Particle size	<100µm
Compartment	Marine
Species	*Mytilus galloprovincialis* (mussel)
Life-stage	4-6cm
Target organ	Haemolymph, gills, gut lumen and epithelium, digestive tubules
No. of individuals	60
No. of replicates	3 replicates for each treatment
Exposure duration	7 days
Concentration of microplastics	1.5 g/L
Endpoints assessed	Histological examination of gills and digestive glands, and haemolymph smears. The occurrence and localization of microplastics was assessed through polarized light microscopy.
Observed outcome/effects	Both virgin and contaminated microplastics induced several effects at transcriptional and cellular levels highlighting the potential risk for organisms' health condition, especially under conditions of long-term, chronic exposure. Cellular effects included alterations of immunological responses, lysosomal compartment, peroxisomal proliferation, antioxidant system, neurotoxic effects, and onset of genotoxicity.
Summary of reliability and quality assessment	No guideline or internationally accepted protocol followed for the exposure of mussels. However, analytical methods and exposure conditions are described in detail and are acceptable.
Klimisch Score	2 (reliable with restrictions)

Table 16: Study Summary – Batel et al. (2016)

Bibliographic details	**Batel, A., Linti, F., Scherer, M., Erdinger, L., & Braunbeck, T. (2016). Transfer of benzo[a]pyrene from microplastics to *Artemia* nauplii and further to zebrafish via a trophic food web experiment: CYP1A induction and visual tracking of persistent organic pollutants. Environmental Toxicology and Chemistry, 35(7), 1656–1666. https://doi.org/10.1002/etc.3361**
No. citations Scopus (07/2018)	39
Summary	The uptake of microplastic particles and the transfer of potential harmful substances along with microplastics has been studied in a variety of organisms, especially invertebrates. However, the potential accumulation of very small microplastic particles along food webs ending with vertebrate models has not been investigated so far. Therefore, a simple artificial food chain with *Artemia* spec. nauplii and zebrafish (*Danio rerio*) was established to analyse the transfer of microplastic particles and associated persistent organic pollutants (POPs) between different trophic levels. Very small (1 - 20 µm) microplastic particles accumulated in *Artemia* nauplii and were subsequently transferred to fish. Virgin particles not loaded with POPs did not cause any observable physical harm in the intestinal tracts of zebrafish, although part of the particles were retained within the mucus of intestinal villi and might even be taken up by epithelial cells.
Test material	Polymer with undisclosed composition and polyethylene
Particle size	1-5µm and 10-20µm
Compartment	Marine
Species	*Artemia* nauplii and *Danio rerio* (Zebrafish)
Life-stage	24-month old fish
Target organ	Intestine, liver, stomach
No. of individuals	10 fish per tank; 60 total (each tank fed 10'000 nauplii)
No. of replicates	2 replicates for each concentration
Exposure duration	14 days
Concentration of microplastics	10 000 nauplii (loaded with MPs) per tank
Endpoints assessed	Nauplii were analysed to determine uptake rate. These were then fed to zebra fish which was followed by an analysis of bioaccumulation.
Observed outcome/effects	The present study clearly documents the transfer of 1-mm to 20-mm microplastic particles from *Artemia* nauplii to zebrafish, simulating a natural food chain from zooplankton to fish. Microplastics passed the intestinal tracts of zebrafish without significant accumulation.
Summary of reliability and quality assessment	No standard guideline or protocol followed for the artificial food chain exposure to microplastics. Only a single concentration of microplastics used although different size ranges or microplastics tested. Approximate microplastic concentrations detailed but no subsequent confirmation of actual exposure concentrations.
Klimisch Score	2 (reliable with restrictions)

Table 17: Study Summary – Besseling et al. (2013)

Bibliographic details	**Besseling, E. et al. (2013) 'Effects of microplastic on fitness and PCB bioaccumulation by the lugworm *Arenicola marina* (L.)', Environmental Science and Technology, 47(1), pp. 593–600. doi: 10.1021/es302763x.**
No. citations Scopus (07/2018)	184
Summary	This article describes a controlled study on the effects of plastic on benthic organisms including transfer of POPs. The effects of polystyrene (PS) microplastic on survival, activity, and bodyweight, as well as the transfer of 19 polychlorinated biphenyls (PCBs), were assessed in bioassays with *Arenicola marina* (L.). PS was pre-equilibrated in natively contaminated sediment. A positive relation was observed between microplastic concentration in the sediment and both uptake of plastic particles and weight loss by *A. marina*. Furthermore, a reduction in feeding activity was observed at a PS dose of 7.4% dry weight. A low PS dose of 0.074% increased bioaccumulation of PCBs by a factor of 1.1−3.6, an effect that was significant for ΣPCBs and several individual congeners.
Test material	Polystyrene pre-equilibrated in natively contaminated sediment
Particle size	400−1300 µm
Compartment	Marine
Species	*Arenicola marina* (L.) (Lugworm)
Life-stage	-
Target organ	Gut contents
No. of individuals	5 per beaker
No. of replicates	4 beakers per treatment
Exposure duration	28 days
Concentration of microplastics	0 – 7.4% dry weight sediment
Endpoints assessed	Mortality and feeding activity were monitored daily. Homogenization by scalpel and then internal plastic content analysed by microscopy.
Observed outcome/effects	Positive relationship between microplastic concentration with both uptake of microplastic and weight loss, and reduction in feeding activity at dose of 7.4% dry weight sediment. Note that without a parallel exposure to 'clean' microplastics, the relative impact of physical presence of the microplastics versus uptake of contaminants cannot be distinguished.
Summary of reliability and quality assessment	No guideline or internationally accepted protocol followed for the exposure of both species. Organisms obtained randomly from the wild and exposed using 3 different concentrations of microplastics. Appropriate endpoints used for the study question and analytical methods described.
Klimisch Score	2 (reliable with restrictions)

Table 18: Study Summary – Besseling et al. (2014)

Bibliographic details	**Besseling, E. et al. (2014) 'Nanoplastic affects growth of *S. obliquus* and reproduction of *D. magna'*, Environmental Science and Technology, 48(20), pp. 12336–12343. doi: 10.1021/es503001d.**
No. citations Scopus (07/2018)	103
Summary	Little is known about the fate and effects of nanoplastic, especially for the freshwater environment. In this study, effects of nano-polystyrene (nano-PS) on the growth and photosynthesis of the green alga *Scenedesmus obliquus* and the growth, mortality, neonate production, and malformations of the zooplankton *Daphnia magna* were assessed. Nano-PS reduced population growth and reduced chlorophyll concentrations in the algae. Exposed *Daphnia* showed reduced body size and severe alterations in reproduction. Numbers and body size of neonates were lower, while the number of neonate malformations among neonates rose to 68% of the individuals. These effects of nano-PS were observed between 0.22 and 103 mg nano-PS/L.
Test material	Polystyrene (PS)
Particle size	nanoparticles (~70 nm)
Compartment	Freshwater
Species	*Scenedesmus obliquus* (green algae) and *Daphnia magna* (copepod crustacean)
Life-stage	*Daphnia magna*: neonates
Target organ	*Scenedesmus obliquus*: photosynthetic capacity and biomass and *Daphnia Magna*: Body size and malformation of neonates
No. of individuals	-
No. of replicates	16 replicates for controls and 12 replicates for exposure treatments
Exposure duration	72h exposure and 21 day exposure for each species respectively
Concentration of microplastics	44−1100 mg nano-PS/L for algae. Pristine exposures were applied at ten nanoplastic concentrations in the range of 0.22−150 mg nano-PS/L. The pristine-kairomone dispersions were applied at concentrations of 0.88 and 1.8 mg nano-PS/L. The aged and aged- filtered treatment was applied at one concentration; 32 mg nano-PS/L.
Endpoints assessed	Algae growth was analysed through cell density. Reproduction rate of the Daphnia was monitored during the experiment and well as malformation of neonates.
Observed outcome/effects	Nano-PS reduced population growth and reduced chlorophyll concentrations in the algae. Exposed Daphnia showed a reduced body size and severe alterations in reproduction. Numbers and body size of neonates were lower, while the number of neonate malformations among neonates increased to 68% of the individuals. These effects of nano-PS were observed between 0.22 and 103 mg nano-PS/L. Malformations occurred from 30 mg of nano-PS/L onward. Such plastic concentrations are much higher than presently reported for marine waters as well as freshwater.
Summary of reliability and quality assessment	21-day OECD guidelines followed for *Daphnia* assay and multiple concentrations tested. Good level of detail regarding study and analytical approaches.
Klimisch Score	1

Table 19: Study Summary – Browne et al. (2008)

Bibliographic details	**Browne, M. A. et al. (2008) 'Ingested microscopic plastic translocates to the circulatory system of the mussel, *Mytilus edulis* (L.)', Environmental Science and Technology, 42(13), pp. 5026–5031. doi: 10.1021/es800249a.**
No. citations Scopus (07/2018)	374
Summary	The mussel, *Mytilus edulis*, was used to investigate ingestion, translocation, and accumulation of microplastic debris. Initial experiments showed that upon ingestion, microplastic accumulated in the gut. Mussels were subsequently exposed to treatments containing seawater and microplastic (3.0 or 9.6 micron). After transfer to clean conditions, microplastic was tracked in the hemolymph. Particles translocated from the gut to the circulatory system within 3 days and persisted for over 48 days. Abundance of microplastic was greatest after 12 days and declined thereafter.
Test material	Polystyrene microspheres
Particle size	3.0 µm and 9.6 µm
Compartment	Marine
Species	*Mytilus edulis* (Mussel)
Life-stage	3-4cm
Target organ	Digestive and circulatory system
No. of individuals	-
No. of replicates	3 replicates for each treatment
Exposure duration	12h for 1st experiment and 3h for second
Concentration of microplastics	40 particles.mL^{-1}
Endpoints assessed	1. Ability of mussel to absorb red dye, simulating the ability to engulf yeast, also changes to feeding pattern were monitored. 2. Tracking of uptake of polystyrene microspheres was used to assess presence in the gut. 3. Analysis of hemolymph to assess the translocation of polystyrene into the circulatory system.
Observed outcome/effects	Microplastics detected in the haemolymph after 3 d exposure and persisted there for over 48 d. No adverse effects observed for the criteria investigated (oxidative status and haemocytes phagocytic ability). Study shows that ingested particles can persist in the haemolymph but no adverse effects observed for the criteria investigated (oxidative status and haemocytes phagocytic ability).
Summary of reliability and quality assessment	No standard guideline or protocol followed for exposure of *Mytilus*. Organisms obtained from the wild and exposed to three microsphere types (at a single concentration). Concentrations of microspheres in second experiment verified by coulter counter and assays described in moderate detail.
Klimisch Score	2

Table 20: Study Summary – Browne et al. (2013)

Bibliographic details	**Browne, M. A. et al. (2013) 'Microplastic moves pollutants and additives to worms, reducing functions linked to health and biodiversity', Current Biology, 23(23), pp. 2388–2392. doi: 10.1016/j.cub.2013.10.012.**
No. citations Scopus (07/2018)	178
Summary	Experiments to examine whether ingested plastic transfers pollutants and additives to animals. Lugworms (*Arenicola marina*) were exposed to sand with 5% microplastic that was pre-sorbed with pollutants (nonylphenol and phenanthrene) and additive chemicals (Triclosan and PBDE-47). Microplastic transferred pollutants and additive chemicals into the gut tissues of lugworms, causing some biological effects, although clean sand transferred larger concentrations of pollutants into their tissues. Uptake of nonylphenol from PVC or sand reduced the ability of coelomocytes to remove pathogenic bacteria by >60%. Uptake of Triclosan from PVC diminished the ability of worms to engineer sediments and caused mortality, each by >55%, while PVC alone made worms >30% more susceptible to oxidative stress.
Test material	Polyvinyl chloride with adsorbed Trisoclan and PBDE-47
Particle size	Virgin PVC (230 µm)
Compartment	Marine
Species	*Arenicola marina* (L.) (Lugworm)
Life-stage	-
Target organ	Feeding (casts and mass) and mortality. Coelomic fluid was used to quantify the phagocytic activity
No. of individuals	3 worms for each replicate
No. of replicates	Two experiments, N=5 and N=6 replicates
Exposure duration	10 days
Concentration of microplastics	5% PVC by sediment mass
Endpoints assessed	Mortality and feeding were monitored along with the oxidative status of the lugworms
Observed outcome/effects	Short-term experiments with large proportions of PVC (5%) show that worms eating microplastic accumulated large enough concentrations of pollutants or additives to reduce survival (Triclosan), feeding (Triclosan and PBDE), immunity (nonylphenol), and antioxidant capacity (PVC).
Summary of reliability and quality assessment	No standard guideline or protocol followed for exposure of lugworms. Moderate level of detail on experimental conditions but some details lacking, such as original of lugworms.
Klimisch Score	2 (reliable with restrictions)

Table 21: Study Summary – Cole et al. (2013)

Bibliographic details	**Cole, M., Lindeque, P., Fileman, E., Halsband, C., Goodhead, R., Moger, J., & Galloway, T. S. (2013). Microplastic ingestion by zooplankton. Environmental Science and Technology, 47(12), 6646–6655. https://doi.org/10.1021/es400663f**
No. citations Scopus (07/2018)	316
Summary	Bio-imaging techniques were used to document ingestion, egestion, and adherence of microplastics in a range of zooplankton common to the northeast Atlantic. Feeding rate studies were used to determine the impact of plastic detritus on algal ingestion rates in copepods.
Test material	Commercial polystyrene spheres
Particle size	7.3 µm (PS)
Compartment	Marine
Species	*Centropages typicus*
Life-stage	Adult
Target organ	Digestive system
No. of individuals	n = ≥6 per exposure
No. of replicates	-
Exposure duration	24h
Concentration of microplastics	4 000, 7 000, 11 000, 25000 particles mL-1
Endpoints assessed	Bio-imaging techniques to document ingestion, egestion, and adherence of microplastics in a range of zooplankton. Employed feeding rate studies to determine the impact of plastic detritus on algal ingestion rates in copepods.
Observed outcome/effects	Decreased algal ingestion rates observed on exposure to high concentrations (≥4 000 particles mL^{-1}) of 7.3 µm polystyrene spheres over 24 hours, with a strong, logarithmic relationship between the ingestion rate of total algae and microplastic concentration. Polystyrene spheres were noted to coat the exoskeleton of copepods and concentrated between the external appendages, such as the swimming legs and feeding apparatus. However, this study did use high concentrations of particles.
Summary of reliability and quality assessment	No standard protocol or laboratory guidelines followed, organisms obtained from the wild but good overall description of method. Number of replicates and treatments are less clear from the method but a range of concentrations tested.
Klimisch Score	2 (reliable with restrictions)

Table 22: Study Summary – Cole et al. (2015)

Bibliographic details	**Cole, M., Lindeque, P., Fileman, E., Halsband, C., & Galloway, T. S. (2015). The impact of polystyrene microplastics on feeding, function and fecundity in the marine copepod *Calanus helgolandicus*. Environmental Science and Technology, 49(2), 1130–1137. https://doi.org/10.1021/es504525u**
No. citations Scopus (07/2018)	124
Summary	Ingestion of microplastics reported to significantly alter the feeding capacity of the pelagic copepod *Calanus helgolandicus*. Exposed to 20 µm polystyrene beads (75 microplastics mL^{-1}) and cultured algae ([250 µg C L^{-1}) for 24 h, *C. helgolandicus* ingested 11% fewer algal cells (P = 0.33) and 40% less carbon biomass (P < 0.01). There was a net downward shift in the mean size of algal prey consumed (P < 0.001), with a 3.6 fold increase in ingestion rate for the smallest size class of algal prey (11.6-12.6 µm), suggestive of postcapture or postingestion rejection. Prolonged exposure to polystyrene microplastics significantly decreased reproductive output, but there were no significant differences in egg production rates, respiration or survival.
Test material	Unlabelled, additive-free polystyrene (PS) beads
Particle size	20 µm
Compartment	Marine
Species	*Calanus helgolandicus* (marine crustacean – copepod)
Life-stage	Adult
Target organ	Digestive and reproductive system
No. of individuals	n=60 in 9 day exposure
No. of replicates	10 beakers (5 controls, 5 with MPs)
Exposure duration	24h and 9 days
Concentration of microplastics	75 particles mL^{-1}
Endpoints assessed	Egg production rates, egg size, hatching success and respiration rates
Observed outcome/effects	An extended 9-day exposure indicated decreased reproductive output, but there were no significant differences in egg production rates, respiration or survival.
Summary of reliability and quality assessment	No guideline or internationally accepted protocol followed. Simple control/exposed test design with no concentration gradient and few replicates. Method description is, however, clear and well documented and endpoints are relevant.
Klimisch Score	2 (reliable with restrictions)

Table 23: Study Summary – Hämer et al. (2014)

Bibliographic details	**Hämer, J. et al. (2014) 'Fate of Microplastics in the Marine Isopod *Idotea emarginata'*, Environmental Science and Technology, 48(22), pp. 13451–13458. doi: 10.1021/es501385y.**
No. citations Scopus (07/2018)	55
Summary	Embedded fluorescent microplastics in artificial agarose-based food were offered to marine isopods, *Idotea emarginata*. The isopods did not distinguish between food with and food without microplastics. Upon ingestion, the microplastics were present in the stomach and in the gut but not in the tubules of the midgut gland, which is the principal organ of enzyme-secretion and nutrient resorption. The faeces contained the same concentration of microplastics as the food which indicates that no accumulation of microplastics occurred during gut passage.
Test material	Polystyrene (PS) microbeads, plastic fragments, and plastic fibres
Particle size	1 – 100 µm (PS)
Compartment	Marine
Species	*Idotea emarginata* (marine Isopods)
Life-stage	Juvenile (5-10mm)
Target organ	Digestive system.
No. of individuals	24 individuals for each feeding experiment
No. of replicates	-
Exposure duration	3 days and 6 weeks
Concentration of microplastics	12 and 120 microbeads mg^{-1} food
Endpoints assessed	Mortality, growth and inter-moult duration
Observed outcome/effects	No significant effects on mortality, growth, and intermolt duration. Microplastics were not present in the tubules of the midgut gland. Long-term bioassays of 6 weeks showed no distinct effects of continuous microplastic consumption on mortality, growth, and intermolt duration. *I. emarginata* are able to prevent intrusion of particles even smaller than 1 µm into the midgut gland which is facilitated by the complex structure of the stomach including a fine filter system.
Summary of reliability and quality assessment	No standard guideline or protocol followed for long term bioassay exposure. Moderate level of detail in method used, organisms originally obtained from the wild.
Klimisch Score	2 (reliable with restrictions)

Table 24: Study Summary - Huerta Lwanga et al. (2016)

Bibliographic details	**Huerta Lwanga, E. et al. (2016) 'Microplastics in the Terrestrial Ecosystem: Implications for *Lumbricus terrestris* (Oligochaeta, Lumbricidae)', Environmental Science and Technology, 50(5), pp. 2685–2691. doi: 10.1021/acs.est.5b05478.**
No. citations Scopus (07/2018)	46
Summary	Survival and fitness of the earthworm *Lumbricus terrestris* (Oligochaeta, Lumbricidae) observed after exposed to microplastics (Polyethylene, <150 µm) in litter at concentrations of 7, 28, 45, and 60% dry weight, percentages that, after bioturbation, translate to 0.2 to 1.2% in bulk soil. Mortality after 60 days was higher at 28, 45, and 60% of microplastics in the litter than at 7% w/w and in the control (0%). Growth rate was significantly reduced at 28, 45, and 60% w/w microplastics, compared to the 7% and control treatments. Microplastic was concentrated in cast, especially at the lowest dose (i.e., 7% in litter). Whereas 50 percent of the microplastics had a size of <50 µm in the original litter, 90 percent of the microplastics in the casts was <50 µm in all treatments, which suggests size-selective egestion by the earthworms. These concentration-transport and size-selection mechanisms may have important implications for fate and risk of microplastic in terrestrial ecosystems.
Test material	Low Density Polyethylene (LDPE)
Particle size	Size distribution 50% with <50 µm, 27% between 50 and 100 µm, and 23% > 100 µm
Compartment	Terrestrial
Species	*Lumbricus terrestris* (earthworm)
Life-stage	Adult
Target organ	Digestive system
No. of individuals	4 worms per replicate
No. of replicates	3 replicates per treatment
Exposure duration	14 and 60 days
Concentration of microplastics	7, 28, 45, and 60% dry weight in plant litter. Translate into concentrations of 0.2, 0.4, 0.5, and 1.2 % on a whole-soil- column basis.
Endpoints assessed	Growth Rate, reproduction (cocoon production and biomass), activity, position, ingestion, and mortality
Observed outcome/effects	Earthworms fitness seems not to be affected by microplastics dosed via litter on the soil surface at a concentration in litter of 7% w/w, but with 28, 45, and 60% w/w microplastics in litter. *L. terrestris* was affected (i.e., decrease in growth rate and consequent weight loss). No effect on reproduction was observed even at higher concentrations.
Summary of reliability and quality assessment	OECD Earthworm, Acute Toxicity Test guidelines employed and mortality and reproduction calculated accordingly. Multiple concentrations tested with a small number of replicates for each.
Klimisch Score	1 (reliable without restrictions)

Table 25: Study Summary – Kaposi (2014)

Bibliographic details	**Kaposi, Katrina, Mos, Benjamin, Kelaher, Brendan, Dworjanyn, S. (2014) 'Ingestion of microplastics has limited impact on a marine larva', Environ. Sci. Technol., 48(3), p. 1638. doi: dx.doi.org/10.1021/es404295e.**
No. citations Scopus (07/2018)	55
Summary	Ingestion of polyethylene microspheres by larvae of the sea urchin *Tripneustes gratilla* was investigated. Ingestion rates scaled with the concentration of microspheres and were, however, reduced by biological fouling of microplastic and in the presence of phytoplankton food. *T. gratilla* larvae were able to egest microspheres from their stomach within hours of ingestion. A microsphere concentration far exceeding those recorded in the marine environment had a small non-dose dependent effect on larval growth, but there was no significant effect on survival. In contrast, environmentally realistic concentrations appeared to have little effect.
Test material	Commercial polyethylene microspheres
Particle size	10-45 µm (PE) mostly (25 – 32 µm)
Compartment	Marine
Species	*Tripneustes gratilla* (collector urchin)
Life-stage	Sea urchin larvae 5-8 days after fertilisation
Target organ	Ingestion
No. of individuals	150 individuals per exposure/ control experiment
No. of replicates	5 replicates for each exposure and control
Exposure duration	5 days
Concentration of microplastics	1, 10, 100 and 300 particles mL^{-1}
Endpoints assessed	Ingestion, growth, survival
Observed outcome/effects	A small not dose-dependent effect on larval growth (decreased body width) was observed. No significant effect on larval survival. The ability of the sea urchin larvae to discriminate between food particles and microplastic, and egest non-food items from their stomachs contributed to minimising the impacts of microplastic ingestion. The authors consider that there is little evidence that microplastics at current concentrations pose a threat to planktotrophic marine larvae. The highest concentration of microplastics recorded in the marine environment (ca. 0.1 microplastic.mL^{-1}) is one order of magnitude lower than the lowest concentration used in this study (1 sphere.mL^{-1}).
Summary of reliability and quality assessment	No guideline or internationally accepted protocol followed for the exposure of *T. gratilla*. Concentration gradient used and multiple replicates per treatment, also concentration confirmed using microscopy before and throughout the experiment. Well documented procedures described in acceptable level of detail.
Klimisch Score	2 (reliable with restrictions)

Table 26: Study Summary – Lee et al. (2013)

Bibliographic details	**Kyun-Woo Lee, Won Joon Shim, Oh Youn Kwon, and Jung-Hoon Kang. Size-Dependent Effects of Micro Polystyrene Particles in the Marine Copepod *Tigriopus japonicas.* Environmental Science & Technology 2013 47 (19), 11278-11283 DOI: 10.1021/es401932b**
No. citations Scopus (07/2018)	76
Summary	The effects of three sizes of polystyrene (PS) microbeads (0.05, 0.5, and 6-μm diameter) on the survival, development, and fecundity of the copepod *Tigriopus japonicus* were investigated using acute and chronic toxicity tests. *T. japonicus* ingested and egested all three sizes of PS beads used and exhibited no selective feeding when phytoplankton were added.
Test material	Polystyrene (PS) beads
Particle size	0.05, 0.5 and 6 μm (PS)
Compartment	Marine
Species	*Tigriopus japonicas* (copepod)
Life-stage	Nauplii and adults
Target organ	-
No. of individuals	-
No. of replicates	-
Exposure duration	96hr and 2 generation chronic
Concentration of microplastics	Up to 25 μg mL^{-1}
Endpoints assessed	Survival, development and reproduction
Observed outcome/effects	No impact on survival of copepods (nauplii and adult females) in 96 hr acute test. In the 0.5-μm PS bead treatment, despite there being no significant effect on the F0 generation, the highest concentration (25 μg/mL) induced a significant decrease in survival compared with the control population in the F1 generation. The 6-μm PS beads did not affect the survival of *T. japonicus* over two generations. The 0.5- and 6-μm PS beads caused a significant decrease in fecundity at all concentrations.
Summary of reliability and quality assessment	Only abstract available (likely to be reliable if full text can be obtained).
Klimisch Score	4 (not assignable)

Table 27: Study Summary – Lithner (2009)

Bibliographic details	**Lithner Damberg, J., Dave, G., Larsson, Å., D. (2009) 'Leachates from plastic consumer products - Screening for toxicity with *Daphnia magna'*, Chemosphere, 74(9), pp. 1195–1200.**
No. citations Scopus (07/2018)	62
Summary	This study investigated if various plastic products release hazardous chemical substances to water. Two leaching methods (batch and diffusion tests) were used and the leachates were tested for acute toxicity to *Daphnia magna*. Nine out of 32 tested plastic product leachates had Daphnia 48-h EC50s ranging from 5 to 80 g plastic material L^{-1}. For the remaining 23 products no effect on mobility was seen even at the highest test concentrations (70-100 g plastic material L^{-1}). A compact disc (recordable) was the most toxic plastic product, but the toxicity was traced to the silver layer not the polycarbonate plastic material. The other products that displayed toxicity were made of either plasticised PVC (artificial leather, bath tub toy, inflatable bathing ring and table cloth) or polyurethane (artificial leather, floor coating and children's handbag).
Test material	Leachates from 32 plastic consumer products
Particle size	n/a
Compartment	Freshwater
Species	*Daphnia magna*
Life-stage	-
Target organ	-
No. of individuals	-
No. of replicates	-
Exposure duration	48 hours
Concentration of microplastics	n/a
Endpoints assessed	Immobilisation
Observed outcome/effects	Acute toxicity tests of plastic product leachates were found to be useful for screening purposes for differentiating between toxic and non-toxic products.
Summary of reliability and quality assessment	Only abstract available, limited relevance to microplastics.
Klimisch Score	4 (not assignable)

Table 28: Study Summary – Lu et al. (2016)

Bibliographic details	**Lu, Y. et al. (2016) 'Uptake and Accumulation of Polystyrene Microplastics in Zebrafish (Danio rerio) and Toxic Effects in Liver', Environmental Science & Technology, 50(7), p. 4054−4060. doi: 10.1021/acs.est.6b00183.**
No. citations Scopus (07/2018)	71
Summary	Uptake and tissue accumulation of polystyrene microplastics (PS-MPs) in zebrafish was identified, and the toxic effects in liver were investigated. After 7 days of exposure, 5 μm diameter MPs accumulated in fish gills, liver, and gut, while 20 μm diameter MPs accumulated only in fish gills and gut. Histopathological analysis showed that both 5 μm and 70 nm PS-MPs caused inflammation and lipid accumulation in fish liver. PS-MPs also significantly induced increased activity of the enzymes superoxide dismutase and catalase, indicating the induction of oxidative stress after exposure to microplastics. In addition, metabolomic analysis suggested that exposure to MPs induced alterations of metabolic profiles in fish liver and disturbed lipid and energy metabolism.
Test material	Virgin polystyrene (PS) spheres
Particle size	70 nm (0.07 μm) and 5 μm (for toxicity testing), 5 μm, and 20 μm (for uptake/accumulation testing)
Compartment	Freshwater
Species	*Danio rerio* (Zebrafish)
Life-stage	Adults (5 months old)
Target organ	Gills, liver and gut
No. of individuals	6 fish in each tank for uptake study. For each size of PS-MPs, 60 fish were used for oxidative stress analysis and histopathological analysis
No. of replicates	3 replicate tanks for each of the sampling times (for uptake/accumulation testing)
Exposure duration	7 days
Concentration of microplastics	Final concentration of 20 mg/L (uptake test). 20, 200, or 2000 μg/L PS-MPs for toxicity test
Endpoints assessed	Histopathology changes, oxidative stress and metabolism variations, as well as accumulation in tissue.
Observed outcome/effects	5 μm microplastics accumulated in fish gills, liver and gut, and 20 μm microplastic accumulated only in fish gills and gut. 5 μm and 70 nm microplastic caused inflammation and lipid accumulation in fish liver (at 2 000 μg L^{-1}), oxidative stress (increased activities of superoxide dismutase (at 20, 200 and 2 000 μg L^{-1}) and catalase (at 200 and 2000 μg L^{-1}) in fish livers), and alterations of metabolic profiles (n=400) in fish liver (at 20, 200 and 2 000 μg L^{-1}). Metabolomics was used to reveal the toxic effects of MPs; MPs disturbed the metabolism of lipid and energy in fish liver.
Summary of reliability and quality assessment	No standard protocol or laboratory guidelines followed but detailed description of method. Number of replicates and treatments are acceptable and consideration given to maintaining concentration of microplastics through solution replenishment.
Klimisch Score	2 (reliable with restrictions)

Table 29: Study Summary – Oliveira et al. (2013)

Bibliographic details	**Oliveira, M. et al. (2013) 'Single and combined effects of microplastics and pyrene on juveniles (0+ group) of the common goby *Pomatoschistus microps* (Teleostei, Gobiidae)', Ecological Indicators. Elsevier, 34, pp. 641–647. doi: 10.1016/j.ecolind.2013.06.019.**
No. citations Scopus (07/2018)	90
Summary	The modulating effect of polyethylene microspheres (1-5 µm) on the short-term toxicity of the polycyclic aromatic hydrocarbon pyrene to juveniles (0+ group) of the common goby (*Pomatoschistus microps*) was investigated. Fish were exposed for 96 h to pyrene (20 and 200 µg L^{-1}) in the absence and presence of microplastics (0, 18.4 and 184 µg L^{-1}). Microplastics delayed pyrene-induced fish mortality and increased the concentration of bile pyrene metabolites.
Test material	Polyethylene microspheres
Particle size	1 and 5 µm
Compartment	Marine
Species	*Pomatoschistus microps* (Common Goby)
Life-stage	Juveniles 1.0–1.2 cm long
Target organ	-
No. of individuals	8 per treatment
No. of replicates	-
Exposure duration	96 hours
Concentration of microplastics	18.4 and 184 µg L^{-1}
Endpoints assessed	Suite of biomarkers, including acetylcholinesterase (AChE) - involved in neuro and neuromuscular transmission
Observed outcome/effects	Reduced activity of AChE. No significant effects for glutathione S-transferase activity or lipid peroxidation.
Summary of reliability and quality assessment	General bioassay conditions followed the OECD guidelines for fish acute bioassays with slight modifications, especially in the number and type of treatments (since the objective was not to calculate lethal concentrations) and in the exposure conditions (since fish were exposed individually). Methods well documented and closely related to guidelines.
Klimisch Score	1 (reliable without restriction)

Table 30: Study Summary – Pedà et al. (2016)

Bibliographic details	**Pedà, C. et al. (2016) 'Intestinal alterations in European sea bass *Dicentrarchus labrax* (Linnaeus, 1758) exposed to microplastics: Preliminary results', Environmental Pollution, 212, pp. 251–256. doi: 10.1016/j.envpol.2016.01.083.**
No. citations Scopus (07/2018)	39
Summary	Study investigating the intestinal response of European sea bass *Dicentrarchus labrax* chronically exposed to microplastics through ingestion. Fish (n = 162) were fed with three different treatment diets for 90 days: control, native polyvinyl chloride (PVC) and polluted polyvinyl chloride (PVC) pellets. Intestines were fixed and processed for histological analysis using standard techniques. Histopathological alterations were examined using a score value (from 0 to 4). The distal part of intestine in all samples proved to be the most affected by pathological alterations, showing a gradual change varying from moderate to severe related to exposure times. The histological picture that characterises both groups, especially after 90 days of exposure, suggests that intestinal functions can be in some cases totally compromised after exposure. The worst condition is increasingly evident in the distal intestine of fish fed with polluted PVC pellets respect to control groups ($p < 0.05$).
Test material	PVC pellets
Particle size	0.3-0.5mm
Compartment	Marine
Species	*Dicentrarchus labrax* (European sea bass)
Life-stage	-
Target organ	Intestine
No. of individuals	162
No. of replicates	3 replicate tanks for each exposure/control treatment
Exposure duration	90 days
Concentration of microplastics	0.1% (w/w) plastic in diet
Endpoints assessed	54 of the 162 fish were considered for a histological analysis. The intestines were examined in three parts (proximal, mid and distal), the distal was the most affected part of the intestine.
Observed outcome/effects	Significant structural damage to the intestine (structural histopathological alterations in the distal intestine such as widening of lamina propria, detachment of mucosal epithelium from lamina propria, shortening and swelling of villi, vacuolation of enterocytes, increase of goblet cells and hyperplasia of goblet cells, and loss of regular structure of serosa). The authors consider gut-obstruction-induced mortality as a potential factor, particularly during early larval stages. No impact on growth, nor indication of inflammation, was observed in the study.
Summary of reliability and quality assessment	No standard approach/guideline followed. Methods described in moderate detail but only limited description of effects methods. More a demonstration of principle paper for ingestion of microplastics through ingestion.
Klimisch Score	3 (not reliable)

Table 31: Study Summary – Rehse et al. (2016)

Bibliographic details	**Rehse, S., Kloas, W. and Zarfl, C. (2016) 'Short-term exposure with high concentrations of pristine microplastic particles leads to immobilisation of *Daphnia magna'*, Chemosphere, 153, pp. 91–99. doi: 10.1016/j.chemosphere.2016.02.133.**
No. citations Scopus (07/2018)	39
Summary	Study of the potential physical effects of microplastics on a representative organism for limnic zooplankton (*Daphnia magna*). The potential for microplastics to be ingested and whether their presence causes adverse effects after short-term exposure was investigated. Daphnids were exposed for up to 96 h to 1-µm and 100-µm polyethylene particles at concentrations between 12.5 and 400 mg L^{-1}. Ingestion of 1-µm particles led to immobilisation increasing with dose and time with an EC50 of 57.43 mg L^{-1} after 96 h. 100-µm particles that could not be ingested by the daphnids had no observable effects.
Test material	Pristine polyethylene (PE) particles
Particle size	1-4 µm and 90-106 µm
Compartment	Freshwater
Species	Daphnia magna (crustacean)
Life-stage	Neonates
Target organ	Gut/intestine
No. of individuals	20 per exposure treatment
No. of replicates	4 replicate (5 individuals per replicate)
Exposure duration	48-96h
Concentration of microplastics	Six concentrations each (12.5 mL^{-1}, 25mL^{-1}, 50 mL^{-1}, 100 mL^{-1}, 200 mL^{-1}, 400 mL^{-1})
Endpoints assessed	Following the 96h exposure the immobilisation rate of the Daphnia were calculated, along with the ingestion analysis. With greater concentration there is greater immobilisation, however ingestion rates are not seen to increase with concentration.
Observed outcome/effects	Impacts of pristine microplastic particles on daphnids show that (1) 1-mm PE-particles can be ingested by limnic zooplankton and (2) that the ingestion of 1-mm particles results in immobilisation of daphnids at high concentrations. Floating particles, which cannot be ingested (100-mm particles) due to their size and availability to the organisms, do not cause any adverse effects.
Summary of reliability and quality assessment	The testing procedure was based on the OECD guideline Daphnia sp. Acute Immobilisation Test (OECD guideline 202). Both particle size classes, durations and (6) concentrations tested using multiple individuals. EC50 calculated.
Klimisch Score	1 (reliable without restrictions)

Table 32: Study Summary – Rochman et al. (2013)

Bibliographic details	**Rochman, C. M. et al. (2013) 'Ingested plastic transfers hazardous chemicals to fish and induces hepatic stress', Sci Rep. 2013/11/23, 3, p. 3263. doi: 10.1038/srep03263.**
No. citations Scopus (07/2018)	260
Summary	Study of the bioaccumulation and toxicity (liver stress biomarkers and histopathology) to fish exposed to polyethylene microplastics sorbed with chemical pollutants from the marine environment. Fish fed virgin polyethylene fragments also show signs of stress, although less severe than fish fed marine polyethylene microplastics.
Test material	LDPE pellets (virgin or 'marine aged')
Particle size	<0.5mm
Compartment	Freshwater
Species	*Oryzias latipes* (Medaka)
Life-stage	7 months old (2.5-3cm)
Target organ	Liver
No. of individuals	Nine 38 L tanks (71 fish per tank)
No. of replicates	3 replicate tanks
Exposure duration	2 months
Concentration of microplastics	10% by weight of diet (translates to 8 ng mL-1 of water)
Endpoints assessed	Measured PAH, PCB and PBDE concentrations within the fish body tissues. Adverse health effects were observed such as liver stress and glycogen depletion.
Observed outcome/effects	Signs of liver stress (including glycogen depletion, fatty vacuolation and single cell necrosis).
Summary of reliability and quality assessment	No standard guideline used for dietary exposure of medaka. Well documented and acceptable test parameters described in detail, along with chemical analysis of water, plastic diet and fish tissues.
Klimisch Score	2 (reliable with restrictions)

Table 33: Study Summary – Sussarellu et al. (2016)

Bibliographic details	**Sussarellu, R. et al. (2016) 'Oyster reproduction is affected by exposure to polystyrene microplastics', Proceedings of the National Academy of Sciences, 113(9), pp. 2430–2435. doi: 10.1073/pnas.1519019113.**
No. citations Scopus (07/2018)	91
Summary	To assess the impact of polystyrene microspheres (micro-PS) on the physiology of the Pacific oyster, adult oysters were experimentally exposed to virgin micro-PS (2 and 6 µm in diameter; 0.023 mg·L^{-1}) for 2 months during a reproductive cycle. Effects were investigated on ecophysiological parameters; cellular, transcriptomic, and proteomic responses; fecundity; and offspring development. Oysters preferentially ingested the 6-µm micro-PS over the 2-µm-diameter particles. Consumption of microalgae and absorption efficiency were significantly higher in exposed oysters, suggesting compensatory and physical effects on both digestive parameters. After 2 months, exposed oysters had significant decreases in oocyte number (−38%), diameter (−5%), and sperm velocity (−23%). The D-larval yield and larval development of offspring derived from exposed parents decreased by 41% and 18%, respectively, compared with control offspring.
Test material	Polystyrene spheres (virgin microplastics)
Particle size	2 and 6 µm
Compartment	Marine
Species	*Crassostrea gigas* (Oysters)
Life-stage	Adults and Offspring
Target organ	Gametes, Larval, Hemolymph, Histology and Cells
No. of individuals	40 oysters per tank
No. of replicates	6 experimental 50L tanks
Exposure duration	8 weeks
Concentration of microplastics	Inflow concentration of 2,062 ± 170 and 118 ± 15 beads per mL^{-1} for 2- and 6-µm particles, respectively (a mass concentration of 0.023 mg L^{-1})
Endpoints assessed	Reproductive cycle and ecophysiological parameters; cellular, transcriptomic, and proteomic responses; fecundity; and offspring development.
Observed outcome/effects	Decrease in oocyte number (−38%), diameter (−5%), and sperm velocity (−23%). Decrease (-41% and -18%) in D-larval yield and larval development, respectively, of offspring derived from exposed parents. Significant shift of energy allocation from reproduction to structural growth, and elevated maintenance costs (measured via dynamic energy budget and transcriptomic profiles).
Summary of reliability and quality assessment	No guideline or internationally accepted protocol followed for the exposure of oysters. Well documented and scientifically acceptable methods described with daily checks of concentration and flow performed
Klimisch Score	2 (reliable with restrictions)

Table 34: Study Summary – Van Cauwenberghe et al. (2015)

Bibliographic details	**Van Cauwenberghe, L. et al. (2015) 'Microplastics are taken up by mussels (*Mytilus edulis*) and lugworms (*Arenicola marina*) living in natural habitats', Environmental Pollution, 199, pp. 10–17. doi: 10.1016/j.envpol.2015.01.008.**
No. citations Scopus (07/2018)	130
Summary	Laboratory study to assess effects of ingestion and translocation of microplastics on the energy metabolism (cellular energy allocation) of the blue mussel *Mytilus edulis* (filter feeder) and the lugworm *Arenicola marina* (deposit feeder). Microplastics were present in all organisms collected in the field: on average 0.2 ± 0.3 microplastics g^{-1} (*M. edulis*) and 1.2 ± 2.8 particles g^{-1} (*A. marina*). Mussels and lugworms exposed to high concentrations of polystyrene microspheres (110 particles mL^{-1} seawater and 110 particles g^{-1} sediment, respectively) showed no significant adverse effect on overall energy budget.
Test material	polystyrene
Particle size	10 µm, 30 µm and 90 µm
Compartment	Marine
Species	*Mytilus edulis* (blue mussel) and *Arenicola marina* (L.) (lugworm)
Life-stage	4-4.5cm and 7-11cm (respectively)
Target organ	-
No. of individuals	*Mytilus* - mussels were placed per three in a 1 L beaker; Lugworms - Control (N = 10) or exposure (N = 20) treatment
No. of replicates	*Mytilus*- a control treatment (5 replicates) and exposure to microplastics (10 replicates).
Exposure duration	14 days
Concentration of microplastics	110 particles g^{-1} sediment (natural) [Concentration in orgs after test (after 24-hour gut clearance): average 9.6 ± 1.8 particles g^{-1} tissue of size 10 µm and 30 µm]
Endpoints assessed	Cellular Energy Allocation, Protein and carbohydrate content. Lipid reserves
Observed outcome/effects	Lugworm - Increased metabolism (18% increase in protein content) but no significant overall effect on the total Cellular Energy Allocation. Mussel - Increased metabolism (25% increase in energy consumption in the digestive gland) but no significant overall effect on the total Cellular Energy Allocation.
Summary of reliability and quality assessment	No guideline or internationally accepted protocol followed and organisms taken directly from the environment. Simple exposed/clean combination experiment but limited information to test individual variability of test organisms. Moderate number of replicates used.
Klimisch Score	3 (not reliable)

Table 35: Study Summary – Von Moos et al. (2012)

Bibliographic details	**Von Moos, N., Burkhardt-Holm, P. and Köhler, A. (2012) 'Uptake and effects of microplastics on cells and tissue of the blue mussel *Mytilus edulis* L. after an experimental exposure', Environmental Science and Technology, 46(20), pp. 11327–11335. doi: 10.1021/es302332w.**
No. citations Scopus (07/2018)	202
Summary	Study into the potential for particles of industrial high-density poly- ethylene (HDPE), a model microplastic free of additives, ranging > 0− 80 µm, are ingested, accumulated and translocated into the cells and tissue of the blue mussel *Mytilus edulis* L. The effects of exposure (up to 96 h) and plastic ingestion were observed at the cellular and subcellular level. Mussel health status was investigated incorporating histological assessment and cytochemical biomarkers of effect and exposure. In addition to being drawn into the gills, HDPE particles were taken up into the stomach and transported into the digestive gland where they accumulated in the lysosomal system after 3 h of exposure. Notable histological changes upon uptake and a strong inflammatory response demonstrated by the formation of granulocytomas after 6 h and lysosomal membrane destabilisation, which significantly increased with longer exposure times.
Test material	Industrial HDPE
Particle size	0− 80 µm
Compartment	Marine
Species	*Mytilus edulis* L. (blue mussel)
Life-stage	-
Target organ	Gills, digestive system (gland/tubules)
No. of individuals	18 mussels per experiment
No. of replicates	Three beakers received the HDPE treatment (i.e., nine mussels) and three beakers served as unexposed negative controls (i.e., nine mussels).
Exposure duration	3, 6, 12, 24, 48, and 96 h
Concentration of microplastics	2.5 $g.L^{-1}$
Endpoints assessed	Presence of HDPE on gills. End point granulocytoma formation caused by accumulation of microplastics and lysomal membrane stability.
Observed outcome/effects	Accumulation in epithelial cells of the digestive system after 3 hrs, inducing a strong inflammatory response accompanied by histological changes. Measured biological effects became more severe with increasing exposure periods. Proof of principle that microplastics are taken up into digestive cells of *Mytilus edulis* L. where they induce distinct adverse effects.
Summary of reliability and quality assessment	No guideline or internationally accepted protocol followed but basic experimental set up described. Moderate numbers of individuals used and organisms originally obtained from the wild. 96 hr exposure organisms fed but none of the other experimental groups. Sampling conducted at the same time of day for relevant endpoints.
Klimisch Score	2 (reliable with restrictions)

Table 36: Study Summary – Wardrop et al. (2016)

Bibliographic details	**Wardrop, P. et al. (2016) 'Chemical Pollutants Sorbed to Ingested Microbeads from Personal Care Products Accumulate in Fish', Environmental Science and Technology, 50(7), pp. 4037–4044. doi: 10.1021/acs.est.5b06280.**
No. citations Scopus (07/2018)	41
Summary	This experiment investigated whether organic pollutants sorbed to microbeads from personal care products were assimilated by fish following particle ingestion. Rainbow fish (*Melanotaenia fluviatilis*) were exposed to microbeads with sorbed PBDEs (BDE-28, -47, -100, -99, -153, -154, -183 200 ng g^{-1}; BDE-209 2000 ng g^{-1}) and sampled at 0, 21, 42 and 63 days along with two control treatments (Food Only and Food + Clean microbeads). Exposed fish had significantly higher ∑8PBDE concentrations than both control treatments after 21 days, and continued exposure resulted in increased accumulation of the pollutants over the experiment (ca. 115 pg g^{-1} ww d^{-1}). Lower brominated congeners showed greatest accumulation whereas higher brominated congeners did not appear to accumulate, indicating they may be too strongly sorbed to the plastic or unable to be accumulated by the fish due to large molecular size or other factors.
Test material	Polyethylene microbeads, clean and spiked with PBDE
Particle size	10-700µm
Compartment	Freshwater
Species	*Melanotaenia fluviatilis* (rainbow fish)
Life-stage	Juvenile
Target organ	Body tissue
No. of individuals	135 (45 tanks and 3 individuals per tank)
No. of replicates	15 replicates per treatment
Exposure duration	21, 42 and 63 days
Concentration of microplastics	-
Endpoints assessed	Accumulation of PBDE in body tissue, following consumption of microbeads contaminated with PBDEs.
Observed outcome/effects	PBDEs sorbed to microbeads from facial soaps accumulated in fish tissue after particles were ingested. Furthermore, brominated congeners with lower octanol−water partition coefficients more readily desorbed and accumulated in fish compared to higher congeners which may be too strongly sorbed to MBs to readily partition.
Summary of reliability and quality assessment	No guideline or internationally accepted protocol followed but clear description of method. Analytical preparation of clean and spiked microbeads well described. Good number of replicates per treatment type
Klimisch Score	2 (reliable with restrictions)

Table 37: Study Summary – Watts et al. (2015)

Bibliographic details	**Watts, A. J. R. et al. (2015) 'Ingestion of Plastic Microfibers by the Crab *Carcinus maenas* and Its Effect on Food Consumption and Energy Balance', Environmental Science and Technology, 49(24), pp. 14597–14604. doi: 10.1021/acs.est.5b04026.**
No. citations Scopus (07/2018)	48
Summary	This study investigated the fate of polypropylene rope microfibers (1−5 mm in length) ingested by the crab *Carcinus maenas* and the consequences for the crab's energy budget. In chronic 4 week feeding studies, crabs that ingested food containing microfibers (0.3−1.0% plastic by weight) showed reduced food consumption (from 0.33 to 0.03 g d^{-1}) and a significant reduction in energy available for growth (scope for growth) from 0.59 to −0.31 kJ crab d^{-1} in crabs fed with 1% plastic.
Test material	Polypropylene rope microfiber
Particle size	500 µm microfiber
Compartment	Marine
Species	*Carcinus maenas* (Crab)
Life-stage	Inter-moult males
Target organ	Gut and energy budget
No. of individuals	40
No. of replicates	4 experimental groups (individual tanks)
Exposure duration	4 weeks
Concentration of microplastics	0% (0 mg), 0.3% (0.6 mg), 0.6% (1.2 mg), 1% (2.0 mg) added to 2 g of the feed.
Endpoints assessed	Food consumption and Scope for Growth (SFG) were determined. Plastic accumulation was also measured throughout the 4 week period.
Observed outcome/effects	There was a reduction in the food consumption rates over time in crabs feeding on food containing plastic microfibers, leading to a small but significant reduction in the available energy for growth. This is, however, very unlikely to have any long-lasting ecological consequences. The rope fibres were physically altered by their passage through the gut, with a reduction of overall size and a tendency to become balled.
Summary of reliability and quality assessment	No standard protocol or test guideline followed. Differing concentrations of plastic microfibers added to the crab feed and relevant endpoints recorded in suitable test organism. Controlled laboratory / exposure conditions indicate scientifically acceptable protocol used although moderate numbers of organisms tested.
Klimisch Score	2 (reliable with restrictions)

Table 38: Study Summary – Wright et al. (2013a)

Bibliographic details	**Wright, S. L. et al. (2013) 'Microplastic ingestion decreases energy reserves in marine worms', Current Biology, 23(23), pp. R1031–R1033. doi: 10.1016/j.cub.2013.10.068.**
No. citations Scopus (07/2018)	157
Summary	Deposit-feeding marine worms maintained in sediments with unplasticised polyvinylchloride (uPVC) microparticles at concentrations overlapping those in the environment significantly depleted energy reserves by up to 50%. Depleted energy reserves arise from a combination of reduced feeding activity, longer gut residence times of ingested material and inflammation.
Test material	Unplasticised polyvinyl chloride. Clean, chemically-inert microplastics
Particle size	130 µm mean diameter
Compartment	Marine
Species	*Arenicola marina* (L.) (Lugworm)
Life-stage	Adult
Target organ	-
No. of individuals	13 per treatment
No. of replicates	-
Exposure duration	28 days (chronic), 48h (short term)
Concentration of microplastics	0.5%, 1% and 5% by weight sediment (natural)
Endpoints assessed	Feeding activity, phagocytic activity, energy reserves (by weight)
Observed outcome/effects	Reduced feeding activity (no. of casts) at 5% dose. Reduced available energy reserves (1% and 5% doses). Increased phagocytic activity (0.5% and 5% doses – not dose-dependent)
Summary of reliability and quality assessment	No guideline or internationally accepted protocol followed but description of method. Small number of replicates per treatment type. Moderate level of detail on chronic exposure conditions.
Klimisch Score	3 (not reliable)

Table 39 describes with some examples (bio)degradability of conventional non-biodegradable plastics, biodegradable plastics and mixture of those. These examples cover (bio)degradation in aquatic environment, soil, sediment and compost. The examples demonstrate the extreme persistency of conventional plastics and provide examples of fast degrading biodegradable plastics.

Table 39: Some examples of (bio)degradation of different type of plastics.

Plastic	Condition	Reported result	Reference
Polyethylene (PE)	Aquatic	1-1.7% in 30 days	Harshvardhan and Jha 2013
PE	Compost	12% after one year of weathering and composting at 58 °C for 3 months	Sivan 2011
Low density polyethylene (LDPE) **High density polyethylene (HDPE)** **Polypropylene (PP)**	Sea water	1.5–2.5 % 0.5–0.8 % 0.5–0.6 % Weight loss of their initial weight after 6 months	Sudhakar et al. 2007
LDPE	Soil	0.2% weight loss in 10 years	Albertsson and Karlsson 1987 as cited in Kyrikou and Briassoulis 2007
LDPE		300 years to break down a film with thickness of 60 µm	Ohtake et al. 1998 as cited in Kyrikou and Briassoulis 2007
LDPE containing degradable plastic additives (TDPA) and pro-oxidants	Soil, pre-thermally-oxidized at 55 °C, fragmented	44% mineralisation in 600 days	Chiellini et al. 2003 as cited in Kyrikou and Briassoulis 2007
LDPE	Without pre-photodegradation	0.2% carbon conversion per 10 years	Guillet et al. 1988 as cited

Plastic	Condition	Reported result	Reference
LDPE **PS**	With pre-photodegradation With pre-photodegradation in soil with growing plants	5.7% carbon conversion per 10 years ~5% biodegradation over 6 months	in Andrady et al. 2011
Polystyrene (PS) **Polymethyl methacrylate (PMMA)**	Fungal species Mixed microbial communities	< 1% within 35 days 0% within one month	Kaplan et al. as cited in Eubeler et al. 2010 II
Toluene diisocyanate (TDI), **Methylenediphenyl diisocyanate (PMDI)** **based polyureas**	Hydrolysis	half-life at 25 °C 18 000 – 300 000 years half-life at 25 °C 84 000 – 12 000 000 years	Sendijarevic et al. 2003
Poly(butylene adidate-co-terephtalate) PBAT	Soil ^{13}C-labelled polymer films with 3 different label positions	13 % biodegradation in 6 weeks P*BAT 8 % biodegradation in 6 weeks PB*AT 8 % biodegradation in 6 weeks PBA*T	Zumstein et al. 2018
Several polymers and plastics **Starch** **Poly (3-hydroxybutyrate-co- 3-hydroxyhexanoate) PHBHHx** **Poly (3-hydroxybutyrate-co-3hydroxyvalerate) (PHBV)** **Poly (ester amide) (PEA)** **Poly (e-caprolactone) (PCL)** **Cellulose** **Chitosan** **Poly (vinyl alcohol) (PVA)** **Poly (ethylene oxide) (PEO)**	ISO 14852, Aquatic with inocula derived from soil	Biodegradation (%) 14 days at 30 °C 78 62 53 36 26 25 15 5 4	Guo et al. 2012

Plastic	Condition	Reported result	Reference
Poly (propylene carbonate) (PPC) **Poly (butylenes succinate-co- adipate) (PBSA)** **Poly (butylenes succinate) (PBS)** **Poly (lactic acid) (PLA)** **Polyethylene (PE)**		3 3 2 1 0	
Poly(3-hydroxy butyrate)-co-(3-hydroxy valerate) (PHBV) polymer (< 32 µm) milled, PHBV foam (125 µm, 250 µm and 500 µm) and sodium benzoate (positive control).	Modified OECD 301B	After 28 days the mineralisation of PHBV milled polymer; 88 % PHBV foam (125 µm, 250 µm and 500 µm); 74%, 71% and 66%. The test duration was extended for 80 days.	McDonough et al. 2017
Polybutylene sebacate (PBSe) **pellets** **milled and sieved (89, 179, 193, 825 and 1650 cm^2g^{-1})**	Soil ASTM D 5988-12	K (mg C-polymer day^{-1}) 2.73 7.22, 13.85, 22,90, 28.17, 31.24 After 138 days all except pellet reached 80-90% degradation (cellulose 80%)	Chinaglia et al. (2018)
Filter paper **Mater-Bi carrier bag (22 µm thick)**	Buried in wet sand Sediment water interphase	Total disintegration in 9 months. 69% biodegradation in 236 days; relative to paper 88% (filter paper that degraded 78 % in 236 d)	Tosin et al. 2012
Mater-Bi **Filter Paper** **Polyhydroxybutyrate (PHB)**	Aerobic biodegradation of plastics buries in sandy marine sediment under controlled conditions (Eulittoral)	Inherent biodegradation in 28 °C Eulittoral in 195 days Mater-Bi; 76-110%	Verification report ET/2015 Aerobic degradation of Third generation Mater Bi under marine condition https://ec.europa.eu/envir

Plastic	Condition	Reported result	Reference
	ISO/DIS 19679 Test method for determining aerobic biodegradation of plastic materials sunk at the sea water/sandy sediment interphase (Sublittorial)	Filter Paper (positive control); 77% PHB (polyhydroxybutyrate); 163 % Sublittoral in 259 days Mater-Bi; 93% Filter Paper (positive control); 96% PHB (polyhydroxybutyrate); 163%	onment/ecoap/sites/ecoap_stayconnected/files/etv/vn20150004_verification_report_novamont.pdf
Nylon 4 film (anionic ring opening polymerisation of 2-pyrrolidone using N-acyl lactam and potassium tert-butoxide **P(3HB)**	Seawater	BOD after 25 days in 25 °C 80% (both samples)	Tachibana et al. 2013
Lactic-acid based poly(ester-urethanes) 6 different polymers with variable stereo structure, crosslinking, and chain length.	Headspace test (CO_2) with compost inoculum	25 °C < 1% in 63 d 37 °C 7-50 % in 98 d 55 °C 53-79 % in 63 d 60 °C > 90% in 63 d	Hiltunen et al. 1997
Starch based polymer and **PLLA (controls)**	Headspace test (CO_2) with compost inoculum	25 °C – 60 °C; Starch 74-79% (63 d) PLLA 8 – 65% (63 d)	Hiltunen et al. 1997

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Plastic	Condition	Reported result	Reference
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Annex D. Impact Assessment

D.1. Analysis of risk management options (RMOs)

The following two sections detail the other evaluated restriction options and the non-Restriction risk management options identified and assessed.

D.2. Other evaluated restriction options

A number of restriction options were identified and analysed prior to the Dossier Submitter selecting its preferred option. This section sets out the reasons for discarding the other restriction options which were assessed against the main criteria for proposing a restriction identified in Annex XV of REACH: effectiveness, practicality and monitorability.

A restriction on the placing on the market and use of all mixtures intended for consumer and professional use containing intentionally added microplastic (≥ 0.01 % w/w) (without derogations (except for industrial uses or to avoid double regulation) or transitional periods).

The main rationale for restricting the placing on the market and use of all mixtures containing microplastics is to reduce emissions into the environment as quickly as possible. Only exemptions for industrial uses (to maintain the scope in the Commission request) and those to avoid double regulation would be included. The emission reduction (a proxy for risk) would be higher than the proposed restriction, although most of the derogated uses will have significantly less emissions than the uses specifically captured in the scope of the proposed regulation. However, it could be expected that more emissions than the proposed restriction are restricted.

Due to the increased number of products in scope, and the lack of time to develop and transition to alternatives, this would mean increased costs for companies to comply with the restriction. The benefits could also be increased but probably not in proportion to the increased costs, so the proportionality of this option would be decreased.

The practicality (implementability, enforceability, manageability) of this option was considered to be lower than the proposed option by the Dossier Submitter due to the lack of transitional periods and the increased scope when considered against the uncertain increase of any benefits. Companies could not plan for their implementation of the restriction, products would have to be removed from the shelves and enforcement would be more complicated. Monitorability of the restriction would also be less straightforward.

Therefore, this option was discarded as it would be less net beneficial to society than the proposed restriction.

Labelling of all mixtures for consumer and professional use containing intentionally added microplastics (≥ 0.1 % w/w) with the phrase 'contains microplastics > 0.1%', with a requirement for user instructions to minimise releases to wastewater (e.g. dispose to municipal waste).

The main rationale for this restriction option is to rely on consumers and professionals to change their purchasing habits and stop buying products containing microplastics.

However, this is unlikely to have the same risk reduction effect as the proposed restriction. The direct costs to duty holders would be minimal if a transition period was given to align labelling changes with normal relabelling cycles. However, if a significant number of consumers changed their buying habits then the profits of the relevant companies would be reduced, or they would have to change their formulations. This is likely to lead to high costs if companies do not have time to transition to alternatives. The benefits are likely to be lower than the proposed restriction so the proportionality of this option would be decreased.

The practicality (implementability, enforceability, manageability) of this option was considered to be lower than the proposed option due to the lack of transitional periods and the increased scope when considered against the uncertain increase of benefits. Companies could not plan for their implementation of the restriction; products would have to be removed from the shelves and enforcement would be more complicated.

Monitorability of the restriction would also be more complicated.

Therefore, this option was discarded as it would be less net beneficial to society than the proposed restriction.

Restriction on the placing on the market and use of specifically identified mixtures or articles for consumer and professional use containing intentionally added microplastic (≥ 0.01 % w/w) (with derogations).

The main rationale for only restricting the placing on the market and use of certain identified uses of mixtures containing microplastic is to reduce the likelihood of capturing significant uses that the industry has not informed the Dossier Submitter about. However, due to the extensive investigation that the Dossier Submitter has undertaken and the wide publicity about the restriction this is assessed as unlikely. The disadvantages of this option would that future uses of microplastics would not be restricted nor would any uses that had not been identified to the Dossier Submitter. Therefore the risk reduction is likely to be lower than that of the proposed restriction but the costs would be similar. Therefore, the proportionality of this option would probably be less than the proposed option.

The practicality (implementability, enforceability, manageability) and monitorability of this option was considered to be similar to the proposed option.

Therefore, this option was discarded as it would be probably less net beneficial to society than the proposed restriction and has several deficiencies when compared to the proposed option.

Restriction on the placing on the market and use of all mixtures for consumer and professional use containing intentionally added microbeads (≥ 0.01 % w/w) (without derogations).

The main rationale for restricting the placing on the market and use of all mixtures containing microbeads (as defined in the proposed option) i.e. certain cosmetic products and detergents is to focus the restriction on those uses already covered in many of the existing national legislations and voluntary agreements. This would have a limited risk reduction capacity as industry has already voluntarily phased out the majority of such uses. There would, however, be some risk reduction in terms of imported mixtures and

from those EU suppliers who did not comply with the voluntary agreement. However, the concern raised by the risk assessment would not be diminished. The costs of the option would also be reduced compared to the proposed option. The option is likely to be proportional but significantly less effective than the proposed option.

The practicality (implementability, enforceability, manageability) of this option was considered to be high as industry are already implementing a similar voluntary agreement. The monitorability of the restriction would also be high.

Therefore, this option was discarded as it would be less net beneficial to society than the proposed restriction.

Restriction on the use of microplastics in consumer and professional products ($\geq$ 0.01%) in a size range of 1µm ≤ x ≤ 1mm.

The main rationale for this restriction option is to potentially increase certain elements of implementability of the measure as compared to the proposed option. Several stakeholders proposed that the lower size range should start at 1 µm as it may be very challenging to perform any measurement by weight for the lower size ranges and that the methodologies available to measure below 1 µm are not widely available. In addition, stakeholders mentioned that 1nm is in the size range of individual polymer molecules and below 1 um it is difficult to distinguish particles from non-particles. Stakeholders also raised doubts about microplastic production from 1 nm to 10 µm particles production. At the other end of the spectrum, restricting the upper size range to below 1 mm would exclude certain plastic raw materials from scope such as 'nurdles'. The Dossier Submitter also notes this may exclude rubber granules from scope (see Background Document, section 2.1) but some granules may be present below that size level.

This option will have a reduced risk reduction as compared to the proposed restriction. For example, it would not capture any of the nanoparticles for which there is some level of concern (see SAPEA evidence review on microplastics where it is concluded that the lack of information on the fate and effects of nanoplastics is particularly acute). The lower upper size limit would also mean some microplastics would not be covered.

The costs to duty holders would be similar to the proposed restriction but there would be some potential savings from the reduced scope and potentially less costly testing methods. However, industry have not yet provided any quantitative evidence that the test methods related to the lower size limit are substantial enough to justify not including the nanoplastics. The benefits are likely to be lower than the proposed restriction (as the risk reduction capacity is reduced) but it is not clear if the proportionality of this option would be increased or not.

The practicality (implementability, enforceability, manageability) of this option was considered to be higher than the proposed option as the testing methods were more accessible.

The monitorability of the restriction would be lower as there would be no additional information on nanoplastics.

Therefore, this option was discarded as it would be less net beneficial to society than the proposed restriction as the risk reduction would be lower and it is uncertain if the costs

would be lower.

Restriction on thermoform and thermoset organic polymer 'plastics' only (≥ 0.01% w/w).

The main rationale for this restriction option is to only cover thermoform and thermoset organic polymers as microplastics. This has been proposed by several stakeholders as an alternative to including all polymers in scope.

This option is unlikely to have the same risk reduction effect as the proposed restriction as less polymers would be in scope. The costs to duty holders may be reduced as less companies are affected. The benefits are likely to be lower than the proposed restriction so it's unclear if the proportionality of this option would be increased.

The practicality (implementability, enforceability, manageability) of this option was considered to be similar to the proposed option.

Monitorability of the restriction would be the same as the proposed option.

Therefore, this option was discarded as it is unclear it would be more net beneficial to society than the proposed restriction.

D.3. Other Union-wide risk management options than restriction

As a first step, the possibility to address the risks posed by the use of microplastics under other REACH regulatory measures, existing EU legislation and other possible Union-wide RMOs was examined. Whilst it was recognised, and taken into account when developing the scope of the proposed restriction, that some existing or proposed EU legislation or other measures could have an impact on the risk management of certain sectors, such as Regulation (EU) No 2019/1009 on EU fertilising products (FPR), these were assessed as inappropriate to address *all* of the sectors and products contributing to risk.

Possible Union-wide risk management measures other than a restriction are outlined in Table 40: below. However, it is concluded that none of these are realistic, effective and balanced means of solving the problem. As such, none of these other risk management options have been analysed further.

Table 40: Possible other Union-wide options discarded at this stage

Option	Reasons for discarding this option
Non-legislative measures	
Voluntary industry agreement to restrict the use of microplastics in mixtures.	The mixtures included in the proposal fall within numerous diverse industry sectors, which belong to different industry groups, often dominated by SMEs. There are also many importers and European producers of mixtures that could contain microplastics that are not organised in European associations. (See Annex C and Annex A for further details). Several voluntary agreements on microbeads have already enacted by several EU trade associations. In 2015, Cosmetics Europe recommended to its members to discontinue the use of plastic microbeads for cleansing and exfoliating purposes in wash-off cosmetic and personal care products. In 2017 Cosmetics Europe announced a decrease of 97.6% in the use of plastic microbeads for cleansing and exfoliating purposes in wash-off cosmetic and

Option	Reasons for discarding this option
	personal care products (See section D.5.3 in this Annex for more details). However, the sheer number of stakeholders makes it difficult to negotiate a voluntary agreement that covers all the different products and uses and it cannot be effectively enforced. In addition, Industry have not shown any willingness to extend the current voluntary initiatives. Any voluntary agreement is also likely affect the timelines for addressing the risks and the possibility to monitor the effectiveness of the proposed measure.
Voluntary agreement for industry to label articles.	Possible labelling options include: • 'Contains microplastics > 0.01%'. The agreement to use this label would be a voluntary measure similar to the rejected restriction option. • 'Use appropriate risk management measures' (exact measures to be determined by industry). The agreement to use this label would be a voluntary measure similar to that proposed for some industry sectors in the proposal. This RMO will also share many of the disadvantages of the voluntary agreement to restrict substances such as enforcement and coverage (as above). The option to label with contains microplastics would also share the issues with the relevant rejected restriction. In the case of the risk management measure label this is not relevant for all uses as would not have a suitable risk reduction.
Information campaign to consumers to avoid buying the articles in question.	This RMO does not seem to be sufficiently effective. For the consumer, it will be difficult to identify the mixtures containing the microplastics.
Legislation other than REACH	
Control of emissions under the IED and/or Water Framework Directive and waste legislation	Mixtures containing microplastics have wide dispersive use by consumers and professional users. Exposure to the environment via emissions occurs mainly during the use phase, not the production phase. However, there is evidence of loss of noodles from production that could be usefully dealt with but maybe not through this RMO. Therefore, measures aimed at point sources would not address the risk of exposure and will not be an effective risk management measure.
Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment	The objective of this Directive is to protect the environment from the adverse effects of urban wastewater discharges and discharges from certain industrial sectors and concerns the collection, treatment and discharge of: Domestic waste water; Mixture of waste water; and Waste water from certain industrial sectors. Increasing the efficiency of wastewater treatment through measures under this Directive could help reduce microplastics reaching the surface water. However, this would mean more microplastics end up in the sludge and therefore would be an increase in the burden to the terrestrial environment and would not adequately control the identified risk.

Option	Reasons for discarding this option
Sewage Sludge Directive 86/278/EEC	This Directive seeks to encourage the use of sewage sludge in agriculture and to regulate its use in such a way as to prevent harmful effects on soil, vegetation, animals and man. It prohibits the use of untreated sludge on agricultural land unless it is injected or incorporated into the soil. The Directive also requires that sludge should be used in such a way that account is taken of the nutrient requirements of plants and that the quality of the soil and of the surface and groundwater is not impaired. As the main environmental compartment affected by intentionally added microplastics is the terrestrial environment, part of the issue could be potentially dealt with via a reduction in sewage sludge application to soil if it contains microplastics. As the majority of sludge will contain such material, it would mean other fertilisers would be needed to replace the sludge and the currently used sludge would need to be incinerated. A measure addressing the sources of microplastics would therefore be a more efficient method of controlling the risk.
Taxation on microplastic content	Taxation in general is not a harmonised measure across the EU. Therefore, whilst it might be effective in encouraging substitution, it is not likely that all Member States would introduce relevant taxes and thereby, not all EU citizens will be protected. This is likely to lead to a non-harmonised situation where different Member States apply different tax rates (if at all).
Sector specific legislation	Uses within the scope of the proposal are varied and widely dispersed. It would be resource intensive to address the risks via a large number of sector specific legislation, which also does not exist for all relevant sectors. In addition, surveys have revealed that REACH restrictions are a convenient way to communicate all-encompassing regulatory measures related to chemicals. However, efforts have been made to derogate mixtures in the restriction proposal which are adequately covered by existing sector specific EU legislations (e.g., medicines, EU fertilisers, etc.) to avoid unnecessary overlap of regulatory actions and improve clarify for stakeholders.
	Medicines Regulations: Directive 2001/82/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 The Union legislation for veterinary and human medicines are set out in Directive 2001/82/EC and Directive 2001/83/EC respectively. They provide the legal framework for the authorisation, manufacture and distribution of medicines in the EU. The centralised authorisation procedure for human and veterinary medicines is based on Regulation (EC) No 726/2004, which established the European Medicines Agency (EMA). All medicines must be authorised before they can be marketed and made available to patients. In the European Union (EU), there are two main routes for authorising medicines: a centralised route and a national route. Under the centralised authorisation procedure, pharmaceutical companies submit a single marketing-authorisation application to EMA. This allows the marketing-authorisation holder to market the medicine and make it available to patients and healthcare professionals throughout the EU on the basis of a single marketing authorisation. EMA's Committee for Medicinal products for Human Use (CHMP) or Committee for Medicinal products for Veterinary Use (CVMP) carry out a scientific assessment of the application and give a recommendation on whether the medicine should be marketed or not.

Option	Reasons for discarding this option
	For veterinary medicinal products, an ERA (Environmental Risk Assessment) is required and mandatory for all types of marketing authorisation applications, including for new medicinal products, generics, variations and extensions. The ERA is taken into account in the risk-benefit analysis in view of the authorisation. With regard to human health medicinal products, since October 2005, an ERA is required for new products to be placed on the market, but the ERA results in this specific case cannot lead to denying a market authorisation, even if some Risk Mitigation Measures (RMM) can be required when considered necessary (see Section D.9 for further discussion).
	The Detergents Regulation (EC) No. 648/2004 This regulation covers the manufacturing, placing and making available on the market and use of detergents. The Regulation harmonises the rules for the placing on the market of detergents and of surfactants for detergents; the biodegradability of surfactants in detergents; restrictions or bans on surfactants on grounds of biodegradability; the additional labelling of detergents, including fragrance allergens; the information that manufacturers must hold at the disposal of the Member States' competent authorities and medical personnel; limitations on the content of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents. However, it does not cover the degradability of polymers and couldn't currently regulate the concerns of microplastics.
	Construction Products Regulation: Under this Regulation the information on the content of hazardous substances in the construction products should be included in the declaration of performance to reach all potential users. As microplastics are not classified as hazardous it is not evident if this legislation would apply.
	Medical Device Directives: Directive 90/385/EEC regarding active implantable medical devices (AIMD); Directive 93/42/EEC regarding medical devices (MDD); Directive 98/79/EC regarding in vitro diagnostic medical devices (IVDD) Three Directives deal directly with medical devices, either as the medical devices themselves, or as implantable medical devices or as in vitro diagnostics. According to these Directives, medical devices must be designed and manufactured taking into account the toxicity of materials used and minimising the risk for substances to leak out of the device. These directives will soon be repealed and replaced by EU Regulations (EU) 2017/745 on Medical Devices (aka MDR), and (EU) 2017/746 on in vitro diagnostic medical devices (aka IVDR) that will come into force respectively on 26 May 2020, and 26 May 2022. The MDR and IVDR bring significant changes in term of Vigilance, Post-market Surveillance and communication on safe use (for humans and the environment).
	Fertilisers Regulation Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (Text with EEA relevance) Fertilisers are chemical compounds providing nutrients to plants. So-called

Option	Reasons for discarding this option
	'EC fertilisers' are regulated by Regulation (EC) No 2003/2003 on mineral fertilisers and may circulate freely within the EU single market. EC fertilisers comply with fertiliser type designations in the annexes to the regulation. They also guarantee farmers a minimum nutrient content of mineral fertilisers and overall safety, in particular for high nitrogen content ammonium nitrate fertilisers. It is the responsibility of the manufacturer to make sure that a fertiliser labelled as an 'EC Fertiliser' meets the technical and labelling requirements of the Regulation. The rules for other fertilisers ("national fertilisers") are currently not harmonised at EU level and are governed by national laws, although mutual recognition applies. The revision of EU's fertilisers regulation. A new regulation for fertilisers has been agreed that will be implemented from the year 2022. See Section 0 of this Annex for more details.
	Cosmetics Regulation (EC) 1223/2009 The Cosmetics Regulation only applies to the human health hazards of cosmetics and not the environmental issues.
Product Safety Directive 2001/95/EC	This Directive only addresses risks related to specific articles and not risks related to a cumulated exposure from different articles. It can be used to restrict articles but this needs annual renewal (similar to the old decision on phthalates in toys that was eventually made into a restriction).
Biocidal Products Regulation (BPR) 528/2012	The Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product. All biocidal products require an authorisation before they can be placed on the market, and the active substances contained in that biocidal product must be previously approved. Microplastics are not active ingredients but could be dealt with substances or mixtures which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists, referred to as 'co-formulants'.
Plant Protection Products Regulation (PPP) 1107/2009.	Plant protection products are 'pesticides' that protect crops or desirable or useful plants primarily used in the agricultural sector but also in forestry, horticulture, amenity areas and in home gardens. They contain at least one active substance - before an active substance can be used within a plant protection product in the EU, it must be approved by the European Commission. They have one of the following functions: protect plants or plant products against pests/diseases, before or after harvest; influence the life processes of plants (such as substances influencing their growth, excluding nutrients); preserve plant products; destroy or prevent growth of undesired plants or parts of plants. They may also contain other components including safeners and synergists. EU countries authorise plant protection products on their territory and ensure compliance with EU rules. Microplastics are not active ingredients but could be dealt with substances or mixtures which are used or intended to be used in a plant protection

Option	Reasons for discarding this option
	product or adjuvant, but are neither active substances nor safeners or synergists, referred to as 'co-formulants'. Co-formulants shall not be accepted for inclusion in a plant protection products where it has been established that they have a harmful effect on human or animal health or on groundwater or an unacceptable effect on the environment. Co-formulants which are not accepted for inclusion in a plant protection product pursuant to paragraph 1 shall be included in Annex III in accordance with the regulatory procedure with scrutiny referred to in Article 79(4). This latter mechanism could be used to deal with non-biodegradable polymers, but this could also be dealt with under a restriction. This is a policy choice of the regulator.
Other REACH processes	
REACH Authorisation process	Microplastics have not been identified as substances of very high concern due to CMR (category 1A or 1B) properties (article 57(a-c)), PBTs or vPvBs properties (article 57 (d-e) nor have they been identified as substances of equivalent concern (article 57(f) and are therefore not included on the Candidate List for Authorisation. Therefore, authorisation cannot be used as a Risk Management Measure for them.
REACH Art. 68.2	REACH Article 68(2) stipulates that substances that are classified as CMR categories 1A or 1B can be subject to a proposal from the Commission to inclusion in Annex XVII for consumer uses without using the procedures in article 69-73 in the REACH Regulation. Microplastics are not so classified and this measure is not applicable to them.

D.4. Agricultural and Horticultural Products

Polymers are widely used in agricultural and horticultural (A&H) products to protect seeds during germination, control and delay the release of fertilisers and plant protection products (PPPs), and as additives such as anti-caking agents, prilling agents, stabilisers, etc. These uses of polymeric material have a common mode resulting in the same foreseeable use condition—after fulfilling their function the polymers remain in the soil treated. This provides for one major pathway of emission of microplastics into the terrestrial environment. However, as the availability and suitability of alternatives varies across the A&H products, different impacts are to be expected from taking regulatory actions on them. Therefore, the socio-economic impacts of a restriction are studied for four broad categories[18]:

- Controlled-release fertilisers (CRFs);
- Fertiliser additives;
- Plant protection products using capsule suspension (CSPs); and
- Seed coatings.

Below, the current uses of non-degradable polymers fulfilling the microplastics definition, potential alternatives, and various impacts of the proposed restriction is assessed for each of the four categories of A&H products. Based on this assessment a proportionality conclusion is presented and some uncertainties and assumptions made in the impact assessment are highlighted. The chapter closes with a brief summary of the implications of the proposed restriction on the A&H sector.

D.4.1. Current use

D.4.1.1. Controlled-release fertilisers

CRFs are granulated fertilisers that release nutrients gradually into the soil.[19] The rate and duration of release depends on the solubility of the chemical compounds in the soil, but common release periods appear to be in the range of 2-18 months after application (Fertilizers Europe, 2018). While conventional fertilisers are soluble in water, and thus nutrients disperse quickly as the fertiliser dissolves, CRFs are not. They have either an insoluble substrate or a semi-permeable membrane encapsulation that prevents dissolution while allowing nutrients to disperse into the soil more slowly.

The membrane encapsulation or 'coating' of fertiliser granules has several advantages. According to the International Fertiliser Society (2016, IFS hereafter), these include

[18] Polymers may also be used as co-formulants in plant protection products, e.g. as surfactants. However, these polymers are typically macromolecules and would, as such, not fall into the microplastics definition adopted in this restriction proposal.

[19] Slow and controlled-release fertilisers contain plant nutrients in a form which either delays the availability for plant uptake after application or is available to the plant significantly longer than common nutrient fertilisers. Whilst there is no clear distinction between 'slow release' and 'controlled release', Trenkel ((2010)) notes that "the microbially decomposed N products, such as UFs (Urea-Formaldehydes), are commonly referred to in the trade as slow-release fertilizers and coated or encapsulated products as controlled-release fertilizers." Accordingly, the term 'CRF' is used here to refer to polymer-encapsulated fertilisers.

increased nutrient use efficiency, reduced nutrient losses to the environment ('run-offs'), prevention of nutrient-fixation in the soil, maintained /increased crop yield rates at a lower nutrient application rate, improved quality of plants that need a continuous supply of nutrients at a low rate, and reduction of labour. In responses to the Call for Evidence (CfE), industry has particularly emphasised the idea of 'doing more with less', i.e. the high efficiency of CRFs in terms of labour, fertiliser quantities, and run-off. The efficiency gains over conventional fertiliser technologies have led to widespread adoption of CRFs, particularly in the ornamental industry where they are used by 90% of the 25 000 nurseries in the EU, which employ 130 000 people and generate revenues of €7 billion (Fertilizers Europe, 2018).

Whilst CRFs provide an efficient alternative to repeated manure of conventional fertilisers and are therefore said to have potential for applications in agriculture as well, their use implies the release of the polymeric material used for the membrane encapsulation. Often, these polymers are essentially non-degradable and remain in the environment for hundreds of years.

Based on the above description of encapsulating membranes, important properties of the barrier material include water-insolubility, limited water-permeability and stability, and a low degradation rate for enabling the controlled release of fertiliser over a period of several months (Trenkel, 2010). Release-facilitating conditions are determined by temperature, moisture, coating material/thickness and potentially pore-forming attributes, whereas the membrane technology reduces the influence of soil pH and the presence of microorganisms which are important factors for CRF technologies (Fertilizers Europe, 2018, IFS 2016).

Materials used for polymeric encapsulation of fertilisers range from cross-linked natural or thermosetting materials to thermoplastic materials (Milani et al., 2017). Table 41 gives an overview.

Table 41: Polymeric substances used in membrane encapsulated fertilisers

Fertiliser type	Coating material	Source
Urea	Polyhydroxybutyearate, polyethylene, polyvinyl acetate, polyurethane, polyacrylic, polylatic acid	Milani et al. (2017)
NPK	Paraffins, ester copolymers, urethane composites, epoxy, alkyd resins, polyolefines	Milani et al. (2017)
--	Acrylamide-based gels, copolymers of VC-acrylic acid esters and copolymers of cyclopentadiene with a glyceryl ester of an unsaturated fatty acid	Milani et al. (2017)
--	Alkyds based on vegetable oil, polyolefin waxes, amines, mineral oils, formaldehyde-naphthalenesulfonic acid condensate sodium salts	Fertilizers Europe (2018)
--	Polyethylene and oxidized polyethylene	CfE#680
--	Hydrolysable triglyceride ester bonds in modified vegetable oils	IFS (2016)
--	PE, P(VC-AEs), copolymers of dicyclopentadiene, PU coating compositions, epoxy resins, polyester,	Akelah (2013)

Fertiliser type	Coating material	Source
	poly(butadiene-b-methylstyearene)s, crosslinked hydrophilic PAA, prepolymer of phenol- or urea-formaldehyde	

According to information submitted by several producers and industry associations during and after the CfE, the coated granules have a diameter of 1-5 mm with a coating thickness of 10-100 µm and a concentration of polymeric material of 1-12% w/w. Main sectors of use are the cultivation of ornamental plants (approx. 90% of ornamental nurseries use CRFs) and the maintenance of turfs for sports (e.g. golf courses) and other landscaping purposes. The use of CRFs in agriculture and forestry appears to be still limited, but a potential for expansion of these markets is predicted due to expected price reductions in the encapsulation technology.

Fertilizers Europe (2018) estimated that the use of CRFs in ornamental horticulture and landscaping of turfs corresponds to 1 000-2 000 tonnes per year of polymeric material. Moreover, they informed that currently less than 1% of the annual agricultural fertiliser use is attributable to CRFs. Based on this information and adjustments for the expected rise in the market share of CRF uses in agriculture, it is estimated that between 2016 and 2022 on average 1% of the agricultural fertiliser use volume is attributable to CRFs.[20] Using Eurostat (2018b) data for 2016, the consumption of mineral fertilisers (nitrogen and phosphorus) in the EU-28 (plus Norway) is estimated at approx. 12.5 million tonnes. Assuming CRFs make up 1% of the total consumption and have a polymer concentration of 1-12%, then 1 000-15 000 tonnes of polymeric material are to be emitted in 2018.[21] This range corresponds well with estimates provided by Fertilizers Europe during the consultation. According to a sector-wide study presented during the International Fertilizers Association (IFA) Conference on CRFs in Dublin on 25.03.2019, the CRF market in Europe comprises about 50 000 tonnes per year. The average polymer content assumed in this study is 7%, leading thus to 3 500 tonnes of polymeric material currently emitted per year. Table 42 summarises the different estimates of the annual volume of polymeric material released through CRFs in the EU.

Table 42: Annual tonnage of polymeric material emitted by CRFs

Concentration in typical product (%)	Polymeric material (tonnes/year)	Time Period	Source
1-12% w/w polymer concentration	1 000-2 000 in ornamental horticulture and turfs/landscaping	2017/2018	Fertilizers Europe (2018)
1-12% w/w polymer concentration	1 000-15 000 in agriculture	2016-2022	Calculations based on information from Fertilizers Europe (2018)

[20] According to information by Fertilizers Europe ((2018)) the current use is somewhere between 0.5-1% of the total EU fertiliser consumption. With moderate growth of the CRF market in developed regions like the EU and the US expected between 2016 and 2022, this market share is unlikely to increase far beyond 1% by 2022 ((Grand View Research, 2018a)).

[21] The overall use of mineral fertilisers over this period is assumed fixed as, whilst demand might increase, the expansion of CRFs technology is considered to enhance fertiliser efficiency.

Concentration in typical product (%)	Polymeric material (tonnes/year)	Time Period	Source
			and Eurostat (2018a, Eurostat, 2018b), see text
7% w/w polymer concentration	<5 000 overall	2019	Fertilizers Europe (2019)
--	1 700-8 000 by 2020	By 2020	Amec Foster Wheeler (2017) [a]
Total	Central estimate: 10 000 Revised central estimate: 5 000[b] Range estimate: 1 000-17 000 Revised range estimate: 1 000-10 000 [b]		

[a] This report considered only microplastic particles >1 µm.

[b] Revised figures based on information received by Fertilizers Europe in the PC.

Once emitted, the encapsulations typically used in the EU remain in the environment as inert dust particles with a degradation rate of 0-15% over 3-4 months (IFS 2016).[22] In agriculture and turf applications, 100% of the polymeric material is directly emitted to the environment where it accumulates until a steady state concentration is reached. To illustrate, IFS (2016) reports on an environmental fate model which predicts the bioaccumulation of polymers on an imaginary plot over 200 years of wheat cultivation. Assuming annual fertilisation with coated urea, the model results in a worst-case soil concentration of 0.25% v/v after 200 years.[23] Assuming instead a biodegradation half-life of 5 years (20 years) lowers the steady state concentration to 0.01% (0.04%).

In ornamental uses, an unknown fraction of the polymeric material eventually enters the open environment as pot media are transferred to soils during planting into open spaces or because users discharge pot media of perished plants to gardens, private compost, etc. Even in case the medium (including the polymer residues) enters the regular waste stream, it may still enter the environment via landfilling and/or industrial composting.

The fertiliser Regulation (EC) No 2003/2003 already required coating material to undergo thorough phytotoxicity and toxicity testing before placing on the market. The regulation on EU fertilising products (FPR, Regulation (EU) No 2019/1009) includes an additional requirement that a polymer has at least 90% of the organic carbon converted into carbon dioxide in a maximum period of 48 months after the end of the claimed functionality period (Art. 42(6)). However, this biodegradability requirement pertains to

[22] Akelah (2013) discusses that not all systems have constant nutrient release rates and material imperfections often limit performance levels. Other sources point to the difficulties of measuring release characteristics under field conditions (Milani et al., 2017). Based on a quality requirement in EN13266, it may be assumed that the described release rates of active ingredients will be accomplished in 75% of the cases. For quality assurance, EN13266 requires that in the first 24 hours less than 15% of the active ingredient be released.

[23] The modelling assumes 7% coating content in fertilisers, 260 kg of nitrogen application per ha, 30 cm soil depth, and 1 200 kg/m^3 soil density.

CE marked fertilising products only which account today for about 50% of the total EU fertiliser market (European Parliamentary Research Service, 2017, EPRS hereafter). The remaining 50% of fertilising products, which are not CE marked, have not been subject to any biodegradability requirement. During the consultation, Fertilizers Europe specified that 95% of the CRFs sold on the EU market are CE marked and thus subject to requirements set in the FPR.

Next to membrane encapsulation, there are other uses of non-natural polymers in CRF systems (Akelah, 2013) which fall under the FPR. Table 43 lists the different polymeric materials used in these other CRF systems. Detailed information on their uses and use volumes in the EU is currently not available. However, they seem to have polymer concentrations that are comparatively higher than those of membrane CRF systems. Akelah (2013) reports increments of 10-50% for physical systems and 80-90% for chemical systems. This suggests that the annual emissions of polymeric material estimated from CRFs in Table 42 have to be considered a lower bound.

Table 43: Polymeric material used in other CRF systems (cf. Akelah, 2013)

CRF Category	Method	Materials
Physical barrier	Dispersion in polymer matrix	PVA, modified starch (alkali-treated starch or starch xanthate)
Physical barrier	Reservoir systems	Porous PVC or PP or hydrogels containing atrazine, 2,2-dichloropropionic acid and cetylpyearidinium chloride
Physical barrier	Monolithic systems	Erodible: Plasticised polymeric matrices including starch xanthate, hydrogels and modified lignin Non-erodible: PVC mixed with plasticiser or uncured prepolymers of silicone rubbers Laminated: Silicone rubber, PE, PVC, nylon (broad range of plastics, rubber, laminates, fibres, coatings and membranes can be combined with this technique)
Chemical attachment	Attachment as pendant side chains	Beads: Oligoethylenoxylated polystyearene Hydrogels: Polymerised oligooxyethylene methacrylate (with crosslinking agent MBAA and comonomers of AAm), oligooxyethylene monoacrylate (with quarternary onium groups), TEGMA (with DEGMA, OEGMA, AAm, 4-VP and crosslinking agent MBAA), PMMA (with hydrazine, ethylene- and hexamethylene diamine and modification by different acid chlorides) P(MMA-AA) for chemical attachment of the turf growth regulator maleic hydrazide Polymerised 2-(1-naphthylacetyl)ethyl acrylate Poly(acryloyl chloride) for urea fertilisers PAA, polymerisable N-(4-chloro-2-methylphenyl)-N-methyl(N,N-dimethyl)-formamidine derivatives, PVC, PS, poly(styearene-butadine), poly-chlorophenols, coumarone resins, bitumen, LDPE, P(PE-MA/orAA), PEP, PEVAc, PEPD elastomers, PANs, polychloroprene plastic rubber blends or waxes for polymeric insecticides Polymerisation of vinylbenzylchloride, MMA, 2-chloroethylvinylether, acrylic acid, maleic anhydride, homopolymers and copolymers of 2,4-D, N-

CRF Category	Method	Materials
		cyclohexylacrylamide and 8-quinolinylacrylate/ methacrylate, polyamide, polyesters, PU and a series of polyketones for polymeric antimicrobials
Chemical attachment	Incorporation in macromolecular back bone	Various condensation polymers (like polyamides, polyurea, poly(Schiff base)s and polyesters), polyurethane derivatives

D.4.1.2. Fertiliser additives

In addition to their use in CRFs, polymers that meet the microplastics definition of this restriction proposal are also used as fertiliser additives; particularly as anti-caking agents, granulation and prilling aids, anti-dust agents, micronutrient binders, de-foaming aids and colouring agents. Only limited information is available on most of these functions and it is understood that they are often combined in one product that consists of a combination of surfactants, surface tension modifiers, parting agents and crystal habit modifiers. Because of limited data, most of the discussion and quantification presented below focuses on anti-caking agents. Yet, as there seems to be a significant overlap in function (e.g. anti-caking foster granulation, micronutrient binders help in avoiding dust, etc.), what is collected for anti-caking agents is suggested to be representative of other functionalities of fertiliser additives as well. Starting point of the impact assessment for the use of fertiliser additives is the presumption that they fall under the regulatory scope of the FPR and, if put on the internal market, they have to meet the biodegradability requirements proposed therein.

Currently, polymeric material is used to produce anti-caking agents (and other functional fertiliser additives) in the form of water-insoluble pastes and waxes and water-soluble powders. What is used depends mainly on the type of fertiliser the material is added to. Estimates of the polymeric material released by anti-caking agents are presented in Table 44 and discussed below.

Table 44: Annual tonnage of polymeric material emitted by anti-caking agents

Concentration in typical product (%)	Polymeric material (tonnes/year)	Time Period	Source
0.03-0.5% w/w polymer concentration	Water-insoluble polymers: 2 000-6 000 in agriculture uses to avoid caking of multi-nutrient fertilisers	2016	Calculations based on information from Fertilizers Europe (2018) and Eurostat (2018b)
0.01-0.5% w/w polymer concentration	Water-soluble polymers: <1 000 in uses of powders to avoid caking of nutrient salts	2018	Assumptions based on information provided by Fertilizers Europe (2018)
Total	**Central estimate: 4 000** **Range estimate: 2 000-6 000**		

As regards water-insoluble materials, anti-caking properties are achieved by polyolefin waxes (polyethylene) applied to multi-nutrient (e.g. NPK) fertilisers with granules of 2-4 mm size. Thereby, a protective layer is built between the host powder and the

environment, which prevents moisture uptake of the host powder during production and/or storage. The reduced caking improves the flow properties of the fertiliser, which leads to more accurate dosing and thus to a more efficient and effective use.

During the CfE, several companies informed that concentrations typically correspond to 0.2% w/w of the fertilising product to which polyolefin waxes are applied to. In a targeted member consultation organised by Fertilizers Europe (2018), the fertiliser producers reported to use 2 000 tonnes of polymeric material. They further informed that the concentration of such polymeric material in the final fertiliser product would be ranging from 0.05-0.5% w/w. However, not all fertilisers might be using anti-caking agents. Indeed, calculating back with the typical concentration of 0.2% w/w the 2 000 tonnes of polymeric material would correspond to 1 million tonnes of final fertiliser product. This implies that less than 10% of the total annual fertiliser consumption of 12.5 million tonnes in the EU-28 (plus Norway)[24] would be enhanced with anti-caking agents containing microplastics. For an upper bound estimate, the Dossier Submitter assumed that up to one third of the final fertiliser products would contain polyolefin waxes (polyethylene). This results in a range estimate of 2 000-6 000 tonnes with a central estimate of 4 000 tonnes of microplastics emitted annually in the EU by the use of multi-nutrient fertilisers. These polymers are widely considered inert and thus do not biodegrade once emitted.

As regards water-soluble powders (with particle sizes <200 µm), these are added to avoid the caking of nutrient salts. Again, their use allows for a more accurate dosing and thus results in a more efficient and effective fertiliser use. Concentrations are typically corresponding to 0.01-0.5% w/w of the fertilising product to which the powders are added. Whilst these powders are completely water-soluble, they appear not to fully dissolve in water and thus to release microplastics. However, based on the response of the consultation of members of Fertilizers Europe (2018) the use volumes are believed to be significantly smaller. As a working estimate, it was thus assumed that they correspond to significantly less than 1 000 tonnes of polymeric material release per year.

D.4.1.3. Capsule suspension plant protection products

CSPs are tailor-made capsules loaded with active substances for plant protection and optimised for targeted release. The so-called 'capsule suspension' technique has a number of advantages over the use of conventional PPPs, including improved operator safety because of reduced dermal toxicity, a better environmental footprint because of reduced volatility of active ingredients and lower phytotoxicity, prolonged efficacy under field conditions due to controlled or delayed release of pesticides, increased UV stability of active substances, and better doseability leading to reduced consumption of PPPs for treating the same area (cf. Tsuji, 2001, Boh and Kornhauser, 2003).

CSPs are typically sold in form of a CS formulation which, when diluted with water in a spray tank, forms a spontaneous suspension with particles in the size range of 0.1 to 20 µm (https://www.crodacropcare.com). When sprayed, the dilute emulsion gives a

[24] This figure reflects the importance of the fertilising products sector in the EU, which according to Commission estimates has an annual turnover of €20-25 billion and provides about 100 000 jobs. In 2012, about 1 200 companies were active in the mineral fertilisers sector in the EU, 25% of which were SMEs (EPRS 2017).

uniform and accurate application of active ingredient on to the crop, which is advantageous for effective pest control. Common materials to achieve this functionality of CSPs are reported in the literature and in response to the CfE, see the summary in Table 45. In accordance with Regulation (EC) No 1107/2009 these materials have to be of very low acute toxicity to aquatic and terrestrial organisms. They are not required to bio-degenerate, however. Indeed, one company informed during the CfE that, under a stable temperature of 25°C, the material half-life of polyurea material obtained by either TDI polymerisation or based on methylenediphenyl diisocyanate might be several ten thousand years (CfE#683).

Table 45: Overview of polymeric substances used in CSPs

Active ingredient	Coating material	Source
Validamycin	Polystyearene, polyacrylamide, polymethylacrylate, polyamides, polyesters	Milani et al. (2017)
Bifenthrin	Polyanhydrides, polyurethanes, amino resins, polycyanoacrylates	Milani et al. (2017), CfE#669
-	Cross-linked, aromatic polyureas	CfE#669
-	Polyureas based on toluene diisocyanate (TDI) or methylenediphenyl diisocyanate	CfE#683
-	Silicone rubbers, LDPE, HDPE with vinyl acetate, PE, PEVAc, flexible PU elastomers, polyamides, plasticised PVC, aminoplasts, PVA, hydrogels, PMMA, polysulfones, poly(ether-co-urethane)	Akelah (2013)

In response to the CfE, alternative materials derived from natural products such as chitosan, alginate and cellulose were discussed by one large producer of PPPs (CfE#669). These have been extensively explored for encapsulation in applications such as drug delivery of active pharmaceutical ingredients, food additives and other selected substances. However, whilst encapsulation of active ingredients is possible, in principle, these materials appear to have a number of serious limitations. One major drawback of the use of chitosan, alginate and cellulose for microencapsulation of active substances is that their water permeability is generally high.

Therefore, active substances encapsulated in microspheres or microcapsules comprising these materials are prone to leak into the aqueous phase at a relatively high rate. As CSPs typically have a shelf life of two years, any protective effect or controlled release function would be lost too quickly. Another problem of chitosan and alginate is their natural variability in crystallinity, molecular weight and isomeric structure, which makes them unattractive for commercial use.

One company (CfE#669) characterised the ingredient carrier as a water-insoluble, solid sphere with a diameter of 0.5-50 µm, a coating thickness of 10-500 nm, and 1-6% w/w

polyuria concentration.[25] Based on this characterisation, they estimate the average annual emissions of polymeric material in the EU from the use of their products to be 30 tonnes. Another company reported diameters ranging from 0.5-20 µm to 100-200 µm and a membrane weight of 8-12% w/w, with 0.1-5% w/w corresponding to polymeric material.

Based on this, one may come up with a rough estimate of the annual tonnage of polymeric material emitted through CSPs. To this end, it is noted that in 2016 close to 400 000 tonnes of PPPs were sold in the EU-28 (plus Norway). In the same year, slow and controlled release pesticides accounted for 2.8% of the global market for crop protection chemicals (Grand View Research, 2018b, Grand View Research, 2018c).

Applying this market share to the approximated tonnage of PPPs sold in the EU suggests that around 11 000 tonnes of PPPs sold were CSP products likely to contain polymeric material. The conversion of revenues into quantities requires some assumptions to be made on the pricing of CSP PPPs. If one assumes that prices are approximately comparable with those of conventional PPPs, 11 000 tonnes may be used as a cautious estimate of the annual PPPs tonnage marketed.[26] Yet, as several manufacturers highlight, CSPs sell at a higher price than conventional PPPs. Thus, the actual tonnage share may be lower than 2.8%. For example, if one assumes the price premium per tonne to be 41.3% as reported by Liu et al. (2014) for CRFs, then the fraction of microencapsulated PPPs sold in 2016 drops to 7 800 tonnes.

With a maximum polymer concentration of 6% w/w, the emissions of polymeric material correspond to 470 tonnes in the EU in 2016. In comparison, the upper bound without adjusting for a price premium would suggest emissions amounting to around 700 tonnes of polymeric material in the EU in 2016. Thus, a central estimate of 500 tonnes will be taken forward.[27] In light of this approximation, the tonnage of polymeric material released per year reported by one of the four largest suppliers of agrochemicals in the EU (CfE#669) is only realistic if a minimum polymer concentration of 1% w/w is assumed. In this case, the total EU polymer emissions from CSPs would be 80-110 tonnes. Table 46 summarises the annual emissions of polymeric material from CSPs in the EU.

[25] As one company informed, water insolubility is a major reason to reject liposome-based encapsulations for PPPs, as these contain poorly soluble compounds in high-loaded formulations for efficient transport and handling by end users.

[26] PPPs using monolithic systems are sold at prices more comparable to conventional PPPs than to membrane encapsulation systems. Therefore, an estimate without adjustment for the price premium provides an upper bound.

[27] This estimate was supported by a submission to the consultation of the European Crop Protection Association (ECPA), which had surveyed companies manufacturing microencapsulation formulations.

Table 46: Annual tonnage of polymeric material emitted by CSPs

Concentration in typical product (%)	Polymeric material (tonnes/year)	Time Period	Source
0.1-5% w/w polymer concentration	--	--	CfE#683
1-6% w/w polymer concentration	30	2015-2017	CfE#669
1% w/w polymer concentration	80-110	2016	Calculations based on information from CfE, Eurostat (2018a), Grand View Research (2018b, Grand View Research, 2018c), Liu et al. (2014)
6% w/w polymer concentration	470-700	2016	Calculations based on information from CfE, Eurostat (2018a), Grand View Research (2018b, Grand View Research, 2018c), Liu et al. (2014)
Total	Central estimate: 500 Range estimate: 100-700		

D.4.1.4. Seed coatings

Seed coating is an omnipresent technology in the global seed market. Thereby, non-degradable polymers are used to coat seeds mostly with water-insoluble formulations of polymer-latex mixed with synthetic organic and/or inorganic particles that form a film around the seed, which protects the latter during germination. This technology has several advantages. In particular, it limits dust formation and allows shaping the seeds for controlled sowing, the coatings may contain active substances (PPPs, fertilisers and/or growth regulators), and the shells are used for seed colouring which fosters safe handling and permits to differentiate between different products and brands. Thus, the seed coating has positive impacts on the sowing process, the germination and the yield whilst also dispensing with the need for spray application of PPPs.

According to several companies, the substances used for seed coating are very similar or the same as those used in CSPs for seeds. Additional material submitted by the European Seed Association (2018, ESA hereafter) after the CfE informed that more than 80% of all commercial seeds supplied in the EU are polymer treated. The total polymer concentration by weight of seed depends on the crop type and ranges anywhere from 3 ppm for wheat and barley to more than 1% for sugarbeet. These differences can be explained by the different coating technologies in use. According to information shared by ESA there are three major treatment types: i) flowable suspensions that contain only minor amounts of polymers and are used primarily on wheat and barley seeds; ii) film-coating which is applied to crops like sunflower and corn to keep nutrients, insecticides and fungicides on the seed; and iii) pelleting and encrusting which is applied to sugarbeet and some vegetable seeds as carrier for nutrients, insecticides and fungicides.

ESA estimated the total current emission of microplastic polymers from the use of seed

coating using on a two-step approach. First, they combined information from annual crop statistics and typical sowing rates to estimate the total weight of seeds cultivated in the EU of roughly 10 000 kilotonnes as reported in Table 47.

Table 47: Estimation of total weight of seeds cultivated per year in the EU

Crop	Area under cultivation in EU (million hectares) [a]	Sowing rate (kg/hectare) [b]	Seed weight (kt)
Wheat	24	200	4 800
Barley	12.5	180	2 250
Other cereals	11.4	200	2 280
Corn	15	30	450
Pulses	2.2	200	440
OSR	6.4	4	26
Sunflower	4.2	5	21
Sugarbeet	1.4	3	4
Cotton	0.3	20	6
Soya	0.9	50	45
Vegetables	2.0	10	20
Total	80	--	10 341

[a] based on Eurostat (2018e); [b] based on Lucchesi et al. (2016).

Second, they conducted a survey among some of their members which together hold ~50% of the global market share to relate this quantity to the quantity of polymeric material used. Whilst the exact application rates are confidential, ESA informed that type i) requires dose rates of less than 2 g per kg of seeds treated and has a polymer concentration of 4% or less; type ii) uses 2-10 g per kg of seeds and has a polymer concentration of 35% or less; and type iii) uses 5-50 g per kg of seeds has a polymer concentration of 35% or less. Applying these rates to the EU seed weight per crop reported in Table 47, one obtains an estimated total of 500 tonnes per year of polymeric material emitted through the use of polymer-coated seeds in the EU (see Table 48).[28]

[28] Again, this estimate was consistent with information submitted to the consultation of ECPA, which had surveyed companies manufacturing seed coating formulations.

Table 48: Estimation of total weight of seeds cultivated per year in the EU

Crop	Seed weight (kt)	Polymer weight (tonnes/year)	Implicit concentration (ppm)
Wheat	4 800	16	3
Barley	2 250	8	4
Other cereals	2 280	2	10
Corn	450	156	347
Pulses	440	91	207
OSR	26	96	277
Sunflower	21	37	1 762
Sugarbeet	4	48	12 000
Cotton	6	3	500
Soya	45	10	222
Vegetables	20	24	1 200
Total	**10 341**	**Central estimate: 500** **Range estimate: 250-1 000**	**--**

D.4.1.5. Synopsis of current uses

Aggregation of the estimated annual tonnages of polymeric material emitted by the four A&H categories suggests that currently a grand total of about 10 000 tonnes of microplastics per year are emitted by the A&H sector (see Figure 1).[29] It is difficult to predict how the total quantity emitted will evolve over the next decade. On the one hand, there is growing political and regulatory pressure to curb the use of non-degradable polymers in A&H applications; on the other hand, the market for seeds and with it the markets for CRFs, CSPs and fertiliser additives have been steadily growing in the EU.

[29] During the dossier preparation, data was collected also on other product categories including superabsorbent polyacrylates (SAP) used in agriculture as soil conditioner. However, in contact with water SAP changes its physical state from solid to a soft gel. This hydrogel is not solid and thus does not fall under the definition of a microplastic used in this restriction.

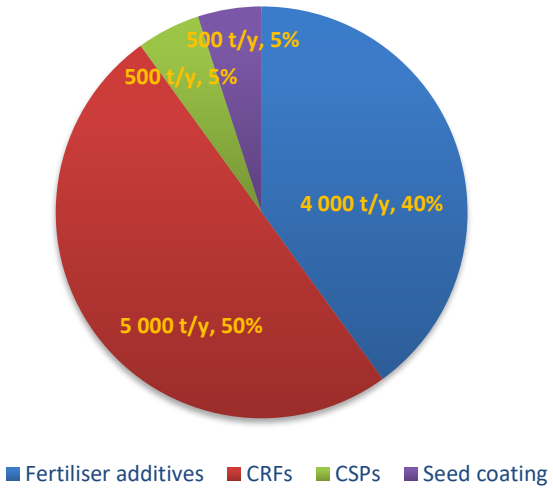


Figure 1: Estimated annual tonnage of polymeric material emitted by the different product groups within the EU A&H sector

D.4.2. Alternatives

D.4.2.1. Microencapsulation for controlled/target release

The challenge of finding suitable alternative coating materials for the purpose of microencapsulation of both fertilisers and PPPs is that one key functional requirement is slow degradation during the period of use, i.e. up to 18 months after application to the field. Some sources indicate modified natural waxes based on amid, rice bran or montan as alternatives to synthetic polymers used in CRF systems (CfE#680). However, most industrial stakeholders participating in the CfE insisted that these materials do not yet provide the necessary properties to achieve equally prolonged release periods of agrochemicals. Cellulose, chitosan, and cyclodextrins have also been indicated as alternative materials for microencapsulation (Milani et al., 2017). According to one company in the CfE, the latter are already in use in certain cosmetics and pharma applications (CfE#683). Likewise, liposome-derived materials are already used for microencapsulation in the agricultural sector.

Potential (future) alternative coating materials are summarised in Table 49. Yet, during the CfE, industry cautioned that in their product portfolios these materials have not been used for the purpose of encapsulation. Common view is therefore that it is currently not feasible to substitute synthetic polymers by alternative materials, if the principal performance features (incl. release mechanism, release duration, protection from environmental factors) are to be maintained. Moreover, the strict approvals for plant protection and fertilising products would mean that the introduction of any alternative material would not only require a reformulation process, but also extensive R&D activities and field-testing. One company (CfE#683) also informed that this could take time as their current R&D pipeline was focused on refining the use of synthetic polymers, hinting thus at a crowding out of other research activities.

Table 49: Overview of alternative substances used in membrane encapsulated fertilisers (cf. Milani et al., 2017)

Agrochemical	Coating material
Urea, KH_2PO_4, NPK, $CaH_4P_2O_8$, KNO_3, Paraquat, Hexazinone, Clopyearalid, 2-chloro-/4-chloro-	Chitosan, chitosan-clay
Urea, NPK, 2-chloro-/4-chloro-	Cellulose
KH_2PO_4	Gellan gum
NPK	Natural gum, rosin, waxes, urethane composites, epoxy, alkide resins
KNO_3	Xanthan
Paraquat, 2-chloro-/4-chloro-	Alginate
$C_8H_6Cl_2O_3$	Other polysaccharides
2-chloro-/4-chloro-	Agarose, dextran, carrageenans, starch, gelatin
2,4,5-Trichloro-phenoxyacetates	Albumin
Bifenthrin	Amino resins

Some of the stakeholders contributing to the CfE and the consultation referred to ongoing substitution activities triggered by the FPR. The timeline of 7 years from entry into force of the FPR for transitioning to biodegradable polymers is seen to be challenging by all manufacturers responding to the CfE. Fertilizers Europe (2018) informed that an ambitious substitution plan could mean a 5-year period for R&D (incl. 2-3 years for developing a new coating technology and another 2-3 years for multiple field tests) followed by a 2-year period of approval by national authorities and market introduction. Fertilizers Europe estimates the costs for these steps to be at least €20 million.[30]

Chemical alternatives to the concept of microencapsulation include recent CRF innovations that use urea-formaldehyde, ammonium polyphosphate, and amorphous silica gel (Xiang et al., 2018). However, the market penetration of these alternatives seems to be still very limited. A technical alternative to CRFs that could be at least technically feasible for certain ornamental uses is drip fertigation, which automatizes the injection of fertilisers, soil additives, water and plant protection products. No information on costs have been provided in the CfE, but common sense suggests that the economic feasibility of drip fertigation is limited, at least for applications outside of specialised nurseries, as this would mean setting up permanent infrastructure which would interfere with other requirements of the cultivator (e.g. harvesting on agricultural fields).

Finally, one alternative widely rejected by industry is to revert to the use of conventional fertilisers. Whilst this is technically entirely possible, it would entail relatively large extra costs on producers of ornamental products, operators of sports turfs and some speciality

[30] This does not include expenditures for developing suitable biodegradability criteria and corresponding test methods.

farmers and may inflict harm to the environment. During the CfE (#669, #670, #680), it was indicated by several companies that the use of CRF systems could reduce the application rates of certain fertilisers by a factor of three, implying less fertiliser manured, less hours of labour needed, and better health protection during those hours. As a rough estimate, it is assumed that both total fertiliser/PPPs consumption and total operating costs for the fertigation/treatment of the same cultivation would triple.

The above discussion of alternatives has to be seen in light of the revision of the existing EU fertiliser regulation (Regulation (EC) No 2003/2003). As mentioned above, the European Commission put forward in March 2016 a legislative proposal on CE marked fertilising products as part of its circular economy action plan.[31] The proposal foresees a three-year transition period after entry into force for manufacturers to achieve biodegradability of their CRF products.[32] The timelines set in the FPR foresee a transition period of 7 years after EiF, which industry indicated as minimal time required for a substantial reformulating of CRF products, i.e. for exchanging, adding or omitting specific co-formulants. For many products under the scope of this restriction, this means there is already today an intention to phase out the use of non-degradable polymeric material such that the costs to substitute could not be attributed to the REACH restriction, as these would accrue regardless of this proposal.

Although Regulation (EC) No 1107/2009 concerning the placing of PPPs on the EU market does not contain such a biodegradability criterion, similar principles could apply to CSPs. Moreover, it is foreseeable that innovation in terms of biodegradability achieved for encapsulation techniques in other sectors (e.g. detergents) could be transferred to CSPs, without prejudging whether such a change in co-formulants would require a re-authorisation pursuant Art. 29 of the aforementioned Regulation. This is what the European Crop Protection Association (ECPA, 2018) has repeatedly expressed concerns about. Information ECPA provided during the CfE and in the consultation suggests that a full re-authorisation might be needed and the average length of such authorisation processes could be up to 42 months.

Based on this, ECPA (2018) suggests that 5 years would be a reasonable transition period for reformulations once suitable alternatives become available. In this regard, ECPA presented in their submission to the consultation a timeline, suggesting a "reasonable" duration of 8 years of R&D activities before a recertification of CSPs could start. During the CfE, they estimated the cost per reformulation to be in the order of $1 million, corresponding to about €860 000 at the time of writing. In their submission to the consultation, ECPA updated the cost per reformulation for microencapsulation to €3.7 million (incl. regulatory costs) and specified that the number of formulations affected by the proposed restriction would be in the range of 40 to 80. The Dossier Submitter considered these arguments and validated the claim that a major re-approval

[31] A revised version of the legislative proposal refers to "[a] fertilising product which is CE marked when made available on the market" as "EU fertilising product". For sake of clarity, the Dossier Submitter keeps the differentiation between CE marked and non-CE marked fertilising products.

[32] From 16 July 2026, the polymers referred to in Annex II, CMC 9, of regulation (EU) No 2019/1009 shall comply with the biodegradability criteria established by delegated acts referred to in Article 42(6) of that same regulation.

was needed with the responsible unit in the European Commission. Based on a confirmatory answer from the European Commission, the Dossier Submitter revised its restriction proposal.

D.4.2.2. Fertiliser additives

Whilst some members of Fertilizers Europe indicated in information provided after the CfE that currently no suitable alternatives for non-degradable polymers in the use of anti-caking and other additives were known, one manufacturer submitted information about an alternative substance for the manufacturing of anti-caking agents for powdered or granule multi-nutrient fertilisers (CfE#702). This alternative is based on hydrophobic silica and may be applied to a wide range of fertilisers including ammonium sulphate and urea fertilisers. As this product is already marketed under the brand name SIPERNAT® D 17, this casts some doubts on industry's claims that at least three years of R&D activities were needed to find alternatives that would not rely on non-degradable polymers.

Since at least one type of technically and economically feasible alternatives seems to be already available on the market, the costs of adopting alternatives appear to be substantially lower than those indicated for the reformulation of CRFs. Indeed, if the supply of such alternative fertilising additives would become large enough and price and performance are not too different from current additives, then any loss to manufacturers of anti-caking agents using non-degradable polymers should, in the long run, be compensated by corresponding gains to manufacturers of alternative products. Fertilizers Europe responded to this reasoning in their submission to the consultation, stating that silica-based alternatives were not suited for use in several fertilisers and had hazardous properties themselves. Whilst the Dossier Submitter takes note of this information, it does not rule out that alternatives to non-degradable polymers in fertilising additives could be found at a significantly lower cost than that required for finding alternatives to CRFs, which are functionally much more demanding.

D.4.2.3. Seed coatings

In the CfE, no information was provided on alternative coating technologies. However, during the consultation, additional information was received from one specialised manufacturer explaining that a substantial fraction of the seed treatment market including some of the market leaders are already today applying coatings based on natural polymers that have not been chemically modified (e.g. potato starch derivatives, molasses derived from waste of sugar production). Further inquiries also suggested that no additional regulatory approval would be needed when applying a new coating technology to a seed treated with approved PPPs or fertilisers because binders and coatings are considered to be inert and thus do not require registration. The Dossier Submitter argues that, compared to CRFs and CSPs, the technical demands on alternative seed coatings are lower, as the service life of the coating layer spans only to the end of the germination of the seed rather than over an 18-month period under field conditions. As for the cost of developing an alternative coating standard that is either polymer-free or biodegrades after one growth season, it will thus be assumed that this would impose costs much smaller than those estimated for finding a suitable alternative coating process in CRFs and CSPs.

D.4.2.4. Synopsis of alternatives

Based on the above discussions, it can be concluded that there are several promising alternative materials and technologies currently researched for their suitability as coating material or additive in A&H applications. The difficulty in finding biodegradable polymers—it appears—relates mostly to the delayed breakup that is required. Once this hurdle has been overcome, there appear to be no genuine reasons for keeping on to non-degradable polymers in the A&H uses studied in this report.

D.4.3. Restriction scenarios

D.4.3.1. General considerations

Fertilisers and PPPs belong to those products for which there is specific EU legislation in place. The thrust of the current restriction proposal is therefore to align the regulatory requirements regarding the biodegradability of polymers used across the specific regulations and to close any regulatory loophole (e.g. with regard to non-CE marked products) in existing EU legislation. Starting point for the restriction is therefore the biodegradability requirement in the FPR which entered into force in mid-2019. According to the FPR, this requirement shall be complied within 7 years after EiF. However, as the biodegradability requirement will be binding only for CE marked fertilising products, the restriction proposal suggests expanding it to all fertilising products placed on either the EU market or on Member States' domestic markets.

The current restriction proposal suggests emulating the biodegradability requirement into Regulation (EC) No 1107/2009 for placing PPPs onto the market within the EU or, should that be impractical, to otherwise extend its coverage to polymer-based co-formulants used in capsule suspensions of PPPs. It is understood that this may require a major re-approval of already approved PPPs. Therefore, the Dossier Submitter considers a longer transition period of eight years after EiF to be justified. In order to minimise the emission of non-degradable polymers in the EU, it is also proposed to extend the coverage of the biodegradability requirements of the FPR to polymer-coated seeds, even if the microencapsulated seed is not loaded with nutrients. Given the availability of alternative coating materials already used in the seed market, the transitional period suggested would be aligned with the FPR acknowledging thus that where biodegradable alternatives need to be developed they would comply with the same degradation criteria than fertilising products.

The proposed restriction is expected to enter into force by mid-2021. To account for transitional periods needed for complying with the biodegradability requirements in the FPR, the restriction scenario will be assessed according to the timeline given by Figure 2.

Figure 2: Indicative timeline for the proposed restriction

D.4.3.2. Restriction scenario

Under the restriction scenario proposed a 5-year transition period after EiF is assumed for fertilising products and seed coatings. From mid-2026 onward, A&H products containing polymers that fulfil the microplastics definition of this restriction proposal would then have to meet the biodegradability requirements to be established as laid out in (EU) No 2019/1009, Annex II, CMC 9 to be placed on either the EU market or on Member States' domestic markets. For CSPs a 8-year transition period after EiF is assumed. Thus, from mid-2029 onward, CSPs containing polymers that fulfil the microplastics definition of this restriction proposal would also have to meet the biodegradability requirements.

Figure 3 illustrates graphically how the cumulative quantities of polymeric material in each of the four A&H categories are expected to develop over the 20 years after EiF under this scenario compared to a baseline scenario, which assumes constant annual emissions (in Section D.4.8 emission predictions under a constant growth rate are assessed). Prediction lines are based on the central estimates reported in Section D.4.1, whilst prediction intervals are based on the upper and lower bound estimates. Note also that the predictions take into account the biodegradability criteria for polymers set in the FPR. Hence, the predicted quantities released from CRFs and fertiliser additives are attributable to non-CE marked products only. The predictions indicate that the total abatement potential attributable to the restriction (i.e. the sum of the areas between the dotted and straight lines) amounts to slightly more than 20 kilotonnes of microplastics over the first 20 years after EiF.

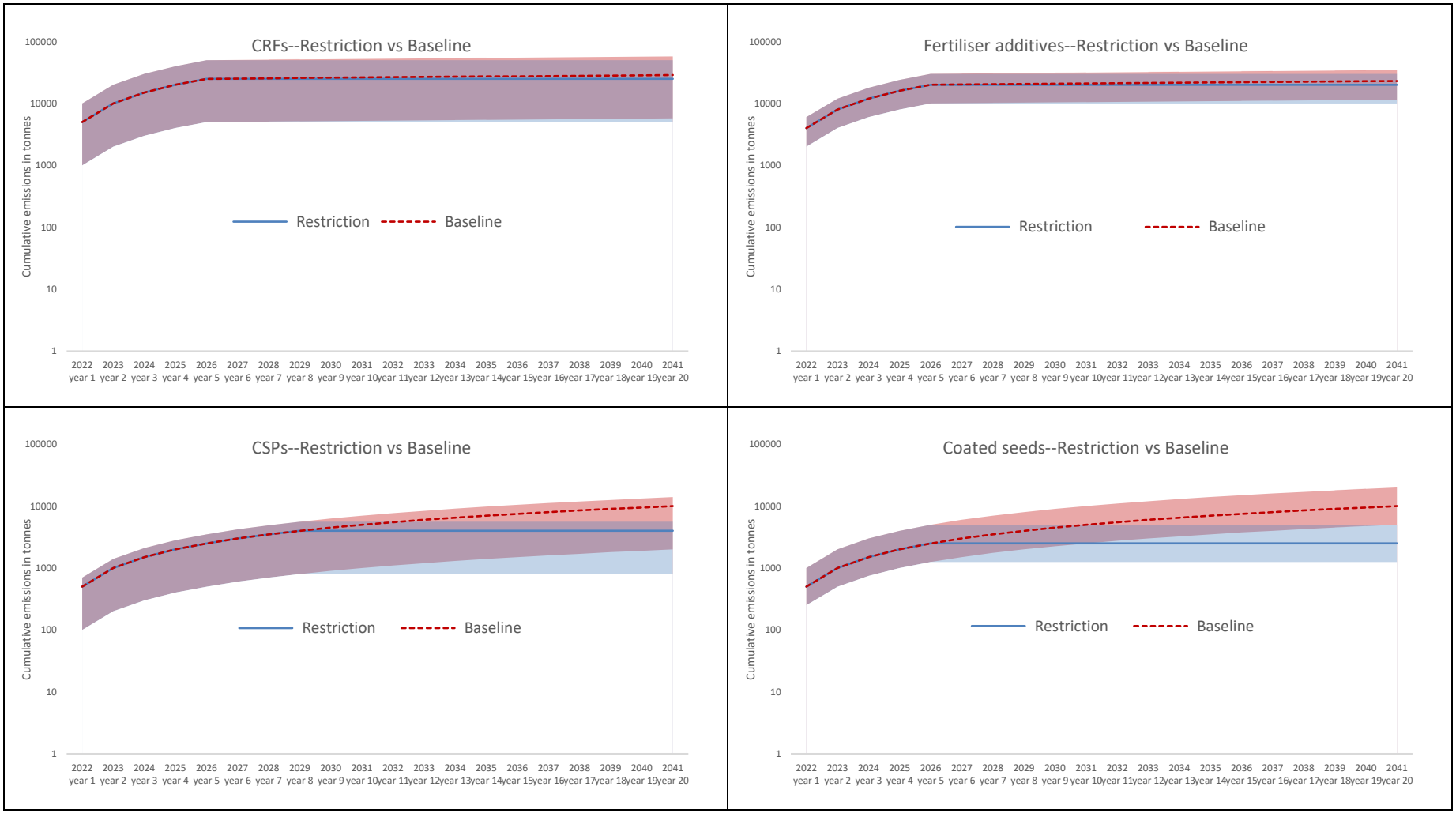


Figure 3: Cumulative emissions for the four use categories under the baseline and restriction scenario

D.4.4. Environmental and health impacts

D.4.4.1. Premises

Before discussing the expected impacts in terms of reduced microplastic emissions brought about by the proposed restriction, it shall be stressed that the Dossier Submitter is fully aware of the beneficial impacts associated with the various uses of polymers in A&H products that are in scope of this restriction proposal. Broadly speaking these pertain to improved operator safety, reduced use of fertilisers and PPPs, and increased productivity of the EU A&H sector. None of these impacts is disputed. On the contrary, the Dossier Submitter is convinced that these uses are very beneficial to humans and the environment. This said, the impact assessment below assumes that the full functionality achieved today with non-degradable polymeric material can be maintained by switching to suitable alternative materials which do not contribute to the microplastic pollution stock (or at least decay fast enough to curb the growth of the pollution stock). Should this premise turn out to be wrong, i.e. should the efforts to substitute non-degradable polymers by degradable ones fail, this would require a re-evaluation of the socio-economic impacts of restricting the use of non-degradable polymers in the A&H sector.

The Dossier Submitter identifies a classical risk trade-off (Graham and Wiener, 1995) that can only be overcome through innovation. Such innovation seems desirable because of both the suspected detrimental effects that microplastic pollution may have on the environment and the fact that—once emitted—microplastics are unlikely to be ever removed from the environment. Although, for the time being, evidence on the adversity of microplastics is still scarce, there is growing concern about the fate of polymeric material accumulating in the terrestrial compartment and the A&H sector is a major contributor of microplastics to the terrestrial environment in the EU. Notwithstanding this concern, it is for the time being impossible to quantify any potential welfare loss related to the impairment of both use and non-use values of ecosystems. Instead, the Dossier Submitter pursues an indicative abatement cost approach as suggested by SEAC for the evaluation of restriction reports and applications for authorisation for PBT and vPvB substances (ECHA, 2016a).[33] The key premise of this approach is similar to the PBT/vPvB approach in that emissions are used as a proxy for the associated risks and, as a corollary of this assumption, abatement efforts can be equated to reductions in risk. As discussed in the main report of the restriction proposal, it is impossible to arrive at a precise quantification of risks. However, it shall be noted that a host of research initiatives have started to look at microplastics pollution and from this research a better understanding of the possible impacts on human health and the environment is expected to emerge in the decade ahead.

D.4.4.2. Emission avoidance

Figure 4 displays emission reductions predicted from adopting the restriction for each of the four use categories. Again, prediction lines are based on the central estimates reported in Section D.4.1, whilst prediction intervals are based on the upper and lower bound estimates. For CSPs, a longer transitional period of 8 years has been assumed.

[33] See https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf

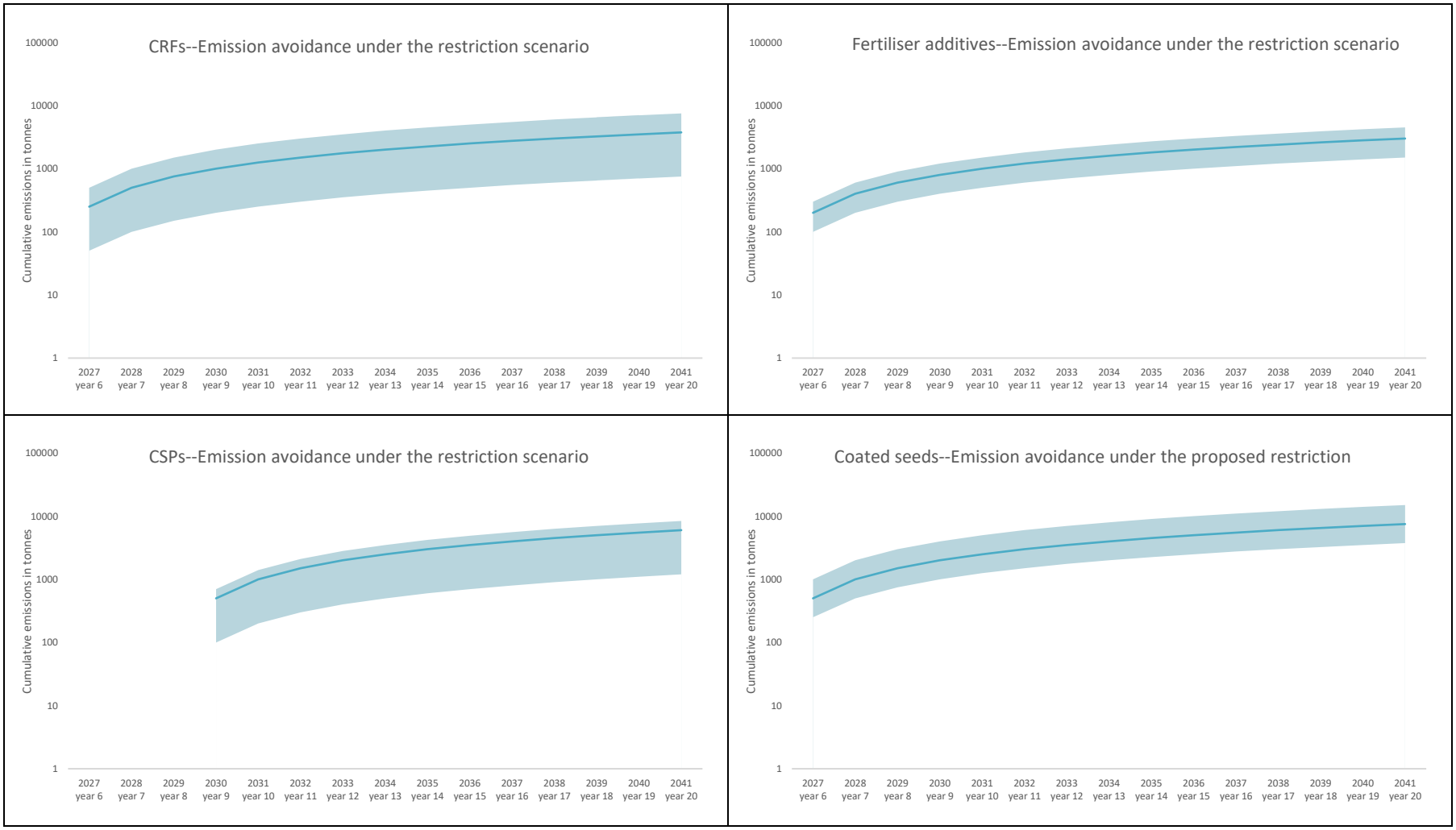


Figure 4: Emission avoidance under the restriction scenario

D.4.5. Economic impacts

D.4.5.1. Preliminary remarks

The analysis of the economic costs of the proposed regulation on microplastics for the A&H sector adopts a number of overarching assumptions which are spelled out below. These assumptions were adopted in the absence of better information and are assumed where not otherwise stated. In particular, the following is considered.

- Meeting the biodegradability requirement of the FPR will cost money for R&D work and requalification campaigns;
- No information was received during the preparation of the Dossier that would suggest that raw material costs would increase or that significant costs would accrue for adapting production processes (i.e. for new equipment);
- Only a fraction of the overall cost for finding polymers that meet the biodegradability requirement is attributable to the proposed restriction as the latter only expands to other A&H products what would be required for CE marked fertilising products;
- Since cost attribution in this context is inherently difficult, all cost figures presented below are only indicative and should be taken with a grain of salt.

D.4.5.2. Cost analysis

It is foreseeable that the major cost driver of the restriction will be the cost of reformulating/modifying the formulation of already authorised fertilising products, PPPs and polymer-coated seeds. The analysis of reformulation costs is based on information received during the CfE on the reformulation of CRFs (which producers have been initiating in anticipation of the FPR) and during the consultation on the reformulation of CSPs and seed coatings.

The EU fertiliser market consists of roughly 1 200 companies, 90% of which are SMEs (European Commission, 2013). In other words, some ~100 large companies operate in the market and these produce 75% of mineralised fertilisers.[34] Assume that each of these large companies has on average 1/5/10 fertiliser products that fall under the scope of the restriction. In the CfE, ECPA (2018) estimated that the total cost per reformulation is roughly $1 million (€0.85 million). Thus, there would be 100/500/1 000 major reformulations needed, if non-degradable polymers could no longer be used. Minor modifications and/or read-across for similar products are considered to be covered by rounding the cost per major reformulation to €1 million.

Hence, the overall cost to large companies operating in the EU fertiliser market would amount to €100 million/€500 million/€1 billion. This cost range was confirmed by Fertilizers Europe in the consultation, stating that "Cumulative development costs of the order of 100 M€ excluding investments in new production facilities are estimated for this". For the cost assessment presented below, it was assumed that SMEs would purchase access to degradable polymer formulations for their coating purposes; this would require costs in a similar range (~15%) as the adaptation costs of major

[34] According to information received during the CfE, different departments of the same companies often also produce fertiliser additives, PPPs and/or seed coatings.

companies. Depending on the number of reformulations needed, the overall reformulation cost would be €115 million/€575 million/€1.15 billion.

These costs need to be properly attributed. Following EPRS (2017), about 50% of the fertilising products are placed only on national markets (i.e. are non-CE marked products) and would thus not be covered by the FPR (Regulation (EU) No 2019/1009). However, Fertilizers Europe informed in the consultation that more than 95% of the CRF products are currently sold as CE-marked fertilisers. Rounding up figures, one is left with low-cost estimates of €10 million/€30 million/€60 million attributable to the restriction, i.e. to the extension of the biodegradability requirement to non-CE marked fertilisers. This is considered a conservative cost estimate as it ignores that national fertiliser markets often trade speciality fertilisers that do not use CR technologies and are thus unaffected by the biodegradability requirement.

An important aspect to consider is that it may take a significant effort to achieve the substitution over the 5-year transition period foreseen after EiF of the restriction. The additional effort is accounted for by assuming that it could be twice as costly to achieve full substitution. This implies high-cost estimates for the reformulation of up to €20 million/€60 million/€120 million.

Lastly, it is unclear how long it will take to reformulate a specific product. The Dossier Submitter therefore assumes that the indicative cost figure provided by ECPA (2018) is a present value cost, i.e. the sum of properly discounted annual costs accruing over the transition period. Technically this assumption treats the costs *as if* they would accrue immediately after EiF, even if it will take more time for reformulating all the products concerned.

Some modifications are warranted when applying this costing approach to the other use categories (fertiliser additives, CSPs, coated seeds). These can be summarised as follows.

- Modifications made for CSPs:
    - One has to account for the fact that CSPs are mostly produced by large agrichemical producers that often also offer CRFs.
    - However, according to information provided in the consultation, the functional requirements of CSPs are different from those of CRFs. Thus, biodegradable polymers developed for CRFs may or may not be adaptable to the use in CSPs;
    - In its response to the consultation, ECPA presented reformulation cost estimates based on a survey to which 25% of its members responded. The central cost estimate indicated by ECPA members amounts to €3.7 million per reformulation (range: €1.0 million to €9.6 million), including both R&D costs[35] and regulatory costs[36]. The Dossier Submitter notes that these

[35] These costs assume the following steps per reformulation: synthesizing new biodegradable polymers, scouting and screening new raw materials, definition of formulations, development studies, and physical, chemical and technical characteristics according to the valid data requirements. The mean R&D cost for one reformulation, independent of the use category of a potential microplastic-containing product was estimated at €2.2 million (range: €0.8m-€6m).

[36] Regulatory costs comprise field-testing, regulatory data collection and associated labour, stability/biological tests, and registration for approval in EU countries (incl. dossier preparation).

costs are substantially higher than indicated by the sector in previous submissions to the CfE and it is doubtful that companies could not transfer knowledge from one product to another hence reducing at least the R&D costs for multiple reformulations. The Dossier Submitter hence considers a reformulation cost of €2 million in present value (range: €1.0 million to €4 million);
    - Based on information from 90% of its members ECPA estimated that 40 to 80 CSP reformulations would be required;
    - Thus, the low-cost estimates are pegged at €40 million/€120 million/€320 million (all in present value). Following the argumentation above an additional effort factor of 2 is assumed to apply for a high-cost scenario of €80 million/€240 million/€640 million.
- Modifications for fertiliser additives:
    - Indications from the CfE suggest that already today there are alternatives on the market that do not use polymers, but rely e.g. on silica instead;
    - No information regarding the relative performance of these alternatives was obtained during the preparation of the Dossier. In the consultation, Fertilizers Europe noted that silica-based additives were not compatible with all fertiliser types and would moreover entail health concerns. Nevertheless, their existence demonstrates that for this use category some non-polymeric materials exist which achieve similar functions;
    - Fertilizers Europe (2018) estimated that the reformulation/replacement of non-degradable polymers for the use as fertiliser additive will cost their members about €20 million and will take at least 3 years;
    - Since Fertilizers Europe represent by their own account about 2/3 of the companies operating in the EU fertiliser market and as particularly SME companies might not be part of the sector association, it is assumed that the total cost of substitution would be in the range of €20 million to €100 million with a low-cost estimate of €50 million;
    - As before, 95% of these costs are to be attributed to the FPR so that the lower bound costs attributable to the restriction proposal are assumed to be €0.5 million/€1.25 million/€2.5 million;
    - The timelines for successfully replacing non-degradable polymers suggested by Fertilizers Europe (2018) indicate that substitution could happen faster than for the more complex controlled-release function. Hence, an effort factor of 1.5 is assumed for the high-cost scenario, resulting in replacement costs of €0.8 million/€1.9 million/€3.8 million.
- Modifications for seed coatings:
    - Based on information received in the consultation, the Dossier Submitter considers the coating of seeds to be technically less demanding than encapsulations that ensure controlled release, since the former have to protect the seed during sowing and the germination stage (i.e. several weeks), whilst the latter are designed to release PPPs over a period of several months;
    - Moreover, there is indication that already today several large seed producers use coatings based on potato starch, molasses and other biodegradable materials;

- Changes to the coating material are unlikely to require re-approval under the regulation of PPPs or fertilising products because binders and coatings are considered to be inert;
- Based on information from 75% of its members ECPA estimated that 180 to 250 coatings would need to be reformulated. The Dossier Submitter considers this to be an overstatement of the actual need and assumes instead that 50/100/150 primary reformulations were needed;
- ECPA members estimated the total cost per reformulation to be €3.4 million (€1.2 million to €4.5 million). Applying this cost estimate the total cost would be €60 million/€340 million/€675 million;
- Finally, an effort factor of 1/3 is applied to obtain a more realistic cost scenario that accounts for the fact that biodegradable seed coating technologies are already on the market and would now need to be modified to replace non-degradable ones. This results in reformulation costs of €20 million/€113 million/€225 million.

Summing all together, the low-cost estimate ranges from €71 million to €608 million and the high-cost estimate ranges from €161 million to €1.44 billion, respectively. These ranges are relatively wide in absolute terms, but in light of the scarce information on substitution costs, they are reasonable narrow in relative terms.

In addition to these reformulation costs, some enforcement costs will accrue. As this restriction proposal is very broad, it would seem incorrect to apply an average enforcement cost estimate of roughly €55 000 per year. Rather, one would consider such costs to accrue to each of the affected sectors. However, one also has to consider that both fertilising products and PPPs are already heavily regulated, and the enforcement of existing regulatory requirements would occur even without the current restriction proposal. Thus, the enforcement cost attributable to the restriction of microplastics in the A&H sector seems to be negligible compared to the estimated reformulation cost even when accounting for use-specific enforcement.

D.4.5.3. Cost-effectiveness analysis

Based on the emission avoidance analysis outlined in Section D.4.4.2 and the cost assessment provided in Section D.4.5.2, one may then obtain abatement cost estimates, which are best interpretable if understood as in the context of the cost-effectiveness approach advocated by SEAC for evaluating PBT and vPvB substances (ECHA, 2016a).[37] Table 50 presents an overview of cost-effectiveness estimates for both restriction scenarios and under the various assumptions made in the relevant Sections of this Annex. It is emphasised that these figures do *not* include emission avoidance that is attributable to the biodegradability criteria introduced by the FPR. In other words, there is no double counting of effects, neither on the cost side nor on the effectiveness side.

Table 50: Cost-effectiveness of the restriction per A&H product category

[37] See https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf

	Cost-effectiveness estimates (€/kg emission avoided)		
Scenarios [emission abatement potential]	**Low**	**Central**	**High**
CRFs			
Low-cost scenario:			
- High effectiveness [7.5 kt/20 years]	1.3	2.7	13.3
- Central effectiveness [3.75 kt/20 years]	4.0	8.0	40.0
- Low effectiveness [0.75 kt/20 years]	8.0	16.0	80.0
High-cost scenario:			
- High effectiveness [7.5 kt/20 years]	2.7	5.3	26.7
- Central effectiveness [3.75 kt/20 years]	8.0	16.0	80.0
- Low effectiveness [0.75 kt/20 years]	16.0	32.0	160.0
CSPs			
Low-cost scenario:			
- High effectiveness [8.4 kt/20 years]	4.8	6.7	33.3
- Central effectiveness [6.0 kt/20 years]	14.3	20.0	100.0
- Low effectiveness [1.2 kt/20 years]	38.1	53.3	266.7
High-cost scenario:			
- High effectiveness [8.4 kt/20 years]	9.5	13.3	66.7
- Central effectiveness [6.0 kt/20 years]	28.6	40.0	200.0
- Low effectiveness [1.2 kt/20 years]	76.2	106.7	533.3
Fertiliser additives			
Low-cost scenario:			
- High effectiveness [4.5 kt/20 years]	<0.1	0.2	0.3
- Central effectiveness [3.0 kt/20 years]	0.3	0.4	0.8
- Low effectiveness [1.5 kt/20 years]	0.6	0.8	1.7
High-cost scenario:			
- High effectiveness [4.5 kt/20 years]	0.2	0.3	0.5
- Central effectiveness [3.0 kt/20 years]	0.4	0.6	1.3
- Low effectiveness [1.5 kt/20 years]	0.8	1.3	2.5
Coated seeds			
Low-cost scenario:			
- High effectiveness [15 kt/20 years]	1.3	2.7	5.3
- Central effectiveness [7.5 kt/20 years]	7.6	15.1	30.2
- Low effectiveness [3.75 kt/20 years]	15.0	30.0	60.0
High-cost scenario:			
- High effectiveness [15 kt/20 years]	4.0	8.0	16.0
- Central effectiveness [7.5 kt/20 years]	22.7	45.3	90.7
- Low effectiveness [3.75 kt/20 years]	45.0	90.0	180.0

Two observations are warranted on the estimates reported in Table 50.

- The cost per kg of microplastics not released into the environment is relatively low (less than €50/kg for the central estimates underlined in Table 50) compared to uses of microplastics in other sectors analysed in this restriction proposal;

- Even under the least favourable scenarios, the cost-effectiveness of restricting the uses identified is less than €300/kg in the central case, which is less than what has been found in other PBT/vPvB restriction proposals.

Taking these points together, one may conclude that the proposed restriction of polymers currently used in the A&H sector and that fall under the microplastic definition of this proposal is very cost-effective.

D.4.6. Other impacts

D.4.6.1. Impact on consumers

If one considers the welfare implications of the proposed regulation, then one important question is whether it will be possible to pass through the incremental cost to the consumer. The answer to this question is unclear because the incremental cost per unit of agricultural/horticultural output produced with the help of A&H products targeted by the restriction (e.g. a flower pot) is only marginally affected by the cost per unit of input (e.g. a bag of CRF).

Therefore, it is possible that:

- the seller passes through the full cost increment resulting in no changes of his producer surplus but a loss in consumer surplus;
- the seller fully absorbs the cost increment, thus leading to a reduction in producer surplus but not affecting the consumer surplus; or
- a situation emerges in which seller and buyer share the extra cost.

Intuitively, it seems unlikely that consumers would be extremely price sensitive, i.e. the Dossier Submitter assumes that demand for many products relevant in the context of this restriction is relatively inelastic.

A second relevant question is whether the restriction can be expected to result in an inferior quality of products. Again, this question is difficult to answer without the alternatives already being placed on the market. Yet it seems plausible to assume that functionally similar polymer coatings that are biodegradable can be developed if a sufficient transitional period is granted for the necessary R&D to be undertaken.

D.4.6.2. Impact on employment

Given the transitional period of 5 years (CRFs, fertiliser additives, seed coatings) and 8 years (CSPs) after EiF of the restriction, no major employment effects are expected from this restriction. Especially, it has to be considered that the implementation of polymeric innovations in the various A&H product categories analysed above have made the agricultural sector less labour-intense. Thus, if anything, this could mean that the non-availability of such technologies would lead to more rather than less labour demand. However, it is assumed—and actors in the CfE have cautiously confirmed—that the development of biodegradable polymers for A&H products will be possible if sufficient transitional time for R&D is given. Thus, employment effects on the A&H sector are assumed irrelevant for the impact assessment of the proposed restriction.

D.4.6.3. Impact on trade

The effects of the proposed restriction on trade with third countries are conceivably small. This conclusion is drawn based on the following reasoning.

- On the import side, one distinctive feature of the EU seed market is that, unlike the rest of the world, it has remained a market for conventional (i.e. non gene-modified) seeds. This has essentially led to a decoupling of the EU seed market from the global seed market (European Commission, 2013) with global seed producers offering a specific product portfolio for the EU market. Hence, a regulation affecting non-degradable polymeric coating material, whilst affecting the EU seed product portfolio, would not affect the trade of seeds on other markets;
- On the other use categories (fertilisers, fertiliser additives, PPPs), no information became available during the CfE that would point towards noticeable impacts on trade which would not occur in absence of the restriction. Notably, fertilising products imported into the EU would have to fulfil the biodegradability requirement set out in the new EU regulation on fertilising products anyhow. CSPs imported into the EU could be negatively affected, yet most large agro-firms are already producing in the EU. Hence, no major market disruptions are expected;
- On the export side, the restriction will not limit EU producers of CRFs, CSPs, fertiliser additives and coated seeds to place their products onto third country markets where these markets do not regulate polymeric material in A&H products.

D.4.6.4. Impact on innovation

In its impact assessment of the legislative proposal on fertilising products (COM(2016) 157), the European Commission foresees positive impacts on economic growth owing to a number of factors including the creation of jobs as well as a 65%-reduction in costs for industry to place new products on the market. Another important aspect identified in the Commission's impact assessment relates to the expected creation of new product and material categories. In this regard, products that are coated with (or use otherwise) biodegradable plastics may become more widely available and, given latest international considerations on regulating microplastics (e.g. by China), seem economically promising. The Dossier Submitter concludes that, whilst it is difficult to quantify the market potential of biodegradable polymers in the A&H sector, such a potential certainly exists.

D.4.6.5. Impact on SMEs

As 90% of the 1 200 companies operating in the EU fertiliser market are SMEs (European Commission, 2013) and a similar split is conceivable for manufacturers of PPPs[38], it is possible that SMEs are disproportionally affected by the proposed restriction. Since the impact on these firms depends on other regulations as well, it is difficult to assess the consequences of the proposed restriction on SME actors. It may be noted though that the establishment of a level-playing field will help EU companies to pass through any regulatory extra cost to their customers since the latter can only switch to non-EU produce if that would not contain microplastics targeted by the restriction.

D.4.6.6. Double regulation

One important issue for companies and industry associations responding to the CfE

[38] Whereas the number of SMEs operating in the EU PPP market is unknown, ECPA informed that they have currently 16 SME members and 7 corporate members. Thus, the actual share of SMEs operating in the EU PPP market may be somewhat smaller than in the EU fertilisers market.

relates to the potential thread of double regulation and the establishment of diverging timelines and standards. The Dossier Submitter agrees that these would be undesirable outcomes and urges the European Commission to coordinate between the regulatory actions proposed in this restriction and other relevant regulations. The overarching objective of the proposed actions on the A&H sector is to avoid diverging regulatory requirements, whilst closing regulatory loopholes and creating a level-playing field for all actors operating in the EU market.

D.4.7. Proportionality to risk

The above discussion of emissions and costs of the proposed restriction scenarios for the A&H sector suggests that curbing microplastics emission is achievable in a cost-effective manner. Indeed, compared to other restriction proposals the cost-effectiveness figures derived for the A&H sector appear to be trivial under both restriction scenarios analysed. Whilst this says nothing about the welfare implications of the proposed action in *absolute* terms—the ladder would require a quantification of the benefits, i.e. the risk reduction brought about by curbing the microplastics pollution stock—it does demonstrate that emission curbing in the A&H sector is possible at relative low cost.

Given the current scientific uncertainty about the harmfulness of microplastics and the option value that obtains from the expected scientific learning (see Annex D.14), the proposed restriction scenarios for the A&H sector seem both proportionate measures to address the risk. However, the Dossier Submitter acknowledges that this conclusion on proportionality is conditional on biodegradable coatings with same or similar functionality becoming available in the nearer term. If this were not the case, then this would cast doubt on the proportionality of the proposed restriction, as the benefits of non-degradable polymers used in agriculture and horticulture are substantial.

One way to reason about the risk of substitution failure is by considering the *expected* cost-effectiveness ratio, which is obtained by dividing the total cost of reformulation effort C by the product of emission abatement E and the probability of substitution success (that is the reciprocal of the probability of failure p): $\kappa = C/(1 - p)E$. One may then use for κ any cost-effectiveness value that one deems still proportionate, e.g. €5 000 per kg of emissions abated (see e.g. Oosterhuis et al. (2017)), and solve for p. For example, consider the central cost-effectiveness estimate for CRFs, which amounts to €8 per kg of microplastic release avoided (see Table 50). Inserting and solving for p indicates that the failure probability would need to be extremely high (p>99%) in order to exceed a cost-effectiveness benchmark of, say, €5 000/kg of emission avoided:

$$\kappa = \frac{C}{(1 - p)E} \Rightarrow €5\,000/kg = \frac{€30m/20y}{(1 - p)3.75kt/20y} \Leftrightarrow p = 1 - \frac{€30m/20y}{€5\,000/kg * 3.75kt/20y} = 99.8\%.$$

In other words, there would need to be an almost zero chance of finding a suitable substitute whilst investing €30 million into specific R&D activities to pass a cost-effectiveness benchmark of €5 000/kg. Such a situation seems unlikely to occur and the Dossier Submitter therefore concludes that, even if the risk of substitution failure is accounted for, the proposed restriction scenarios seem both proportionate.

When one considers the optimal length of transition before the biodegradability requirement becomes binding, several aspects need to be balanced against each other. On one hand, more time for adoption allows a smoother transitioning which may be particularly important for SMEs; on the other hand, a shorter period is more effective in

curbing emissions and may thus be preferable from an emission-reduction point of view. In any case, alignment with the biodegradability requirement for CE marked fertilising products as set out in the FPR seems desirable and the Dossier Submitter therefore recommends the Decision maker coordinate the regulatory rollout of this restriction proposal and the aforementioned EU regulation on fertilising products in order to avoid confusion about the exact legal requirements stakeholders have to comply with.

The non-availability of suitable alternatives for specific A&H uses of non-degradable polymers remains a caveat of this restriction proposal. Should—contrary to the assumption made here—no suitable alternative be found during the transition period, this would ask for a detailed assessment and, possibly, a derogation of these specific uses. Based on the current state of R&D and the information received during the preparation of this restriction proposal, the Dossier Submitter is confident, however, that over the next five to ten years biodegradable alternatives will become widely available for uses in the A&H sector.

D.4.8. Uncertainties and sensitivities

In Sections D.4.4 and D.4.5, the Dossier Submitter identified various uncertainties with regard to both the emission avoidance and the cost of switching to biodegradable polymers (or alternative technologies that make the use of polymers obsolete). Whilst these uncertainties are large in absolute terms, their impact on proportionality is relatively modest. Figure 5 illustrates this statement for the forecasted emissions under the baseline scenario. Over the 20-year analytical horizon, the central estimate of cumulative emissions from A&H uses amounts to almost 50 kilotonnes of microplastics. However, as Figure 5 shows, cumulative emissions could just as well be 200 kilotonnes. In relative terms, this discrepancy would still appear relatively modest given that the forecasting horizon is so long.

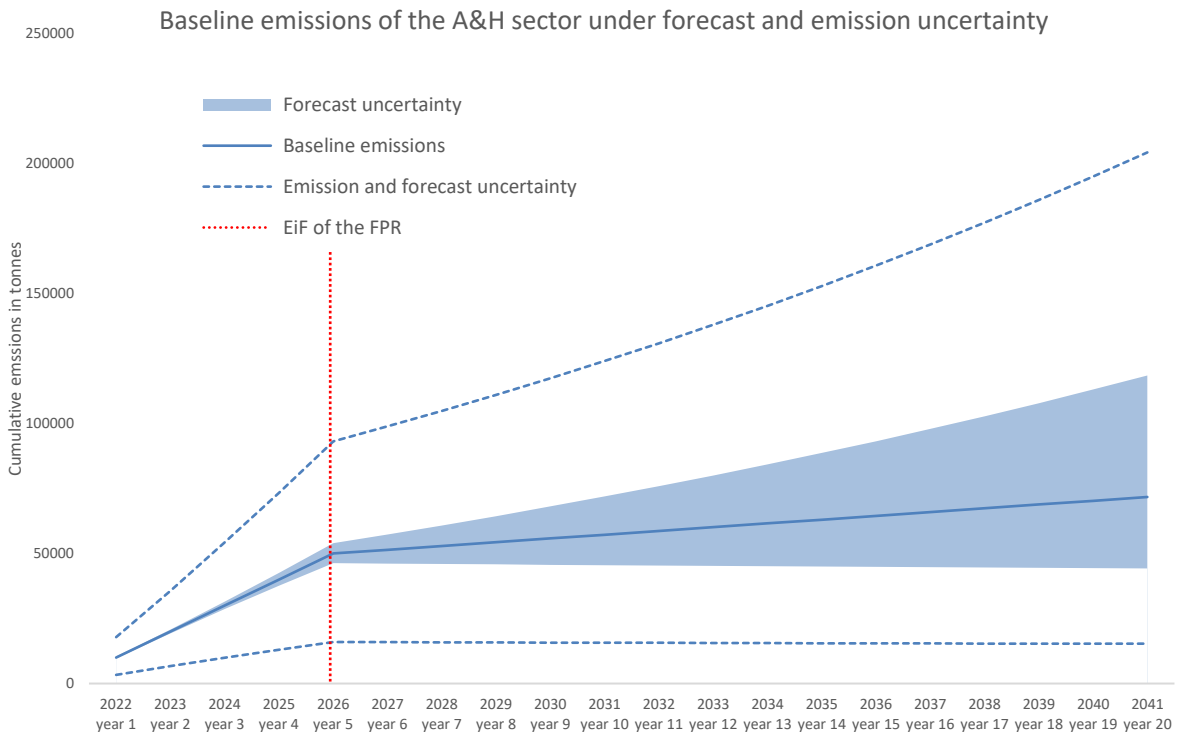


Figure 5: Uncertainty in cumulative baseline emissions

It should be noted that some uncertain aspects rely on specific assumptions which are positively correlated with each other; e.g. if the number of products that would have to be reformulated is in the high range, then it appears also more likely that the emission avoidance potential from substituting non-degradable polymers in these products is in the high range, and vice versa. This said, the single most important uncertainty relates to the achievability of the biodegradability requirements set out in the FPR. If such biodegradable polymers do not become available by the end of the transition period of 5 years and 8 years, respectively, and hence specific fertilising products and PPPs could no longer be used in the EU, this would entail a potentially vast loss to society that relates to the benefits of microencapsulation for human health and safety, for environmental health and safety as well as in economic terms. It is therefore of outmost importance that the progress in substituting non-degradable polymers is closely monitored.

D.4.9. Summary

This section has assessed a restriction of non-degradable polymers that fall under the microplastics definition outlined in the Background Document. As discussed in section D.4.7, close alignment with sector-specific legislation (in particular the new EU regulation CE marked fertilising products) seems desirable both from an analytical and practical perspective. This would imply that a transition time be given to firms operating in the A&H sector to develop biodegradable polymers that would achieve same or similar functionality than those polymers currently used.

D.5. Cosmetic Products

Socio-economic impacts of a regulatory action under REACH on microplastic use in cosmetic products are studied for three broad categories of cosmetic products:

- Rinse-off cosmetics containing microbeads (also referred to rinse-off cosmetics containing microplastics with exfoliating or cleansing functions): They are a type of rinse-off cosmetic products intended specifically to remove dirt, unclog pores, or remove dead skin cells. These microplastics are also commonly referred to as plastic microbeads. The type of products with these functions include facial exfoliating products, face wash, soaps, make-up remover, shampoos, oral care (e.g., toothpaste, tooth whiteners) and others.
- Other rinse-off products: This group of cosmetic products includes all remaining rinse-off products other than those described in the preceding section, e.g., conditioners (other than leave-in conditioners), hair colouring products, bleach for body hair products, hair (nourishing) masks, etc.
- Leave-on products: This diverse group included skin care products (e.g., moisturisers, body lotions), make-up (e.g., foundation, powder, concealer, mascara, eye shadow/pencil/liner, lipstick or sealer), products for correction of body odour or perspirations (e.g., deodorants), tanning products, hair care and styling products (e.g., leave-on conditioner, dry shampoo, hair spray/foam/gel), nail care (e.g., polish, hardeners, glue), etc.

This approach to assessing the socio-economic impacts is taken because cosmetics have various modes of use and therefore, have various emission pathways of microplastics to the environment. Furthermore, microplastics can impart broad range of functions in cosmetic products. The availability of suitable alternatives for these diverse uses varies, as does the current market share of the alternatives or the anticipated resources required to substitute these microplastic uses. Because of these variations, different impacts are expected from potentially different necessary regulatory actions.

The following sections present the anticipated impacts of the proposed restriction for each of these three categories of cosmetics products. Table 51 contains the relevant sections in the restriction wording for cosmetics. Please see Table 3 in the main report for the full content of the proposed restriction.

Table 51: Proposed restriction elements for microplastic use in cosmetics

Polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006)	1. Shall not, from [entry into force (EiF)], be placed on the market as a substance on its own or in a mixture as a microplastic in a concentration equal to or greater than 0.01% w/w. 6. Paragraph 1 shall apply from: a) EiF for cosmetic products[39] and other mixtures containing microbeads; c) EiF + 4 years for 'rinse-off cosmetic products'[40] not already included in paragraph 6(a); g) EiF + 6 years for 'leave-on cosmetic products.'[41]

Source: Table 3 in the main report.

Other Union-wide risk management measures than restriction

Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products or the Cosmetic Products Regulation (CPR) defines cosmetic products as "any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours." The CPR establishes rules for any cosmetic product placed on the EU market, in order to ensure the functioning of the internal market and a high level of protection of human health. Environmental risks from substances in cosmetic products are not regulated under the CPR; therefore, a restriction is proposed under REACH as shown in Table 51 to manage the risks to the environment from microplastics.

D.5.1. Use and functions

Microplastics are used in cosmetics for variety of purposes: from exfoliants to thickening agents to delivery mechanisms for active cosmetic ingredients (e.g., antimicrobial or antioxidant) or fragrances. Microplastics, made of polymers (first patented in cosmetics applications in the 1960s (UNEP, 2015) and additives, are common cosmetic ingredients. Their use has proliferated due to their advantageous properties (consistent quality and supply, favourable physicochemical properties, non-sensitising (due to their higher molecular weight they are not absorbed by the human cells), economically acceptable, etc.) in comparison to some natural plant or mineral ingredients.

Similar to other sectors, microplastics used in cosmetics are polymer particles meeting the definition of this restriction proposal for morphology, state, dimensions, non-

[39] "Cosmetic product" in the meaning of Regulation (EC) No 1223/2009, article 2: any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

[40] "Rinse-off cosmetic product" in the meaning of Regulation (EC) No 1223/2009: a cosmetic product which is intended to be removed after application on the skin, the hair or the mucous membranes

[41] "Leave-on cosmetic product" in the meaning of Regulation (EC) No 1223/2009: a cosmetic product which is intended to stay in prolonged contact with the skin, the hair or the mucous membranes

biodegradability, intentional use (intentionally added and/or released).

Intentional use:

Microplastics are intentionally added to cosmetic products to impart specific functions (Table 52). These products are intended to be washed off with water during/after use and discharged into wastewater (i.e., many rinse-off cosmetics such as shampoos, shower gels, toothpaste, etc. but also some leave-on: e.g., deodorants, sun lotions, skin care and hair care, herein also referred to as "down-the-drain" leave-on cosmetics) or to be removed via cotton pad/wipe (many leave-on cosmetics such as make-up, lip or nail products). According to consumer habits surveys, these pads/wipes are either flushed in the sewer system or disposed in household trash (YouGov, 2017)(CfE AI (2018). Thus, following use, microplastics in cosmetic products are not collected for recycling as potentially their packaging but they largely enter the municipal wastewater system, which is not always equipped to effectively remove them.[42] Microplastics can therefore be emitted via raw sewage, treated effluent, or with sewage sludge applied as fertiliser (biosolids) on agricultural or park land, landfilled, used in land reclamation or disposed at sea (UNEP, 2015). Due to their extremely slow decomposition, microplastics remain in the environment for decades. Remediation is challenging because of dispersed contamination on a vast scale (e.g., marine environment), potential ecological damage due to remediation (removal and destruction of smaller organisms), and substantial costs (UNEP, 2015).

Morphology:

Microplastics used in cosmetics can be spheres or be irregular shape but they are unlikely to be fibrous. That is why they are sometimes referred to as: microbeads, microspheres, nanospheres, microcapsules, nanocapsules, plastic particulates, etc. (UNEP, 2015).

Size:

Depending on the function, microplastics can have various sizes, with most of them (99%) are below 1 mm in all dimensions (CfE 2018), (UNEP, 2015).

State:

The building blocks of microplastics - polymers - come in many forms. The same polymer may be used as a liquid in one product and a solid in another (cosmeticsinfo.org, 2018).[43] Identifiers such as the INCI (International Nomenclature of Cosmetic Ingredients: a formal descriptor that must be used for mandatory ingredient labelling of cosmetic products) name do not provide information on the physical state (Abrutyn, 2013).[44] This

[42] IVM 2014 brings into question the effectiveness of an end-of-pipe type of solution for halting microplastics emissions via wastewater streams as treatment facilities are not designed to retain plastic particulates, and applying further microfiltration is expected to be costly both in terms of energy inputs and financial investments. Furthermore, during high flow periods, wastewater is discharged to the surface water untreated. A significant percentage of households across Europe are not connected to wastewater treatment facilities, meaning microplastics are discharged directly to surface water in many communities.

[43] Information subsequently submitted during the consultation on the submitted dossier revealed that the majority of the polymers used in cosmetics may be liquid. (PC #2220, 2361, https://www.mibellegroup.com/blog/general/microplastics-in-cosmetics-mibelle-turns-to-alternatives/)

[44] Also see https://www.personalcarecouncil.org/wp-content/uploads/2019/08/INCIandMicroplastics.pdf .

is because the state (phase) depends not only on the monomers that make up the polymer or copolymer, but also on properties like chain length (i.e., lengthening the chain leads to solid materials, while shorter chains lead to softer materials), degree of crosslinking (i.e., cross-linking tends to decrease water solubility of polymers) and molecular weight (e.g., polyethylene molecules less than about 700 carbons in length are waxy, and alkane chains with less than 20 carbons are liquids or gases). Sometimes the ratio of different monomers in copolymer materials determines the phase, e.g., the random copolymers of ethylene oxide and propylene oxide, INCI name PPG-N-Buteth-M, are water insoluble if they contain <50% ethylene oxide (UNEP, 2015).

This element of the definition has proven an analytical challenge when interpreting available information on polymers used in cosmetics in order to conclude which of them meet the regulatory definition of a microplastic in the proposed restriction. This has led to the need to make a number of assumptions. Information received from industry was based on the CfE 2018 definition of microplastics,[45] which presented difficulties for some stakeholders. Therefore, Cosmetics Europe, the main contributor of information on the sector, surveyed their membership based on a list of previously sited polymers for use in cosmetics (i.e., UNEP (2015)). This provided comprehensive information on the use, functions, and characteristics of these polymers (Table 52) as well as socio-economic impacts of their potential restriction.

However, the INCI database contains information on hundreds of polymers. Other cosmetic ingredient databases at the disposal of the Dossier Submitter indicate that at least 520 polymers are used in cosmetic products in the EEA (see Table 113:). A comprehensive analysis of their molecular weight, chain length and degree of cross-linking of this long list of polymers was considered disproportionate and no such work has been done to date by other stakeholders, although the Dossier Submitter conducted a rough preliminary analysis. Therefore, for the purposes of the high scenario developed for the cost assessment (see below), the data on polymer use in cosmetic products is assumed to be equivalent to likely microplastic use (i.e., as defined to fall into the scope of the proposed restriction).[46] The impacts of this assumption on the conclusions are highlighted.

As a result, the Dossier Submitter used the information provided by Cosmetics Europe as a lower bound of the scope of the proposed restriction in terms of polymer particles impacted (herein also referred to as the 19-polymer scope used in the Low Scenario for impact assessment) and CosmEthics (2018) as the upper bound of the scope (herein also

[45] "Any polymer-containing solid or semi-solid particle having a size of 5mm or less in at least one external dimension." (ECHA CfE 2018 BD: https://echa.europa.eu/documents/10162/11e12346-fbdd-0929-c8e0-30d5181aa44f).

[46] The Dossier Submitter conducted a brief analysis of the polymer list with a view to identify which polymers may be most likely impacted by the scope on the basis of their physico-chemical properties (no assessment of the function or mixture was performed), which estimated that potentially around half the polymer uses may be outside the scope of the proposed restriction. Therefore, about half the estimated tonnage was taken into account in an effort not to overstate the relative contribution of cosmetic products to the microplastic pollution. However, the same approach was not taken for estimating the reformulations required to comply with the proposed restriction. The approach rests on several assumptions and the consultation on the proposed restriction was used to further refine the assumptions employed if needed. See section Use and function for further details.

referred to as the 520-polymer scope used in the High Scenario). The CosmEthics database has the advantage of a broad European coverage (see Table 53) and a pre-defined list of polymers. The results of the analysis of product characteristics of the CosmEthics database are comparable to those of two other databases available to the Dossier Submitter (Que Choisir and the Danish consumer council THINK

Therefore, the Low and High scenarios are developed purely to address information gaps and to assist with the assessment of the impacts of the proposed restriction. They do not represent a variation in the impacts associated with changes to the scope of the proposed restriction. Some polymer uses in both the Low and High scenario (although more so in the High scenario) are unlikely to fall in the scope of the proposed restriction. However, as outlined above, the lack of industry/company level information available to the Dossier Submitter makes it challenging to adequately exclude these uses from the assessment.

Polymers:

Broad spectrum of polymers (natural or synthetic – from organic based on alpha olefins to inorganic based on silicone) are used in a wide range of cosmetics. The type of polymers used are as varied as the applications which include them. Even within a certain class of polymers, the structural variations can also dictate the properties obtained. Features such as the degree of polymerization, the amount of branching, and the ratio of the units within a copolymer can have dramatic impact on the final performance attributes. Whether the copolymers are random versus block or whether they are ABA or (AB)n can influence the characteristics (Patil and Ferritto, 2013).

Diverse polymers can be engineered to provide a wide range of properties to the final cosmetic products that provide a gamut of tangible and perceived benefits to consumers. This can be done by copolymerisiation,[47] cross-linking[48] of polymers or blending,[49] leading to a very dynamic growth in the number of microplastics available for applications in cosmetics formulations.

Concentration:

While concentration is not a proposed criteria for defining microplastics, it conveys important information for their use. Microplastics are high performance cosmetic ingredients and sometimes very small quantities (less than 1%, CfE 2018) are sufficient to impart the desired function or characteristics in the final product. Average concentration has been reported as 3.5%, although, in some products it may be close to

[47] Copolymerisiation is the polymerisation of different monomers in the same chain (either in random or alternating order or as blocks)[47] to produce copolymers. For example, acrylates copolymer (with functions as a film former, viscosity modifier, binder) is made of two or more monomers consisting of acrylic acid, methacrylic acid or their simple esters (Abrutyn, 2013), (CosIng, 2018).

[48] Cross-linking forms a bond that links one polymer chain to another usually to improve the physical properties of the polymers and deliver specific desirable characteristics. The links can be covalent or ionic. For example, acrylates crosspolymer is a copolymer of acrylic acid, methacrylic acid or one of its simple esters, crosslinked with glycol dimethacrylate (EWG Skin Deep Cosmetics database - https://www.ewg.org/skindeep/ingredient/700124/ACRYLATES_CROSSPOLYMER/, (CosIng, 2018).

[49] Blends are made by combining different polymer materials after the polymerization process. Copolymer design and blending enables formulators to combine desirable properties from individual (co)polymers in one material, without the expense and effort required for developing an entirely new polymer type (UNEP, 2015).

100% such as glitters (CfE 2018).

Biodegradability:

Both natural (e.g., cellulose) and synthetic polymers find applications in cosmetics. Natural polymers are inherently biodegradable and therefore, not included in the scope. Most synthetic polymers and some chemically modified natural polymers may not meet the biodegradability criteria outlined in the restriction proposal. See Appendix X to the restriction wording in main report).

Note on Film forming:

Film forming is one of the essential functions of microplastics in particular for leave-on cosmetics. It helps enhance the wear of the product, extend sunscreen protection, builds water or oil resistance, improves product aesthetics. Film forming polymer particles are intended to yield a (non-continuous) polymer film on use, i.e., the particles coalesce and it is assumed to be limited release of the free polymer particles to the environment. Therefore, this use of microplastics is considered to be outside the scope of the proposed restriction.

Table 52: List of polymers in Low scenario (19-polymer scope)*

Polymer material	Associated INCI name(used for searching in database)	Functions reported in CosIng 2018 and UNEP 2015
Polyethylene	POLYETHYLENE	abrasive, film forming, viscosity controlling
Polypropylene	POLYPROPYLENE	viscosity controlling
Polymethylmethacrylate	POLYMETHYL METHACRYLATE	film forming, sorbent for delivery of active ingredients
Polytetrafluoroethylene	POLYTETRAFLUOROETHYLENE ACETOXYPROPYL BETAINE	hair conditioning, bulking agent, slip modifier, binding agent, skin conditioner
Polyurethane crosspolymer – 1	POLYURETHANE CROSSPOLYMER-1	Binding
Polyurethane crosspolymer – 2	POLYURETHANE CROSSPOLYMER-2	film forming
Polyamide (nylon) 5	POLYAMIDE-5	skin conditioning
Polyamide (nylon) 6	NYLON-6 NYLON 6/12	emollient/moisturiser, skin conditioning, viscosity controlling, bulking
Polyamide (nylon) 12	NYLON-12 NYLON-12 FLUORESCENT BRIGHTENER 230 SALT NYLON 12 [a] NYLON 6/12	bulking, opacifying, viscosity controlling
Styrene acrylate copolymer	STYRENE/ACRYLATES COPOLYMER	opacifying, film forming
Polyethylene terephthalate	POLYETHYLENE TEREPHTHALATE	film forming
Polyethylene isoterephthalate	POLYETHYLENE ISOTEREPHTHALATE	bulking, adhesive, film forming, hair fixative, viscosity controlling, aesthetic agent
Polybutylene terephthalate	POLYBUTYLENE TEREPHTHALATE	film forming, viscosity controlling
Polyacrylates, acrylates copolymer	ACRYLATES COPOLYMER ACRYLATES CROSSPOLYMER	antistatic, binding, film forming, hair fixative, suspending agent
Ethylene/Acrylate copolymer	ETHYLENE/ACRYLIC ACID COPOLYMER	film forming, gellant
Polystyrene	POLYSTYRENE	film forming
Methyl methacrylate crosspolymer	METHYL METHACRYLATE CROSSPOLYMER	film forming
Polymethylsilsesquioxane	POLYMETHYLSILSESQUIOXANE	opacifying

Polymer material	Associated INCI name(used for searching in database)	Functions reported in CosIng 2018 and UNEP 2015
Poly lactic acid	POLYLACTIC ACID	abrasive

Source: Cosmetics Europe, INCI name sourced from CosIng 2018 (http://ec.europa.eu/growth/tools-databases/cosing/index.cfm), Functions sourced from Cosmetics Europe, CosIng 2018 and UNEP 2015

Note a: Not an official INCI name, but a name encountered on cosmetic packaging

*Not all uses of the polymers included in this list may meet the proposed microplastic definition.

Table 53: Characteristics of cosmetics databases at the disposal of the Dossier Submitter

	CosmETHICS	Que Choisir	Danish consumer council THINK
Extraction date	28 September 2018	14 September 2018	August 2018
Number of products in database at extraction date	95 764 products[50]	117 220 products	ca. 10 000 products
Market	Nordic countries & French	French	Denmark
Period	Since 2013, with 78% of products since 2016	Since March 2018	Since 2015

Source: CosmETHICS 2018; Que Choisir 2018; Danish consumer council THINK 2018

Microplastic uses in cosmetics are very diverse and subject to continuous innovation. Thus, listing all their uses in in cosmetics is challenging. Table 54 gives examples of functions of polymers in cosmetics. More detailed information on the more typical functions for rinse-off or leave-on products is discussed in the sections below.

Table 54: Examples of polymers used in cosmetics and their functions*

Function	Examples of synthetic polymers used in cosmetics
Adhesives	hydroxypropyl cellulose
Antifoam	simethicone and dimethicone silylate
Binders	aluminium starch octenylsuccinate and polyethylene wax
Emulsifiers, emulsion stabilizers	poloxamers with polyacrylic acid, PEG-30 dipolyhydroxystearate, poloxamer, polymers containing polyaclkylpolyether-grafted poly-dimethylsiloxane blocks, acrylates/C10-30 alkyl acrylate crosspolymer, polyquaternium-3, PEG-4 oleate, polyglyceryl-6 distearate, steareth-2,
Film-formers	acrylates copolymer, biosaccharide gum-4, PVP (polyvinylpyrrolidone)/eicosene copolymer, sodium polystyrene sulfonate, siloxanes & copolymers
Hair conditioning, fixatives	acrylates copolymers (e.g., of 2-acrylamido-2-methil-1-propane sulfonic acid or its salts in combination with nonionic/anionic monomers), AMP-acrylates copolymer, polyquaternium-X, PVP/VA copolymer, starch derivatives, poly-N-vinylacetamide, amophoteric urethanes, polymethacryloxyethyltrimethyl ammonium methosulfate, polyN-methylvinylpyridinium chloride, PVP/Dimethylaminoethyl methacrylate copolymer, VP (vinylpyrrolidone)/DMAPA acrlylate copolymer, Diquaternary polydimethylsiloxane, Amodimethicone, Trimethylsiloxyamodimethicone, ionenes (delsette 101, silicone quaternium-8/12)

[50] Products in the databases are differentiated on the basis of unique barcode. Each unique barcode is assumed to represent a separate formulation, although some products change their barcodes over time and very similar products, e.g., deferent shade of make-up, are identified with unique barcodes.

Function	Examples of synthetic polymers used in cosmetics
Skin conditioning	alternating copolymer of α-w-organohydrogenpolysiloxane and triglycerol diallyl ether, polyisoprene, bis-diglyceryl polyacryladipate-2, glycereth-31, dimethicone, PEG-45M,
Surfactants	PEG-X, PEG-X/PPG-Y, PVP and natural-derived, potassium alginate, chitosan lauroyl glycinate
Surface modifiers, viscosity modifiers/ gellants/ thickeners	copolymers of ethyl acrylate, methacrylic acid and ethoxylated long chain alkyl acrylates, hydrophobically-modified derivateives of acryloydimethyltaurine (AMPS) copolymers, cellulose derivatives, corn starch derivatives, dextran, PEG-150 distearate, PEG-150/decyl alcohol/SMDI copolymer, polyehylene oxide, hydropropyl guar, hydrogenated styrene/isoprene block copolymers, triglyceride gellants, hydrogenated polydecene, trideceth-6, PEG-15 glyceryl stearate, acrylates copolymer, sodium polyacrylate, C8-22 alkyl acrylate/butyl dimethicone methacrylate copolymer, other carbomers (cross-linked polyacrylic acid, acrylates/C10-30 alkyl acrylate crosspolymer),
Controlled release	acrylates copolymer
Exfoliants	aluminium silicate, polyethylene powder or spheres and ethylene/acrylic copolymer
Cleansing	Polydimethylaminoethylmethacrylate-co-dimethylacrylamide/acrylic acid/mathacrylic acid/mathacrylic acid-co-acrylic acid/mathacrylic acid-co-dimethylacylamide, polypeptides
Other sensorial	Polyols, PEG-300, PEG-400, polymethylstyrene-co-2-ethylhexyl acrylate, polystyrene-co-2-ethylhexyl acrylate.isobutyl methacrylate
Antimicrobials	polyhexamethylene biguanide, polyornithine, polylysine
UV absorbing, SPF sunscreens & boosters	n-[3-(dimethylamino)propyl]mathacrylamide-N-(3-bromopropul)phthal-imide quarternary salt (DMAPMA-PQ), n-[3-(dimethylamino)propyl]mathacrylamide 1-chloromethylnaphthalene quaternary salt (DMAPMA-MNQ), (3-alloxy-2-hydroxyl)-[3-(2-hydroxybenzoyl-amino)propyl[-dimethyl ammonium hydroxide, [(4-carboxy-3-xydroxyphenyl-carbamoyl)methyl]-dimethyl-[3-(2-methyl-acryloylamino)propyl] ammonium hy-droxide, 4-methacrylamidosalicylic acid(4-MASA), polyester-7, polyamide-2 and polysilicone-15
Carriers	cetereth-20 and PEG-8/SMDI copolymer
Foamer/foaming agents	vinylpyrrilidone/vinylimidazole copolymer
Dispersant, coupling agents	C20-40 pareth-10 and PEG-40 hydrogenated castor oil

Source: Abrutyn (2013), Lochhead (2007), Patil and Ferritto (2013)

*Not all uses of the polymers included in this list may meet the proposed microplastic definition.

The most well-known functions of microplastics are exfoliating and cleansing. In view of the increasing public concerns related to plastic litter in the marine environment, a number of companies took action to reduce the use of microplastics for exfoliation or cleansing. Phase out accelerated with the Cosmetics Europe recommendation in 2015 to discontinue, by 2020, the use of synthetic, solid plastic particles used for exfoliating and cleansing that are non-biodegradable in the marine environment. Several Member States have introduced national bans primarily for rinse-off products with exfoliating functions

(e.g., UK, Sweden, Belgium,[51] Denmark[52]). Some are considering further bans. (See section A.1 for further information on national actions.) Furthermore, the European Parliament issued a Resolution on 13 September 2018 that calls for a ban on microplastics in cosmetics, personal care products, detergents and cleaning products as of 2020 (European Parliament, 2018)[53].

D.5.2. Baseline

Use of microplastics in cosmetics products is estimated in excess of 8 800 tonnes (Table 55). They are primarily used in rinse-off cosmetics (more than three-quarters of the use) but they also find wide application in leave-on products.

Table 55: Microplastic use in cosmetic products: Baseline scenarios (in tonnes)

Scenarios	2017	2018	2019	2020	2021	2022-2041 (average)
Low tonnage						
Exfoliant/cleansing	107	54	27	-	-	-
Other rinse-off	2 900	2 900	2 900	2 900	2 900	2 900
Leave-on	1 100	1 100	1 100	1 100	1 100	1 100
- down-the-drain*	635	635	635	635	635	635
- make-up/lip/nail products**	480	480	480	480	480	480
Grand Total	**4 100**	**4 100**	**4 000**	**4 000**	**4 000**	**4 000**
Central tonnage						
Exfoliant/cleansing	107	54	27	-	-	-
Other rinse-off	6 700	6 700	6 700	6 700	6 700	6 700
Leave-on	2 100	2 100	2 100	2 100	2 100	2 100
- down-the-drain*	1 100	1 100	1 100	1 100	1 100	1 100

[51] The Belgium legislation proposes that after 31 December 2019, cosmetic rinse-off products or any oral care products that contain 'plastic microbeads' cannot be placed on the Belgian market. Plastic microbead is defined as microplastic used as an ingredient with an abrasive effect and/or for cleaning, depending on the form and structure of the particle. Microplastic is defined as a solid particle, of less than 5 mm, used as an ingredient in consumer products and consisting in whole or in part of synthetic polymers that are insoluble in water and non-biodegradable in the aquatic environment. The term polymer is as referred to in Article 3(5) of REACH. (Source: DG Growth Notifications, http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2017&num=465)

[52] From 1 January 2020 the use of solid plastic pieces less than five millimetres in diameter will not be permitted in rinse-off cosmetic products such as scrubs. In addition, an analysis will be made of whether intentionally added microplastic can also be banned nationally in other cosmetic products within three years. (Source: Ministry of Environment and Food of Denmark, https://mfvm.dk/nyheder/nyhed/nyhed/regeringen-vil-forbyde-mikroplast-i-kosmetik/)

[53] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2018-0352+0+DOC+XML+V0//EN&language=EN

Scenarios	2017	2018	2019	2020	2021	2022-2041 (average)
- make-up/lip/nail products**	1 000	1 000	1 000	1 000	1 000	1 000
Grand Total	**8 800**	**8 800**	**8 700**	**8 700**	**8 700**	**8 700**
High tonnage						
Exfoliant/cleansing	107	54	27	-	-	-
Other rinse-off	10 400	10 400	10 400	10 400	10 400	10 400
Leave-on	3 000	3 000	3 000	3 000	3 000	3 000
- down-the-drain*	1 300	1 300	1 300	1 300	1 300	1 300
- make-up/lip/nail products**	200	200	200	200	200	200
Grand Total	**13 400**	**13 400**	**13 400**	**13 400**	**13 400**	**13 400**

Notes: * Includes primarily cosmetics washed off with water and discharged into wastewater: skin care, sun/self-tanning products, deodorants/perspirants, hair care & other.

** Includes cosmetics primarily removed after use with a cotton pad/wipe, which in turn are either flushed in the sewer system or disposed in household trash/waste.

Due to the considerable uncertainty related to the polymers falling in the scope of the proposed restriction, three baseline scenarios are prepared. Historical information on uses in the Low tonnage scenario is based on information from Cosmetics Europe (CfE 2018). The High tonnages is based on information on the number of formulations containing microplastics from CosmETHICS database (520-polymer scope), scaled up based on the average amount of microplastics per formulation (CfE 2018) and reduced on the basis of assumption in the consultation that 40% of polymer uses will fall out of scope of the restriction (ECHA consultation 2019, #2220, #2361). (See section D.5.5.3.) The Central scenario represents an average of the two.

The forecasted use of microplastics takes into account the Cosmetics Europe recommendation to phase out the use of plastic microbeads with exfoliating or cleansing functions by 2020. It further takes into account the work of two opposing forces:

- Increased use of microplastics as a result of increased use of cosmetics based on population and consumer spending growth.
- Downward trend of use due to growing consumer awareness and concern with microplastics emissions to the environment.

As it is challenging to estimate the impact of consumer awareness on future use of microplastics in cosmetics, it is assumed that this downward trend is equal but diametrically opposite to the upward trend due to growth in population and consumer spending. The result of this assumption is no net change from 2020 levels to 2041: the end of the temporal scope of the analysis.

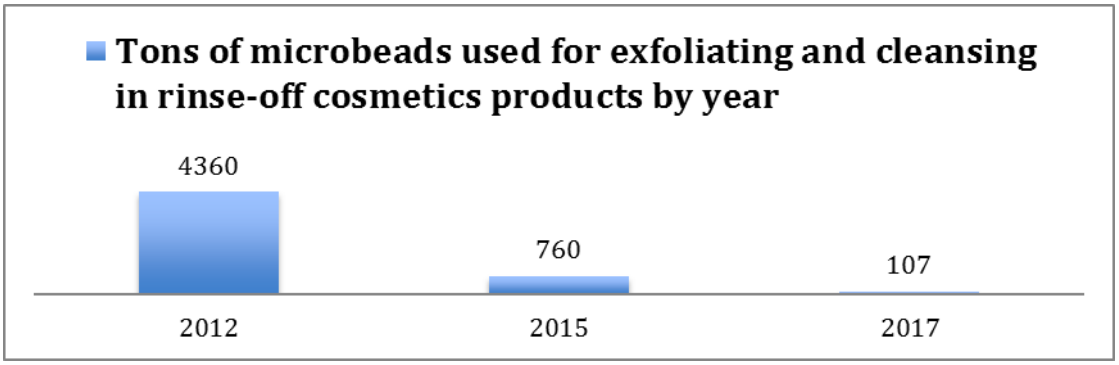
D.5.3. Rinse-off cosmetic products containing microbeads with exfoliating or cleansing functions

D.5.3.1. Uses, functions and alternatives

Cosmetic products containing microplastics (microbeads) with exfoliating or cleansing functions are a type of rinse-off cosmetic products intended specifically to remove dirt, unclog pores, or remove dead skin cells. These microplastics are also commonly referred to as plastic microbeads. The type of products with these functions include cleansing products (e.g., facial exfoliating products, face wash, soaps, make-up remover), shampoos, oral care (e.g., toothpaste, tooth whiteners) and others. Most of the microbeads are polyethylene but polyurethane crosspolymer – 1, poly lactic acid and nylon-11 are also used. (Table 52 and Table 54) According to DEFRA, polyethylene microbeads comprise more than 90% of microbeads used in cosmetics. (DEFRA, 2017) Typically they range between 1 µm and 5 mm. (CfE 2018)

In view of the increasing public concerns related to plastic litter in the marine environment, a number of companies took action to reduce the use of plastic microbeads for exfoliation or cleansing. This phase out accelerated with the 2015 Cosmetics Europe recommendation to replace plastic microbeads: "Cosmetics Europe recommended to its membership to discontinue, in wash-off cosmetic and personal care products placed on the market as of 2020: the use of synthetic, solid plastic particles used for exfoliating and cleansing (i.e. microbeads) that are non-biodegradable in the marine environment." For the purpose of the recommendation, wash-off product was defined as "a cosmetics product intended to be removed with water a short period of time after use, e.g. in a bath or shower" and a microbead as "an intentionally added, 5 mm or less, water insoluble, solid plastic particle used to exfoliate or cleanse in wash-off personal care products."[54] A rapid and substantial reduction in the use of plastic microbeads took place: 82% of the use was phased out between 2012 and 2015 and by two years later 97.5% were phased out. Figure 6 shows that the industry is "on track" to meet their objective for full phase out "ahead of" 2020,[55] with only 107 tonnes of microbeads still used in this product category in 2017. (CfE 2018).

Figure 6: Microbeads with exfoliating or cleansing functions used in rinse-off cosmetics



[54] https://www.cosmeticseurope.eu/news-events/reduction-use-plastic-microbeads downloaded on August 15, 2018.

[55] https://www.cosmeticseurope.eu/news-events/reduction-use-plastic-microbeads downloaded on August 15, 2018.

Source: CfE 2018

The phase-out of microbeads primarily with exfoliating and cleansing properties was further accelerated by the regulatory actions taken on national level in the EU and internationally. (See sections 1.1.3 and 1.1.4.) Uses of polymers meeting the criteria for microplastics outlined in the restriction proposal for other functions in rinse-off products (e.g., opacifying, sensorial) have not been included in the Cosmetics Europe recommendation and national bans, the UK action being a notable exception. (See Annex A for details on national regulations on microbeads.)

According to Cosmetics Europe (CfE 2018), for the exfoliating functions, ingredients are either solid, abrasive particles to mechanically remove dead skin or hydroxy acids to chemically enhance the shedding of dead skin cells. To be able to perform the mechanical exfoliation function, the ingredient needs to be able to retain its shape in the product and use, to have soft edges (to avoid damaging the skin), and it should be inert, non-sensitising and non-absorbent. Some of the alternatives are from natural plant or mineral origin (see Table 56) and as demonstrated by the significant phase out due to voluntary action, these alternatives are technically and economically feasible for the industry. As reported by (DEFRA, 2017), the cheapest (and most popular at the time of the introduction of the ban) substitute for plastic microbeads is silica, [56] with a base price of £7-10 per kilogram (£2-5 more expensive per kilogram than polyethylene microbeads), while natural alternatives could range up to £60 per kilogram. However, higher priced alternatives are assumed to be selected for substitution for reasons besides the microbeads ban (for example, in order to have a unique selling point for the product). There have been no reports of reduced quality or price increases for end-users, the latter being consistent with the industry model where the final price is driven primarily by brand image.

Table 56: Examples of potential alternatives to microbeads with exfoliating or cleansing function

• silica, incl. precipitated or hydrated • cellulose • corn or oatmeal • poppy seeds • almond or walnut or pecan shells • sugar (cyclodextrins) • pumice • cocoa beans • sea salt • citric acid	• apricot kernels • argan pit shells • wood dust • hydrogenated castor oil • jojoba beads or waxes • hydrogenated vegetable oil • beeswax • rice bran wax • castor oil • mica

[56] Recently, the SCCS released an opinion on nano safety of silica and is currently assessing its solubility https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_175.pdf

• rice nuts or barks/shells • pineapple/orange barks/shells • peach or rosehip seeds	• montmorillonite • bentonite • calcinated kaolin

Source: CfE 2018, various entries

Due to their normal occurrence in nature, it is expected that the transitioning to these alternatives will not result in a greater environmental burden in comparison to the use of synthetic polymers. Some concerns were raised related to eutrophication (similar to the effects known from excess fertilising and use of phosphate in detergents) from the use of ingredients with plan origin. (CfE 2018, #667) However, it is not expected that alternatives will be used in such quantities to lead to significant environmental problems.

Very few tonnes remain and are expected to be phased out by industry by 2020, i.e., prior to entry into force (EiF) of the proposed restriction (assumed to be in 2022) and there are a variety of alternatives to microbeads with exfoliating or cleaning functions. There are no reports of price increases of cosmetic products due to supply shortages, although it has been reported that certain natural alternatives (e.g., beeswax, walnut shells) can be susceptible to unstable supply (for example, due to a poor harvest) (DEFRA, 2017). However, no such reports have been found for others and in general, it is expected that the alternatives are available at the necessary quantities as the market has transitioned without significant disruptions.

In summary, stakeholders and EEA society as a whole are expected to react as follows prior to 2022 (i.e., prior to the assumed entry into force of the proposed restriction):

- EEA cosmetics industry to fully phase-out microbeads by 2020, transitioning primarily to natural (plant- or mineral-based) ingredients to derive other benefits in addition to the exfoliating or cleansing functions.
- Importers, given the growing interest for microbead-free products in the EEA and the increasing regulatory action at a national level, to have informed their international supply chains and repositioned to source alternative, microbead-free, products.
- Enforcement authorities to be ready to enforce an EU-wide restriction on the basis of the experience of several national authorities that currently have or are in the process to put in place bans. Member States with national bans have already began the development of analytical methods.
- Supply of technically feasible alternatives at affordable prices to continue EEA-wide. As cosmetics ingredient suppliers typically supply both plastic microbeads and their substitutes, the net effect on microbead suppliers is expected to be zero, assuming similar profit margins (DEFRA, 2017).
- Consumers to continue to enjoy access to the same quality cosmetics with exfoliating or cleansing functions at similar price levels, as the cosmetics industry is highly competitive and prices of final products are dependent on variety of factors, the main being brand image. No issues have been reported to date with the quality of products using alternatives to plastic microbeads and such are not expected in the future given the small volume remaining to be substituted.

- Emissions to the environment to have gradually been eliminated by 2022 or sooner. Therefore, impacts on the environment and human health (via the environment) from plastic microbeads with exfoliating or cleansing function are also expected to have been eliminated.

As it is expected that stakeholders will be prepared to comply with a ban on uses of microbeads with exfoliating or cleansing functions prior to 2022, an EU-wide action, if proposed to enter into effect at that time, will not require a transitional period and will ensure that microbeads for these uses are not used in the future.

D.5.3.2. Economic and other impacts

As demonstrated by the progress of the voluntary action led by Cosmetics Europe, technically and economically feasible alternatives to plastic microbeads are available and their use is expected to be largely phased out prior to the entry into force of the proposed restriction. The results in Figure 6 represent primarily larger companies (manufacturers, exporters, importers, and distributers), including 15 among the 21 of the world's biggest cosmetics companies. (CfE 2018) The results are seen as representative of the EEA situation as the sector is otherwise comprised of small companies (98% are SMEs according to Cosmetics Europe and Euromonitor International 2016), which are unlikely to be using plastic microbeads, since these manufacturers tend to focus on boutique or artisanal products (DEFRA, 2017).

In addition to the voluntary phase out of microbead use in cosmetics, as discussed in sections 1.1.3 and 1.1.4., a number of EU and international jurisdictions have introduced or plan to introduce national bans. As noted by CfE 2018, companies tend to phase out microbeads for all markets.

The type of economic costs that have been considered to be borne by industry as a result of national bans include material and enforcement agency costs. However, for example, for the UK ban, the following costs were not considered:

- Reformulation costs: industry consultations revealed that companies have been able to phase out microbeads at no additional cost because reformulation and relabelling of cosmetics is a routine process that takes place periodically and the timescale of the ban gave manufacturers time to reformulate their products as normal;
- Machinery and equipment;
- Reduced product shelf life: replacing microbeads with a natural alternative could reduce product shelf life (from 10 years to between 1-2 years). However, this effect is assumed to have no additional cost since products are not expected to remain on shelves for that length of time;
- Impacts on suppliers of microbeads: Cosmetics ingredient suppliers in the UK typically supply both plastic microbeads and their substitutes. Therefore, assuming similar profit margins, the net effect on microbead suppliers is assumed to be zero (DEFRA, 2017).

No other costs, such as loss of product quality, industry administrative costs, effects on employment or other social costs, were seen as likely for industry and society as a whole to comply with the UK ban.

Therefore, while it can be expected that some companies will incur additional costs to

transition to alternatives, it is unlikely that these costs can be associated with the proposed restriction, given the significant substitution (anticipated full substitution by 2020, or two years prior to the anticipated entry into force of the proposed restriction) due to the concerted industry voluntary action to substitute the use of microbeads with exfoliating or cleansing function, as well as bans on the use and marketing in several Member State and international jurisdictions. (See Annex A) Even if no further substitution occurs, i.e., the historical downward trend of microplastics use does not continue, it is more likely that in the event of the restriction the market share of these remaining uses is taken over by microbeads-free products (within the existing capacity of the industry) as their share is currently very high (in excess of 97.5%). Therefore, no net reformulation or profit losses (assuming the profit margin is the same for microbead-containing and microbead-free products) or other impacts are likely in this scenario.

This conclusion is supported by information in CfE 2018. Cosmetics Europe expressed support for a ban on plastic microbeads for exfoliation and cleansing in rinse-off products by 2020, as a "scenario in line with the industry voluntary measures and existing national bans, and will bring benefits to society at reasonable costs for industry, as alternatives do exist and are being implemented" and they are "already replaced with alternatives that guarantee a similar level of performance."

D.5.3.3. Proportionality

It is anticipated that the remaining companies who have not yet phased out microbeads with exfoliating or cleansing functions, will do so before the entry into force of the proposed restriction. This is primarily driven by industry action but also due to the need to access several EU (and international markets) that have banned these microbead uses. Therefore, it can be inferred that the emissions reduction (and therefore, the risk reduction capacity and overall benefits) as well as the costs to society from the introduction of this restriction measure would be minor. The substantial substitution to date, which is expected to be completed by 2020, (in excess of 97.5% decline between 2012 and 2017) demonstrates that the transition to alternatives is affordable to industry and consumers.

D.5.4. Other rinse-off cosmetic products

D.5.4.1. Use and function of microplastics

This group of cosmetic products includes all remaining rinse-off products other than those described in the preceding section (i.e., containing microplastics with characteristics in the scope of the proposed restriction that perform functions other than exfoliating or cleansing), e.g., conditioners (other than leave-in conditioners), hair colouring products, bleach for body hair products, hair (nourishing) masks, etc. but also shampoos, soaps, etc., which contain microplastics with functions other than exfoliating or cleansing. The main function that microplastics perform in other rinse-off cosmetics is opacifying. Microplastics which perform this function are made of styrene acrylate copolymer (SAC), a synthetic polymer typically used in its solid state with particle size of less than 1 mm. (See Table 54 for other examples.) Similar to other cosmetic ingredients, SAC has co-benefits such as sun protection and ensuring longevity of the final product due to its ability to modify light transmission in the product package. (ECHA WM 2018) Opacifiers make formulae less transparent, giving them a richer and creamers (milky) appearance. The ideal substitutes are stable and have good compatibility with the

formulation and the ability to modify light transmission. Other polymer particles reportedly used in this group of rinse-off products include polymethylmethacrylate, polyamide (nylon) 6, polyamide (nylon) 12, polyethylene terephthalate, other polyacrylates/acrylates copolymers, and polymethylsilsesquioxane (CfE 2018). They can be used as binders or for other sensorial functions (CfE, AI 2018).

The average concentration of microplastics in cosmetics is about 3.5% (CfE 2018, ECHA consultation 2019, #2220), but they can be used in much smaller or larger quantities. Some reports have brought to light the fact that some cosmetics contain as much plastic added as ingredients as the plastic they are packaged in (UNEP 2015). ECHA consultation 2019 informs that a facial cream containing approximately 0.68% w/w of polyethylene contains approximately 1.48 million particles with a diameter varying between 1.6 and 103 µm (ECHA consultation 2019, #2075). Other submissions stated that the concentration of microplastics in rinse-off cosmetics could range from 0.01% to 2% w/w (ECHA consultation 2019, #2107, #2256, #2259, #2266, #2492, #2726).

Typically, rinse-off cosmetics contain only one microplastic ingredient (more than 99.5% of rinse-off products) (CfE 2018), although an analysis of the CosmEthics database revealed that up to five polymeric ingredients may be present in some rinse-off cosmetics.[57] These microplastic-containing cosmetics are intended to be washed off after/during use, discharged to wastewater and ultimately released to the environment following several possible pathways. (See introduction to Cosmetic products section.)

D.5.4.2. Alternatives

It is more difficult to answer whether there are alternative ingredients to microplastics in the high number of other rinse-off (and also leave-on) cosmetic formulations (in total exceeding 400 000 on the EU market, EC 2008), as described below, drop in substitutes are not known at moment for all formulations on the market. However, alternative ingredients of natural origins have been reported as well as some suppliers and manufacturers have announced development of biodegradable alternatives.[58] Bertling et al. (2018) reviewed the CosIng[59] database for non-polymeric cosmetic ingredients.[60] The authors of the study and the Dossier Submitter postulate that the share of non-polymeric substances on the CosIng database is an indication for the ease of substitution of polymers used in cosmetics. Out of all substances in the database, polymers represented less than 20% of all substances listed in the majority of the cosmetic function categories. Those include the main function of polymers in rinse-off products: opacifying but also:

[57] Although it is uncertain to what extent all polymers included in the CosmEthics database meet the definition for microplastics for the purpose of the proposed restriction.

[58] E.g., https://www.henkel.com/sustainability/positions/microplastics; https://www.roelmihpc.com/portfolio/celus-bi-feel/ ; Ecocert/COSMOS standard has certified in excess of 2000 ingredients that do not contain synthetic, or chemically modified agricultural products: https://www.ecocert.com/en/certification-detail/natural-and-organic-cosmetics-cosmos

[59] https://ec.europa.eu/growth/sectors/cosmetics/cosing_en

[60] Out of the 28 357 substances on the CosIng database, respectively 964 and 2 298 met the search terms used "polymer" or "poly". Mikroplastik und synthetische Polymere in Kosmetikprodukten sowie Wasch-, Putz- und Reinigungsmitteln. Endbericht. Bertling, Jürgen; Hamann, Leandra; Hiebel, Markus. Fraunhofer-Institut für Umwelt-, Sicherheits- und Energietechnik UMSICHT. 2018

binding, emulsion stabilising, nail conditioning, stabilising, depilatory, antifoaming, absorbent, gel forming, plasticiser, anticaking, hair waving or straightening, solvent, bulking, antistatic, humectant, chelating, antiseborrhoeic, cleansing, foam boosting, UV filter, hydrotrope, cosmetics colorants, abrasive, antioxidant, oral care, UV absorber, antidandruff, antimicrobial, deodorant, antiperspirant. The functions for which polymers represent more than 80% of all substances listed are: film forming (which is derogated via paragraph 5b in proposed wording of the restriction) or skin conditioning function. Polymers represent between 20% and 50% of the substances listed on CosIng to perform the following functions: emulsifying, hair fixing, viscosity controlling, surfactant, hair conditioning, and emollient. As stated previously, not all polymer uses in cosmetics meet the microplastic definition; therefore, these percentages represent an overestimation of the share of microplastic ingredients per cosmetic function.

Furthermore, a number of certification programs focusing on natural and organic cosmetic products demonstrate the availability of microplastic-free products in all rinse-off (as well as leave-on) categories of cosmetic products, although the slight differences in definitions do not ensure that all products bearing these certificates automatically meet the obligations of the proposed restriction. These include: EU Ecolabel (rinse-off only), Nordic Swan Ecolabel, NATRUE, Look for the Zero/Zero plastic inside (Beat the Microbead), Ecocert and COSMOS standards.[61]

In addition, a number of organisations track ingredients of cosmetic products, including those that contain (or do not) polymers: e.g., CosmEthics, Plastic Soup Foundation,[62] Que Choisir and Forbrugerrådet Tænk. Although not all polymers meet the definition of microplastics, a survey of these databases shows a large number of products, in all rinse-off (and leave-on) categories that do not contain in excess of 500 polymers. (See Table 57, Table 61, and discussion below.) There are a high number of cosmetic products on the market, in all rinse-off (and leave-on categories) that do not contain any polymers, including those that may meet the microplastic definition. As shown in Table 57 even in the case when it is assumed that all 520 polymers fall within the scope of the proposed restriction, there are products on the market that do not contain microplastics. Alternative products (i.e., cosmetic products that do not contain microplastics according to the definition of the proposed restriction) represent between 70% and 90% (respectively based on the 520-polymer and 19-polymer scenario) of the rinse-off cosmetic formulations (estimate based on CosmEthics database).[63] Polymer-free products represent a substantial number of cosmetics in each product category on the EEA market. The hair removal category has the lowest number of polymer-free products (65%) under the 19-polymer scenario, while the exfoliators category has the lowest share under the 520-polymer scenario (42%). These figures are likely an underestimation as polymers used in cosmetic products may be in liquid form, may have

[61] ; http://www.nordic-ecolabel.org/product-groups/group/?productGroupCode=090 ; https://www.natrue.org/our-standard/natrue-criteria-2/ ; https://www.beatthemicrobead.org/zero-products/ ; https://www.ecocert.com/en/certification-detail/natural-and-organic-cosmetics-cosmos

[62] https://www.beatthemicrobead.org/product-lists/

[63] Each unique barcode is assumed to represent a separate formulation, although some products change their barcodes over time and very similar products, e.g., deferent shades of make-up, are identified with unique barcodes. As no information on the market share of the numerous cosmetics formulations is available, each product with unique barcode is assumed to have an equal share of the market.

a film forming function[64] or may not meet the microplastic definition at point of use or release for other reasons and therefore, do not fall in scope of the proposed restriction. Furthermore, the data contains historical information on use of microbeads with exfoliating or cleansing functions. They were included in the analysis of other rinse-off cosmetics as microplastics may still be present in the product for the purpose of other functions. On the other hand, the analysis of alternatives of microplastics may be overestimating the number of alternatives as there may be other polymers that have not been included in this list, e.g., some chemically modified natural polymers. (See Table 57 for further detail.)

Many of the alternative microplastic ingredients in cosmetics are of natural (plant or mineral) origin. For example, starch, xanthan or guar gum, carrageenan, alginates, polysaccharides, pectin, gelatin, agar, and cellulose derivatives can be used as thickening agents, while examples for hair care include polysaccharides, such as starch and cellulose derivatives, natural gums, and hydrolysed proteins (cosmeticsinfo.org, 2018).[65] Other reported natural ingredients include dextrin for adhesives and guar as emulsifier or emulsion stabiliser (Abrutyn, 2013). These natural ingredients are reportedly priced (sometimes significantly) higher than microplastics.

Due to their normal occurrence in nature, it is expected that the transitioning to alternatives to microplastics of natural origin will not result in a greater environmental burden in comparison to the use of synthetic polymers. Some concerns were raised related to eutrophication (similar to the effects known from excess fertilising and use of phosphate in detergents) from the use of ingredients with plant origin (CfE 2018, #667). However, it is not expected that alternatives will be used in such quantities to lead to significant environmental problems (as estimated, about 3 100 tonnes are released in the environment annually under the central scenario). Other concerns were raised by stakeholders that liquid polymers may pose similar environmental concerns as microplastics (ECHA consultation 2019).

Table 57: Share of formulations not containing polymers: other rinse-off cosmetics

Cosmetic product	**Proportion not containing polymers**	
Subcategory	**19-polymer (Low scenario)**	**520-polymer (High scenario)**
Baby wash	88%	75%
Bath foam/oil/salt/	84%	75%
Body wash	75%	53%
Cleansers*	93%	68%
Cleansers/Scrubs*	77%	53%
Conditioner	100%	91%

[64] The vast majority of polymer ingredients are not plastic but are in liquid or other form(cosmeticsinfo.org, 2018). Many polymers used in cosmetics are water soluble or water dispersible. (UNEP 2015)

[65] Downloaded on 17/08/2018.

Cosmetic product	Proportion not containing polymers	
Subcategory	**19-polymer (Low scenario)**	**520-polymer (High scenario)**
Exfoliators*	70%	42%
Exfoliators/Body scrub*	73%	51%
Foot scrubs*	80%	53%
Foot wash/bath	100%	92%
Hair colour	96%	49%
Hair removal*	65%	49%
Hand wash	78%	66%
Intimate care	95%	84%
Make up remover	99%	80%
Mouthwash	100%	97%
Shampoo	92%	65%
Shaving foam	97%	76%
Shaving gel	99%	72%
Shower gel	86%	46%
Soap	100%	92%
Soaps	94%	89%
Toothpaste	99%	91%
Total Rinse-off	**89%**	**69%**

Notes: Table assumes that polymer use is equivalent to microplastic use. Based on historic data. Exfoliating & cleansing functions (marked with *) have not been excluded from Rinse-off averages, as they may contain microplastics with other functions.

Source: CosmETHICS database. Results consistent with Que Choisir (France) and Forbrugerrådet Tænk (Denmark). The percent of formulations does not reflect market share in the EEA.

D.5.4.3. Overview of restriction response and restriction scenarios

In summary, stakeholders and EEA society as a whole are expected to react as follows to the proposed restriction on microplastics in other rinse-off cosmetic products:

- For the majority of rinse-off subcategories, where microplastic-containing products represent less than 30% of the market, the alternatives are expected to take over their market share and very few of these products are expected to be reformulated (assumed 5%). Given the large share of alternatives on the EEA market, it is expected that this will occur within the existing manufacturing capacity; therefore, the transitioning to alternatives for these product categories

is expected to lead primarily to higher material costs (due to price premium of alternatives ingredients in comparison to microplastics). These costs are unlikely to be passed on to end consumers and are likely to constitute loss of producer surplus. (See below for further detail.) Assuming similar profit margin, the profit losses of discontinued microplastic-containing rinse-off products are expected to be compensated with gains from manufacturers of microplastic-free products.

- For 11 rinse-off product categories,[66] where the microplastic-containing products represent between 30% and 70% of all products in the worst-case scenario (but all except Hair removal products represent less than 30% in the Low scenario), EEA cosmetic companies currently using microplastics to reformulate about half of their products using alternative to microplastic ingredients. The remaining 50% of formulations containing microplastics are expected to be discontinued and their market share is expected to be taken over by alternatives.[67] This is similar to the experience with reformulations for microbeads with exfoliating functions, where less than 50% of formulations were reformulated and the remaining were discontinued and replaced by other products (CfE AI, 2018). This response is likely to result in higher material costs for formulators, in addition to reformulation costs. Similarly, no net profit effect is expected for discontinued products assuming similar profit margins for microplastic and microplastic-free cosmetics.
- The anticipated reformulation and higher material costs for industry are unlikely to be passed on to consumers as end-user pricing of cosmetics is primarily determined by brand image (ECHA WM, 2018).
- Importers to inform their international supply chains and to reposition to source alternative, microplastic-free, products. This is expected to require fewer than four years.
- Existing stocks to be depleted. It is anticipated that three years will be sufficient as a typical shelf life of cosmetics products is 30 to 36 months (CfE 2018).
- Stocks of obsolete labels to be depleted and new labels to be aligned with requirements of the proposed restriction and other relevant EU legislation. It is anticipated that four years will be sufficient as it is likely that new labelling may need to be produced in the meantime due to other regulatory requirements or due to other changes in the product formula. (See frequency of minor and major reformulations under Baseline reformulation assumptions.)
- Enforcement authorities to be prepared to enforce an EU-wide restriction. This is

[66] Body wash, cleansers/scrubs, cleansers, exfoliators, exfoliator/scrubs, foot scrubs, hair colours, hair removal, hand wash, shampoos and shower gels. Under the worst-case scenario (in terms of polymer particles falling in scope), exfoliators is the category of rinse-off products with the highest share of microplastic-containing products, i.e., 58% (CosmETHICS). The results are based on historical information and it is likely that the share of polymer-containing products has decreased with the phase out of microbeads for exfoliating or cleansing purposes. These products were including also in other rinse-off products, however, as they are possible to contain other polymers performing functions other than exfoliating or cleansing.

[67] Biodegradable alternatives with opacifying functions are already under development: https://www.henkel.com/sustainability/positions/microplastics

expected to require less than four years, as authorities can build on the experience of several national authorities that currently have or are in the process of putting in place bans on microbead use.

- The quality of some cosmetic products to be affected but this is expected to be acceptable for many consumers as they value products with lower impact on the environment.
- Emissions to the environment to have gradually been eliminated by 2026 or sooner. Therefore, impacts on the environment and human health (via the environment) from microplastics in other rinse-off cosmetics are also expected to have been eliminated by that time, except those occurring due to existing stock accumulated in the environment due to historical uses.

Transitional period

As shown in this section, reformulations are expected to constitute the largest impact of the proposed restriction (other than the impact on the environment), requiring considerable time and other resource investment. Therefore, aligning the transitional period of the proposed restriction with the reformulation time required by industry would minimise the economic, social and distributional impacts of the restriction on society. On the other hand, each additional transitional year of the restriction would lead to further releases of microplastics, increasing the environmental pressure from their rising stock in the environment. Therefore, unnecessary delays in the effective application of the proposed restriction are undesirable. Industry has suggested that on average it would take approximately five years to reformulate rinse-off and leave-on products, stressing the higher complexity of leave-on reformulations. Also, a voluntary phase out of more than 97% of plastic microbeads has taken less than 5 years (CfE 2018). The typical reformulation process has been reported to take 2.5-4.5 years (cosmeticsinfo.org, 2018);[68] however, industry has stressed that this is the situation when suppliers of cosmetic ingredients are familiar with the available alternatives (as typically they supply both microplastics and their alternatives), while this may not be the case for all microplastic functions in cosmetics (CfE 2018, industry interviews). Therefore, it is assumed that industry will be able to complete reformulations within four years. Much less time is likely needed for the remaining stakeholders to comply with the restriction (e.g., enforcement authorities).

The sections below provide further detail on the likely response to the proposed restriction on rinse-off cosmetics, quantify this response where possible and justify the proportionality of the proposed action with a four-year transitional period.

Restriction scenarios and key assumptions

On the basis of the available information on the specificities of the market segment of rinse-off cosmetics, the use of microplastics in these products and the anticipated reactions of stakeholders, three restriction scenarios are developed to assist with the

[68] https://www.cosmeticsinfo.org/product-reformulation. The reformulation process is described capturing the following activities: 12-18 month for raw material research and development, 6-12 months product testing and qualification, 6-12 months safety and regulatory requirements, 6-12 months manufacturing and marketing, post-market surveillance and evaluation.

assessment of the impacts of the proposed restriction on EEA society. They are summarised in Table 58. Where appropriate (due to market specificities and data availability), the approach for the scenarios builds on the methodology and assumptions made for estimating impacts of similar restrictions, e.g., the proposal for a restriction on the use of D4/D5 in wash-off cosmetic products submitted by the UK in 2015 (UK Health and Safety Executive, 2015) and subsequent SEAC opinion (ECHA, 2016b) and has been coordinated with other ongoing regulatory activities (i.e., the proposed restriction on D4/5/6 in variety of consumer and professional products).

Table 58: Restriction scenarios: Summary of assumptions used in impact assessment of rinse-off cosmetic products

Impact category	Low scenario	Central	High scenario
Tonnes of microplastics used	2 900 tonnes (assuming 19 polymers in scope, see Table 55)	6 500 tonnes	10 000 tonnes (assuming 520 polymers in scope, see Table 113:)
Number of reformulation	300 (estimated based on Cosmetics Europe number of reformulations & availability of alternatives data, i.e., as number of alternatives is >70%, only 5% of reformulations will take place)[69]	8 800	17 400 (estimated based on total formulations on EEA market & availability of alternatives data, i.e., - number of alternatives is >70%, only 5% of reformulations will take place; - number of alternatives is >30% but < 70%, 50% of reformulations will take place)[70]
Price premium for materials	€650/tonne		
Costs per reformulation	€365 000 per major & €36 500 per minor reformulation (case) for large companies. €42 000 per major & €4 200 per minor reformulation (case) for SMEs (accountable for 50% of reformulations)		
Baseline reformulations	Coordination with major (during transitional period + five years) & minor (during transitional period) reformulations		
Other impacts	Negligible as number of alternatives is high	Negligible	Negligible as number of alternatives is high
Uncertainties (impact on restriction costs)	- likely more polymers fall in scope (↑) - based on historical data: exfoliating & cleansing functions have not been excluded (↓) - increase or decrease of microplastics used & emitted (↑↓) - assumes Cosmetics Europe data comprises of data on large companies only, they represent 50% of microplastics use (↓)	Mid-point between Low & High scenario	- several products are likely to represent one reformulation case (↓) - - based on historical data: exfoliating & cleansing functions have not been excluded (↓) - increase or decrease of microplastics used & emitted (↑↓) - some uses may not meet the microplastic definition at point of use/release or can meet the biodegradability criteria and are therefore out of scope, e.g., liquid or water soluble polymers (↓) - other polymers may also fall in scope, e.g., some chemically modified natural polymers (↑)

Restriction induced reformulations and tonnages of microplastics impacted

The three restriction scenarios primarily differ in terms of the assumptions used to

[69] Under the low scenario, hair removal are the rinse-off product category with the highest share of products containing microparticles of the polymers assumed to fall in scope, i.e., 35% (CosmETHICS).

[70] Under the high scenario, exfoliators are the rinse-off product category with the highest share of products containing microparticles of the polymers assumed to fall in scope, i.e., 58% (CosmETHICS).

estimate the number of induced incremental reformulations and the tonnages of microplastics used that will have to be replaced by alternatives as a result of the proposed restriction.

The starting point for the Low scenario is the information provided by Cosmetics Europe based on a survey of their membership on the number of reformulation cases and tonnages microplastics impacted by a restriction on solid and semi-solid particles of 19 polymers (Table 52). The estimates were doubled to produce an overall estimate for the EEA cosmetics industry, based on the assumption that the Cosmetics Europe survey estimates represent approximately 50% of the market. The stakeholder notes that "this is a very conservative approach and in doing so it is likely to overestimate the total […] in the whole EEA sector." (CfE 2018) As noted earlier, SMEs (under-represented in the Cosmetics Europe survey)[71] are less likely to use microplastics in their products as they tend to focus on niche products. Although some SMEs were included in the survey, for simplicity, the Dossier Submitter has assumed that the reformulations reported by Cosmetics Europe are reformulations for large companies only, and therefore, the average costs per reformulation for large companies was applied to 50% of the estimated reformulations. The estimates for number of reformulations and tonnages microplastics to be phased-out were adjusted to exclude those associated with the film forming functions of the microplastics, which are outside the scope of the proposed restriction (CfE 2018). These possible reformulations were allocated by product category based on information of the share of microplastic-containing products within a product category of total microplastic-containing cosmetics in the CosmETHICS database.

The tonnes impacted by the proposed restriction under the Low scenario are estimated in a similar way: based on information from Cosmetics Europe, excluding those associated with film forming functions (CfE 2018, entry #x).

The starting point for the estimation of the number of possible reformulations and tonnes microplastics to be phased-out under the High scenario is information on the total cosmetic formulations on the EEA market: 430 000. The estimate is based on information from a European Commission impact assessment report on the simplification of the Cosmetics Directive (European Commission, 2008), updated based on the current number of large companies and SMEs (Cosmetics Europe, 2018). These formulations were allocated by product category based on information of the share of microplastic-containing products within a product category of total microplastic-containing cosmetics in the CosmETHICS database. The tonnes impacted by the proposed restriction under the High scenario are estimated based on information from Cosmetics Europe about the amount of microplastics used per formulation (CfE 2018) and subsequently applying this number to the resulting estimated number of reformulations.

Experience from the phasing out of microbeads with exfoliating and cleansing functions showed that less than half of expected reformulations took place, with the remaining products being discontinued or replaced by other products (CfE AI 2018, #6). The

[71] 20 out of 56 respondents are SMEs, or 36%. In comparison, 98% of the cosmetics sector are SMEs (5 500), majority of which are micro companies with less than 20 employees (ECHA CfE 2018, CE 2018, European Commission (2008)). Of the remaining companies surveyed by Cosmetics Europe, 15 companies are among the biggest 21 companies in the world (ECHA CfE 2018, ECHA consultation 2019, #2220). The total surveyed companies by Cosmetics Europe is estimated to represent 1% of the total number of cosmetics companies.

Dossier Submitter has assumed that the number of alternatives can be a suitable predictor whether reformulations would take place, as it is assumed that if there is already a critical mass of alternatives on the market, they would be better positioned to compete for consumer demand. Therefore, it is assumed, in both the Low and High scenario, that:

- very few reformulations will take place (5%) in product categories where non-microplastic containing products represent a majority (more than 70%);
- half of the reformulations will take place in product categories where non-microplastics represent more than 30% but less than 70%;
- almost all of the anticipated reformulations (95%) will take place in product categories where microplastic-free cosmetics represent a small number of the product category (30% of less). This last assumption is not applicable for rinse-off products, as even in the worst-case scenario, the alternatives represent more than 42% of the product category. (See Table 57.) This assumption is, however, used for leave-on products groups.

This approach does not take into account other factors that may impact the company's decision to reformulate a product to comply with regulatory action or to discontinue its placing on the market. These could include market share, product profit margin, overall profitability, market strategy, experience with substitution, etc. The approach however recognises events from the recent substitution of microbeads in exfoliating or cleansing products where less than 50% of the microbead-containing products were not reformulated (ECHA C4E 2018, ECHA consultation 2019, #2220).

Although some of the assumptions may lead to overestimation of the number of reformulations and tonnages of microplastics impacted by the proposed restriction (e.g. inclusion of historical information on exfoliating/cleaning functions, assuming similar share of reformulations undertaken by SMEs although they were underrepresented in the Cosmetics Europe survey), the Low scenario is viewed by the Dossier Submitter as a low bound of the possible impacts of the proposed restriction as it is likely that a larger number of polymer microparticles would be impacted than the 19 surveyed by Cosmetics Europe.

Similarly, although some of the assumptions may lead to underestimation of the impacts of the proposed restriction (e.g., some chemically modified polymers may not be captured), the High scenario is viewed by the Dossier Submitter as a high bound of the possible impacts of the proposed restriction primarily because it is likely that many of the polymer uses may fall outside the scope of the proposed restriction (e.g., those in liquid state or with film forming functions).

Therefore, it is expected that the Central scenario, which represents an average of the Low and High scenarios and therefore, inherently reflects some of their deficiencies, can give an order of magnitude estimate of the anticipated impacts of the proposed restriction.

Reformulation costs

Essential function:

Synthetic polymers are high performance cosmetic ingredients and often, a small quantity is required to perform key functions. Therefore, it is assumed that microplastics

are an essential ingredient in cosmetics formulations and their substitution requires substantial modifications of the cosmetics formulae.

Difficulty to reformulate:

Reformulating cosmetic products has several specificities that can lead to challenges when reformulating products containing microplastics. The industry does not replace individual substances but in most cases, mixtures, each with a specific cosmetic function. This means that a single substance targeted by a restriction can be a key component of several mixtures. As a result, replacing a substance means replacing several raw materials with a specific function. In addition, the highly competitive nature of the industry has led to many formulators being protected by patents, therefore, one alternative may not "fit all". An alternative will only be available to the cosmetics manufacturer that has patented it in a specific formulation and/or has an exclusive contract with the individual supplier. This may mean that suppliers will need to create not one alternative, but a family of alternatives per function. (ECHA WM, 2018)

According to Cosmetics Europe (CfE 2018), industry has a limited choice of raw materials, as innovation on ingredient level has been limited. "With the implementation of the Cosmetics Regulation in 2013 and, the ban on animal testing for cosmetics, coupled with a very slow path of developing and validating alternative testing methods, the industry's ability to complete a state of the art toxicological evaluation of new cosmetics ingredients has been limited, especially for ingredients that have the potential to become systematically available." As a result, the "cosmetics industry depends on its suppliers for the identification of potential alternatives to microplastics [… and to] evaluate whether they perform in the products and can become confirmed alternatives." (CfE 2018)

Costs per reformulation:

UK Health and Safety Executive (2015) presents an extensive review of available information on reformulation costs and common practices of reformulation in the cosmetics sector. The intent is not to repeat the same review; therefore, the approach taken is similar to that supported by SEAC after the evaluation of the UK proposal (ECHA, 2016b) and with the assumptions in the recently submitted ECHA dossier, proposing a restriction on D4/5/6 in variety of consumer and professional products. This is done to the extent there is similarity in the socio-economic factors influencing the impacts of a restriction on microplastics with those of a restriction measure on D4/5/6.[72]

In summary, it is assumed that the costs for major reformulations of cosmetics products (cases) are €365 000 for larger companies (in this particular case those as assumed to represent about 50% of the forecast reformulations, similar to the assumed by Cosmetics Europe, although the association also represents some SMEs) and €42 000 for the remaining industry comprised primarily of SMEs (more than 98% in the whole sector, according to Cosmetics Europe and Euromonitor International 2016). These represent the

[72] The costs per reformulations used in the UK proposal build on information gathered in RTI 2002. The study identifies the following stages of the reformulation process and includes estimates for each of these stages in the overall reformulation estimate: idea generation, product development (research, development, coordination activities: purchasing, legal, marketing, quality control), product testing (safety and shelf-life studies), packaging development, and production/ manufacturing (change process, plant trial, start-up and verification).

central values used in the UK Annex XV proposal for D4/D5 in wash-off cosmetics (UK Health and Safety Executive, 2015), updated using CPI to 2017 price levels. This report also assumes that minor reformulations are 10 times less costly than major (UK Health and Safety Executive, 2015, ECHA, 2016b).

Calculations based on industry R&D spending suggest that these costs per reformulation may be overestimated. According to EuroStat, the cosmetics industry spent €1.3 billion on R&D in 2014. Cosmetics Europe (2018) assumed that spending on R&D is approximately 5% of industry turnover, resulting in €2.35 billion in 2017. Assuming that all R&D is used for reformulation (i.e., excluding new product development), that minor reformulations are about 10 times less costly than major reformulations, and the same share of annual major and minor reformulations as reported by the UK Health and Safety Executive (2015)(every year 5% of formulations undergo major reformulation and 15% undergo minor ones, see below for details), the cost per minor reformulation is between €4 700 to €8 400 and for major: between €47 000 and €84 000. The experience from companies replacing microbeads with exfoliating/cleansing functions suggests that costs per reformulation were about twice this upper range but still less than 40% than the costs per major reformulation used in the restriction proposal for D4/D5 in wash-off cosmetic products (CfE AI 2018, #6).

Industry has argued that reformulation of microplastic-containing products is difficult and time and other resource intensive; therefore, suggesting that the costs per reformulation will be €1 million (CfE 2018), although this is an average value for leave-on cosmetics as well, which tent to be more complex. As shown above, this estimate is considerably higher than the average costs per reformulation for industry in the past.

Therefore, the Dossier submitter proposes to use the average values per reformulation used in the UK restriction proposal for D4/D5 in wash-off cosmetic products adjusted for inflation to 2017 values: €365 000 per major reformulation for large companies and €42 000 for small. This is in recognition of the difficulty to reformulate (also noted in by the UK) and for consistency with similar assessments. The Dossier Submitter recognises that it is possible that some reformulations may involve higher costs (e.g., due to complexity and the need to reiterate some reformulation stages) but also some that may have lower costs due to increased experience to reformulate. While this may be recognised to a certain extent in the Low scenario, declining reformulation costs with experience has not been factored in the High scenario. Therefore, also taking into account demonstrated industry averages, it is unlikely that on average the reformulation for the industry would significantly exceed the selected average values.

Linkages to other regulatory actions:

A restriction on the use of D4/5/6 in various consumer products, including cosmetics is also proposed. Between 10% (rinse-off, 30% leave-on) of all cosmetic products contain both microplastics and D4/5/6 (19-polymer scenario). The presented estimates in this restriction dossier see the impacts of the restriction in isolation as under the baseline scenario only planned regulatory actions are considered. In the event both restrictions enter into force as proposed, industry would likely approach the reformulation of the products at the same time to comply jointly with the proposed restrictions. This would likely result in lower total reformulation costs than the sum of estimated for microplastics and D4/5/6 separately as it can be expected that some reformulations can be approached at the same time, and thus, leading to lower total number of reformulations

and lower total reformulation cost. On the other hand, the complexity of these reformulations may increase, leading to higher resource requirements. As the overlap between the two restrictions is primarily for leave-on cosmetics,[73] this issue is more relevant for that market segment.

Incremental reformulation costs:

This analysis recognises that the cosmetics industry is highly innovative and R&D/reformulations are undertaken on annual basis to ensure the product portfolios on the market respond to the latest market demands and advancements in the industry. While there are different tendencies and resource allocation to R&D in larger and smaller companies (reflected in the assumptions for costs per reformulation), on average it is assumed that every year 5% of formulations undergo major reformulations and 15% undergo minor ones. These assumptions are in line with the UK restriction proposal for D4/D5 in wash-off cosmetic products (UK Health and Safety Executive, 2015, ECHA, 2016b) and the ECHA restriction proposal for D4, D5 and D6 in consumer and professional products.

Also broadly in line these assessments, it is assumed that it would be possible to coordinate some of the reformulations required to comply with the proposed restriction on microplastics with those that would already have happened under the business as usual scenario (i.e., baseline reformulations). Specifically:

(i) baseline major reformulation that would have taken place during the transitional period would be coordinated with removal of microplastics and therefore, there would be no additional costs as a result of the restriction.
(ii) baseline major reformulation that would have taken place five years after the end of the transitional period would be coordinated with removal of microplastics and therefore done earlier, during the transitional period. Thus, the restriction cost would consist of the costs of bringing those reformulations forward in time.
(iii) baseline major reformulation that would have taken place six years or more after the end of the transitional period would not be coordinated with removal of microplastics. Coordination would be unlikely, as it would be difficult to anticipate market demands that far in advance. Therefore, for these products, the full cost of an additional reformulation would be incurred as a result of the restriction.

Furthermore, it can be expected that baseline minor reformulations that would have occurred during the transitional period likely would not take place, i.e., they would be in a way 'saved', as they would be incorporated into the major reformulations to phase out microplastic use. Therefore, the costs of reformulations to comply with the proposed restriction can be reduced with the costs of these baseline minor reformulations. The schedule of minor reformulations would then continue as usual after the transitional period.

Material costs

For the purpose of this analysis, the Dossier Submitter is using the assumptions provided

[73] The restriction on D4/5 in rinse-off cosmetics is to take effect from 31 January 2020.

by industry: one-to-one substitution and a 50% price premium (CfE 2018). However, this may not be applicable to all substitutes. Synthetic polymers are high performance cosmetic ingredients and often, a small quantity is required to achieve their function. While this may not be the case for some leave-on cosmetics where the concentration of polymers may approach 100% (e.g., glitter), it is possible that several or higher quantities of alternatives may be necessary to replace microplastics in other rinse-off products. Detailed information at this stage is not available to amend the working assumptions provided by industry, although industry input is noted that some alternative ingredients are substantially higher: more than 100% and in some cases more than 20% (ECHA CfE 2018, ECHA consultation 2019, #2168, #2220).

As the analysis assumes that overall demand for cosmetics products will not decline and there is a one-to-one substitution of microplastics with alternative ingredients, these costs are associated with the replacement of the total amount of microplastics used in cosmetics at the time of the entry into force of the proposed restriction. These costs would be incurred by either the manufacturers of microplastic-containing products (that would transition to the alternatives after reformulating the products) or the manufacturers of microplastic-free cosmetics (that would ramp-up their production in order to fill in the demand for non-reformulated microplastic-containing products). Therefore, the costs to society will be the difference between the price * tonnes used of alternative ingredients and price * tonnes used of microplastics.

Enforcement & labelling costs

The CPR has strict requirements for labelling of cosmetics products which mandate that every ingredient must be included on the product label sold to consumers. Therefore, the need to test for the presence of microplastics in materials or final products will be minimal for industry as information on the ingredients is passed on along the supply chain as well as for enforcement authorities as products can be enforced primarily via the information on the label. Testing methods to assess the presence of microplastics in cosmetics are being developed and published, e.g., by the Canadian federal government (Government of Canada, 2018). Their current cost is about CA $40/test.

The incremental administrative compliance costs associated with familiarisation of the restriction requirements are also expected to be negligible in an environment where regulatory requirements change regularly (i.e., under the CPR). Furthermore, as there are existing strict labelling requirements for cosmetic products, it is unlikely that there will be considerable labelling costs associated with the proposed restriction, including disposal of obsolete labels or printing of new labels, as it is likely that in the course of the transitional period, product labels will have to be redesigned and reprinted due to product changes (as a result of baseline reformulations) or due to the need to meet other regulatory requirements. Therefore, given the length of the transitional period – four years – any such labelling costs would be low and unlikely to be solely associated with the proposed restriction.

For the purpose of the quantitative analysis of this sector, it is assumed that the enforcement costs (administrative, testing, and labelling) for enforcement authorities and industry will be €55 000 per year (ECHA, 2017)[74] for the duration of the study period.

[74] Unpublished study

However, it should be highlighted that this is likely an overestimate, due to the already existing need to comply with various requirements also foreseen by other legislation and this proposed restriction (e.g., labelling) and surveillance costs of a new restriction would likely be incurred in the years immediately following the entry-into-effect and approach zero by the end of the study period as compliance increases. While there is considerable uncertainty related to these costs, they are expected to remain minor in comparison to other restriction costs.

Essential vs non-essential use

A number of studies have been dedicated to the beneficial effects of cosmetic products for human health, e.g., toothpaste to prevent caries, sun screens to prevent skin cancer (CfE 2018). Numerous other studies have shown that cosmetics improve self-esteem and wellbeing of the general population and in particular those with skin imperfections due to chronic skin disorders, surgeries or accidents e.g., Cosmetics Europe (2017), IKW (2017). As the number of microplastic-free formulations is high and sufficient time for reformulations is provided with the proposed transitional period, it is assumed that the restriction would not have an impact on these tangible and perceived benefits from cosmetic use.

On the other hand, discussions with stakeholders has highlighted that functions of cosmetic products cannot be compared to other "essential" or "critical" functions such as in water purification, for example. The dossier does not take a stance on the essential vs non-essential function of cosmetic products. The analysis of the socio-economic impacts of the restriction takes the approach that consumers are willing to pay for cosmetics and are able to differentiate between products on the basis of perceived or tangible benefits and derive utility (benefits) from these products. Changes in the market equilibrium such as possible reduced supply (in the event industry do not have adequate time to scale up production of microplastic-free products) or reduced performance, could erode social welfare as a whole. Therefore, the presented restriction costs are associated with the costs industry and other stakeholders would incur as a result of the proposed restriction in order to minimise the disruption of the necessary supply to fulfil the demand for cosmetic products. The benefits of the proposed restriction and its overall proportionality are also taken into account in the evaluation of the proposed action as outlined in Annex XV of REACH.

Economic impacts

Material costs

For the purpose of this analysis, the Dossier Submitter is using the assumptions provided by industry: one-to-one substitution and a 50% price premium. (CfE 2018) On this basis, material costs are estimated at €34.4 million in net present values (NPV) in the Central case, ranging between €15.4 to €53.4 million in respectively the Low and High scenario.

The transition to some of the alternatives may also lead to the following additional costs to industry which are not quantified due to lack of information:

- Some natural ingredients may lead to increased microbiological risks due to their natural source (CfE 2018). This may lead to the need for sterilisation or the additional use of preservatives or shorter shelf-life for the product. Discussions with natural cosmetics manufacturers indicated that they also tend to use ingredients that ensure shelf life of at least three years, as manufacturing, storage

and distribution can be a lengthy process. In the event increased use of preservatives or sterilisation is needed, additional costs may be likely for formulators.

- Some alternative ingredients may be less effective, e.g., to achieve the same level of light modification or sun protection a higher quantity of the product may be necessary.

Incremental reformulation costs

Total annual incremental costs for the study period are estimated to range from €36.3 million (Low scenario) to €2.1 billion (High scenario) or about €1 billion in the Central case. Table 59 shows the estimated costs applying the assumptions described above.

Table 59: Other rinse-off products - estimated incremental reformulation costs (2017 values, Central scenario)

Cost component (million €)	NPV
Total induced major reformulations (1)	1 300
- Baseline repurposed major reformulations (2)	270
- Baseline repurposed minor reformulations (3)	80
Total baseline reformulations (4)=(2)+(3)	350
Acceleration of major baseline reformulations (5)	55
Total incremental to restriction (1)-(4)+(5)	1 000

Loss of product quality

The results of some reformulations or the discontinuation of some products may lead to loss of certain features and perceived or tangible benefits for the end-users. Therefore, it is possible that the proposed restriction may lead to an erosion of consumer surplus. Given the high number of non-microplastic containing products currently on the EEA market (70%-90%), it is likely that any such erosion would not be significant.

Enforcement & labelling costs

As explained above, enforcement and labelling costs are expected to be minor in comparison. They are assumed at €55 000 per year from the entry into effect of the proposed restriction. While there is considerable uncertainty related to these costs, they are expected to remain minor in comparison to other restriction costs.

D.5.4.4. Other impacts

Social impacts

Given the small number of total cosmetic products impacted (about 10% in the Low scenario, (CosmETHICS, 2018)) and the high number of microplastic-free formulations (close to 70% in the worst-case (High) scenario, (CosmETHICS, 2018)), it is unlikely that significant employment effects would occur as a result of the proposed restriction on rinse-off products or if such occur, they would likely be compensated by gains in microplastic-free manufacturing activities.

Impacts on SMEs

The cosmetics sector is comprised primarily of small companies: 98% are SME (Cosmetics Europe, 2018), Euromonitor International 2016) with the majority having less than 20 employees; more than 80% of total according to European Commission (2008). It is generally recognised that SMEs have fewer resources to allocate to R&D and therefore, extraordinary expenses requiring reformulation for a large share of their products may put substantial pressure on their business. On the other hand, SMEs currently marketing microplastic-free products (e.g., natural and organic cosmetics, those containing polymers that fall outside the scope of the proposed restriction) could directly benefit from a restriction on microplastic-containing products as they already have on the market microplastic-free formulations. Also taking into account the large number of microplastic-free rinse-off cosmetics on the market, it is unlikely that on balance the impacts on EEA SMEs would be negative.

Distributional and Wider-economic impacts

Manufacturers of cosmetics are dispersed throughout Europe and internationally. Given the small number of products impacted and the high number of alternatives, it is unlikely that any significant distributional effects would take place.

Similarly, significant trade or competition effects are not expected as a result of the proposed restriction on rinse-off products. Many of the microplastic-containing cosmetic manufacturers also manufacture the alternatives and are part of complex international supply chains.

D.5.4.5. Cost-effectiveness, affordability and proportionality to risk

Table 60 shows the total restriction costs of the proposed restriction on other rinse-off cosmetics with four-year transitional period. They range from €52 million (Low scenario) to €2.1 billion (High scenario) or about €1 billion in the Central case. This suggests a cost-effectiveness of about €22 per kilogram of reduced microplastic emissions in the Central scenario. This is considerably lower than other REACH actions on environmental pollutants, including actions on cosmetic products. For example, the cost-effectiveness of the UK restriction on D4/5 in wash-off cosmetics was estimated to range from negligible to less than €1 000 per kilogram of reduced emissions, with a mid-point value of about €400/kg for the proposed restriction with a two-year transitional period (ECHA, 2016b).

Table 60: Restriction costs – other rinse-off cosmetic products (NPV, 2017 values)

Restriction costs \ Scenarios	Low	Central	High
Material	15.4	34.4	53.4
Reformulation	36	1 000	2 060
Enforcement	0.5	0.5	0.5
Total Restriction costs	**52**	**1 080**	**2 100**
Emissions (cumulative)	**22 500**	**50 200**	**78 000**
Cost effectiveness (€/kg)	**2**	**22**	**27**

The costs of the restriction for each estimated reformulation (i.e., allocating the total restriction costs for each reformulation estimated to take place in order for the industry to comply with the restriction) represent between 15% and 20% of the estimated average profits per reformulation (€60 000/reformulation: see profit loss assumptions in

section on Leave-on cosmetic products below). Therefore, the proposed restriction on other rinse-off cosmetics is deemed affordable. During the consultation information was submitted that some SMEs may find this challenging both financially and in terms of garnering reformulation capacity. However, it is important to note that the estimates above are associated with considerable uncertainty as not all non-microplastic uses have been excluded from the analysis.

In summary, on the basis of cost-effectiveness and affordability considerations, the proposed restriction on rinse-off cosmetic products is proportionate to risk.

D.5.4.6. Impact of scope variations on proportionality to risk

Variations of lower and upper size limit

During the dossier development and the opinion-making process, the Dossier Submitter considered a number of variations in the upper and lower limit of microplastics, i.e., upper limit of 1 mm, no lower limit and a lower limit of 100 nm.

According to Cosmetics Europe, 99% of the microplastics used in cosmetics (19-polymer, i.e., in the Low scenario) are less than 1 mm. These smaller microplastics appear to be used in all three cosmetic segments (CfE 2018). It is uncertain whether the situation is any different for the 520-polymer (High) scenario and whether the replacement of these smaller microplastics is associated with higher or lower costs. Therefore, separate cost-effectiveness for a restriction on microplastics with no dimension greater than 1 mm cannot be estimated.

Again, according to Cosmetics Europe (ECHA CfE 2018, ECHA consultation 2019), the polymers used in cosmetics can be in particle form with one dimension greater than 100 nm (19-polymer, i.e., in the Low scenario). On the basis of this information, the change in the lower limit to 100 nm or the elimination of the lower limit would not lead to different impacts than those estimated in the preceding sections. However, a review of the cosmetics list of ingredients in nano form reveals that several polymers that may fall in the scope of the proposed restriction.[75] Furthermore, several colourants and UV filters are allowed in nano form in cosmetics and if they are coated with polymers, they may fall in the scope of the restriction. Therefore, it cannot be excluded that cosmetics can contain microplastics in nano form and therefore, the increase of the lower limit could result in lower impacts. This is more likely for leave-on cosmetics, as ingredients in nano form appear to have more applications in leave-on products.

Different transitional period

The proposed transitional period is selected to optimise the benefits to society by introducing a reduction in microplastic emissions while minimising the costs to society, by aligning the entry into effect of the proposed restriction to the extent possible with the time required to transition to alternatives. It also takes into account other critical elements impacting society's readiness to implement and comply with the restriction (e.g., time needed for enforcement authorities to prepare to monitor the compliance with the requirements), as well as the magnitude of the various impacts of the proposed

[75] Catalogue of cosmetic ingredients from the European Union Observatory for Nanomaterials: https://euon.echa.europa.eu/catalogue-of-cosmetic-ingredients and Catalogue of nanomaterials in cosmetic products placed on the market - Version 2, DG Grow: https://ec.europa.eu/docsroom/documents/38284

restriction, e.g., emissions to the environment from rinse-off cosmetics and their overall contribution to emissions of intentionally added microplastics, cost-effectiveness, non-monetised impacts of the restriction, practicality and monitorabilty. A shorter transitional period would increase the costs to society as impacts as industry would have less time to reformulate or existing manufacturers of microplastic-free products to scale up production to satisfy the growing demand. A longer transitional period would lead to lower costs to society but will also reduce the benefits of the proposed restriction on rinse-off cosmetics.

The proposed restriction assumes that 6-12 months for product testing will be sufficient. During the consultation on the submitted dossier, industry commented that 30-36 months for stability testing will be required. However, none of the stakeholders explained why accelerated stability testing cannot be applied to microplastics. (See section D.5.6 for further discussion on this topic).

D.5.4.7. Uncertainties and sensitivity analysis

Uncertainties are discussed in the relevant sections above. Their impact on the conclusions of the analysis is also summarised in Table 58. Sensitivity analysis is also performed. While the effects of some uncertainties lead to overestimation or underestimation of the overall costs of the proposed restriction on rinse-off cosmetic products, on balance the Low scenario can be seen as a lower bound of these impacts, while the High scenario, as a higher bound of the anticipated restriction costs. Therefore, the Central scenario, even though it does not eliminate all uncertainties, can give an order of magnitude estimate of the anticipated impacts of the proposed restriction on rinse-off cosmetics.

D.5.5. Leave-on cosmetic products

D.5.5.1. Use and function of Microplastics

Leave-on cosmetic products is a diverse group, which includes skin care products (e.g., moisturisers, body lotions), make-up (e.g., foundation, powder, concealer, mascara, eye shadow/pencil/liner), lip products (e.g., lipstick or sealer, lip balm), products for correction of body odour or perspirations (e.g., deodorants), sun and self-tanning products, hair care and styling products (e.g., leave-in conditioner, dry shampoo, hair spray/foam/gel), nail care (e.g., polish, hardeners, glue), etc. The concentration of microplastics in some of these products could exceed 90%. Leave-on cosmetics have more polymer ingredients on average, although not all polymer uses are in scope of the propose restriction, i.e., about 40% as stated by industry (ECHA CfE 2018, CosmETHICS 2018, ECHA consultation 2019, #2361).[76] Those with the highest number of different polymer particles in the same formulation are products that are likely to be primarily removed by consumers using cotton pads or wipes and disposed of in the household solid waste/trash, e.g., nail varnish and lipstick products. On average, these microplastic-

[76] 1.1 polymers per rinse-off product vs 1.4 in leave-on in the Low scenario and 1.3 vs 1.6 polymers in the High scenario (Cosmethics 2018). Specifically, 74% vs 60% of the polymer containing leave-on products have one polymer respectively under the Low and High scenario assumptions, 20% vs 25% have two, 5% vs 11% three, 1% vs 5% four, 1% vs 2% five, 0.1% vs 0.2% six, and 0 vs 0.3% have between six and 10 (Cosmethics 2018).

containing products have two polymeric ingredients.

Some of the more common polymers used in leave-on cosmetics, include: polypropylene, polytetrafluoroethylene, polyamide (nylon) 5, polyethylene isoterephthalate, ethylene/acrylate copolymers, methyl methacrylate crosspolymer, although the polymers already listed for use in rinse-off products are also found in leave-on formulations (CfE 2018).

Consultation submissions stated that the concentration of microplastics in leave-on cosmetics could range from 0.01% to 3% w/w (ECHA consultation 2019, #2107, #2256, #2259, #2266, #2492, #2726).

The microplastics can have the following functions in leave-on products:

- Skin conditioning: Skin conditioning agents include:
    - Emollients: help maintain the soft, smooth, and pliable appearance of skin. Emollients function by remaining on the skin surface to act as lubricants, to reduce flaking, and to improve skin appearance;
    - Humectants: intended to increase the water content of the skin top layers;
    - Occlusives: They are generally lipids which tend to remain on the skin surface and retard the evaporation of water from the skin (different from antiperspirant, see below). By blocking the evaporative loss of water, occlusive materials increase the water content of skin;
    - Other special effects on the skin. These are imparted by substances believed to enhance the appearance of dry or damaged skin and materials which adhere to the skin to reduce flaking and restore suppleness.
- Antiperspirants: They interfere with the delivery of liquid to the skin surface.
- Soft focus, i.e., to optically reduce the contrast and hide the imperfections of the skin surface. Such materials have a high diffuse transmission of light. The reflected light is evenly dispersed which makes the skin surface appear more even and imperfections less visible.
- Matifying/absorbents: These polymers have a large capacity to absorb oil, helping to reduce shine on the skin. Absorbents are usually solid, with a large surface area, which can attract dissolved or finely dispersed substance from another medium.
- Glitter: It may be precision-cut specialty film incorporating layers of pigment laminated between a plastic (often PET) film. Alternatives to polymers include pearlescent glitter particles (such as mica) based on mineral silicates and coated with a metal oxide to produce the colour.
- Other sensorial functionalities (e.g. touch, feel): Softening and smoothing ingredients usually have moisturising benefits. They are hydrophilic ingredients which trap and conserve water within the skin, although powders also act as smoothing ingredients by filling in tiny gaps and unevenness on the skin's surface. Conditioning and 'silky feel' ingredients are generally longer chain silicones or hydrocarbons. Shorter chain length alcohols will give a lighter texture and longer chain length alcohols will give a thicker, moister texture. Double bonds can increase the oily texture and branched structures may feel lighter and silkier, less viscous
- Fillers/Bulking agents: These are usually chemically inert, solid ingredients employed as diluents or carriers for other solids, or liquids. Bulking agents are

useful for combining pigments in a powder form or for encapsulating other materials. Bulking agents are also used to increase the volume (bulk) of a cosmetic. (CfE 2018, CE AI 2018) Many polymer ingredients on the CosIng database[77] are registered with film forming function. (CfE 2018)

D.5.5.2. Alternatives

It is more difficult to answer whether there are alternative ingredients to microplastics in the high number of leave-on cosmetic formulations (total cosmetic formulations exceed 400 000 on the EU market, EC 2008), as described below, drop in substitutes are not known at moment for all formulations on the market. However, alternative ingredients to microplastics of natural origins have been reported and used in the past as well as some suppliers and manufacturers have announced development of biodegradable alternatives.[78] Alternatives to microplastic ingredients of natural (plant or mineral) origin are, for example, natural polymers such as starch, xanthan or guar gum, carrageenan, alginates, polysaccharides, pectin, gelatin, agar, and cellulose derivatives can be used as thickening agents, while examples for hair care include polysaccharides, such as starch and cellulose derivatives, natural gums, and hydrolysed proteins (cosmeticsinfo.org, 2018). Other reported uses of natural polymers include dextrin for adhesives and guar as emulsifier or emulsion stabiliser (Abrutyn, 2013).

Bertling et al. (2018) reviewed the CosIng[79] database for non-polymeric cosmetic ingredients.[80] The authors of the study and the Dossier Submitter postulate that the share of non-polymeric substances on the CosIng database is an indication for the ease of substitution of polymers used in cosmetics. Out of all substances in the database, polymers represented less than 20% of all substances listed in the majority of the cosmetic function categories. Those include: opacifying, binding, emulsion stabilising, nail conditioning, stabilising, depilatory, antifoaming, absorbent, gel forming, plasticiser, anticaking, hair waving or straightening, solvent, bulking, antistatic, humectant, chelating, antiseborrhoeic, cleansing, foam boosting, UV filter, hydrotrope, cosmetics colorants, abrasive, antioxidant, oral care, UV absorber, antidandruff, antimicrobial, deodorant, antiperspirant. The functions for which polymers represent more than 80% of all substances listed are: film forming (which is derogated via paragraph 5b in proposed wording of the restriction) or skin conditioning function: both fairly important for leave-

[77] http://ec.europa.eu/growth/tools-databases/cosing/index.cfm

[78] E.g., https://www.roelmihpc.com/portfolio/celus-bi-feel/ and https://www.roelmihpc.com/portfolio/celus-bi-esters/ which are reported readily biodegradable according to OECD 301 method; https://www.cossma.com/ingredients/article/pet-free-glittering-effects-35881.html ; https://www.beatthemicrobead.org/plastic-free-sunscreens/ ; https://www.beatthemicrobead.org/plastic-free-body-lotions-butters/ ; Ecocert/COSMOS standard has certified in excess of 2000 ingredients that do not contain synthetic, or chemically modified agricultural products: https://www.ecocert.com/en/certification-detail/natural-and-organic-cosmetics-cosmos; Biodeg glitter (without any synthetic material) which is able to reflect any colour: https://www.enterprise.cam.ac.uk/wp-content/uploads/2017/05/Vig-3336-16-Structurally-coloured-microparticles_better-quality.pdf

[79] https://ec.europa.eu/growth/sectors/cosmetics/cosing_en

[80] Out of the 28 357 substances on the CosIng database, respectively 964 and 2 298 met the search terms used "polymer" or "poly". Mikroplastik und synthetische Polymere in Kosmetikprodukten sowie Wasch-, Putz- und Reinigungsmitteln. Endbericht. Bertling, Jürgen; Hamann, Leandra; Hiebel, Markus. Fraunhofer-Institut für Umwelt-, Sicherheits- und Energietechnik UMSICHT. 2018

on products. Polymers represent between 20% and 50% of the substances listed on CosIng to perform the following functions: emulsifying, hair fixing, viscosity controlling, surfactant, hair conditioning, and emollient. As stated previously, not all polymer uses in cosmetics meet the microplastic definition; therefore, these percentages represent an overestimation of the share of microplastic ingredients per cosmetic function.

Furthermore, a number of certification programs focusing on natural and organic cosmetic products demonstrate the availability of microplastic-free products in all rinse-off (as well as leave-on) categories of cosmetic products, although the slight differences in definitions do not ensure that all products bearing these certificates automatically meet the obligations of the proposed restriction. These include: EU Ecolabel (rinse-off only), Nordic Swan Ecolabel, NATRUE, Look for the Zero/Zero plastic inside (Beat the Microbead), Ecocert and COSMOS standards.[81]

In addition, a number of organisations track ingredients of cosmetic products, including those that contain (or do not) polymers: e.g., CosmEthics, Plastic Soup Foundation,[82] Que Choisir and Forbrugerrådet Tænk. Although not all polymers meet the definition of microplastics, a survey of these databases shows a large number of products, in all leave-off (and rinse-off) categories that do not contain in excess of 500 different polymers. (See Table 61 and discussion below.) There are a high number of cosmetic products on the market, in all leave-on categories that do not contain any polymers, including those that may meet the microplastic definition. Table 61 shows that under the 19-polymer scenario of microplastics (Low scenario) the majority of cosmetic products on the EEA market do not contain polymers, i.e., close to 80%, while in the High scenario (520-polymer) about 50% contain polymers (as per CosmETHICS). The categories of products with the smallest number of non-polymer containing products are primarily for subcategories of leave-on products which are primarily disposed in the household trash (CfE AI, 2018), i.e., some nail polish, lipstick and powder make-up products, followed by sun/self-tanning and other skin care products (in High scenario). Often polymers are used in these categories of products as film formers, i.e., during use the polymer particles coalesce and become part of a matrix (i.e. are no longer particulate) and are therefore, out of scope of the proposed restriction. (See section on Microplastic definition.) Therefore, the share of products in these (and also other) leave-on products not impacted by the proposed restriction is likely higher.

As shown in Table 61, polymer-free products are available in all product categories.

Similar arguments related to rinse-off products could be made for the risks arising from the alternatives to microplastics in leave-on products: due to their normal occurrence in nature and emissions (on average 650 tonnes annually), it is expected that the transitioning to alternatives to microplastics of natural origin will not result in a greater environmental burden in comparison to the use of synthetic polymers. Stakeholders raised concerns that soluble or liquid polymers may present similar concerns to the

[81] https://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html ; http://www.nordic-ecolabel.org/product-groups/group/?productGroupCode=090 ; https://www.natrue.org/our-standard/natrue-criteria-2/ ; https://www.beatthemicrobead.org/zero-products/ ; https://www.ecocert.com/en/certification-detail/natural-and-organic-cosmetics-cosmos

[82] https://www.beatthemicrobead.org/product-lists/

environment as those in the scope of the proposed restriction (ECHA consultation 2019, confidential submissions).

Table 61: Share of formulations not containing polymers: leave-on cosmetic products

Leave-on cosmetics		**Proportion not containing polymers**	
Subcategory	**Type**	**19 polymer (Low scenario)**	**520 polymer (High scenario)**
After shave	skin care	95%	49%
After sun	sun/self-tanning	98%	36%
After sun gel	sun/self-tanning	100%	30%
After sun moisturiser	sun/self-tanning	90%	46%
Anti cellulite	skin care	92%	38%
Anti-age cream	skin care	75%	36%
Antiseptic	skin care	98%	83%
Baby Oil	skin care	100%	98%
Blush/Bronzer/Contour	make-up & lipstick	57%	49%
Body butter	skin care	99%	67%
Body lotion	skin care	96%	68%
Body lotion/Balm/Cream/Gel	skin care	96%	46%
Body oil	skin care	99%	96%
Butter	skin care	100%	75%
Concealer	make-up & lipstick	54%	34%
Cream	skin care	99%	77%
Creams and lotions	skin care	96%	49%
Deodorant	deodorant/perspiration	96%	93%
Diaper Ointment	skin care	97%	89%
Dry shampoo	hair styling & other	87%	84%
Eau de Parfum	deodorant/perspiration	99%	96%
Eau de Toilette	deodorant/perspiration	99%	91%
Eye gel	skin care	87%	32%
Eye moisturiser	skin care	80%	40%
Eye shadow	make-up & lipstick	51%	42%

Leave-on cosmetics		Proportion not containing polymers	
Subcategory	**Type**	**19 polymer (Low scenario)**	**520 polymer (High scenario)**
Eyebrow pen/gel/powder	make-up & lipstick	49%	28%
Eyeliner liquid/gel	make-up & lipstick	45%	11%
Eyeliner, pen	make-up & lipstick	51%	35%
Facial care	skin care	88%	44%
Facial moisturizers	skin care	79%	32%
Foot cream	skin care	98%	68%
Foot lotion	skin care	97%	48%
Foundation/BB Cream	make-up & lipstick	53%	35%
Hair gel	hair styling & other	93%	20%
Hair spray	hair styling & other	91%	31%
Hair styling	hair styling & other	94%	29%
Hair wax	hair styling & other	97%	56%
Hand sanitizer	skin care	94%	45%
Hands and Nails	skin care	100%	67%
Highlighter	make-up & lipstick	52%	31%
Holding or styling foam or mousse	hair styling & other	92%	49%
Lip balm	make-up & lipstick	87%	78%
Lip gloss	make-up & lipstick	64%	22%
Lip liner, pen	make-up & lipstick	61%	34%
Lipstick	make-up & lipstick	37%	19%
Loose powder	make-up & lipstick	71%	66%
Lotion	skin care	99%	55%
Mascara	make-up & lipstick	59%	17%
Masks	skin care	97%	63%
Massage oil	skin care	99%	93%
Moisturisers/Face cream	skin care	87%	44%
Nail polish	nail polish/remover	26%	21%

Leave-on cosmetics		Proportion not containing polymers	
Subcategory	**Type**	**19 polymer (Low scenario)**	**520 polymer (High scenario)**
Nail polish remover	nail polish/remover	98%	96%
Other baby products	hair styling & other	95%	86%
Other nail or cuticle products	nail polish/remover	73%	58%
Perfume/Parfum/Eau de Parfum	deodorant/perspiration	99%	93%
Powder	make-up & lipstick	98%	98%
Pressed powder	make-up & lipstick	50%	45%
Scalp Care	hair styling & other	95%	68%
Self tanner face	sun/self-tanning	77%	55%
Self-tanner	sun/self-tanning	95%	62%
Serum/oil	skin care	100%	87%
Serums and treatments	skin care	86%	51%
Styling cream	hair styling & other	96%	43%
Sunscreen	sun/self-tanning	80%	29%
Thickening product	hair styling & other	96%	44%
Tinted lip balm	make-up & lipstick	59%	51%
Toners and mists	skin care	98%	88%
Treatments	skin care	98%	81%
Wipes	skin care	100%	84%
Total Leave-on		**78%**	**50%**

Notes: Table assumes that polymer use is equivalent to microplastic use. Based on historical data.

Source: CosmETHICS database. Results consistent with Que Choisir (France) and Forbrugerrådet Tænk (Denmark). The percent of formulations does not reflect market share in the EEA.

D.5.5.3. Overview of restriction response and restriction scenarios

Restriction response and transitional period

In summary, stakeholders and EEA society as a whole are expected to react as follows to the proposed restriction on microplastics in leave-on cosmetic products:

- Similar to rinse-off cosmetics, for leave-on subcategories, where polymer-containing products represent less than 30% of the market, the polymer-free formulations are expected to take over their market share and very few of these products are expected to be reformulated (assumed 5%) and where they represent between 30% and 70% of the market, EEA cosmetic companies

currently using polymers to reformulate about half of their products using alternatives. The remaining 50% of formulations containing polymers are expected to be discontinued and their market share to be taken over by polymer-free products. The transitioning to alternatives for these product categories is expected to lead to reformulation and higher material costs. Assuming similar profit margin, the profit losses of discontinued microplastic-containing leave-on products are expected to be compensated with gains from manufactures of microplastic-free products.

- For nine leave-on product categories,[83] where the polymer-containing products represent more than 70% of all products in the worst-case (High) scenario, EEA cosmetic companies currently using microplastics to reformulate almost all their products using alternatives (95%). These companies are expected to incur reformulation and higher material costs.
- EEA cosmetics companies undertaking reformulations are expected to complete them within six years. Industry has suggested that on average it would take approximately five years to reformulate rinse-off and leave-on products, stressing the higher complexity of leave-on products. A six-year reformulation period is 1.5 times the length of an average reformulation process (about 4 years) and takes into consideration that suppliers of cosmetics ingredients are familiar with the available alternatives as typically they supply both microplastics and their alternatives (CfE 2018, industry interviews). Furthermore, failed dissatisfactory reformulations may not require that the R&D process is restarted at step one.
- While it is possible that some reformulations may not be successfully completed by the end of the transitional period (and therefore, discontinued or the prospect of high reformulation costs may lead to relocation of manufacturing to non-EEA markets), it is unlikely that their number would be large given the length of the proposed transitional period and the high percentage of polymer-free products already on the market in most leave-on categories (Table 61). In the event some reformulations are not completed profit and employment losses may occur for some stakeholders. If such impacts materialise, they would likely only be associated with leave-on cosmetics categories where polymer-containing products represent more than 70% of the product category, i.e., where substitution would likely be more difficult. As demand for cosmetic products is unlikely to decline in the future and many cosmetics are substitutes, these welfare losses for EEA society are expected to be of temporary nature, i.e., by the end of the second full reformulation cycle (year 7 to 9 after the entry into force). By the end of year 9, manufacturers of alternatives are expected to have taken over their share of the market and the welfare losses from microplastic-containing products are expected to be compensated by gains of alternatives.
- The anticipated reformulation and higher material costs for industry are unlikely to be passed on to consumers as end-user pricing of cosmetics is primarily

[83] Eyebrow pen/gel/powder, eyeliner liquid/gel, hair gel, hair styling, lip gloss, lipstick, mascara, nail polish, and sunscreen. Under the worst-case scenario (in terms of polymer particles falling in scope), the use of microplastics for film-forming functions (out-side the scope of the proposed restriction) as well as polymers in liquid form which are also out of scope have not been excluded.

determined by brand image (ECHA Workshop on microplastics, 2018) and the market is fairly competitive.

- Importers to inform their international supply chains and to reposition to source alternative microplastic-free products. This is expected to require fewer than six years.
- Existing stocks to be depleted. It is anticipated that three years will be sufficient as a typical shelf life of cosmetics products is 30 to 36 months (CfE 2018) and turnover of cosmetic products is relatively high.
- Stocks of obsolete labels to be depleted and new labels to be aligned with requirements of the proposed restriction and other relevant EU-wide legislation. It is anticipated that six years will be sufficient as it is likely that new labelling may need to be produced in the meantime due to other regulatory requirements or due to other changes in the product formula.
- Enforcement authorities to be prepared to enforce an EU-wide restriction. This is expected to require fewer than six years, as authorities can build on the experience of several national authorities that currently have or are in the process of putting in place bans on microbead use.
- The quality of some cosmetic products to be affected but this is expected to be acceptable for many consumers as they value products with lower impact on the environment.
- Emissions to the environment to have gradually been eliminated by 2028 or sooner. Therefore, impacts on the environment and human health (via the environment) from microplastics in leave-on cosmetics are also expected to have been eliminated by that time, except those occurring due to existing stock accumulated in the environment due to historic uses.

It is anticipated that six years sufficiently minimises the negative impacts (primarily on industry stakeholders) of the proposed restriction, while taking into account the necessity for timely action on reducing microplastic emissions to the environment and their subsequent effects. The sections below attempt to quantify the likely response to the proposed restriction on leave-on cosmetics and justify the proportionality of the proposed action with a six-year transitional period.

Restriction scenarios and key assumptions

The approach to estimating socio-economic impacts on leave-on products is similar to the presented for rinse-off products (and similar regulatory actions under REACH restrictions). Where the specificities of this market segment warrant the use of different assumptions, i.e., due to the generally higher number of polymer-containing leave-on products, justifications are provided below.

Costs per reformulation

About 85% of Cosmetics Europe survey respondents indicated that an alternative does not exist for their applications (both rinse-off and leave-on, Cosmetics Europe, ECHA CfE 2018, ECHA consultation 2019, #2220). Although it is unclear whether respondents were referring to leave-on applications specifically, it is assumed that the answers applied primarily for leave-on uses as they tend to be more numerous and more complex. For

example, considering the 19-polymers scope, in close to a quarter of the required reformulations, more than one microplastic ingredient would need to be replaced (CfE 2018). Considering the 520-polymer (High scenario), 40% of leave-on products containing polymers, contain more than one polymer (although not all of them can be considered microplastics, i.e., about 40% according to industry or 16% of all). Therefore, it is possible that some R&D cases would require more resources. Therefore, to reflect the increased complexity and potentially greater efforts required to reformulate in comparison to rinse-off products, the Dossier Submitter assumes that the costs per reformulation to be 1.5 times higher, i.e., costs per major reformulation of €547 500 for larger companies and €63 000 for smaller. This implies that 50% of the required reformulations would result in a failure and would require a second round of reformulation activities or would cost 50% more due to their complexity. This is nearly 3.5 times the reported actual reformulation costs for substituting microbeads with exfoliating or cleansing functions of Cosmetics Europe members (CE AI 2018). The 1.5 premium is roughly in line with the average number of polymers in cosmetics: 1.1 polymers per rinse-off product vs 1.4 in leave-on in the Low scenario and 1.3 vs 1.6 polymers in the High scenario (Cosmethics 2018), although not all polymer uses fall within the scope of the proposed restriction, i.e., about 40% according to industry (ECHA consultation 2019, #2361).

Profit losses

Industry estimates that the proposed restriction would result in profit losses as alternatives for all microplastic uses in rinse-off products are unknown and would need to be identified and tested for separate formulation cases (CfE 2018). To mitigate these possible effects, a transitional period of nearly 1.5 times the typical reformulation period is proposed. This, coupled with considerations related to the impacted products and the information on available alternatives, leads to the conclusion that profit losses are not likely as a result of the proposed restriction on leave-on products because:

- Under the 19-polymer (Low scenario) of microplastics, data from the CosmETHICS database shows that for almost all 70 leave-on product categories, except four, the microplastic-free cosmetics represent the majority of leave-on products on the EEA market;
- Under the 520-polymer (High scenario) of microplastics, polymer-containing products represent about half of all products in this category (CosmETHICS). However, as explained previously, this data extraction does not reflect the fact that liquid, soluble and film-forming polymers are out of scope. The latter is of particular importance for leave-on products as film-forming has wide application to ensure pigments and other ingredients remain on the skin (i.e., substantivity and transfer-free characteristics), to reduce imperfections, to improve water resistance, among others.

Therefore, no profit losses are assumed by the Dossier Submitter in the Low and Central scenario. For the purpose of presenting an absolute upper bound of possible impacts, the Dossier Submitter assumes that profit losses may be possible in the extreme worst-case scenario for product categories with low number of polymer-free, i.e., less than 30% per category and high number of polymer ingredients within the same formulation. These include nine out of 70 leave-on product categories: eyebrow pen/gel/powder, eyeliner liquid/gel, hair gel, hair styling, lip gloss, lipstick, mascara, nail polish, and sunscreen.

Film-forming polymers have wide application in these products. It is assumed that 25% (similar to information provided in CfE 2018) of these formulations could lead to profit losses in the High scenario. The profit losses are assumed to be of a temporary nature: from the entry into effect of the proposed restriction (end of transitional period) to the end of a second full and consecutive reformulation cycle (i.e., between year 7 and year 9 from the entry into force of the proposed restriction).[84]

Profits are assumed to be about €60 000 per formulation on the basis of 15% profit margin and information on revenues per formulation (CfE 2018). It should be noted that this is likely an overestimation as the profits estimated on the basis of total number of formulations on the market (430 000) and turnover for the cosmetics industry (Cosmetics Europe, 2018) suggests that the profits per formulation are less than €20 000.

Employment losses

Industry estimates that the proposed restriction would give rise to temporary unemployment (CfE 2018). Following similar reasoning as for profit losses, the Dossier Submitter concludes that employment losses are unlikely. Furthermore, there is indication that SMEs, which tend to be less resilient to temporary profit losses, are less likely to use microplastics in their formulations. For the purpose of presenting an absolute upper bound of possible impacts, the Dossier Submitter assumes that employment losses may be associated with difficult to substitute formulations in the High scenario (i.e., those for which profit losses are assumed). The Dossier Submitter assumes that these losses are associated with SMEs. Relevant SME statistics (average number of employees per SME and number of companies), is estimated on the basis of European Commission (2008) updated with current information on the number SMEs in the EEA (Cosmetics Europe, 2018). Employment effects are assumed to last half a year with a loss of average income of €30 000 (CfE 2018).

Loss of product quality

The results of some reformulations or the discontinuation of some products may lead to loss of certain features and overall experience for the end-users. Therefore, it is possible that the proposed restriction on leave-on cosmetics may lead to an erosion of the consumer surplus.

UK Health and Safety Executive (2015) presented in detail the results of a discrete choice experiment study eliciting the following:

- A willingness to pay (WTP) value for the consumer loss connected to the functionality provided by D4 and D5 in cosmetics. This was estimated at €5/person/year.

[84] For comparison, SEAC often takes one year of profit losses for the purpose of authorisation applications to account for net changes of producer surplus. This is as changes in profits made by the applicant do not necessarily reflect net changes in economic surplus across the EU economy because the profit losses of the applicant over a long time period does not take into account the possibility of mitigating actions that could reduce the economic impacts (e.g. resources being redeployed by the applicant or by other companies) and may overstate the long-term impacts.

- A value for willingness to pay to avoid the potential risks of accumulation of D4 and D5 in the aquatic environment. This was estimated at €46 /person/year for D4 and €40 /person/year for D5.

The study results are not directly applicable to the microplastics restriction case although a number of parallels can be drawn:

- A trade-off is examined between cosmetic product quality (i.e., loss of key features), reduction of risk to the aquatic environment (specifically from D4 or D5) as a result of continued accumulation of D4/5, and product price.
- The loss of key features measured (e.g., silky, smooth, dry feel; rub in smoothly, lightly and evenly; silky, shiny, sleek hair that is not weighed down; quick-drying without feeling cold; dry, non-greasy feel leaving not residue; long shelf life: 2-3 years; no or low smell; no or low skin irritation) are also applicable to microplastic ingredients, although microplastics can impart a broader range of effects in cosmetics.

The study demonstrates that while consumers value superior quality products, they place a higher value on potential environmental benefits. This is also supported by information from natural and organic cosmetics which demonstrate that consumers place a value on products that do not put pressure on the environment or human health (Natrue, 2016).[85] The consultation comments quoted studies that revealed that price and performance are of the highest importance for consumers (ECHA consultation 2019, #2220).

Furthermore, several other studies (UK Health and Safety Executive, 2015, ECHA, 2016b, ECHA, 2019) demonstrate that product price is governed by a number of factors that influence the consumer perception of product quality or health or environmental benefits, such as brand image. Therefore, it is difficult to derive the value consumers place on the impact of microplastics on the environment through revealed preferences.

Taking the above in consideration, the Dossier Submitter concludes that while the reformulation or discontinuation of some leave-on products may lead to loss of perceived product quality, it is likely that such loss of quality will be acceptable for consumers who also value that products are not damaging to the environment or human health.

Consultation comments on the submitted dossier

Upon review of the consultation comments, the following changes were introduced to the High scenario which in turn impact the Central scenario:

a) Revision of emissions rates:

The Dossier Submitter is applying the revised emission rates provided by Cosmetics Europe (ECHA consultation 2019, #2361) summarised in Table 62 below.

Table 62: Emission rate assumptions

Cosmetic product groups	Wipes*	Wipes in bin**	Emissions down the drain***
Skin care	20%	94%	81%
Sun lotion	13%	93%	88%
Hair styling	6%	88%	95%

[85] For example, 66% of respondents replied that they choose a product that is not polluting (Natrue, 2016).

Deodorant (antiperspirant)	8%	89%	93%
Make-up	75%	93%	
Lipstick	69%	94%	33%
Nail	76%	95%	28%

Notes:
*Percent of users who used both removal methods involving cotton pads or wipes only or cotton pads or wipes and then water.
** Percent of users who throw the cotton pads or wipes in the bin (household garbage) after removal of cosmetic products.
*** Calculated as (1-"Wipes")+(1-"Wipes in bin")*"Wipes". Used in the main analysis.
Source: ECHA consultation 2019, #2361.

The calculated emissions above assume that removal with cotton wipes or pad will not result to emissions down the drain. However, especially for consumers who follow-up with water the removal with a cotton pad (e.g., by washing their face), emissions down the drain can be expected and their level will depend on the effectiveness of the cotton pad removal of microplastics. Furthermore, other surveys, e.g., YouGov 2019, suggest higher emissions down the drain. In addition, these rates may not fully take into account emissions during the summer months in particular when releases directly to the environment take place (e.g., due to swimming in water bodies).

For the purpose of demonstrating proportionality with conservative assumptions, the Dossier Submitter is applying the emission rates submitted by industry. The impact of higher emission rates are presented for sensitivity purposes for make-up/lip/nail product categories.

b) Higher average cost per major reformulation

The consultation comments presented by industry suggest that costs per reformulation of microplastic mixtures can range from less than the Dossier Submitter's assumption for minor reformulation for large companies and in excess of €800 000. The Dossier Submitter considered that there are a number of reasons that would suggest that on average the costs per reformulation would not be higher than the mid-point of these values. (For further analysis of the information provided, please see section D.5.6 point i.) For the purpose of demonstrating proportionality with conservative assumptions, the Dossier Submitter has presented a sensitivity analysis assuming microplastic reformulations for SMEs and large companies of €550 000. This is nearly 4.5 times higher than the average rate used in the restriction on D4/5/6 in various consumer products.

c) Share of polymer uses in the scope of the proposed restriction and revision of tonnage estimates

Based on information submitted during the consultation, the Dossier Submitter further refined the analysis of the polymer list (focusing on those most frequently present in formulations) with a view to identify which polymers may be most likely impacted by the scope on the basis of their physico-chemical properties (i.e., excluding liquid or soluble polymers). On that basis, it was estimated that approximately 60% of polymer uses could fall in the scope of the proposed restriction. As further polymer uses may be with film forming properties – 19% by estimates from Cosmetics Europe survey – the resulting estimate of polymer uses falling in scope is 45%. Therefore, the Dossier Submitter chose to revise the estimated tonnages of microplastics used in leave-on cosmetics using the assumption provided by industry that only 40% of polymer uses would fall in scope (ECHA consultation 2019, #2220, #2361). Therefore, the tonnages of

microplastics used were estimated on the basis of the estimated number of formulations on the EEA containing polymers, scaled up by the ratio of tonnes microplastics per formulation (based on information provided by Cosmetics Europe, ECHA CfE 2018) and multiplied by 40%.[86] Such reduction was not applied to the estimated number of reformulations required to comply with the proposed restriction. This is because the number of required reformations is estimated on the basis of the share of polymer-containing formulations on the market. These estimates cannot be revised not knowing which particular formulations are in the 60% falling outside the scope of the proposed restriction. This approach results in a significant overestimation of the number of required reformations to comply with the proposed restriction and therefore, in the total restriction costs of the proposed ban on the placing on the market of leave-on products.

d) Other quantified impacts

Some stakeholders outlined other categories of costs that industry would incur as a result of the proposed restriction, e.g., export losses, patent filing costs. The Dossier Submitter considers that there is considerable uncertainty related to whether and to what extent these costs can be considered attributable to the proposed restriction. For the purpose of demonstrating proportionality with conservative assumptions, the Dossier Submitter is including these costs as estimated by industry. (For further details, please see below subsections of Economic impacts and Other impacts.)

Table 63 presents the revised assumptions as a result of incorporating the consultation comments. The analysis presented in subsequent sections utilise these assumptions.

Table 63: Restriction scenarios: Summary of revised assumptions used in impact assessment of leave-on cosmetic products

Impact category	Low scenario	Central	High scenario
Tonnes of microplastics used	1 100 tonnes	2 100 tonnes	3 000 tonnes
Number of reformulation	11 000 (estimated based on Cosmetics Europe number of reformulations & availability of alternatives data, i.e., - if number of alternatives is >70%, only 5% of reformulations are assumed to take place - if number of alternatives is < 70% but >30%, 50% of reformulations are assumed to take place)	51 000	92 000 (estimated based on total formulations on EEA market & availability of alternatives data, i.e., if: - number of alternatives is >70%, only 5% of reformulations are assumed to take place; - number of alternatives is >30% but < 70%, 50% of reformulations are assumed to take place - number of alternatives is < 30%, 95% of reformulations are assumed to take place)
Price premium for materials	€650/tonne		
Costs per reformulation	€550 00 per major & €55 000 per minor reformulation (case) for large companies. €63 000 per major & €6 300 per minor reformulation (case) for SMEs (assumed to account for 50% of estimated reformulations)[87]		
Baseline reformulations	Coordination with major (during transitional period + five years) & minor (during transitional period) reformulations		

[86] In comparison, the multiplier used in the submitted dossier was roughly 0.7 for leave-on and 0.4 for rinse-of, or 0.5 on average for all cosmetics.

[87] For sensitivity purposes: €550 00 per major reformulation for large and small companies. Other assumptions as in Low & Central scenario.

Impact category	Low scenario	Central	High scenario
Profit losses	Negligible net impacts	Minor net impacts	Unlikely & only temporary associated with 25% of reformulations where the number of alternatives is <30%
Employment losses	Negligible as number of alternatives is high	Unlikely net impacts	Unlikely & only temporary associated with SMEs assumed to have 25% of reformulations where the number of alternatives is <30%
Other impacts	Negligible	Unlikely	Unlikely. Possibly temporary related to export losses, patent filing costs, loss of performance.
Uncertainties (impact on restriction costs)	- likely more polymers fall in scope (↑) - based on historical data (↑↓) - increase or decrease of microplastics used & emitted (↑↓) - assumes that large companies represent 50% of microplastics use, although based on number of companies on the market, they represent less than 2-3% (↓)	Mid-point between Low & High scenario	- several products are likely to represent one reformulation case & the substitution would likely benefit from a learning curve & economies of scale (↓) - some uses may not meet the microplastic definition at point of use/release or can meet the biodegradability criteria and are therefore out of scope, e.g., liquid or water soluble polymers, or those with film forming function (↓) - based on historical data (↑↓) - increase or decrease of microplastics used & emitted (↑↓) - other polymers may also fall in scope, e.g., some chemically modified natural polymers (↑) - assumes that large companies represent 50% of microplastics use, although based on number of companies on the market, they represent less than 2-3% (↓)

Table 68 illustrates the staging of the costs of the proposed restriction over the study period under the revised High scenario assumptions. The staging of the costs for the Low and Medium scenario are similar and based on the described assumptions presented in Table 63.

D.5.5.4. Economic impacts

The sections below present the results of the analysis using the revised assumptions in the High scenario, which in turn impact the Central scenario.

Material costs:

Assuming a one-to-one replacement with potential alternatives that are on average 50% more expensive (CfE 2018), the material substitution costs for this market segment are estimated to range between €5 million and €13 million or about €9 million in the Central case (NPV). As with rinse-off cosmetics, higher material costs may be expected if higher sterilisation or preservative use is expected or a higher quantity of the alternatives are necessary to perform the same function as the microplastics.

Reformulation costs

The incremental reformulation costs for the proposed restriction on leave-on cosmetics are estimated to be substantial (Table 64). Based on the described assumptions, they are estimated to range between €1.6 billion and €13.3 billion annually or approximately €7.3 billion in the Central case. The majority of these reformulations (55%-98%) are associated with the replacement of microplastics in leave-on products which are primarily disposed of via the household waste (i.e., nail varnish, make-up and lip products) and

therefore, leading to lower emissions to the environment in comparison to "down-the-drain" leave-on products. However, many of the polymer uses in make-up/lip/nail products are for the purpose of forming a film and therefore, out of scope of the proposed restriction.

Table 64: Leave-on products - estimated incremental reformulation costs (2017 values, Central scenario, billion)

Cost component	NPV (€)
Total induced major reformulations (1)	11.3
- Baseline repurposed major reformulations (2)	3.4
- Baseline repurposed minor reformulations (3)	1.0
Total baseline reformulations (4)=(2)+(3)	4.4
Acceleration of major baseline reformulations (5)	0.6
Total incremental to restriction (1)-(4)+(5)	7.3

These estimates do not take into account a learning curve for the companies, where an experience with the reformulation of some cosmetics would lead to less resource intensive substitution in other leave-on formulae. The estimates are heavily driven by the number of polymer-containing products estimated in the High scenario, which do not take into account the fact that only 40% of the polymer uses may fall into the scope of the proposed restriction, as liquid or soluble polymers as well as polymers with film forming functions are out of scope of the proposed restriction.

Profit losses

Given the number of polymer-free cosmetics and the type of products in the product group, profit losses are unlikely. For the purpose of presenting an upper bound of the impacts of the proposed restriction, profit losses are assumed in the High scenario for those product categories where the number of polymer-free formulations is low and the number of polymer ingredients is high. Applying the assumptions presented in Table 55, profit losses are estimated at about €1.1 billion (NPV). Nearly 80% of these impacts are associated with product groups that tend to be disposed primarily via household waste (i.e., make-up/lip/nail products) and therefore, lead to lower releases to the environment.

Enforcement & labelling costs

Similar to rinse-off cosmetics, enforcement and labelling costs are expected to be minor in comparison. They are assumed at €55 000 per year from the entry into effect of the proposed restriction. Further estimation of the overall impact of the instructions for use and reporting requirements of the proposed restriction is presented separately for all sectors. (See relevant section on labelling and reporting requirements in the main report.)

Patent costs

During the consultation, one stakeholder stated that the restriction would lead to patent costs, i.e., those associated with the existing patent costs becoming obsolete and those

associated with the need to file new ones. The Dossier Submitter notes that typically patents have 20-year validity; therefore, some patents would expire in the near future with or without the restriction. It is unclear whether this is considered in the estimated impacts by the stakeholder. Second, the economic value of a patent is the future stream of profits for the individual company and the costs for patent filing are sunk costs. Therefore, for society, the net impact on profits is of primary concern. These are estimated as part of Profit losses above. Costs of acquiring a new patent do not appear to be included in the reformulation values used in the Dossier Submitter's analysis (values based on D4/5, in turn based on RTI 2002). These costs are uncertain as not all companies file a patent for their formulations. Furthermore, not all new patent costs can be considered incremental for the restriction as the industry is highly innovative and patent costs would also be incurred for baseline reformulations (see assumptions above). If these costs can be considered incremental for the restriction, based on information from stakeholders and assuming mostly large companies would patent, the costs can approach up to €800 million in NPV.

Other costs

Some final products may be less effective, e.g., as a result of transitioning to the alternatives, the longevity of some products when applied on the skin may be reduced and would require reapplication or a larger amount of the product to fulfil the same function. This would likely lead to higher costs to consumers but also to higher gains to producers. Therefore, in the absence of detailed information on the demand and supply curve, it is assumed that these effects would lead to a transfer of consumer surplus to producers, resulting in no net welfare effect to society as a whole.

D.5.5.5. Other impacts

Social/Employment losses

Given the number of microplastic-free products, the type of products in the product group and the tendency of larger companies (which are more resilient to profit losses) to use microplastics, employment effects are unlikely. For the purpose of presenting an upper bound of the impacts of the proposed restriction, employment losses are assumed in the High scenario for those product categories where the number of alternatives is low and the number of microplastic ingredients is high. Applying the assumptions presented in Table 63 and the description of restriction scenarios, less than 2 700 people are assumed to be laid off in 2028 for sensitivity purposes in the High scenario. The one-time employment losses in 2017 values are estimated at €70 million. About 80% of these losses are associated with product groups that tend to be disposed via household waste (make-up/lip/nail leave-on products) and therefore, lead to lower releases to the environment.

Impacts on SMEs

The cosmetics sector is comprised primarily of small companies: 98% are SME ((Cosmetics Europe, 2018) Euromonitor International 2016) with the majority having less than 20 employees: more than 80% of total, according to European Commission (2008). It is generally recognised that SMEs have fewer resources to allocate to R&D and therefore, extraordinary expenses requiring reformulation for a large number of their products may put substantial pressure on their business.

It is however, important to differentiate between different SMEs in the supply chain:

SMEs manufacturing microplastic-free products, SMEs specialising in contract manufacturing of microplastic-containing cosmetics; and SMEs suppliers and manufacturers specialising in manufacturing proprietary microplastic-containing cosmetics. SMEs currently marketing microplastic-free products (e.g., natural and organic cosmetics, those containing polymers that fall outside the scope of the proposed restriction) could directly benefit from a restriction on microplastic-containing products as they already have on the market microplastic-free formulations. SMEs manufacturers of microplastic-containing proprietary ingredients or consumer products are likely to experience the largest impact of the restriction, as they would have to reformulate within the transitional period. However, the exact net impact on the SMEs is uncertain, as one of the main factors influencing the SME's ability to comply with the proposed restriction – the number of reformulations required – is also very uncertain. In the event all leave-on cosmetics are restricted with a transitional period of six years, the SMEs currently marketing several proprietary microplastic-containing products may experience difficulties garnering resources to reformulate all their products by the end of the transitional period according to comments sent in during the consultation on the submitted dossier.

Distributional and Wider-economic impacts

The EEA market is the largest world market for cosmetics products. Manufacturers of microplastic-free and -containing cosmetics (and often both) are dispersed throughout Europe and internationally. Recent export statistics show a stable increase in exports, reaching €20.1 billion in 2017 (CfE 2018). Industry has expressed concerns that the restriction may lead to the expatriation of manufacturing leading to potentially lower EEA value added and lower exports (CfE 2018). While it is possible that in the worst-case scenario these impacts may materialise for microplastic-containing products, it is also possible that value-added and exports of microplastic-free products may increase.

During the consultation on the restriction proposal, additional information was submitted estimating these losses of export markets to €150 million per year (ECHA consultation 2019, #2220). The Dossier Submitter highlights that only the placing on the market is in the scope of the proposed restriction; therefore, manufacturing, and by extension exports, of microplastic containing products is not in the scope of the proposed restriction. The Dossier Submitter also is not able to ascertain whether using the same production line, with the necessary assurances for minimisation of cross-contamination, would not be possible. Therefore, if such impacts can be associated with the proposed restriction, they could be considered induced by the restriction only from the moment from which manufacturing of microplastic-free products takes full scale (after the end of the transitional period) and only if manufacturers could not maintain manufacturing for domestic and international markets.[88] Furthermore, such impacts on EEA society would

[88] During the consultation in the submitted dossier, one stakeholder expressed the opinion that in the future, the highest standard of leave-on products performance outside the EU will remain driven by the microplastic technologies. Therefore, it is likely that manufacturers would have to maintain two product lines to manufacture

last only until such a time in the future when profits from the exports of microplastic-free products offset losses from the discontinuation of microplastic containing products (e.g., as a parallel to profit losses, nine years after the entry into force). As result, if these costs can be considered incremental to the restriction, the NPV of these impacts can be estimated at €200 million in the worst case for leave-on products (assuming allocation of annual reported export losses to leave-on and rinse-off proportionate to estimated reformations under the High scenario).

D.5.5.6. Cost-effectiveness, affordability and proportionality to risk

The total restriction costs on leave-on cosmetics products, assuming six years transitional period, are estimated to range between €1.6 billion and €15 billion or about €7.4 billion in the Central case. The majority of these costs (about 60% in the Central case) are due to the need to reformulate leave-on products which are disposed of largely via household waste and thus, account for about one-quarter of microplastics emissions from leave-on cosmetics.

The resulting cost-effectiveness per kilogram of reduced microplastic emissions is about €870, which is similar to the cost-effectiveness of previously agreed restrictions under REACH on other environmental pollutants. Therefore, the proposed action is as proportionate as previous REACH restrictions on environmental pollutants.

Table 65: Restriction costs – leave-on cosmetic products (NPV, 2017 values)

Restriction costs \ Scenarios	Low	Central	High
Economic costs (million €)			
• Material	5	9	13
• Reformulation	1 600	7 300	13 300
• Enforcement	0.4	0.4	0.4
• Profit losses	-	-	1 100
• Patent costs	-	-	800
• Employment losses	-	-	70
• Export losses	-	-	200

microplastic-free products for the EEA market and microplastic-containing products designated for exports. According to the stakeholder, this would entail additional costs for equipment, indirect costs for raw materials, and "increased excess and obsoletes". The stakeholder does not provide sufficient information to ascertain the relevance of the latter two cost categories. The Dossier Submitter cannot prejudge whether the quality of microplastic-free products would be inferior and whether the EEA's leadership for phasing out microplastic uses would create demand for more such products internationally. The Dossier Submitter also is not able to ascertain whether using the same production line for manufacturing microplastic-free and microplastic-containing products, with the necessary assurances for minimisation of cross-contamination, would not be possible. However, the stakeholder would either bear costs of manufacturers maintaining separate product lines for exports or export losses or none. As the estimates for export losses are based on Cosmetics Europe survey of 56 of their members, the Dossier Submitter assumes those in the High scenario.

Restriction costs \ Scenarios	Low	Central	High
Total Restriction costs	**1 600**	**7 400**	**15 500**
Emissions (cumulative)	**4 200**	**8 500**	**12 200**
Cost effectiveness (€/kg)	**380**	**870**	**1 300**

Table 68 illustrates the staging of the costs of the proposed restriction over the study period under the revised High scenario assumptions. The staging of the costs for the Low and Medium scenario are similar and based on the described assumptions presented in Table 63.

Table 66: Restriction costs – leave-on cosmetic products: Detailed presentation, High scenario

Cost component	NPV (2017)	2017-21*	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033-2041*
Reformulation														
- large companies	-	-	4200	4200	4200	4200	4200	4200	-	-	-	-	-	-
- small companies	-	-	500	500	500	500	500	500	-	-	-	-	-	-
Total induced major ref's	20200	-	4700	4700	4700	4700	4700	4700	-	-	-	-	-	-
Baseline														
major reformulations														
- large companies	-	-	1300	1300	1300	1300	1300	1300	-	-	-	-	-	-
- small companies	-	-	100	100	100	100	100	100	-	-	-	-	-	-
Baseline repurposed major ref's	6100	-	1400	1400	1400	1400	1400	1400	-	-	-	-	-	-
minor reformulations														
- large companies	-	-	400	400	400	400	400	400	-	-	-	-	-	-
- small companies	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Baseline repurposed minor ref's	1800	-	400	400	400	400	400	400	-	-	-	-	-	-
Total baseline reformulations	7900	-	1800	1800	1800	1800	1800	1800	-	-	-	-	-	-
Acceleration														
- to be rescheduled (reduce)	4100	-	-	-	-	-	-	-	1400	1400	1400	1400	1400	-
- rescheduled (increase)	5100	-	1200	1200	1200	1200	1200	1200	-	-	-	-	-	-
Acceleration of major baseline ref's	1000	-	1200	1200	1200	1200	1200	1200	-1400	-1400	-1400	-1400	-1400	-
Profit loss	1100	-	-	-	-	-	-	-	600	600	600	-	-	-

Cost component	NPV (2017)	2017-21*	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033-2041*
Material costs	13	-	-	-	-	-	-	-	2	2	2	2	2	2
Enforcement costs	0.4	-	-	-	-	-	-	-	0.1	0.1	0.1	0.1	0.1	0.1
Employment impacts	100	-	-	-	-	-	-	-	100	-	-	-	-	-
Export loss	200	-	-	-	-	-	-	-	100	100	100	-	-	-
Patent costs	800	-	-	-	-	-	-	1200	-	-	-	-	-	-
Total incremental to restriction	**15500**	**-**	**4100**	**4100**	**4100**	**4100**	**4100**	**5300**	**-600**	**-700**	**-700**	**-1400**	**-1400**	**2**

Notes: NPV 2017, millions of euro, rounded. *Annual costs over the period.

The costs of the restriction presented in Table 65 for each estimated reformulation (i.e., allocating the total restriction costs over the 20-year study period for each reformulation estimated to take place in order for the industry to comply with the restriction) represent between 17% and 20% of the estimated average profits per reformulation (€60 000/reformulation/year: see profit loss assumptions above). Therefore, the proposed restriction on rinse-off products is deemed affordable. During the consultation on the restriction proposal, information was submitted that some SMEs may find this not affordable (ECHA consultation 2019).

In summary, on the basis of cost-effectiveness and affordability considerations, the proposed restriction on leave-on cosmetic products is proportionate to risk. The restriction is considered justified with the proposed transitional period as:

- Leave-on cosmetics have more complex reformulations and would require more time to complete (based on the average number of polymer ingredients about 1.5 times longer);

- Higher number of reformulations are estimated to be required to comply with the proposed restriction on leave-on cosmetics and industry (SMEs in particular) may have difficulty to reformulate so many formulations within a shorter period;

- The cost-effectiveness and affordability of the proposed restriction is lower in comparisons to other sectors in scope of the proposed ban on the placing on the market of microplastic containing products;

- Leave-on cosmetics have comparatively lower contribution to emissions from intentionally added microplastics.

However, it is important to note that the estimates presented in Table 65 are associated with considerable uncertainty which overall points to an overestimation of the impacts rather than underestimation. The following bullets briefly outline these uncertainties and their impacts on the overall cost-effectiveness of the proposed restriction on the placing on the market of leave-on products containing microplastics:

a) Number of reformulations required to comply with the proposed restriction

Sections D.5.4.3 and D.5.5.3 explain that the number of reformulations required to comply with the restriction on the placing on the market of microplastic-containing leave-

on products is determined dynamically, i.e., on the basis of the number of polymer-free reformulations estimated on the EEA market. The approach is that the fewer polymer-free products are on the market, the higher percentage of the polymer-containing products within a product sub-category are assumed to require reformulations, i.e., if less than 30%, 95% of polymer-containing formulations would need to be reformulated, if between 30% and 70%, 50% are assumed to require reformulation, etc. (See sections D.5.4.3 and D.5.5.3 for further detail.) However, as explained earlier, not all polymer uses fall within the scope of the proposed restriction. Therefore, the share of the estimated microplastic-free products by subcategory is significantly lower as it does not include all polymer uses with film-forming function, liquid or soluble or biodegradable polymers. While the available information allowed for the tonnage estimates to reflect that not all polymer uses fall within the restriction scope, i.e., by applying a flat assumptions that 60% do not (based on industry comments submitted during the consultation on the restriction proposal, although biodegradable polymers do not appear to be taken into account in this estimate), the available information does not allow to segregate the polymer uses that do not fall in scope by product subcategory. Therefore, the approach of the Dossier Submitter is to demonstrate that the proposed restriction on the placing on the market of leave-on products containing microplastics is proportionate even in the presence of such significantly overestimated impacts and to recognise this assumption as a source of significant uncertainty.

The difficulty to exclude uses that are out of scope is the largest source of overestimation of the number of required reformulations to comply with the proposed restriction. Other source of overestimation include the use of historical information (i.e., a product whose barcode has changed over time, each unique barcode will be considered as a separate reformulation case) and the consideration of unique reformulation case products by the same manufacturer which have very similar ingredients, e.g., make-up line with the same ingredients except for the pigment used, whose different colours have unique barcodes are each treated as separate reformulation case, while there will be significant synergies in terms of their reformulation. Overall, the learning-by-doing benefits are not reflected in the estimation of the number of required reformulations to comply with the restriction.

b) Cost per reformulation

The Dossier Submitter used 1.5 times higher costs per reformulation for leave-on products in comparison to rinse-off products, recognising their greater complexity due to the presence of more than one microplastic ingredients. Recognising that SMEs have limited resources, and in line with the RTI study (the basis for the D4/5 and D4/5/6 dossiers), lower values were used for 50% of the estimated reformulations. The Dossier Submitter also discusses that the value of €550 000 per reformulation is nearly four times higher than the average cost of reformulating microbeads (as reported by industry survey) and 8.5 times higher than the estimated average R&D investment based on data on R&D investments by the cosmetics industry. (See section on Costs per reformulation in D.5.4.3)

The values per reformulation provided by industry during the consultation on the restriction proposal ranged from more than 20 times lower to in excess of €800 000 per case (ECHA consultation 2019). While the Dossier Submitter agrees that some reformulations would employ substantial resources, on average, costs per reformulation

are unlikely to exceed the assumed because of the following main reasons:

- the nature of other available information: To estimate the total reformulation costs incremental to the proposed restriction, the Dossier Submitter applies the discussed costs per reformulation to the incremental number of reformulations estimated on the basis of information from the CosmEthics database. It is assumed that each product with unique barcode is a separate formulation. Therefore, a product whose barcode has changed overtime would be counted as a unique product more than once. In addition, same brand products that have very similar composition (e.g., same brand make-up with different colourants) have unique barcodes and therefore, counted as unique required reformulations. It is likely that these reformulations would be undertaken as one reformulation case and not, e.g., 20, with a total cost of 20*€550 000 as the analysis assumes.
- learning-by-doing and economies of scale: It is expected that over time, with increased experience in substitution of microplastics, the average cost per reformulation would decline. Furthermore, the industry has communicated that they do not replace individual ingredients (polymers) but mixtures in each impacted formulation, referring to core technologies used in several formulations. It is highly likely that once the core technology is reformulated for one of the formulations, there could be financial and other savings to adjust the formula of the remaining. Furthermore, the reformulation of core technologies may to a certain extent be centralised with suppliers of microplastic ingredients, allowing for a faster diffusion throughout the industry and savings on a per product reformulation basis.
- potential for double counting: the Dossier Submitter applies 1.5 times higher costs per reformulation (on what is already a significantly overestimated number of reformulations, see section D.5.5.6) for leave-on cosmetics in comparison to rinse-off cosmetics and higher than the effective costs per reformulation used in the D4/5/6 dossier in recognition of the higher complexity to reformulate mixtures containing more than one microplastic ingredient. The approach of some stakeholders to reflect the complexity of the reformulations of all microplastics is to assume scaled-up cost per reformulation, while at the same time, scaling up the number of reformulations required on the basis of the number of microplastic ingredients contained in the mixture requiring substitution (e.g., given 10 mixtures containing four microplastic ingredients, the stakeholders have assumed that the restriction would induce 20 incremental reformulations with total costs of 20 times their assumed cost per reformulation). Thereby, increasing the costs per reformulation and the number of reformulations at the same time and thereby, reflecting twice the same issue: the complexity of the reformulation. The Dossier Submitter concludes that this approach produces estimates in the extreme case and may lead to double counting.

Therefore, the Dossier Submitter is of the view that applying higher than the assumed

costs per reformulation to the already overestimated number of reformulations will present an extreme case of impacts of the proposed restriction. In the event costs per reformulation are higher, effective rate for both large and small companies as the mid-point of industry answers (€550 000) the proportionality of the restriction is eroded but the overall cost-effectiveness remains within the range of similar restrictions with environmental concern: less than €2 000 per kilogram reduced microplastic emissions. In the event, the costs per reformulation are higher than those, given the number of estimated reformulations to comply with the restriction, a case can be made to adjust the scope of the ban on the placing on the market to fewer product categories (those with high emissions but and lower costs, i.e., leave-on products other than make-up/lip/nail products) or to adjust the proposed transitional period.

c) Overlap with D4/5/6 restriction on cosmetic and other consumer and professional products:

As stated in the paper "Potential overlap between proposed restrictions on D4, D5, D6 and microplastics"[89] published on ECHA's website with the submitted dossier, both restrictions would impact cosmetic products, leave-on to a greater extent. As some reformulations of cosmetics products containing microplastics and D4, D5 or D6 would likely be pursued at the same time (if they have broadly consistent transitional periods), it is likely that the grand total of the estimated reformulations for both dossiers would be lower than the sum of the reformulation costs estimated for each of the dossiers.

d) Overlap with D4/5/6 restriction on cosmetic and other consumer and professional products:

As stated in the explanations for Table 62 in section D.5.5.3, other publications suggest (e.g., YouGov2019) that the emission rates for leave-on products are higher than the study submitted during the consultation on the submitted dossier. Assuming that down-the-drain products have similar emission rates to rinse-off products and that make-up/lip/nail products have on average emission rates of about 40%, the tonnages emitted increase by more than 22% and the overall cost-effectiveness by 18%.

Table 67: Impacts of uncertainties on cost-effectiveness conclusions for leave-on cosmetic products

Uncertainties	Estimated impact on cost-effectiveness (C/E)
Estimated number of reformulations	(+++) Likely fewer reformulations, thereby lower total reformulation costs and higher C/E of the restriction
Cost per reformulation	(-) Possibly higher reformulation costs and lower C/E of the restriction
Overlap with D4/5/6 restriction proposal	(+) Likely fewer combined reformulations, thereby lower combined reformulation costs and higher C/E of the combined restrictions
Emissions to waste water	(+) Higher tonnages emitted and improved C/E due to higher

[89] https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/22921/term

Uncertainties	Estimated impact on cost-effectiveness (C/E)
	emission rates to waste water

Notes: "+" denotes an improved C/E (lower absolute value), while "–" denotes reduced C/E.

Overall, based on the analysis above, it can be concluded that the uncertainties in the analysis point towards overestimation rather than underestimation of the total restriction costs and the cost-effectiveness of the proposed restriction.

D.5.5.7. Impact of scope variations on the proportionality to risk

Restriction on "down-the-drain" leave-on products only

Down-the drain leave on products include: sun and self-tanning products, skin care, deodorants/anti-perspirants, hair care and other cosmetic products. They are referred to as "down-the-drain" as they have very similar emissions pathway to rinse-off products: consumer habits reveal that about 90% on average of these products are disposed of via washing with water (ECHA consultation 2019, #2361). This leads to emissions primarily to waste water treatment or directly to the environment if such is not available and during summer months when bathing in open water is common. This group of products accounts for the less that 40% of the estimated impacts of the proposed restriction on all leave-on products and close to 75% of the estimated emission reduction in the event of a restriction.

As highlighted above, a large share of the impacts (more than 60% in the Central case) of the proposed restriction on leave-on products is associated with product categories that consumers tend to dispose of after use via household solid waste (trash), i.e., make-up/lip/nail leave-on products, thus leading to substantially lower emissions to the environment: they account for about 25% of all leave-on emissions in the Central scenario. In the event these products are not included in the scope of the proposed restriction, the cost-effectiveness of a restriction on leave-on products that are primarily washed off down the drain after use would be significantly higher: €460 per kilogram of reduced emissions (ranging from €70 to €750 per kilogram). The results show that a restriction on "down-the-drain" only leave-on products has similar proportionality to risk as the majority of adopted actions under REACH restrictions on substances with environmental concern, including the restriction on D4/5 on rinse-off cosmetic products. Table 68 shows the results in detail. Furthermore, the thus amended scope of the restriction would make it more affordable, when using the share of profits of the costs per reformulation as an indicator. This share is estimated to be lower than the proposed restriction on leave-on cosmetics, about 11% of profits.

Table 68: Restriction costs – impact of scope variations: leave-on cosmetic products (NPV, 2017 values, Central scenario)

Restriction costs (million €)\ Scenarios	Make-up, lip & nail Leave-on cosmetics	Other Leave-on cosmetics*
Material	4.4	4.9
Reformulation	4 400	2 900
Enforcement	0.4	0.4
Total Restriction costs	**4 500**	**2 900**
Emissions (cumulative)	**2 200**	**6 250**
Cost effectiveness (€/kg)	**2 000**	**460**

Notes:

* Includes leave-on cosmetics categories of sun and self-tanning products, skin care, deodorants/perspirants, hair care and other cosmetic products.

As shown in Table 68, the cost-effectiveness of an action solely on make-up/lip/nail leave-on products is significantly lower. This is primarily because high compliance costs are estimated to reduce emissions of 160 tonnes of microplastics annually. The conclusions of the cost-effectiveness for these product categories is burdened with similar uncertainties stemming from the lack of information on the exact number of reformulations required to comply with the restriction. These uncertainties are more pronounced for the make-up/lip/nail product groups as:

- The film forming function of polymers (derogated use under paragraph 5b) has ubiquitous application in the make-up, lip, and nail care products, higher than the average for all cosmetics products. As the assumption of 19% of polymer uses are with film forming function is an average for all cosmetic products (ECHA consultation 2019, #2220), it is likely that, on average, more formulations containing polymers in the leave-on categories, and in particular in the make-up/lip/nail products, would not be impacted by the restriction than estimated. Therefore, the cost-effectiveness of this group of products would likely be even higher (lower in absolute value);

- Liquid polymers likely have less applicability in these product categories than the average assumed for the sector (ECHA consultation 2019, #2220); therefore, it is possible that the number of reformulations is higher (and therefore, the cost-effectiveness in absolute value is lower) than estimated;

- Make-up, lip, and nail products are categories of cosmetic products with unique barcodes that more often than others are primarily differentiated on the basis of colour within the same brand name and product series in the Cosmethics database – used as a basis for estimating the number of required reformulations to comply with the proposed restriction. Therefore, for example, for cosmetic eye-shadow series of the same brand, consisting of 10 different colours with otherwise similar list of ingredients, the analysis would treat them as unique formulations, i.e., requiring 10 separate reformulations, while it is likely that industry would approach their reformulation as a group, likely identifying one alternative for all these separate reformulations. This line of argument is suggesting that lower than the estimated reformulations would likely be required for make-up/lip/nail products, leading to lower overall reformulation costs as a result of the restriction and therefore, improved cost effectiveness of the proposed ban on the placing

on the market.

- The Dossier Submitter assumes that only about 30% of the microplastic use in these categories leads to emissions to municipal wastewater – the main route of releases to the environment. This is on the basis of a recent study of consumer habits commissioned by Cosmetics Europe (ECHA consultation 2019, #2361), which stated that the majority of consumers dispose of make-up, lip and nail products with cotton pad which they then dispose of in the household trash. The Dossier Submitter did not have access to the survey questions or the raw survey results and therefore, was not able to identify whether there were other relevant routes of exposure over the service life of the products. Other surveys place releases to water as a result of eye or make-up or lip products much higher: respectively, 47%, 40%, and 38% (YouGov, 2017). The use of the YouGov rates will result in increased emissions to the environment by close to 40% of microplastic use in these product categories; thereby improving the cost-effectiveness of the proposed restriction to €1 500 per kilogram of microplastics emitted, i.e., comparable to other adopted restrictions with similar environmental concern.

Table 69: Impacts of uncertainties on cost-effectiveness conclusions for make-up/lip/nail cosmetic products

Uncertainties	Estimated impact on cost-effectiveness
Film forming function	(+) Likely fewer reformulations, thereby lower reformulation costs and higher C/E of the restriction
Liquid polymers	(-) Possibly higher number of reformulations thereby higher reformulation costs and lower C/E of the restriction
Unique barcodes	(+) Likely fewer reformulations, thereby lower reformulation costs and higher C/E of the restriction
Emissions to wastewater	(+) Likely higher emissions to the environment, thereby lower restriction costs per kg of microplastics emitted and thereby higher C/E of the restriction

Notes: (+) denotes an improvement in the C/E (i.e., lower absolute value of the ratio); while (-) denotes a reduction of the C/E.

Other elements that may impact the proportionality and practicality of the proposed restriction on make-up/lip/nail products are:

- Industry has identified the use of polymers in powder make-up and liquid polymers as particularly difficult to substitute (ECHA consultation 2019, #2220).
- While there are considerable uncertainties with the estimated number of reformulations (see Table 69), the highest number of reformulations estimated to be needed to comply with the restriction are associated with these product categories, accounting to more than 70% of all estimated formulations for Leave-on cosmetic products. The consultation on the submitted dossier revealed that SMEs in particular (other than those engaged primarily in manufacturing non-proprietary products) may find it challenging to garner resources (both financial

and in terms of human resources) to conduct so many reformulations concurrently within the six years transitional period.

With these considerations in mind, other variations to the proposed restriction on leave-on cosmetics are longer transitional period (see below section on Different transitional periods) or reduced product scope of the ban on the placing on the market. With respect to the latter, one potential alternative to a restriction on the use of microplastics in make-up/lip/nail products is the introduction of comprehensive labelling requirements which instruct users to dispose of cosmetics (after use) in household trash to minimise emissions to the environment. While this action would likely not eliminate emissions to the environment from make-up/lip/nail products, it would lead to decline in emissions sooner (from 2024 if similar to other sector requirements are proposed) by at least one-third on the basis of information from consumer habits of reading and following instructions on cosmetic product labels (YouGov, 2017). If the ban on the placing on the market of microplastics in make-up/lip/nail products is substituted with instructions on use and reporting requirements similar to other sectors impacted by paragraph 7 and 8 of the proposed restriction, a comprehensive ban on the placing on the market can be introduced later (following the five-year review) if it is found that the instructions for use do not effectively reduce emissions of these products.

Microplastics with film-forming functions are included in the scope

Film forming is one of the essential microplastic functions in many leave-on products. The Dossier Submitter concludes that this use of microplastics does not inevitably result in an release of microplastics to the environment. Therefore, assumptions are made to exclude possible tonnages, material and reformulation costs associated with microplastics with film-forming functions from the Low scenario based on information from ECHA CfE 2018. While an attempt was made to adjust the tonnages impacts in the High scenario to exclude film forming uses, no sufficient information was available to do the same for the estimated number of reformulations required under the High scenario assumptions. Therefore, in the event the scope of the proposed restriction is expanded to include microplastics with film-forming functions, the tonnages impacted would likely be higher but the costs would have lower variation than those estimated in Table 65, assuming that substitution of this particular microplastic function is not more costly than the substitution of microplastics with all other functions in leave-on products.

Variations of lower and upper size limit

During the dossier development and the opinion-making process, the Dossier Submitter considered a number of variations in the upper and lower limit of microplastics, i.e., upper limit of 1mm, no lower limit and a lower limit of 100 nm.

According to Cosmetics Europe, 99% of the microplastics used in cosmetics (19-polymer, i.e., in the Low scenario) are less than 1 mm. These larger microplastics appear to be used in all three cosmetic segments (ECHA CfE 2018). It is uncertain whether the situation is any different for the 520-polymer (High) scenario and whether the replacement of these larger microplastics is associated with higher or lower costs. Therefore, separate cost-effectiveness for a restriction on microplastics with no dimension greater than 1 mm cannot be estimated.

Again, according to Cosmetics Europe (ECHA CfE 2018, ECHA consultation 2019, #2220), the polymers used in cosmetics can be in particle form with one dimension greater than

100 nm (19-polymer, i.e., in the Low scenario). On the basis of this information, the change in the lower limit to 100 nm or the elimination of the lower limit would not lead to different impacts than those estimated in the preceding sections. However, a review of the cosmetics list of nano ingredients reveals several polymers that may fall in the scope of the proposed restriction.[90] Furthermore, several colourants and UV filters are allowed in nano form in cosmetics and if they are coated with polymers, they may fall in the scope of the restriction. Therefore, it cannot be excluded that cosmetics can contain nano microplastics and therefore, the increase of the lower limit could result in lower impacts. This is more likely for leave-on cosmetics, as ingredients in nano form appear to have more applications in leave-on products.

Different transitional period

The proposed transitional period is selected to optimise the benefits to society by introducing a reduction in microplastic emissions while minimising the costs to society, by aligning the entry into effect of the proposed restriction to the extent possible with the time required to transition to alternatives. A shorter transitional period would increase the costs to society as impacts such as profit and employment losses may become more likely. While some of the reformulations contain both microplastics and D4/5/6, and thereby synergies in reformulations may lead to lower per reformulation costs than the estimated separately for the two restrictions, the need to comply with both restrictions may further increase the complexity of the reformulation process.

A longer transitional period would lead to lower costs to society but will also reduce the benefits of the proposed restriction on leave-on cosmetics. In the selection of an appropriate transitional period, a number of other elements need to be considered, such as: emissions to the environment and their growing stock, their extreme persistence and inability to address emissions from all sources via means other than a restriction on their placing on the market, the relative contribution of leave-on cosmetic products to the overall stock of intentionally added microplastics in the environment, cost-effectiveness, non-monetised impacts, as well as practicality and monitorability of the restriction. Furthermore, consideration needs to be given to calls for shorter transitional periods submitted during the consultation on the restriction proposal (ECHA consultation 2019) as well as calls for a much longer review period (10+ years) or calls for a derogation of all leave-on categories of cosmetic products, largely on the grounds that industry, particularly SMEs, would have difficulties conducting so many reformulations within the proposed six-year transitional period and that extensive testing would be needed to qualify alternatives to microplastics which according to industry, currently do not exist for each microplastic containing formulation on the EEA market. The Dossier Submitter's response to these comments is included in section D.5.6 of this document.

D.5.5.8. Uncertainties and sensitivity analysis

Uncertainties are discussed in the relevant sections above. Their impact on the conclusions of the analysis is also summarised in section D.5.5.6, Table 63, Table 67 and Table 69. Sensitivity analysis is also performed. While the effects of some uncertainties

[90] Catalogue of cosmetic ingredients from the European Union Observatory for Nanomaterials: https://euon.echa.europa.eu/catalogue-of-cosmetic-ingredients and Catalogue of nanomaterials in cosmetic products placed on the market - Version 2, DG Grow: https://ec.europa.eu/docsroom/documents/38284

lead to overestimation or underestimation of the overall costs of the proposed restriction on rinse-off cosmetic products, on balance the Low scenario can be seen as a lower bound of these impacts, while the High scenario, as a higher bound of the anticipated restriction costs. Therefore, the Central scenario, even though it does not eliminate all uncertainties, can give an order of magnitude estimate of the anticipated impacts of the proposed restriction on rinse-off cosmetics.

D.5.5.9. Practicality

The proposed restriction on cosmetics products is expected to be implementable & manageable. It allows sufficient time to transition to alternatives, minimising costs to society, while ensuring the restriction enters without undue delay. No other EU-wide measure can address the risks of microplastics in cosmetics. However, according to consultation comments on the submitted dossier (ECHA consultation 2019), in the event all forecast reformulations need to be undertaken to comply with the restriction, industry, in particular SMEs, may find it challenging to comply with the proposed transitional period. See section D.5.6 of this document for further detail.

The proposed restriction has a clearly defined scope. It defines the mixtures included in the scope on the basis of definitions already used by industry (CPR and Cosmetics Europe). Methods, prepared for national actions on microplastics, can be used as a basis, e.g., the method for microbeads in toiletries prepared by the Canadian Federal Government (Government of Canada, 2018). See Section 2.6.1. Enforceability in the main report for practicality considerations for all sectors in the proposed restriction scope.

D.5.5.10. Monitorability

Compliance can be monitored via existing CPR labelling requirements and compliance testing. Microplastic concentrations in the environment can be monitored with existing methods. See Section 2.6 in the main report outlines monitorability considerations of the proposed restriction.

D.5.6. Consultation comments on cosmetics and their implications on the conclusions of the socio-economic impact assessment

During the consultation on the submitted dossier (ECHA consultation 2019), 61 comments were submitted concerning the proposed restriction on cosmetic products. As many of the submissions raised multiple topics laid out over several thousand pages, it is not possible to address each individual comment separately. Therefore, the following section attempts to summarise the main comments raised specifically related to the socio-economic impact of the proposed restriction on the cosmetics sector and resulting proportionality of the proposed restriction measures presented in Sections D.5.4 and D.5.5 in the Annex to the Background Document.

For comments from the cosmetics industry submitted on the topics of scope, definitions, derogations under paragraph 5 of the proposed restriction wording, and impacts on the proposed labelling and reporting requirements, please see the relevant sections.

The following main themes can be identified in the submitted comments:

(i) Socio-economic impacts of the proposed restriction are large

Many submissions expressed concerns that the impacts from the proposed restriction on the cosmetics industry are substantial. A few consultation submissions presented their assessment of the socio-economic impacts of the proposed restriction (ECHA consultation 2019, #2220, #2361, confidential submissions), resulting in a cost-effectiveness for a restriction on rinse-off products in excess of €1 000 per kg of emitted microplastics per year, based on a 5-year timeframe of analysis, assuming that all costs associated with the restriction would occur annually within this period: reformulation, material, unemployment effects, profit losses, and performance loss. For leave-on, stakeholders reported values in excess of €10 000 kg/year.

The Dossier Submitter has recognised that the proposed restriction would have substantial impacts on the cosmetics industry. The Dossier Submitter noted the higher impact estimates submitted by industry and investigated the sources of the variations and their impact on the overall conclusions on the proportionality of the proposed restriction.

a) Saved or accelerated baseline reformulations:

The stakeholders do not take into account any coordination with baseline reformulations similar to the approach agreed by SEAC in the D4/5 opinion (ECHA 2016b) and recently reflected in the SEAC D4/5/6 opinion (under development). As this is an approach agreed by SEAC, the Dossier Submitter is not proposing changes at this stage.

b) Higher assumed costs per reformulation:

The Dossier Submitter used the same cost per reformulation already employed in the D4/5 restriction proposal (CPI adjusted to 2017 values) which based their estimates on an RTI study (RTI 2002), i.e., €365 000 per major reformulation for rinse-off products and 1.5 times higher for leave-on products recognising their greater complexity due to the presence of more than one microplastic ingredient. Recognising that SMEs have limited resources, and in line with the RTI study, lower values were used for 50% of the estimated reformulations. The Dossier Submitter also discusses that the value of €365 000 per reformulation is nearly 2.5 times higher than the average cost of reformulating microbeads (as reported by industry survey) and 5.5 times higher than the estimated average R&D investment based on data on R&D investments by the cosmetics industry. (See section on Costs per reformulation in D.5.4.3 in the Annex to the Background Document for details.)

Several submissions mentioned that costs per reformulation would be higher than €800 000 per product (ECHA consultation 2019, #2220, #2361, #2375, confidential submissions), at the same time other confidential submissions from large EEA-based cosmetics companies placed the costs per reformulation even lower than the costs assumed by the Dossier Submitter for major reformulations for SMEs.

While the Dossier Submitter agrees that some reformulations would employ substantial resources, it concludes not to use larger values for major reformulations as an average cost per reformulation for the industry because of:

- the nature of other available information: To estimate the total reformulation

costs incremental to the proposed restriction, the Dossier Submitter applies the discussed costs per reformulation to the incremental number of reformulations estimated on the basis of information from the CosmEthics database. The Dossier Submitter assumed that each product with unique barcode is a separate formulation. Therefore, a product whose barcode has changed overtime would be counted as a unique product more than once. In addition, same brand products that have very similar composition (e.g., different colour make-up) have unique barcodes and therefore, counted as unique required reformulations. It is likely that these reformulations would be undertaken as one reformulation case and not 20 with a total cost of 20*€550 000 as the analysis assumes.

- learning-by-doing: It is expected that over time, with increased experience in substitution of microplastics, the average cost per reformulation would decline. Furthermore, the industry has communicated that they do not replace individual ingredients (polymers) but mixtures in each impacted formulation, referring to core technologies used in several formulations. It is highly likely that once the core technology is reformulated for one of the formulations, there could be financial and other savings to adjust the formula of the remaining. Furthermore, the reformulation of core technologies may to a certain extent be centralised with suppliers of microplastic ingredients, allowing for a faster diffusion throughout the industry and savings on a per product reformulation basis.

- potential for double counting: the Dossier Submitter applies 1.5 times higher costs per reformulation (on what is already a significantly overestimated number of reformulations, see the discussion in section D.5.5.6 in the Annex to the Background Document) for leave-on cosmetics in comparison to rinse-off cosmetics and these are higher than the effective costs per reformulation used in the D4/5/6 dossier in recognition of the higher complexity to reformulate mixtures containing more than one microplastic ingredient. The approach of some stakeholders to reflect the complexity of the reformulations of all microplastics is to assume scaled-up cost per reformulation, while at the same time, scaling up the number of reformulations required on the basis of the number of microplastic ingredients contained in the mixture requiring substitution (e.g., given 10 mixtures containing four microplastic ingredients, stakeholders have assumed that the restriction would induce 20 incremental reformulations with total costs of 20 times their assumed cost per reformulation). This stakeholder approach is increasing the costs per reformulation and the number of reformulations at the same time and, thereby, reflecting twice the same issue: the complexity of the reformulation. The Dossier Submitter concludes that this approach produces estimates in the extreme case and leads to double counting. Nevertheless, the Dossier Submitter presents a detailed sensitivity analysis testing the effects of higher costs per reformulation in section D.5.5.6 in the Annex to the Background Document.

c) Tonnage estimates: Submission #2220 suggests that as the majority of polymers are liquid (assumed fraction of 50% for simplicity) and that according to results of their survey, 19% of formulations contain film formers which are proposed to be derogated (paragraph 5b of proposed restriction), the estimated tonnages by the Dossier Submitter should be reduced by 40.5%. As explained in section D.5.1 in the Annex to the Background Document, in recognition that many of the uses of the polymers assumed to fall in scope of the High scenario may not meet the microplastic definition, the Dossier

Submitter took a back-of-the-envelope approach to reduce the tonnages of the High scenario by roughly 50%. As the objective of the Dossier Submitter was to demonstrate proportionality based on an upper bound of potential impacts of the proposed restriction, such adjustment was not made on the estimated number of reformulations due to lack of information. (Such information was requested under Specific Question 6 – see below.) While the Dossier Submitter accepts the stakeholder's approach as another back-of-the-envelope approach to address the issue of lack of information provided on the polymer uses that will be impacted by the proposed restriction and has made the necessary revisions to the leave-on tonnage estimates, it disagrees that "These calculations should not be used to reduce the number of reformulation for the Central scenarios, which are only based on the number of alternative products present on the market." (ECHA consultation 2019, #2220) If fewer polymers or fewer polymer uses (about 40% as estimated by the stakeholder) would be impacted by the restriction, the estimated number of formulations on the market containing microplastic ingredients would be lower than currently estimated on the basis of the High scenario by the Dossier Submitter. As a direct consequence, the estimated number of reformulations induced by the proposed restriction would also be lower. Furthermore, if fewer polymers/polymer uses are in the scope of the restriction, the average number of microplastic ingredients that would need to be substituted would also decline, thereby reducing the complexity of the reformulation and the expected average cost per reformulation.

d) Incremental net costs to society: Some submissions have attributed costs to the restriction which would also incur under the baseline (e.g., patent costs), or are sunk costs in economic terms: patent costs or manufacturing equipment for the microplastic technologies. Others have argued supplier impacts should be added to the already estimated impacts by the Dossier Submitter. It is expected that demand for cosmetics (e.g., mascara) will continue after the entry into effect of the restriction and this demand would be supplied by microplastic-free products, thereby increasing the demand for microplastic-free ingredients and increasing income for their suppliers. Therefore, if those suppliers are within the EEA – which is likely as the EEA has been a regulatory leader in the substitution of microplastic ingredients – the effect on microplastic product/ingredient suppliers may be at least partially compensated by gains of microplastic-free product suppliers. Hence, the net effect of the proposed restriction on the EEA society would not be equivalent to the negative impacts of suppliers of microplastic products but would have to account for the sectoral opportunity gains that arise from the ban of microplastics as well. When assuming similar profit margins and continued steady demand for cosmetics, the net effect on the EEA society may not even be negative in the long run. Furthermore, some submitters have assumed that profit losses will take place over the entire study period or the remainder of the study period after the transitional period. While these losses may materialise for individual companies as a result of the proposed restriction, it is unlikely that those impacts would be net effects to society for an extended period of time. Once a critical mass of microplastic-free products is available on the market, assuming similar profit margins and similar demand for cosmetic products, the profit losses of microplastic-containing products would be compensated by gains made from microplastic-free products. The Dossier Submitter assumes that this would take place at the latest nine years after the entry into effect of the proposed restriction (or three full reformulation cycles for a typical cosmetic ingredient) for leave-on cosmetics as the share of microplastic-containing formulations in some cases is more

than 70%.

e) Other relevant impacts are not quantified: The Dossier Submitter analysed the submitted information and reflected the costs of such impacts (if and where credible) in the analysis. Please see sections on Patent costs and Distributional and wider economic effects for Leave-on cosmetics in D.5.5.4 and D.5.5.5 in the Annex to the Background Document.

f) Differences in terms of expected effective date and duration of impacts: For example, profit losses in some submissions are assumed to begin from the entry into force of the restriction even though microplastic-containing products can be placed on the market until the end of the transitional period, respectively, four and six years under the existing proposal and thus, such profit losses cannot be directly attributable to the proposed restriction.

(ii) Longer transitional period for rinse-off cosmetics:

Several stakeholders requested a longer transition period for rinse-off cosmetic products, e.g., ECHA consultation 2019, #2068, #2107, #2137, #2210, #2215, #2220, #2266, #2375, #2547, #2678, #2726, confidential submissions) Most of these submissions recommended that the transitional period is extended to 8 to 10 years or longer, while others did not specify a period. The submissions in most cases did not include a quantitative or qualitative justification for the need for a longer review period. A notable exception is submission #2220 that resubmitted partially modified information from ECHA CfE 2018 and a critical review of the Dossier Submitter's analysis. (See point A above.)

The reasons brought up in support of the requests for a longer transitional period include:

- Lack of alternatives and longer period required to reformulate
- Insufficient time for stability testing and the technical time for a shelf-life test (between 30 and 36 months) is to be added to the transitional period
- Significant pressure on industry, in particular SMEs.

At the same time some submissions (e.g., ECHA consultation 2019, #2024, #2075, #2112, #2155, #2161, #2168, #2180, #2201, #2372, #2575, #2690, confidential submissions) raised the opposite concerns, e.g.:

- the transitional periods for cosmetics are too long and emissions to the environment need to be addressed sooner
- alternatives are available and some submitters provided reports that they do not use microplastics or are able to transition to microplastic-free alternatives within the transitional period

The Dossier Submitter took the following information into account in the recommendation of the 4-year transitional period:

- the length of activities required for a typical reformulation: 2.5 to 4.5 years according to https://www.cosmeticsinfo.org/product-reformulation, for the following activities: 12-18 month for raw material research and development, 6-12 months product testing and qualification, 6-12 months safety and regulatory requirements, 6-12 months manufacturing and marketing, post-market surveillance and evaluation. (The Dossier Submitter notes several submissions that have provided alternative/longer timelines for the reformulation process spanning similar activities.)

- information that there are non-polymeric ingredients on the EEA market, biodegradable alternatives are emerging, and that there are a large number of formulations that do not contain any of the 500+ polymers tracked for the purpose of the High Scenario (on average about 70% of the formulations in the CosmEthics database, ranging from 42% to 97% for different rinse-off categories). (See section D.5.4.2 in the Annex to the Background Document.)

- information from ECHA CfE 2018, partially modified for the purpose of ECHA consultation 2019 (#2220), which stated that it will take on average five years to transition to alternatives (assumed an average for rinse-off and leave-on cosmetics) and that "Using alternatives should be possible in a couple of years, when opacifiers that behave like microplastics might be replaced."

- emissions to the environment from rinse-off cosmetics and their overall contribution of emissions of intentionally added microplastics;

- other stakeholders' readiness to comply with the restriction in addition to industry whose readiness is dependent on their ability to transition to alternatives (e.g., enforcement authorities to put in place the necessary protocols to monitor the compliance with the restriction)

- cost-effectiveness, non-monetised impacts of the restriction, practicality and monitorabilty of the proposed restriction.

With respect to the last point, the Dossier Submitter notes that industry representatives have calculated a lower cost-effectiveness of the restriction (more than €1 000 per kg of emitted microplastics per year). The Dossier Submitter maintains that there are no strong cost-effectiveness justifications for a longer transitional period as even if the negative impacts of the restriction are 100 times higher than the estimated by the Dossier Submitter, i.e., even higher than estimated by industry, the cost-effectiveness continues to be comparable to already adopted restrictions on substances of environmental concern.

There may however be arguments for a longer transitional period with respect to the practicality of the restriction, in particular its manageability for SMEs if all rinse-off and leave-on categories are in the scope of the proposed restriction. Please see the discussion below on impacts on SMEs. As RAC concluded that due to the persistent nature of microplastics, all emissions to the environment need to be minimised and as each additional year of transitional arrangements would lead to an annual increase of the stock of microplastics in the environment, the Dossier Submitter concludes that strong justifications are needed to support a longer transitional period.

As stated above, the Dossier Submitter considered 6-12 months stability testing in the setting of the review period. This is fully consistent with Cosmetics Europe recommendation that "Accelerated tests, developed because of the relatively short development cycle for cosmetic products, enable the prediction of stability. A commonly accepted practice is to support the forecasts obtained from accelerated stability testing by carrying out periodic post-launch monitoring of retained samples stored at ambient temperatures. The resultant information can also be useful in further improving the product and in refining the methodology used for accelerated stability testing." The Dossier Submitter hence concludes that, while there may be an argument to extend the transitional period by an additional two years to reflect the total time needed for stability testing, none of the stakeholders requesting such extension provided sufficient justification, including information on the required tests, their duration, whether this considers the possibility for accelerated testing, and why accelerated testing is not appropriate for microplastics when it is recommended for other ingredients.

(iii) Derogation for leave-on products

Several submissions expressed concerns with the proportionality of the proposed restriction on leave-on products, industry's capacity to be able to handle so many reformulations, the lack of alternatives, and that six years is insufficient to reformulate. E.g., ECHA consultation 2019, #2085, #2093, #2107, #2137, #2155, #2210, #2220, #2358, #2361, #2375, #2547, #2586, #2588, #2635, #2678, #2738, confidential submissions. Other submissions argued for longer transitional periods: in excess of 12 years, while yet others discussed how a few leave-on cosmetic product groups could be reformulated within the transitional period but others would require more than 12 years. Some submitters argue that the transitional periods proposed by the Dossier Submitter are already too long, e.g., #2075, #2121, #2201, #2372, #2575. While the majority of the submissions provided brief qualitative statements for a derogation, other submissions such as #2220, #2361 and confidential submissions, provided detailed quantitative and qualitative justifications.

The Dossier Submitter recognised in its analysis that the leave-on cosmetics sector has one of the lowest contributions to the emissions of intentionally added microplastic to the environment, while it would have to face the highest cost per kg of emissions reduced. The Dossier Submitter also highlighted that some groups of leave-on cosmetics (make-up, lip and nail leave-on products) could bear a larger cost than other product groups while they contribute less emissions to the environment than some of the other sectors in the scope of the proposed restriction. See section D.5.5.7 in the Annex to the Background Document for details and the Dossier Submitter's discussion on the proportionality of an alternative action on leave-on cosmetics. At the time of the dossier submission, these conclusions were associated with considerable uncertainty related to which polymer uses are impacted by the proposed restriction. This uncertainty to a large degree remains despite attempts by the Dossier Submitter to gather additional information via the consultation on the submitted dossier. (See section on response to Specific Question 6.)

Using the assumptions made by stakeholders (e.g., ECHA consultation 2019, #2361, confidential submissions, also see point (i) above) for sensitivity purposes shows low overall proportionality for the leave-on cosmetics and the cost-effectiveness falls within

the so-called "grey zone" where action on environmental pollutants of between €1 000 and €50 000 per kg of emission avoided may or may not be approved by regulators (Oosterhuis et al., 2017). The Dossier Submitter concludes that the sensitivity analysis using industry assumptions may strengthen the case for an alternative action for make-up/lip/nail leave-on products. The disadvantage of the introduction of comprehensive instructions for use for such products is that it would likely not eliminate emissions from these products, although it would lead to a decline in emissions sooner (from 2024 if similar to other proposed instructions for use requirements) and allow for a subsequent action at the five-year review if emissions do not decline.

As presented in the section D.5.5.7 in the Annex to the Background Document, the Dossier Submitter concludes that a ban on the remaining leave-on categories (excluding make-up, lip and nail products) has a cost-effectiveness comparable to the cost-effectiveness of the recently adopted restriction on D4/5 in wash-off cosmetic products. These categories of other leave-on cosmetics account for less than 40% of the total restriction costs for the proposed ban on the placing on the market of leave-on products and more than 70% of the leave-on emissions to the environment.

(iv) The Dossier Submitter has assumed that there are alternatives

Several stakeholders expressed concerns that in their analysis the Dossier Submitter has assumed that there are alternatives for all uses of microplastics. (E.g., ECHA consultation 2019, #2168, #2172, #2220, #2361, confidential submissions). While many of the submissions did not provide supporting information, ECHA consultation 2019 #2220 referred to a survey of their membership which showed that for 85.5% of the formulations there are no readily available alternatives. At the same time, several stakeholders spoke of the availability of alternatives, e.g., ECHA consultation 2019, #2024, #2075, #2372, #2375, #2575, confidential submissions).

For all sectors in the scope of the proposed restriction, where there are known alternatives, such as for rinse-off cosmetics with exfoliating or cleansing functions, the Dossier Submitter has not proposed a transitional period. Instead, the proposed ban on the placing on the market is to enter into effect from the entry into force of the proposed restriction.

For uses for which the Dossier Submitter has recognised that it will take time to identify and transition to alternatives, e.g., other rinse-off and leave-on cosmetics, the Dossier Submitter has proposed a transitional period. The length of the transition period was selected on the basis of an evaluation of several factors: please see point B above.

At the same time, the Dossier Submitter cannot ignore information demonstrating that there are:

- non-polymeric cosmetic ingredients for all microplastic functions: a review (Bertling et al., 2018) of the CosIng database showed that the only two functions where polymers represent more than 80% of all registered ingredients are film forming (out of scope of the proposed restriction) and skin conditioning;

- polymer- or microplastic-free formulations are available on the market in all categories

of cosmetic product categories: this is demonstrated by the several certification programs for cosmetic products as well as databases that track cosmetic ingredients. Such databases reveal that for the majority of the cosmetic product categories, those containing polymers are less than 50%. The categories where polymers represent more than two-thirds of the formulations are primarily those products that are expected to be primarily disposed of during household trash, i.e., nail, lip and make-up products. (See Table 57 and Table 61.)

- polymer uses that do not meet the microplastic definition in the proposed restriction, e.g., soluble/liquid polymers, natural polymers, biodegradable polymers, or polymers with film forming function, are not excluded from the results above. Therefore, i) the reported percentages above likely overstate the share of microplastic-containing products and ii) these polymer uses may also be potential substitutes for the microplastic ingredients.

(v) Impacts on SMEs are greater

Several submissions express concerns that the impacts of the proposed restriction would be greater than estimated as the resources required to undertake concurrently a large number of reformulations within the transitional period may be particularly burdensome for SMEs. E.g., ECHA consultation 2019, #2107, #2168, #2172, #2180, #2210, #2220, #2358, #2515, #2547, #2635, #2678.

Based on information provided from stakeholders, it can be concluded that the impact on SMEs would depend on their role in the supply chain:

- SMEs currently manufacturing microplastic-free cosmetics: These would include manufacturers of natural or organic cosmetics, representing about 5.9% of Cosmetics Europe membership (Cosmetics Europe survey, Feb 2019, ECHA consultation 2019, #2220) but also other manufacturers whose products do not meet the microplastic definition in the proposed restriction (about 60% of the polymer uses in leave-on cosmetics, ECHA consultation 2019, #2361). These manufacturers are expected to directly benefit from the restriction as they already have on the market formulations meeting the proposed requirements, hence they would not require resources to reformulate and would be able to respond quicker to the increased demand for alternative products.

- SMEs that manufacture products on behalf of clients: Many large cosmetics companies outsource the production of certain products to SMEs which then produce the products using microplastic ingredients. For example, in Italy, 126 out of 135 Italian contract manufacturers or 93% are SMEs (ECHA consultation 2019, #2169, #2220, #2515). Contract manufacturers generally have a selection of basic formulas that customers can choose from, adding or subtracting ingredients to create a custom item, or they will make a client's formula or develop something original. If SMEs focus on manufacturing of microplastic-containing products based on client formulas, it is expected that reformulation activities – the largest impact expected from the proposed restriction – would not be conducted by them. Individual impacts may be expected on selected contract manufacturers which are unable to secure contacts for microplastic-free alternatives. However, assuming continued demand for cosmetics in the EEA and no

substantial changes in the manufacturing equipment or the business model for the manufacture of microplastic-free cosmetics, no overall net effect is expected from the restriction for this supply chain segment because manufacturing of microplastic-free alternatives would scale up and by the end of the transitional period take over manufacturing capacity from microplastic-containing products. Increased material costs are expected to be passed on to the contracting party. Those are taken into account by the Dossier Submitter under material costs. (See section D.5.5.4 in the Annex to the Background Document).

- SMEs suppliers of microplastic containing ingredients: In addition to contract manufacturers, these SMEs represent another large group of companies engaged in business-to-business (B2B) activities. According to a cosmetics industry expert, 94% of SMEs are in a B2B relationship with larger companies (SEAC meeting minutes, June 2019). These SMEs are expected to have to invest substantial resources in the reformulation of their products. Taking into account information about the turnover and typical investment in R&D of Italian SMEs (ECHA consultation 2019, #2515), it can be concluded that these companies may experience substantial difficulties finding the capacity and resources to reformulate several microplastic ingredients within the transitional period. It is expected that these difficulties could be experienced primarily for leave-on cosmetics, considering the diversity of functions that can be performed by microplastics, the substantially larger number of reformulations estimated to be needed to comply with the restriction and overall higher complexity of the reformulation process for leave-on cosmetics.

- SME manufacturing proprietary cosmetics products containing microplastics: These SMEs are likely to experience similar difficulties to SME suppliers with the proposed restriction on leave-on cosmetics if they have several products requiring reformulation.

The exact net impact on SMEs is uncertain, as one of the main factors influencing the SME's ability to comply with the proposed restriction – the number of reformulations required – is highly uncertain and difficult to predict even by sector organisations. (See section D.5.5.6 in the Annex to the Background Document.) The Dossier Submitter deems it unlikely that the net effect of the proposed restriction on SMEs would be negative from the proposed restriction on rinse-off products, considering the large number of microplastic-free reformulations already available on the market and primarily one main function – opacifying - that requires reformulation of microplastic containing products. In the event all leave-on cosmetics are restricted with a transitional period of six years, it can be concluded from comments submitted during the consultation that only some of the SMEs currently marketing proprietary microplastic-containing products may experience difficulties garnering resources to reformulate by the end of the transitional period.

(vi) INCI codes are not an adequate way to define microplastics and references to INCI names should be removed

Several stakeholders expressed concerns that polymers listed in Table 52, Table 113, and others in Section D.5 in the Annex to the Background Document cannot be considered microplastics. (E.g., ECHA consultation 2019, #2108, #2110, #2172, #2352, #2418, #2510, confidential submissions.) As quoted by some of these consultation contributors,

the section on "State" in chapter D.5.1 of the Annex to the Background Document discusses that the building blocks of microplastics - polymers - come in many forms with the same polymer being used as a liquid in one product and a solid in another and that identifiers such as the INCI name do not provide information on the physical state of the polymer in the cosmetic formulations. This is because the state (phase) depends not only on the monomers that make up the polymer or copolymer, but also on properties like chain length, degree of crosslinking and molecular weight, or the ratio of different monomers in copolymer materials. Whether the polymer use is within the scope of the restriction proposal also depends on the function of the polymer (e.g., film forming such that the particles lose their microplastic form is proposed to be derogated from the ban on placing on the market), the nature of the mixture (in particular as it relates to the solubility of the polymer due to interaction with the mixture ingredients), and whether the polymer meets the biodegradability conditions outlined in Appendix X of the proposed restriction wording.

All this suggests that whether a specific polymer use falls in the scope of the proposed restriction has to be determined on a level of an individual formulation. As such information is not available to the Dossier Submitter for more than 400 000 formulations on the EU market, some assumptions needed to be made in terms of the polymer uses that would fall in the scope of the proposed restriction. Therefore, for the purpose of the Low Scenario, all uses of the 19 polymers identified by Cosmetics Europe (see Table 52) during the ECHA CfE 2018 were assumed to be falling in the scope of the proposed restriction and in the High Scenario were included in excess of 500 polymers for which there is information that they may be ingredients in cosmetic formulations (Table 113). Therefore, at the time of publication of the dossier for the purpose of the launch of the consultation on the Annex XV report, and in addition to the information presented in the section on "State", a footnote was included with Table 113 stating that "Not all uses of these polymers may meet the proposed microplastics definition in Table 3 of the report…". Such similar text was included with the remaining tables in section D.5.5 of the Annex. The list of polymers in the Low and High scenario are purely an analytical aid and do not intend to imply that all the listed polymers would meet the regulatory definition of a microplastic or imply different options for the scope of the proposed restriction. The restriction scope is as defined in Table 3 of the Background Document

(vii) Responses to Specific Question 6 in the Consultation of the submitted dossier

Because of difficulties to identify microplastics on the basis of INCI information, specific information was requested during the consultation from manufacturers and formulators of cosmetic products on the share of their formulations that contain ingredients meeting the microplastic definition. Several stakeholders provided information (ECHA consultation 2019, #2161, #2256, #2259, #2278, #2727) and a number of other submissions provided confidential or partial answers on this topic. The information provided was by-and-large not sufficiently robust to narrow down the list of polymers in order to query the CosmEthics database and revised the current socio-economic impact assessment. Instead, the Dossier Submitter used the information provided to further identify which polymers may be most likely impacted by the scope on the basis of their physico-chemical properties (i.e., excluding liquid or soluble polymers), i.e., to refine the

approach which lead to a rough reduction of the microplastic tonnages in the High scenario by about 50% on average (this reduction was not applied to the number of reformulations however).

This additional analysis focused on the polymers present in leave-on products, primarily because as the uncertainty in the proportionality assumptions for leave-on products was greater but also because of the nature of the information provided. On that basis, the Dossier Submitter estimated that approximately 60% of polymer uses could fall in the scope of the proposed restriction. As further polymer uses may have film forming properties – 19% by estimates from Cosmetics Europe survey – the resulting estimate of polymer uses falling in scope is 45%: which is close to the assumption provided by industry that only 40% of polymer uses would fall in scope Therefore, the Dossier Submitter chose to revise the estimated tonnages of microplastics used in leave-on cosmetics using the 40%assumption provided by industry (ECHA consultation 2019, #2220, #2361).

To summarise, the Dossier Submitter estimated the tonnages of microplastics used in leave-on cosmetics on the basis of the estimated number of formulations on the EEA market containing polymers, scaled up by the ratio of tonnes microplastics per formulation (based on information provided by Cosmetics Europe, ECHA CfE 2018) and multiplied by 40%. Such reduction was not applied to the estimated number of reformulations required to comply with the proposed restriction. This is because the number of required reformations is estimated on the basis of the share of polymer-containing formulations on the market. These estimates cannot be revised not knowing which particular formulations fall outside the scope of the proposed restriction.

The Dossier Submitter concludes that this approach results in a significant overestimation of the number of required reformations to comply with the proposed restriction and therefore, overestimate the total restriction costs of the proposed ban on the placing on the market of leave-on products. (See detailed response on this topic above under section i.c.)

Therefore, the results presented in the revised analysis for leave-on products confirm earlier results: a restriction on leave-on cosmetics has similar proportionality to previously adopted restrictions addressing environmental pollutants. However, many of the uncertainties identified in the original analysis in the submitted dossier are also present in this revised analysis. The main uncertainty in the analysis relates to the fact that while an attempt was made to exclude liquid or less relevant uses of polymers in the estimation of the tonnages used and emitted from leave-on cosmetics, the analysis still does not exclude irrelevant formulations from the estimation of the reformulation costs – the cost category that accounts for more than two-thirds of the total restriction costs. As a consequence, the total costs estimated are likely an overestimate the actual costs imposed on the cosmetic sector by the restriction proposal. Please see section D.5.5.6 in the Annex to the Background Document for further discussion on the uncertainties in the assessment.

D.6. Detergents and maintenance products

Polymers used in detergents and maintenance[91] products provide numerous technical functions, depending on the polymers used and on the product category in which they are used. The socio-economic impacts of a regulatory action under REACH will be analysed for four broad categories:

- **Microbeads contained in detergents**: Microbeads are used in detergents for their abrasive and cleaning effects. These microplastics are commonly referred to as plastic microbeads. They are used in products such as hard surface cleaners, toilet cleaners, bathroom acid cleaners and stainless steel cleaners.

- **Polymeric fragrance encapsulates:** Polymeric fragrance encapsulates are used in detergents and other consumer products to give a long-lasting scent while reducing the quantity of perfume used. Examples of products in this category are laundry detergents and fabric softeners. While the majority of fragrance encapsulates is used in the detergents sector, a small part is also applied in rinse-off and leave-on cosmetics. It should be noted that these cosmetic applications are also covered in this section's assessment, even though the focus is on detergents and maintenance products.

- **Other microplastics contained in detergents:** This group includes all remaining microplastics contained in detergents other than those described above. The microplastics in these products may provide a variety of functions, such as anti-foaming or sequestering. Examples of products in this category include laundry detergents and manual dishwashing liquid.

- **Waxes, polishes and air care products (maintenance products)**: Waxes are generally applied as processing aids and as base materials or additives for the creation of certain product properties. Waxes are also the major ingredient in polishes where their task is to deliver surface protection for various materials. Furthermore, they are used as viscosity regulators in the production process of coatings where they deliver surface protection and serve as a matting and slip agent in the final product. Examples of air care products include aerosol, electric, gel and liquid air fresheners, scented candles and car air fresheners.

The categorisation is due to differences in uses, emissions to the environment and alternatives. Because of these variations, different impacts are expected from potentially different necessary regulatory action.

D.6.1. Other Union-wide risk management measures than restriction

The Detergents Regulation (EC) No 648/2004 establishes common rules to enable detergents and surfactants to be sold and used across the EU, while providing a high degree of protection to the environment and human health. It defines a detergent as "any substance or preparation containing soaps and/or other surfactants intended for

[91] According to A.I.S.E. (AI 2018, #013), the maintenance product category is made up of air care products (i.e. aerosol, electric, gel and liquid air fresheners as well as scented candles and car air fresheners), polishes (i.e. shoe, floor, furniture and metal polishes) and home insecticides.

washing and cleaning processes. Detergents may be in any form (liquid, powder, paste, bar, cake, moulded piece, shape, etc.) and marketed for or used in household, or institutional or industrial purposes." The Detergents Regulation stipulates that surfactants used in detergents must be fully biodegradable. In addition, it regulates how products should be labelled with ingredient and dosage information in order to protect human health (e.g. skin allergies) and avoid overuse of detergents. The Detergents Regulation was updated by Regulation (EU) No 259/2012 which amended it with regard to the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents. Waxes and polishes (e.g. for furniture, floors and cars) are not covered by the Detergents Regulation.

The Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (CLP) (EU 1272 /2008) is also of relevance to the detergents and maintenance sector. The CLP Regulation aims to provide consumers and workers with relevant and adequate information that allows them to recognise the real hazard of a product and get relevant safe use guidance. Most cleaning and maintenance products are mixtures and therefore they must comply and be classified, labelled and packaged according to CLP.

D.6.2. Use

The definition of microplastics is a critical factor in outlining the use of microplastics in detergents and maintenance products, as well as in determining the possible scale of impacts of a potential REACH restriction. In the initial Annex XV report, the Dossier Submitter used information provided by industry related to both the definition of microplastics presented in the call for evidence (CfE) and the definition proposed by the International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.). The two definitions are presented below:

- The CfE's definition of microplastic particles: "Any polymer-containing solid or semi-solid particle having a size of 5 mm or less in at least one external dimension[92]."
- A.I.S.E.'s definition of microplastic particles: "Water-insoluble solid plastic particles with a size less than 5 mm that can be found as aquatic litter."

In the impact assessment in the initial Annex XV report, the Dossier Submitter used the information related to the A.I.S.E. definition as the starting point for the Low Scenario and the information related to the ECHA CfE as the starting point for the High Scenario. When no additional information was available, the midpoint between the High tonnage and the Low tonnage scenarios were used for the Central tonnage scenario.

As part of the consultation, industry respondents were able to provide more specific information based on the definition proposed in the initial Annex XV report. For example, A.I.S.E. undertook a survey and targeted interviews amongst its members regarding the impacts based on the refined definition. The respondents to this survey account for around 60% of the overall sector (with the exact percentage varying by product

[92] The solid form of a polymer in the environment (at ambient temperature and pressure of 101.3 kPa) may, for example, be defined via a melting point above 20 °C (includes waxes). Thermosetting plastics, however, will decompose rather than melt. Semi-solid refers to a material which is in a physical state between a solid and a liquid. A polymer can, for example, be defined to be a semi-solid when its melting point (at ambient temperature and pressure of 101.3 kPa) is above 20 °C and its glass transition temperature is below 20 °C.

category). The Dossier Submitter considers this sufficiently representative for extrapolation. The total tonnages provided in the consultation (16 900 tonnes) are closer to the upper estimates used in the Annex XV report (where the assumed tonnage range was 2 000 – 17 400). Since the Dossier Submitter now has more specific information related to tonnages, the wide tonnage ranges used in the Annex XV report are no longer needed. The central scenario in the updated impact assessment is based on the updated tonnage information provided as part of the consultation. In order to account for some remaining uncertainties, the Dossier Submitter has introduced new low and high tonnage scenarios with more narrow ranges than those used in the initial Annex XV report.

D.6.2.1. Scope of use according to the definition proposed in the Annex XV report

According to A.I.S.E. (#2382), the detergents and maintenance sector is estimated to use more than 120 polymers that fall under the proposed definition and are not within the scope of any of the derogations. It should be noted that there are some uncertainties related to this estimate, as some of the polymers can exist in different forms, e.g. polyethylene can be either solid plastic or semi-solid wax.

Based on the survey undertaken by A.I.S.E. following the publication of the Annex XV report, A.I.S.E. has estimated the total volume of polymers used by the entire EU sector. There were 14 respondents to the survey, with 4 of them being SMEs and the other 10 being large multinationals. The respondents have a market share of around 60%, although the exact percentage varies between the product categories. It should however be noted that according to A.I.S.E. (2018) there are currently 700 manufacturing sites in Europe, with 85% of these being SMEs. A.I.S.E. has used other sources of information, such as Euromonitor data from 2018, to extrapolate the results for the whole sector. The results, broken down by product category, are presented in the below table.

Table 70: Breakdown of the total volume of polymers used by product category

Product category	Total volume (tonnes) of polymer used by respondents in 2018	Total volume (tonnes) of polymer used by entire sector in 2018	Estimated number of polymer used in 2018
Solid laundry detergent	4 600	6 800	17
Liquid laundry detergent	3 700	5 300	23
Fabric conditioner	400	700	12
Glass/window, bathroom, kitchen cleaners	100	400	12
All-purpose hard surface cleaners	100	200	4
Toilet cleaners	<100	<100	1
Automatic dishwasher detergent	100	400	5
Manual dishwasher detergent	200	500	9

Product category	Total volume (tonnes) of polymer used by respondents in 2018	Total volume (tonnes) of polymer used by entire sector in 2018	Estimated number of polymer used in 2018
Waxes and polishes	400	1 200	27
Air care products	<100	<100	1
Professional building care	<100	<100	1
Bleaches	0	0	0
Water treatment	1 400	1 400	37
Industrial cleaning and disinfectants			
Other			
Total	**Approx. 11 000**	**Approx. 16 900**	**112**

Notes:

1. Respondent data based on 10/14 companies – two companies were excluded as raw material volumes were reported instead of polymer volumes, and two companies did not provide volume data.

2. For confidentiality reasons water treatment volumes have to be reported along with the "other" product category.

3. Volume data are reported to the nearest 100 tonnages to avoid the impression of false accuracy.

4. The total number of polymers used in 2018 is lower than the sum of the total number of polymers per product category as some polymers are used in more than one product category.

5. Volume data do not include, to the extent possible, volumes of polymers that fall under one of the derogations.

Source: A.I.S.E. #2382

There may be still be some uncertainties related to the above data, as a few respondents to the A.I.S.E. survey said that they still found some ambiguity in the definition proposed in the Annex XV report. Furthermore, A.I.S.E. noted that the products in the "other" category typically relate to the professional cleaning and hygiene sector for which there is no readily available market share information that can be used for extrapolating the survey results. Therefore, it considers it likely that the tonnage reported for that category is underestimated. Nevertheless, the tonnages are the best available estimates of the polymers considered within the scope of the proposed definition.

The A.I.S.E. survey also collected information on the concentration of polymers for the different product categories. The results are outlined in the table below.

Table 71: Concentration of polymer used per product category

Product category	Concentration of polymers used				
	10th Percentile	**90th Percentile**	**Median**	**Standard Deviation**	**Sample Size**
Solid laundry detergent	0.03%	29.64%	0.75%	4.78%	25

Product category	Concentration of polymers used				
	10th Percentile	**90th Percentile**	**Median**	**Standard Deviation**	**Sample Size**
Liquid laundry detergent	0.01%	3.10%	0.20%	2.80%	31
Fabric conditioner	<0.01%	3.45%	0.04%	4.41%	11
Glass/window, bathroom, kitchen cleaners	0.01%	5.00%	0.99%	1.78%	11
All-purpose hard surface cleaners	0.02%	3.08%	0.98%	1.37%	18
Toilet cleaners	-	-	-	-	1
Automatic dishwasher detergent	0.23%	14.01%	1.93%	6.01%	13
Manual dishwasher detergent	0.01%	3.54%	0.94%	0.88%	9
Waxes and polishes	0.03%	14.85%	1.14%	6.74%	40
Air care products	0.56%	32.00%	1.60%	14.08%	5
Professional building care	-	-	-	-	2
Bleaches	0.16%	0.50%	0.25%	0.14%	5
Water treatment	0.08%	26.90%	1.20%	26.90%	39
Other					
TOTAL	**0.01%**	**14.49%**	**0.73%**	**12.75%**	**210**

Note:
1. Percentiles and median values are presented instead of minimum / maximum and mean values in order to exclude outliers.
2. For confidentiality reasons water treatment volumes have to be reported along with the "other" product category.

Source: A.I.S.E. #2382

In response to a specific information request in the consultation, A.I.S.E. also provided information on the proportion of products that contain microplastics to achieve their intended function in different concentration ranges. The survey results show that 95% of the affected products contain microplastics above the proposed 0.01% w/w concentration limit. The detailed results are outlined in the following table.

Table 72: Breakdown (%) of products affected by proposed restriction - by concentration limit bands

Product category	Concentration				
	Greater than 1.0% w/w	**Between 0.1% w/w and 1% w/w**	**Between 0.01% w/w and 0.1% w/w**	**Between 0.001% w/w and 0.01% w/w**	**Less than 0.001% w/w**
Solid laundry detergent	61%	31%	7%	0%	0%
Liquid laundry detergent	10%	65%	15%	10%	1%
Fabric conditioner	23%	51%	25%	0%	0%
Glass/window, bathroom, kitchen cleaners	64%	31%	4%	1%	0%
All-purpose hard surface cleaners	50%	30%	19%	0%	0%
Toilet cleaners	34%	64%	1%	1%	0%
Automatic dishwasher detergent	75%	25%	0%	0%	0%
Manual dishwasher detergent	25%	52%	15%	6%	2%
Waxes and polishes	72%	22%	2%	3%	0%
Air care products	22%	78%	0%	0%	0%
Professional building care	41%	54%	3%	3%	0%
Bleaches	28%	70%	2%	0%	0%
Water treatment	52%	30%	10%	6%	2%
Other					
Total	**46%**	**39%**	**10%**	**4%**	**1%**

Notes:

1. For confidentiality reasons water treatment volumes have to be reported along with the "other" product category.

Source: A.I.S.E. #2382

It should be noted that a few respondents to A.I.S.E.'s survey consider that microplastics may also be present in a substance or mixture as an impurity. If the concentration is below 0.1% in a product, the polymer is not expected to have a functional use in the actual product but may rather have that in one of the raw materials (e.g. for the viscosity of the raw material).

In the impact assessment, the central tonnage scenario will assume that a total of 16 900 tonnes of microplastics is used per year, based on the respondent data from A.I.S.E.'s latest survey extrapolated to the whole sector (#2382). To account for uncertainties, the low tonnage scenario will assume that a total of 11 000 tonnes of microplastics is used per year, based on the quantities reported by respondents to the survey (i.e. with no extrapolation for the rest of the sector). The low tonnage scenario is 35% lower than the central tonnage. To account for any underestimations in the tonnages provided by industry, the high tonnage scenario will assume that the tonnages are 35% higher than in the central tonnage scenario, giving a total of 22 800.

The assessment covers four broad product categories. The estimated tonnages for these four categories are outlined below:

- **Microbeads contained in detergents**: According to a consultation performed by A.I.S.E. in 2017 (AMEC, 2017), the total amount of *microbeads* used in soaps, detergents and maintenance products was approximately 200 tonnes in the EU[93]. In an updated consultation by A.I.S.E in May 2018, the amount of intentionally added microbeads had decreased by about 54%, to approximately 95 tonnes, when extrapolated to the whole market. Where the companies that provided data for the consultation in 2017 did not provide an update in 2018, A.I.S.E. assumed the same tonnages as communicated in the first response. Hence, it is clear that the use of microbeads is decreasing rapidly. According to A.I.S.E., a number of companies using microbeads have already announced their intention to reformulate their products, considering the use of alternatives where available. The Dossier Submitter will assume that the use of microbeads continues to decrease and is phased out by 2020 in all tonnage scenarios.

- **Polymeric fragrance encapsulates:** The International Fragrance Association (IFRA, #2421) estimates that the total volume of shells used for all fragrance encapsulation is at least 400 tonnes per year, with the majority being used in liquid laundry detergents and liquid fabric softeners. While the use of fragrance encapsulation technologies is increasing, the overall tonnage has remained stable due to a reduction of polymeric material used in the shells. The Dossier Submitter will assume that 400 tonnes of microplastics would be used annually in fragrance encapsulates in the central tonnage scenario. In line with the assumptions for the overall tonnages for the whole sector, the Dossier Submitter will assume a +/- 35% difference to account for uncertainties. Hence the low tonnage scenario will assume that 260 tonnes of microplastics are used in fragrance encapsulates per year, while the high tonnage scenario will assume that 540 tonnes are used per year.

- **Waxes, polishes and air care products (maintenance products)**: Respondents to the A.I.S.E. survey reported a total of 1 300 tonnes of microplastics used per year in this product category. Since this figure was the same for both the respondent data and the extrapolated data, the Dossier Submitter will assume that it is valid for all three tonnage scenarios.

- **Other microplastics used in detergents:** This group includes all remaining microplastics contained in detergents products. The tonnage is derived by subtracting the tonnages of the other product categories from the total sectoral tonnages. Hence, the impact assessment will assume that this product category annually accounts for 15 200 tonnes in the central tonnage scenario, 9 440 tonnes in the low tonnage scenario and 20 960 tonnes in the high tonnage scenario.

D.6.2.2. Baseline

The estimated tonnages and releases of microplastics in detergents and maintenance products are outlined in Table 73. For detergents it is assumed that 100% of the releases go down the drain. For waxes and polishes, the releases have been estimated in accordance with Environmental Release Category (ERC) 8C: 30% release to water, 15% release to air.

Table 73: Microplastic use in detergents and maintenance products: Baseline scenarios (tonnes/year)

Scenarios	2017	2018	2019	2020	2021	2022-2041 (average)
Low tonnage						
Microbeads contained in detergents	200	95	40	-	-	-
Polymeric fragrance encapsulates	260	260	260	260	260	260
Other microplastics contained in detergents	9 440	9 440	9 440	9 440	9 440	9 440
Waxes, polishes and air care products	1 300	1 300	1 300	1 300	1 300	1 300
- releases to water*	390	390	390	390	390	390
- releases to air*	195	195	195	195	195	195
Total use	11 400	11 295	11 240	11 200	11 200	11 200
Total releases	5 618	5 565	5 537	5 516	5 516	5 516
Central tonnage						
Microbeads contained in detergents	200	95	40	-	-	-
Polymericfragrance encapsulates	400	400	400	400	400	400
Other microplastics contained in detergents	15 200	15 200	15 200	15 200	15 200	15 200

Scenarios	2017	2018	2019	2020	2021	2022-2041 (average)
Waxes, polishes and air care products	1 300	1 300	1 300	1 300	1 300	1 300
- releases to water*	390	390	390	390	390	390
- releases to air*	195	195	195	195	195	195
Total use	16 900	16 900	16 900	16 900	16 900	16 900
Total releases	8 615	8 562	8 534	8 513	8 513	8 513
High tonnage						
Microbeads contained in detergents	200	95	40	-	-	-
Polymericfragrance encapsulates	540	540	540	540	540	540
Other microplastics contained in detergents	20 960	20 960	20 960	20 960	20 960	20 960
Waxes, polishes and air care products	1 300	1 300	1 300	1 300	1 300	1 300
- releases to water*	390	390	390	390	390	390
- releases to air*	195	195	195	195	195	195
Total use	23 000	22 895	22 840	22 800	22 800	22 800
Total releases	11 614	11 561	11 533	11 512	11 512	11 512

Notes: *In accordance with ERC 8C: 30% to water, 15% to air

The forecasted use of microplastics takes into account the evidence that the use of microbeads is decreasing rapidly. The tonnage of microbeads for 2017 is based on the A.I.S.E. consultation in May 2018, as it is assumed that the tonnage reported in that consultation refers to the preceding year. It is assumed that the use of microbeads in detergents will continue to decrease and be phased out by 2020.

The forecasted use of microplastics further takes into account the work of two opposing forces:

- Increased use of microplastics as a result of increased use of detergents and maintenance products based on population and consumer spending growth.
- Downward trend of use due to growing consumer awareness and concern with microplastics emissions to the environment.

As it is challenging to estimate the impact of consumer awareness on the future use of microplastics in detergents and maintenance products, it is assumed that this downward trend is equal but diametrically opposite to the upward trend due to population and consumer spending. The result of this assumption is no net change from 2020 levels to 2041: the end of the temporal scope of the analysis.

D.6.3. Uses, functions and alternatives

According to A.I.S.E. (ECHA AI 2018, #013), the polymers most commonly used in detergent and maintenance product formulations can be grouped into six polymer categories, as outlined in Table 74. The properties of these polymers vary depending on the type and size of the polymer used.

Table 74: Functions provided by different types of polymers

Polymer Chemical Group	**Key technical functions provided by polymer (non-exhaustive list)**
Polyethers (e.g. Polyethylene glycol and Ethoxylated lauryl alcohol)	• Viscosity modifier • Anti-foaming agent (e.g. stops excess foaming in bottles during filling) • Emulsifier • Dye • Builder/co-builder.
Polyacrylates (e.g. Acrylic styrene copolymer and sodium polyacrylate)	• Opacifier (e.g. optical differentiation of products that affects consumer choice) • Rheology modifier • Binder • Builder/co-builder (e.g. provides functions essential for controlling water hardness) • Complexing/sequestering agent • Cleaning agent/booster • Film former/softening agent (e.g. leaves a protective layer on surfaces upon drying, offering high gloss, durability, and detergent resistance with excellent removability) • Soil release agent • Surface modifying agent (helps control surface tension properties) • Thickener • Improves cleaning (i.e. makes cleaning faster and easier as treated surfaces resist dirt, soap scum and grease).
Siloxanes and Silicones (e.g. Polydimethylsiloxane)	• Foam control/anti-foaming agent (e.g. reducing/eliminating the risk of foam generation during the washing process) • softening agent • Surface protectant and polishing agent - Nourishes and covers surfaces with a thin layer of oil that creates a subtle gloss whilst also providing a lot of free space within its structure for individual water vapour molecules to pass through that allows air to pass through the substrate and therefore the coverage that it creates allows the article/substrate to breath.
Polysaccharides (e.g. Cellulose gum, Xanthan gum and starch)	• Viscosity/rheology modifier, thickener • Opacifier • Anti-redeposition agent • Film former • Encapsulating fragrance • Water retention • Suspension agent
Polyvinyl (e.g. Polyvinylpyrrolidone)	• Anti-foaming agent required to avoid excess foaming in bottles during filling • Thin soluble films • Dye transfer inhibitor reducing/eliminating the risk of colour transfer between fabrics during the washing process.
Polyesters (e.g. Polyethylene terephthalate)	• Surfactant • Soil release agent (helps remove soil and prevents it's build-up) • Detergent booster (increasing the efficacy of the product).

Source: A.I.S.E. (ECHA AI 2018, #013)

Some of the technical functions of microplastics used in the detergents and maintenance sector, as well as the available information on their alternatives, are described in further detail below.

D.6.3.1. Abrasives

Abrasive ingredients are used to polish, buff, or scour away soils such as dirt and dust. In a report for RIVM, Verschoor et al. (2016) describe four factors that contribute to effective cleaning: mechanical force (motion), chemicals, duration and temperature. Abrasives are added to some detergents to increase the motion, resulting in the need for less aggressive chemicals or less time to obtain the same result. Abrasive cleaners are typically based on polyurethane particles and are mainly used for gentle cleaning of hard surfaces, such as floors, equipment and work pieces, mainly in kitchens and bathrooms. They can be found e.g. in pot and pan cleaners, floor cleaners, stainless steel cleaner, machine dish detergents and bathroom acid cleaners.

According to Verschoor et al. (2016) the abrasive function is obtained through microbeads that should have a size of between 50 and 1000 µm in order to be effective. RIVM screened over 400 (abrasive) cleaning agents and found ten products suspected of containing microplastics serving as abrasive agents. All ten products were for cleaning floors. Verschoor et al. (2016) estimated that 2.6 tonnes of microplastics[94] were used in abrasive cleaning products in the Netherlands. Extrapolating this quantity based on population gives a total volume of 77.3 tonnes for the EU.[95]

A range of alternatives are available for microbeads used as abrasives. Natural mineral components, such as silica, ground walnut shell or clay, can be used to provide abrasive functions in cleaning products. Silica is commercially available in large quantities and seems to overall have a lower tonnage price than microplastics. AMEC (2017a) assessed silica as an alternative were microplastics serve as abrasive agents in cleaning products, based on a literature review alongside an industry consultation exercise and research on specific products. AMEC found that a typical commercial price for silicon dioxide is around €700 per tonne and compared this price with that of microplastics, which they estimated to be in the order of €1 100 per tonne, suggesting that the price of this alternative would not negatively affect the economic feasibility of substituting microplastics.

However, for some types of delicate surfaces, such as ceramic furnaces and stainless steel surfaces in the kitchen, natural mineral components may not be suitable alternatives. Silica is considered to be an inappropriate alternative for delicate surfaces due to its relative hardness. Silicon carbide may also be a feasible alternative in certain applications but is not appropriate for applications requiring a soft abrasive function. Aluminium oxide or silicon oxide may then be used instead of calcium carbonate. Verschoor et al. (2016) note that an abrasive that is too hard or coarse may remove too much material or leave undesired scratch marks. A finer/softer abrasive is likely to leave much finer scratch marks. While plastic particles are generally softer than mineral particles, they are also more expensive. Therefore plastic particles are only used in products that are specifically designed to clean delicate surfaces. Some of the respondents to A.I.S.E.'s latest survey also stated that alternatives, such as silica and ground walnut shell, may be more expensive, have a lower performance and have

[94] The definition applied by RIVM was: Microplastics are solid, synthetic polymer particles with a size smaller than 5 mm, with a low solubility in water (<1mg/L) and a low degradation rate70. Microplastics may contain non-polymeric additives, oils, fillers or other product aids.

[95] Population in the Netherlands (2017): 17.08 million. Population in the EU (2017): 508 million.

stability issues (A.I.S.E. #2382).

According to Verschoor et al. (2016), a ban on primary microbeads could be effective and relatively cheap in phasing out primary microplastics in abrasive cleaning agents because alternative ingredients are available. For certain niche products, such as cleaning agents for lenses and precision instruments, the alternative ingredients may however not be feasible. Nevertheless, these niche products are considered to account for a small share of the overall use of microbeads since Verschoor et al. (2016) conclude that the effectiveness of a ban would be high, as almost 100% reduction can be achieved.

As described previously, the use of microbeads as abrasives is clearly decreasing in the EEA. Responses received in the consultations with A.I.S.E.'s members showed that the annual use of microbeads as abrasives in hard surface cleaners (glass ceramic cleaners) had decreased from 126 tonnes in 2017 to 51.1 tonnes in 2018. For stainless steel cleaners, the annual use of microbeads as abrasives had remained at 3.5 tonnes.

D.6.3.2. Fragrance encapsulation systems

Perfume encapsulation systems are used in fabric enhancers, detergents and in wash scent beads to achieve a long-lasting scent. Encapsulate shells are polymeric materials that form a thin, flexible film around droplets of liquid fragrance oil. The polymers form a spherical thin film that ruptures on use, thereby releasing the liquid perfume content. The shells are not expected to be soluble in water and they show limited biodegradability. Their function is to increase deposition on fabrics and allow for gradual release of perfume through slow diffusion or rupture via friction during wear. They thereby allow the perfume to be perceivable in the fabric for a long time after washing while reducing the quantity of perfume used. (ECHA AI 2018, #015)

The International Fragrance Association (IFRA, #2421) estimates that the total volume of shells used for all fragrance encapsulation is at least 400 tonnes per year, with the majority being used in liquid laundry detergents and liquid fabric softeners. While the use of fragrance encapsulation technologies is increasing, the overall tonnage has remained stable due to a reduction of polymeric material used in the shells. The use of fragrance encapsulation technologies in new applications, such as rinse-off cosmetics, skin care, deodorants and household surface cleaners, is expanding although these new applications still account for a relatively small share of the market (#2421). According to IFRA (#2577), the percentages of the total EU market that contains fragrance encapsulates are:

- Laundry detergents: 10-20%
- Fabric softeners and laundry fragrance boosters: ~60%
- Other cleaning products :<1%
- Deodorants: <1%
- Other cosmetic products and other personal care products: <1%[96]

The latest generation of encapsulation formula contains approximately 1.5% of polymeric shells. For melamine chemistry, which is the most common fragrance encapsulation technology, IFRA and A.I.S.E. (ECHA AI 2018, #193 and #017) state that the

[96] Note that the percentages do not sum to 100% since they relate to different product types

concentration of shell wall (polymers) in finished products are within the following ranges:

- laundry detergents: 0.0013 - 0.095%;

- fabric softeners: 0.0018 - 0.04%;

- scent boosters (a niche application): 0.0063 - 0.115%.

It should be noted that these values represent the concentrations of the polymeric shell in the mixture and not the whole polymer-containing particles (i.e. including the content), which would be higher. Industry was not able to provide the weight by weight concentration of particles within the mixture. However, it can be noted that the polymer wall represents on average 2-6% of the perfume encapsulate (ECHA AI 2018, #015). In its comment to the consultation, IFRA (#2239) stated that at polymer levels below 0.01% consumer performance is lost rendering the finished product non-functional for fragrance delivery. Therefore, the functional benefit of fragrance formulations are only delivered when capsule polymers are present above 0.01% in the finished product.

The polymers used in fragrance encapsulation for detergents include melamine-formaldehyde, polyurea/polyurethane and polyacrylate (ECHA AI 2018, #657). Information received by IFRA (ECHA AI 2018, #193) indicates that the use of fragrance encapsulation technologies, in terms of tonnage amounts, is allocated primarily to laundry detergents (50-55% of total volume) and fabric softeners (35-40% of total volume), with other products accounting for 5-15% of the total volume. The percentage of products on the EU market containing fragrance encapsulates is approximately 60% for fabric softeners, 10-20% for laundry detergents and less than 1% for other products. (IFRA, CfE #657).

The use of encapsulation technologies enables slower perfume evaporation, prolonging the perfuming effect, while requiring less perfume. According to stakeholders (CfE #666 and AI 2018 #303), only about 1% of the perfume oil added to a detergent and about 10% in a fabric softener survive the washing, rinsing and drying process without encapsulation. When the perfume is added in an encapsulated form, about 20% for detergents and 50% for fabric softeners is retained on fabrics, i.e. the retention efficiency is 5-20 times higher. As a result, the technology allows to use at least 33% less perfume oil per year in products that utilize perfume encapsulate technology. It also means less organic chemical release to water and air.

According to IFRA (CfE #657), there are no viable alternatives to the polymeric encapsulation systems in the major applications of liquid laundry detergents and liquid fabric care that provides the required performance attributes. The required performance attributes are said to be primarily:

- Ability to resist various changes in physical and chemical environments to perform their intended function;
- Provide appropriate release of the fragrance in time and space to drive a consumer-perceivable scent;
- Minimisation of raw material consumption to reduce waste and cost;
- Ability to encapsulate a wide range of fragrance ingredients;
- Ability to be easily incorporated into, and be compatible with consumer products;
- Maintaining of the fragrance within the capsule during storage in the consumer product;

- Deposit on the target substrate sufficiently;
- Not cause any gross negatives in the product, during application, or after use; and
- Cost-effective and safe to use.

The option of using higher levels of traditional perfume molecules instead of encapsulation systems would increase costs and not provide the long lasting performance of encapsulation. Traditional perfume molecules are inherently volatile and therefore they quickly evaporate from the surface that they have been deposited onto. Most laundry products contain high levels of surfactants which prevent perfume deposition onto the surface. Furthermore, IFRA and another industry stakeholder (ECHA AI 2018, #303) note that the use of traditional perfume molecules would result in significantly higher use of perfume oil, hence increasing environmental exposure of perfume ingredients. In addition to the increased discharge of organic molecules into the environment, A.I.S.E. (ECHA AI 2018, #013) notes that the substitution of encapsulates with higher levels of perfume oil would increase concentrations of skin allergens and other classified components.

IFRA (CfE #657) highlights challenges in developing and identifying potential alternatives particularly for the two major products, liquid laundry detergents and fabric softeners. Using natural materials (e.g. pectin and cellulose) as alternatives for the encapsulation shell wall usually gives higher molecular weights and limited crosslink density. This makes the capsules more fragile and more porous to fragrance diffusion. Inorganic materials (e.g. clay and silica) tend to produce capsule systems that have issues surviving the product use cycle because they are too brittle or release fragrance uncontrollably during the wash cycle. This lends certain alternatives only being appropriate for use in dry powder or other non-liquid applications, which account for a smaller share of the market than the liquid laundry detergents and fabric softeners.

According to A.I.S.E. (CfE #666), there is a vision to make the walls of the perfume microcapsules fully biodegradable in the future, but this would need substantial efforts in R&D and related time.

D.6.3.3. Waxes, polishes and air care products (maintenance products)

Waxes provide a range of functions and are used by several industry sectors. They can have both natural and synthetic origin. The use is primarily as processing aids or as base materials or additives to provide product properties. Waxes serve as the major ingredient in polishes where their task is to deliver surface protection for various materials such as, among others, leather, floors and cars. They are also used as viscosity regulators in the production process of coatings where they deliver surface protection and serve as a matting and slip agent in the final product. Thus the function of waxes in detergent, household care and maintenance products is often to form a film upon usage, but it may also have other functions in the product. (ECHA AI 2018, #013)

In a survey among A.I.S.E. member companies, waxes and polishes were identified as having no known alternatives today. Examples of products with polymers stated to have no known alternatives are floor polish emulsions, polyethylene wax and polypropylene wax. In addition, beeswax and carnauba wax emulsion were reported to have no alternatives although they would be expected to be "biodegradable" and thereby derogated from the restriction. Acrylic copolymers and alcohol ethoxylate in waxes and polishes were also mentioned to have no alternatives today, but there is insufficient information from the call for evidence to determine if these types of polymers would fall

within the scope of a restriction. (ECHA AI 2018, #013)

Based on the information submitted by A.I.S.E. in the consultation (#2382), less than 100 tonnes of microplastics are also used in air care products. These products, which were not covered in the Annex XV report, include aerosol, electric, gel and liquid air fresheners, scented candles and car air fresheners.

D.6.3.4. Other functions

Rheology modifiers enable high low-shear viscosity and pseudoplasticity, which is important to maintain the stability of the dispersion and for pourability of the product. Without the stability, there could be separation of phases in the detergents formulation, which would have a negative impact on aesthetics, shelf life and performance. Pseudoplasticity, on the other hand, ensures a formulation that flows readily but does not leave long, stringy tendrils hanging from the mouth of the dispenser after the user has finished pouring. Rheology modifiers are used in detergent products. (A.I.S.E. CfE #666)

Opacifiers are used to give a milky, lotionized appearance to a wide variety of household liquid products, especially for mild products and products intended for sensitive skin. Mackadet OPR-1 was suggested as an alternative opacifier/viscosity modifier in toilet cleaners although it was noted that it has a negative effect on shine, that the shelf-life may be affected and that there would be an additional cost of handling and making it compatible with existing automated systems. Titanium dioxide TiO2 (or similar inorganic whitener) may be an alternative opacifier/viscosity modifier in a range of products, although it was noted that the appearance is likely to be affected, that the cost could be an issue and that several types of testing would be required. Furthermore, TiO2 has recently been classified as suspected of causing cancer by inhalation. Alternatively, it was suggested that the opacifier could be removed completely that formulations could be created as stable, opaque emulsions or that they could be replaced with alternative organic opacifiers, although this may affect consumer perception and costs. (ECHA AI 2018, #013; #2382)

Silicones used as **anti-foaming agents** have an important role in the manufacturing process but also in the use of final detergent products. As a processing aid they prevent the creation of foam during the manufacturing process. Silicones also serve as foam control agents and help to maintain the cleaning efficiency in various products, such as laundry detergents, fabric softeners and hard surface cleaners. They help to maintain the cleaning efficiency by ensuring the build-up of the correct foam level. Silicones are considered the most cost-effective foam control agents by industry due to their long-lasting performance. The use levels are usually 0.1% - 0.4%. (ECHA AI 2018, #013)

Complexing/sequestrating agents are used in laundry detergents to help preventing the resettling of soil on fabrics after it has been removed during washing. According to A.I.S.E. (CfE #666), sodium carboxymethylcellulose is cited as the most widely used complexing/sequestrating agent but other polymers are also commonly used.

Encapsulated enzyme granulates are used in detergents to reduce the potential for dust generation. Enzymes remove stains/soils effectively at low temperature and can also contribute to the compaction of detergent products. The enzyme granulates are coated with inorganic salts and typically contain insoluble polymers, such as natural polymers like cellulose, to give robustness and flexibility. They may also contain soluble polymers such as polyethylene glycol and starch to keep the structure. (CfE #673)

D.6.4. Overview of restriction response and restriction scenarios

In summary, stakeholders and EEA society as a whole are expected to react as follows to the proposed restriction on microplastics in detergents and maintenance products:

- The EEA detergents industry is expected to fully phase out microbeads by 2020, transitioning to silica or other alternatives for the abrasive and cleaning functions. Therefore, by the time the restriction enters into force (estimated to happen in 2022), it is assumed that no additional costs will arise for companies producing detergents containing microbeads.

- Comments received in the consultation (#2421, #2239 and #2160) indicates that the fragrance encapsulate industry intends to develop potential alternatives that would be out of scope of the restriction (e.g. biodegradable encapsulates). According to IFRA (#2421), a transitional period of 10-15 years would allow industry to develop alternatives. According to another industry submission (#2160), it has historically taken approximately 10 years to bring new encapsulate innovations to the market. If industry did not have enough time to develop feasible alternatives within the end of the transitional period, companies would be forced to remove the polymeric encapsulates and reformulate products to increase the amount of perfume contained in them. The Dossier Submitter has tested what the costs would be depending on how long it would take industry to implement alternatives. Assuming that industry is now starting to develop alternatives to microplastic-containing fragrance encapsulates, the main analysis will assume that the alternatives could be implemented by the start of 2030, which would mean 8 years after entry into force (since 2022 is the first full year when the restriction is expected to be in force). The lower boundary analysis will assume that alternatives could be implemented by 2027 (i.e. 5 years after entry into force, in line with the transitional period proposed in the Annex XV report), while the high boundary analysis will assume that alternatives could be implemented in 2032 (which would mean approximately 10 years from entry into force). The Dossier Submitter has assessed the costs for both a 5- and an 8-year transition period.

- Most companies using other microplastics in detergents or maintenance products are expected to attempt to reformulate products to substitute the microplastics. This is assumed to entail reformulation costs and changes to raw material costs. Companies are expected to complete reformulations within five years. A routine reformulation in the detergents sector can take 1-5 years if an alternative has already been identified (A.I.S.E. CfE #666 and AI 2018 #013). On average, it is expected that a reformulation takes approximately three years. A 5-year transitional period is more than 1.5 times the average time. Furthermore, failed reformulations may not require that the R&D process is restarted at step one. Feedback collected from industry

suggests that it could be possible to reformulate products within five years, although some companies would prefer to have longer[97]. Therefore, it is assumed that industry will be able to comply and complete the reformulations within five years from entry into force. This will entail reformulation costs from immediately after the restriction enters into force until entry into effect (i.e. from the start of 2022 to the end of 2026). From entry into effect, changes to raw material costs are also assumed from the implementation of alternatives.

- While the socio-economic analysis report submitted by A.I.S.E. during the preparation of the Annex XV report (ECHA AI 2018, #013) assumes that the majority of products could be reformulated within 5 years, it has in its own calculations assumed that 90% of products covered under the A.I.S.E. definition and 75% of the products covered under the CfE definition would require more than 5 years (up to 10 years) to be successfully reformulated. In A.I.S.E.'s survey following the publication of the Annex XV report, respondents stated that for most of the product categories, 50% of the reformulations could be completed in 5 years, 75% in 7 years, and 100% could be completed in 10 years. The respondents also emphasised that some products would be more difficult to reformulate than others. The Dossier Submitter has decided to test what impact such unsuccessful reformulations could have as a sensitivity check, assuming as a worst-case scenario that 50% of the reformulations will not be completed by the end of the transition period. With a 5-year transitional period for other microplastics contained in detergents as well as for maintenance products, the products that have not been successfully reformulated might be discontinued or the manufacturing of them may be relocated to outside the EEA. The possible profit losses associated with these formulations will therefore be included in the high-cost calculations as an upper bound of impacts for both polymeric fragrance encapsulates, other microplastics contained in detergents, and waxes, polishes and air care products. As demand for detergents and maintenance products is unlikely to decline in the future and many products are substitutes, these welfare losses for EEA society are expected to be of temporary nature and to only last for one reformulation cycle after the end of the transitional period (i.e. from 2027 until the end of 2029). By the end of

[97] In a consultation related to the costs of responding to a REACH restriction on microplastics, responses were collected from six companies. Two, who only reported needing to undertake two or four reformulations under the ECHA definition, indicated that they would require six months to reformulate their portfolios to remove microplastics. One of these companies reported that this would cause other R&D to be postponed, and that a three-year compliance period would be preferable. The remaining four companies responded that three to five years would be the minimum period required to reformulate over 800 products between them. However, they said that they would prefer between five and 10 years to comply with a restriction under an ECHA definition of microplastics as it would at least minimise disruption of other R&D activities. (A.I.S.E. additional information #013)

2029, manufacturers of alternatives are expected to have taken over their share of the market and the welfare losses from microplastic-containing products are expected to be compensated by gains of alternatives.

- Importers are expected to inform their international supply chains and reposition to source alternative, microplastic-free, products.

- Stocks of obsolete labels are expected to be depleted and new labels to be aligned with the requirements of the proposed restriction and other relevant EU-wide legislation. It is anticipated that five years will be sufficient as it is likely that new labelling may need to be produced in the meantime due to other regulatory requirements or due to other changes in the product formula.

- The quality of some detergents and maintenance products may be affected but this is expected to be acceptable for many consumers as they value products with lower impact on the environment.

As it is expected that companies will be prepared to comply with a ban on uses of microbeads contained in detergents prior to 2022, an EU-wide action, if proposed to enter into effect at that time, will not require a transitional period and will ensure that microbeads for these uses are not used in the future.

It is anticipated that a five year transitional period for the other microplastics contained in detergents and maintenance products will sufficiently minimise the negative impacts of the proposed restriction on industry while taking into account the necessity for timely action on reducing the emissions of microplastics to the environment and their subsequent effects. The sections below provide further detail on the likely response to the proposed restriction.

D.6.5. Restriction scenarios and key assumptions

The scenarios and the assumptions are summarised in Table 75. The lower and upper bound values used for sensitivity purposes are included in brackets. Since it is expected that microbeads will be phased out already before the restriction comes into force, they are not included in the table.

Table 75: Restriction scenarios: Summary of assumptions used in impact assessment of detergents and maintenance products

Impact category	Low tonnage scenario	Central tonnage scenario	High tonnage scenario
Tonnes of microplastics used per year			
Polymeric fragrance encapsulates	260	400	540
Other microplastics contained in detergents	9 440	15 200	20 960
Waxes, polishes and air care products	1 300	1 300	1 300
Tonnes of emissions reduced per year			

Impact category	Low tonnage scenario	Central tonnage scenario	High tonnage scenario
Polymeric fragrance encapsulates	133	203	275
Other microplastics contained in detergents	4 798	7 725	10 652
Waxes, polishes and air care products*	585	585	585
Number of formulations affected			
Polymeric fragrance encapsulates	2 900	4 500	6 100
Other microplastics contained in detergents	3 840	5 940	8 040
Waxes, polishes and air care products	60	60	60
Raw material costs			
Polymeric fragrance encapsulates	75% more perfume required (50 - 100%)/ alternatives to microplastics 50% more expensive (0 - 100%)		
Other microplastics contained in detergents	50% (0 - 100%)		
Waxes, polishes and air care products	50% (0 - 100%)		
R&D costs			
Polymeric fragrance encapsulates	€450 000 (€400 000 - €500 000) spread out over the period when alternatives are developed		
Costs per reformulation / R&D			
Polymeric fragrance encapsulates	€40 000 (€30 000 - €50 000)		
Other microplastics contained in detergents	€15 000 (€10 000 – €240 000)		
Waxes, polishes and air care products	€15 000 (€10 000 – €240 000)		
R&D premium (only for other microplastics contained in detergents and waxes, polishes and air care products)	12.5% (upper boundary assumes no R&D premium)		
Baseline reformulations	Coordination during transitional period		
Other impacts	Profit losses included as upper bound		

Impact category	Low tonnage scenario	Central tonnage scenario	High tonnage scenario
Transition period			
Polymeric fragrance encapsulates	5/8 years		
Other microplastics contained in detergents	5 years		
Waxes, polishes and air care products	5 years		
Sensitivity analysis: Instructions for use and reporting requirements			
Reformulations undertaken to avoid requirements	*16 000*		
Cost for updating label	*€8 000/ formulation for 52 900 affected formulations*		
Cost of reporting	*€10 000/ year/ company for 675 affected companies*		
Uncertainties (impact on restriction costs)	- based on limited sources of information -time required to develop and implement alternatives for polymeric fragrance encapsulates (different assumptions tested) -reported reformulation costs have a fairly wide range (accounted for by using lower and upper values)	Mid-point between Low & High scenario	- based on limited sources of information -time required to develop and implement alternatives for polymeric fragrance encapsulates (different assumptions tested) -reported reformulation costs have a fairly wide range (accounted for by using lower and upper values)

Notes: *In accordance with ERC 8C: 30% to water, 15% to air

D.6.5.1. Raw material costs

Specific information on changes to raw material costs was received only for polymeric fragrance encapsulates in relation to the increased perfume costs required if the polymeric encapsulates were to be removed (ECHA AI 2018, #193, #303 and #304). For these products the removal of the polymeric encapsulates would mean that the perfume costs would on average be 50% - 100% higher. In some extreme cases the perfume cost could be up to 200% higher but since this would only be the case in very specific instances, an average of up to 100% was considered a more realistic upper limit. The Dossier Submitter will assume a 75% increase for the main calculations, with a lower and upper boundary of 50% - 100% for sensitivity purposes. While the current tonnages of perfume and the price of perfume were claimed as confidential, the total increase in raw material costs will be presented.

The call for evidence did not provide any clear information on changes in costs due to the use of alternatives for the other product groups. Information on the cost of alternatives is

mainly available for abrasive functions, where e.g. AMEC (2017a) found that most silica formulations were cheaper than microplastics and Verschoor et al. (2016) concluded that it would be "relatively cheap" for industry to substitute to alternatives for abrasive functions. In the survey for A.I.S.E. (ECHA AI 2018, #013), some respondents stated that natural ingredients (e.g. ground walnut shell as an alternative abrasive agent) would be more expensive than the polymers currently used. Eventually the cost estimates in the socio-economic analysis report submitted by A.I.S.E. (ECHA AI 2018, #013) did not factor in any changes in the costs of raw materials.

In the absence of any information on additional material costs, the Dossier Submitter will assume that the alternatives are 50% more expensive than the currently used microplastics and that the use ratio is equal, i.e. that alternatives will be used in the same quantities as the microplastic particles currently in use. Assuming that the average cost of microplastics is €1 100/tonne in accordance with AMEC (2017a), the raw material costs are expected to increase by €550/tonne. For sensitivity purposes, a 0% and a 100% price increase will also be analysed.

D.6.5.2. R&D costs

Companies producing fragrance encapsulates will incur R&D costs from developing new alternative dosing technologies. In its submission to the consultation (#2421), IFRA estimated that the total industry cost for this would be €400 - 500 million (representing 30% of existing expenditure on science over a 6-8 year period). For the purpose of the analysis, a cost of €450 000 (€400 000 as the lower bound, €500 000 as the upper bound) will be spread out evenly over the period when industry is assumed to be developing and implementing alternatives.

D.6.5.3. Reformulation

The main economic impact of the proposed restriction is expected to be related to the one-off costs associated with reformulating products to replace microplastics. Reformulation generally involves undertaking R&D to develop and test the new formula, as well as marketing to communicate product and performance changes to consumers, including advertising and relabelling (A.I.S.E. CfE #666). It is important to note that companies regularly reformulate their products in the absence of any restriction, for example in response to changing consumer needs. The restriction would effectively require forced reformulations, although there may be some synergies with the baseline reformulations which would occur in the absence of the restriction.

The following issues will be considered when estimating the reformulating costs: the number of affected formulations, the cost per reformulation and the possibility to coordinate the restriction-induced reformulations with the baseline formulations.

D.6.5.4. Number of reformulations

The central tonnage scenario is based on the results from a study of the fragrance encapsulates market undertaken by IFRA and the survey undertaken by A.I.S.E. following the publication of the Annex XV report. The IFRA study found that at least 4 500 unique capsule-fragrance formulations would be affected by the proposed restriction. While this figure is significantly higher than the assumption used by the Dossier Submitter in the Annex XV report (750, with 1 500 as the upper value), IFRA argues that the initial estimate was based on a limited sample and did not adequately

recognise the scale of usage of fragrance encapsulation, including the multiplicity of consumer offers within specific product categories, while the revised figure is more evidence-based. The Dossier Submitter assumes that these formulations are additional to the number of formulations reported by A.I.S.E., since the fragrance encapsulate formulations are not sold to consumers but rather to downstream users (i.e. members of A.I.S.E. and Cosmetics Europe). The Dossier Submitter will assume that 4 500 formulations are affected by the restriction in the central tonnage scenario. In line with the assumptions for tonnages, the Dossier Submitter will assume that the number is 35% lower in the low tonnage scenario (giving 2 900 affected formulations) and 35% higher in the high tonnage scenario (giving 6 100 affected formulations).

A.I.S.E. found that the entire sector would reformulate 22 000 formulations as a consequence of the proposed restriction (#2382). However, it should be noted that only 6 000 of these reformulations would be due to the ban, while about 16 000 would be driven by companies wanting to avoid the 'instructions for use' and reporting requirements laid out in paragraphs 7 and 8 of the proposed restriction. The Dossier Submitter notes that companies would not be obliged to undertake these 16 000 reformulations and finds it questionable that companies would choose to reformulate at a cost of up to €240 000 per reformulation (as argued in the results of A.I.S.E. latest survey, see the section on cost per reformulation below) to avoid the 'instructions for use' and reporting requirements. The Dossier Submitter also notes that industry argues that these reformulations could not be completed before the 'instructions for use' and reporting requirements would come into force, meaning that even if the companies reformulated to avoid these requirements, they would be affected by them until the reformulations were completed. Therefore, the main analysis will only focus on the cost of reformulating the 6 000 formulations affected by the ban. Nevertheless, the Dossier Submitter will undertake a sensitivity analysis of the potential cost of the additional 16 000 reformulations possibly undertaken to avoid the 'instructions for use' and reporting requirements.

In line with the assumptions for tonnages, the Dossier Submitter will assume that the number of affected formulations is 35% lower in the low tonnage scenario (giving 3 900 reformulations) and 35% higher in the high tonnage scenario (giving 8 100 reformulations). According to the A.I.S.E. respondent data, about 1% of the reformulations required due to the restriction would be waxes and polishes (air care products, which are also part of the maintenance product category, would not require any reformulations). Therefore, the Dossier Submitter will assume that 60 reformulation would be required due to the ban in the waxes, polishes and air care product category in all tonnage scenarios. It will be assumed that the rest of the reformulations based on the A.I.S.E. data are within the 'other microplastics contained in detergents' category.

D.6.5.5. Costs per reformulation

The Dossier Submitter has received information suggesting that the reformulation costs would be €30 000 – €50 000 for polymeric fragrance encapsulates (ECHA AI 2018, #193). The Dossier Submitter will use these as the lower and upper ranges, with a central estimate of €40 000.

For other microplastics contained in detergents and for waxes, polishes and air care products, the estimates of reformulation costs are drawn from the report prepared by RPA for the Evaluation of the Detergents Regulation. RPA (2018) estimated the R&D

costs of routine reformulation to be in the range of €10 000 - €20 000 per product on average. Relabelling was estimated at around €200 - €3 000 per product. But the costs of relabelling will depend on the timing of the introduction of the restriction and whether the relabelling requirements could be incorporated into the usual label renewals which are undertaken for all products periodically. Some respondents to the study reported that the costs (based on person days required in reformulation) would be significantly higher than the €10 000 – €20 000 estimates. However, RPA (2018) compared the highest reported cost estimates based on person-days with the average turnover for the EU-28 detergents sector and concluded that they would appear to be a significant overestimate of average reformulation costs per product, as such costs would have driven many companies (especially SMEs) out of business.

Indicative figures provided in ECHA's call for evidence[98] differ somewhat from the estimates by RPA, but the number of respondents was too low to produce robust estimates based on that information. The responses to the survey by A.I.S.E. (ECHA AI 2018, #013) indicate that the annual costs of reformulation for those who quoted a short period of time required (e.g. 1-3 years) were aligned with the unit cost reported by RPA for routine reformulations. This assumes no difficulties in finding alternative formulations, i.e. where there are alternatives available and when reformulation is successful. However, to account for the fact that some reformulations may require more time and be more expensive, the calculations provided in the socio-economic analysis submitted by A.I.S.E. (ECHA AI 2018, #013) assumed that the unit cost of reformulation increases over time by an R&D premium of 5% under the A.I.S.E. definition and 20% under the ECHA CfE definition.

In the Annex XV report, the Dossier Submitter assumed a reformulation cost of €15 000 per product (with €10 000 as the lower boundary and €20 000 as the upper boundary). In line with the socio-economic analysis submitted by A.I.S.E. (ECHA AI 2018, #013), the Dossier Submitter also applied an R&D premium to the reformulation costs. In this way, the reformulation cost will increase by 5% per year in the Low tonnage scenario, and by 20% per year in the High tonnage scenario. An increase of 12.5% was assumed for the Central tonnage scenario. With the updated tonnages and numbers of reformulations from the consultation, the Dossier Submitter has been able to narrow down the ranges and will therefore also assume a 12.5% R&D premium in all tonnage scenarios.

Based on interviews and questionnaire responses with affected companies following the publication of the Annex XV report, A.I.S.E. found that the average cost per reformulation is €240 000 (with a reported range between €4 000 and €650 000). Most respondents said that the cost for simple reformulations would be within the range reported in the Annex XV report but that more complex reformulations would cost significantly more. As a sensitivity check, the Dossier Submitter has therefore used the €240 000 reformulation cost for the upper boundary (without the R&D premium). The R&D premium is applied only to the product categories 'other microplastics contained in detergents' and 'waxes, polishes and air care products' while the 'polymeric fragrance

[98] In the socio-economic analysis prepared for A.I.S.E. (ECHA AI 2018, #013) a few respondents reported estimates of the cost of routine reformulation. The estimates on company basis ranged between €2 000 - €10 000 per formulation.

encapsulates' category is based on the product-specific information obtained through both the consultation and during the development of the Annex XV report.

D.6.5.6. Baseline reformulations

In their study to support the evaluation of the Detergents Regulation, RPA (2018) also gathered information from a literature review and consultation on the frequency of reformulation among detergent manufacturers in the EU. In its input to that study, A.I.S.E. suggested that it can be assumed that:

- For consumer detergent products, 50% are reformulated every two years, and 50% are reformulated every five years.
- In the industrial and institutional detergent sector, 50% are reformulated every year and 50% every two and a half years.

RPA (2018) considered these assumptions from A.I.S.E. to be broadly representative of the sector, taking into account information gathered from other sources[99]. This would imply that approximately 35% of all consumer detergents and 70% of all industrial and institutional detergents are reformulated each year. This can be compared with the consultation undertaken for A.I.S.E.'s input to the restriction dossier (additional information #013), although only six companies responded (with most information coming from three companies). The shortest time between baseline reformulations was reported by one manufacturer as 10 months (waxes and polishes), and the longest by one manufacturer as 48 months (fabric conditioners).

However, it is not clear what share of any of the above baseline reformulations are major ones and what share are minor ones. It should be recognised that replacing some polymer ingredients may constitute a more fundamental level of reformulation than, for example, simply tweaking the fragrance or colour. Therefore, it is uncertain what share of the baseline reformulations would be possible to coordinate with the restriction-induced reformulations.

The frequency of reformulation may differ depending on the type of product and market characteristics. Consumer automatic dishwasher detergents (CADD) has been mentioned as a fast-moving market, while for other products reformulation might occur less frequently. For example, RPA (2018) assumed that 30% of consumer laundry detergents but 95% of CADD reformulated as a direct result for the Detergents Regulation. A similar assumption may be applicable in the case or replacing polymer particles that are proposed to be restricted, i.e. that part of the incurred reformulation costs are considered business as usual and that the rest are due to the restriction.

In the absence of more precise data, the Dossier Submitter will assume that only 5% of all products undergo a large enough baseline reformulation each year that the restriction-induced reformulations can be coordinated with them. Furthermore, it will be assumed that this coordination will only be possible over the transitional period. Therefore, the costs of the baseline reformulations during the transitional period are subtracted from the

[99] RPA (2018) also refer to an Evaluation of the use of phosphates in Consumer Automatic Dishwasher Detergents (Bio by Deloitte (2014)) prepared for the European Commission, where it was concluded that detergent manufactures reformulate their products regularly to maintain competitiveness, averaging every three and a half years. RPA also refer to responses from two individual companies.

restriction-induced reformulation costs. In this way the calculations assume that the baseline reformulations will continue as normal immediately after the transitional period. It should be noted that this is unlikely to be the case, as companies are likely to be able to coordinate the R&D required for some of these baseline reformulations with the restriction-induced reformulations. Therefore, the net reformulation costs presented in this impact assessment are likely to be overestimated.

In summary, the incremental reformulation costs for the proposed restriction will be calculated in the following way:

1. Estimation of the total restriction-induced reformulation costs. These reformulations are assumed to be spread out over the five-year transitional period, with the costs increasing according to the R&D premium each year (after the first year).
2. Estimation of the cost of the baseline reformulations which would have taken place in the absence of the restriction and which are instead assumed to be coordinated with the restriction-induced reformulations.
3. Subtraction of the baseline reformulations from the total restriction-induced reformulation costs (1-2).

D.6.5.7. Profit losses

As previously explained, the socio-economic analysis submitted by A.I.S.E. during the preparation of the Annex XV report (additional information #013) assumed that 90% of products covered under the A.I.S.E. definition and 75% of the products covered under the CfE definition would require more than 5 years to successfully reformulate (up to 10 years would be required). In this case, the products that have not been successfully reformulated might be discontinued or the manufacturing of them may be relocated to outside the EEA, resulting in profit losses. The Dossier Submitter has decided to test what impact this could have as a sensitivity check.

In A.I.S.E.'s survey following the publication of the Annex XV report, respondents stated that for most of the product categories, 50% of the reformulations could be completed in 5 years, 75% in 7 years, and 100% could be completed in 10 years. However, considering that only 6 000 of the 22 000 reformulations that A.I.S.E. argued would be undertaken would be required due to the ban itself, the Dossier Submitter does not consider it likely that there would be profit losses associated with 50% of these reformulations. To test the upper boundary of the impacts, the Dossier Submitter will assess the profit losses related to 17.5% of the reformulations required, in line with the assumption used in the central tonnage scenario in the Annex XV report.

As demand for detergents and maintenance products is unlikely to decline in the future and many products are substitutes, these welfare losses for EEA society are expected to be of temporary nature and to only last for one reformulation cycle after the end of the transition period. For other microplastics contained in detergents, as well as waxes, polishes and air care product, this would be in year 6 to 8 after entry into force, or 2027-2029 in the calculations. By year 8 (i.e. end of 2029), manufacturers of alternatives are expected to have taken over their share of the market and the welfare losses from microplastic-containing products are expected to be compensated by gains of alternatives. For polymeric fragrance encapsulates, there would be profit losses after the end of the transition period, in case the new alternatives were not yet ready to be

implemented then. It will be assumed that these profit losses would be incurred until alternatives could be implemented for a maximum of one reformulation cycle, i.e. three years.

According to Eurostat (2018c), the gross operating surplus of the sector manufacturing soap and detergents, cleaning and polishing preparations in the EU was €3 823 million in 2016. Assuming that this covers a market of up to 103 000 formulations (RPA, 2018), the profit per formulation would be on average €37 000.

D.6.5.8. Enforcement & labelling costs

The Detergents Regulation contains specific labelling requirements regarding ingredients and recommended use. All detergents that are classified as hazardous must also be labelled and packaged in accordance with the requirements of the Classification, Labelling and Packing of Substances and Mixtures (CLP). It is likely that in the course of the transitional period, product labels will have to be redesigned and reprinted due to product changes (as a result of baseline reformulations) or due to the need to meet other regulatory requirements. Therefore, the labelling costs and administrative compliance costs associated with familiarisation of the restriction requirements are expected to be small.

For the purpose of the quantitative analysis of this sector, it is assumed that the enforcement costs (administrative, testing, and labelling) for enforcement authorities and industry will be €55 000 per year per product group for the duration of the study period. However, it should be highlighted that this is likely an overestimate, due to the already existing need to comply with various requirements also foreseen user this restriction (such as labelling) and surveillance costs of a new restriction would likely be incurred in the years immediately following the entry-into-effect and approach zero by the end of the study period as compliance increases. While there is considerable uncertainty related to these costs, they are expected to remain negligible in comparison to other restriction costs.

D.6.5.9. Sensitivity analysis: instructions for use and reporting requirements

Some companies with derogated uses will be subject to the instructions for use (also referred to as 'labelling') and reporting requirements laid out in paragraphs 7 and 8 of the proposed restriction. These are discussed further in the Main Report.

As outlined in the section on the number of affected formulations, A.I.S.E. has argued that industry would undertake 16 000 additional reformulations to avoid the instructions for use and reporting requirements (#2382). The Dossier Submitter finds it questionable that companies would choose to voluntarily reformulate at a cost of up to €240 000 per reformulation (as argued in the results of A.I.S.E. latest survey). The Dossier Submitter also notes that industry argues that these reformulations could not be completed before the 'instructions for use' and reporting requirements would come into force, meaning that even if the companies reformulated to avoid these requirements, they would be affected by them until the reformulations were completed.

According to A.I.S.E., 52 900 formulations would require updated labels when factoring in those products that will not be reformulated. According to A.I.S.E. the average cost of such a label change would be €8 000 per formulation. The Dossier Submitter finds this

cost higher than costs reported in other studies (such as RPA (2018), which assumed that the one-off cost of producing new labels was €200 - €3 000 per detergent product) and notes that it is likely that some of the label updates could be coordinated with regular updates to the labels over the transitional period, thereby reducing the costs.

In terms of the reporting requirements, A.I.S.E. estimated that 675 companies would be affected at an average cost of €10 000 per company. At the same time, A.I.S.E. notes that it was difficult for respondents to provide cost estimates as they would need more clarity on what they would need to report.

The Dossier Submitter finds that the above assumptions are not sufficiently justified and therefore likely to highly over-estimate the costs of the instructions for use and reporting requirements. Nevertheless, it has decided to undertake a sensitivity analysis based on these assumptions to test the upper boundaries of the costs.

Results of analysis:

D.6.5.9.1. Economic costs

In relation to the substitution of microbeads contained in detergents, while it can be expected that some companies will incur additional costs to transition to alternatives, the majority of these costs would not be associated with the proposed restriction, given the substitution which is already occurring. Even if no further substitution occurs, i.e., the historical downward trend in the use of microbeads does not continue, it is more likely that in the event of the restriction the market share of these remaining uses is taken over by microbeads-free products (within the existing capacity of the industry) as their share is increasing (the use of microbeads in detergents decreased by over 50% only between 2017 and 2018). Therefore, no net reformulation or profit losses (assuming the profit margin is the same for microbeads-containing and microbeads-free products) are assumed for the substitution of microbeads in detergents.

For the other product categories, the economic impacts over the 20-year analytical period are outlined in the subsections below.

D.6.5.9.2. Raw material costs

For polymeric fragrance encapsulates:

- Under a 5-year transition period: the raw material cost is expected to increase by €85.6 million in the Central scenario. When considering the lower and upper bounds of all three tonnage scenarios, the increase in raw material costs ranges from €0 to €183.1 million.
- Under an 8-year transition period: the raw material cost is expected to increase by €1.2 million in the Central scenario. When considering the lower and upper bounds of all three tonnage scenarios, the increase in raw material costs ranges from €0 to €79.5 million.

For other microplastics contained in detergents, the raw material cost is expected to increase by €62.8 million in the Central scenario. When considering the lower and upper bounds of all three tonnage scenarios, the increase in raw material costs ranges from €0 to €173.2 million.

For waxes, polishes and air care products, the raw material cost is expected to increase by €5.4 million in the Central scenario. When considering the lower and upper bounds of

all three tonnage scenarios, the increase in raw material costs ranges from €0 to €10.7 million.

Table 76: Raw material costs (NPV, 2017)

		Low tonnage scenario	Central tonnage scenario	High tonnage scenario
Polymeric fragrance encapsulates (5-year TP)	Lower	€0	€0	€0
	Central	€85.2M-	€85.6M	€86M
	Upper	€181.7M	€182.4M	€183.1M
Polymeric fragrance encapsulates (8-year TP)	Lower	€0	€0	€0
	Central	€0.8M-	€1.2M	€1.7M
	Upper	€77.9M	€78.7M	€79.5M
Other microplastics contained in detergents	Lower	€0	€0	€0
	Central	€39M	€62.8M	€86.6M
	Upper	€78M	€125.6M	€173.2M
Waxes, polishes and air care products	Lower	€0	€0	€0
	Central	€5.4M	€5.4M	€5.4M
	Upper	€10.7M	€10.7M	€10.7M

D.6.5.9.3. Reformulation/R&D costs

For polymeric fragrance encapsulates:

- Under a 5-year transition period: the incremental reformulation/R&D costs for the proposed restriction (i.e. subtracting the cost of the baseline reformulations that can be coordinated from the cost of the restriction-induced reformulations) are expected to be €440.4 million in the Central scenario. When considering the lower and upper bounds of all three tonnage scenarios, the incremental reformulation/R&D costs range from €292.7 to €554.1 million.
- Under an 8-year transition period: the reformulation/R&D costs are expected to be €311.3 million in the Central scenario. When considering the lower and upper bounds of all three tonnage scenarios, the incremental reformulation/R&D costs range from €292.7 to €521.5 million.

For other microplastics contained in detergents, the incremental reformulation/R&D costs are expected to be €66.6 million in the Central scenario. When considering the lower and upper bounds of all three tonnage scenarios, the incremental reformulation/R&D costs range from €43.1 million to €1 059.1 million.

For waxes, polishes and air care products, the incremental reformulation/R&D costs are expected to be €0.7 million in the Central scenario. When considering the lower and upper bounds of all three tonnage scenarios, the incremental reformulation/R&D costs

range from €0.4 million to €7.9 million.

Table 77: Incremental reformulation/R&D costs (NPV, 2017)

		Low tonnage scenario	Central tonnage scenario	High tonnage scenario
Polymeric fragrance encapsulates (5-year TP)	Lower	€292.7M	€293.1M	€292.7M
	Central	€400.9M	€440.4M	€479.9M
	Upper	€455.4M	€504.8M	€554.1M
Polymeric fragrance encapsulates (8-year TP)	Lower	€292.7M	€292.7M	€292.7M
	Central	€311.3M	€311.3M	€311.3M
	Upper	€422.8M	€472.2M	€521.5M
Other microplastics contained in detergents	Lower	€43.1M	€44.4M	€60.1M
	Central	€43.1M	€66.6M	€90.2M
	Upper	€505.8M	€782.5M	€1 059.1M
Waxes, polishes and air care products	Lower	€0.4M	€0.4M	€0.4M
	Central	€0.7M	€0.7M	€0.7M
	Upper	€7.9M	€7.9M	€7.9M

D.6.5.9.4. Profit losses

Profit losses have been estimated to test the upper bounds of costs and have not been included in the central calculations.

For polymeric fragrance encapsulates:

- Under a 5-year transition period: the profit losses could be up to 74.3 million.
- Under an 8-year transition period: the profit losses could be up to €50.5 million.

For other microplastics contained in detergents the profit losses could be up to €97.9 million and for waxes, polishes and air care products the profit losses could be up to €0.7 million.

Table 78: Profit losses (NPV, 2017)

		Low tonnage scenario	Central tonnage scenario	High tonnage scenario
Polymeric fragrance encapsulates (5-year TP)	Lower			
	Mid			
	Upper	€35.3M	€54.8M	€74.3M
Polymeric fragrance encapsulates (8-year TP)	Lower			
	Mid			
	Upper	€24M	€37.2	€50.5M
Other microplastics contained in detergents	Lower			
	Mid			
	Upper	€46.8M	€72.3M	€97.9M
Waxes, polishes and air care products	Lower			
	Mid			
	Upper	€0.7M	€0.7M	€0.7M

D.6.5.9.5. Enforcement & labelling costs

As explained above, analytical costs associated with the compliance of the proposed restriction are assumed to be €55 000 per year, which amount to an NPV of €413 100 for each category with a 5-year transition period and €311 000 for polymeric fragrance encapsulates if the transition period was 8 years. While there is considerable uncertainty related to these costs, they are expected to remain negligible in comparison to other restriction costs and their uncertainty can be considered reflected in the upper ranges of the restriction scenario, where the total restriction costs have been overestimated.

Given that a transitional period of at least five years is proposed and the existing labelling requirements under the Detergents Regulation and CLP, the Dossier Submitter assumes in the main analysis that any labelling costs would be negligible, as they are unlikely to be solely associated with the proposed restriction (but also with the need to update the information on the product formula as a result of baseline reformulation or to meet other regulatory requirements).

D.6.6. Other impacts

D.6.6.1. Impact on consumers

As a result of reformulations and potentially discontinuation of products, there may be a loss of certain quality characteristics and perceived or tangible benefits for the end-users. Therefore, it is possible that the proposed restriction may lead to a loss of consumer surplus. Nevertheless, given that there are non-microplastic detergents and maintenance products on the market, it is assumed that any such loss of consumer surplus would not be significant.

D.6.6.2. Impact on employment

A restriction on microplastics contained in detergents and maintenance products may affect employment in companies producing the affected products and in companies producing alternative products. The expected restriction-induced reformulations may have a short-term impact on the deployment of staff to reformulation activities, which might increase employment. On the other hand, any unsuccessful reformulations or discontinuation of products could have negative implications for employment.

On balance, and given the transitional period of at least five years, no major impacts on employment are expected. In case there are employment impacts, most of them are likely to be compensated by gains to companies producing microplastic-free products.

D.6.6.3. Distributional and Wider-economic impacts

The proposed restriction may have some limited distributional impacts in the detergents and maintenance products market. Some of the negative impacts in the market for products containing microplastics may be partly offset by positive impacts in the markets for alternative products.

Similarly, significant trade or competition effects are not expected as a result of the proposed restriction.

D.6.7. Sensitivity analysis: instructions for use and reporting requirements

The Dossier Submitter has undertaken a sensitivity analysis of the potential costs of undertaking additional reformulations to avoid the 'instructions for use' and the reporting requirements, as well as of updating existing labels to include instructions for use and implementing the reporting requirements in practice. As previously stated, the Dossier Submitter considers that the assumptions used in the sensitivity analysis are likely to highly over-estimate the costs of the instructions for use and reporting requirements. Therefore, the below costs are only presented to consider the upper boundaries of the costs. The ranges provided for the reformulation costs are based on the same unit cost ranges for reformulations as in the main analysis.

	Sensitivity analysis
Reformulation costs to avoid the instructions for use and reporting requirements	€179.4M (€119.6M – 2 107.6M)
Cost of updating label	€334.5M
Cost of reporting	€5 334.6M
Total	€519.3M (€459.4M - €2 447.4M)

D.6.8. Cost-effectiveness, affordability and proportionality to risk

Table 79 presents the total costs of the proposed restriction related to detergents and maintenance products over the 20-year analytical period. These costs comprise raw material costs, reformulation/R&D costs, profit losses (only in the upper boundaries) and

enforcement costs.

For polymeric fragrance encapsulates:

- Under a 5-year transition period: the total restriction costs are expected to be €526.4 million in the Central tonnage scenario. When considering the lower and upper bounds of all three tonnage scenarios the total costs range from €293.1 to €811.9 million.
- Under an 8-year transition period: the total restriction costs are expected to be €312.8 million in the Central tonnage scenario. When considering the lower and upper bounds of all three tonnage scenarios the total costs range from €293 to €651.8 million.

For other microplastics contained in detergents, the total restriction costs are expected to be €129.8 million in the Central tonnage scenario. When considering the lower and upper bounds of all three tonnage scenarios the total costs range from €29.1 million to €1 330.6 million.

For waxes, polishes and air care products, the total restriction costs are expected to be €6.5 million in the Central tonnage scenario. When considering the lower and upper bounds of all three tonnage scenarios the increase in costs range from €0.9 million to €19.8 million.

Table 79: Restriction costs for detergents and maintenance products (NPV, 2017 values)

		Low tonnage scenario	**Central tonnage scenario**	**High tonnage scenario**
Polymeric fragrance encapsulates (5-year TP)	Lower	€293.1M	€293.1M	€293.1M
	Central	€486.5M	€526.4M	€566.3M
	Upper	€672.9M	€742.4M	€811.9M
Polymeric fragrance encapsulates (8-year TP)	Lower	€293M	€293M	€293M
	Central	€312.4M	€312.8M	€313.3M
	Upper	€525M	€588.4M	€651.8M
Other microplastics contained in detergents	Lower	€29.1M	€44.8M	€60.5M
	Central	€82.5M	€129.8M	€177.2M
	Upper	€631M	€980.8M	€1 330.6M
Waxes, polishes and air care products	Lower	€0.9M	€0.9M	€0.9M
	Central	€6.5M	€6.5M	€6.5M
	Upper	€19.8M	€19.8M	€19.8M

The cost-effectiveness can be calculated based on the above costs and the emissions reduced reported in Table 75 in the section on restriction scenarios and key assumptions.

For polymeric fragrance encapsulates:

- Under a 5-year transition period: the cost-effectiveness is expected to be €173 in the Central tonnage scenario. When considering the lower and upper bounds of all three tonnage scenarios the cost-effectiveness ranges from €147 to €197.
- Under an 8-year transition period: the cost-effectiveness is expected to be €128 in the Central tonnage scenario. When considering the lower and upper bounds of all three tonnage scenarios the cost-effectiveness ranges from €184 to €198.

For other detergents, the cost-effectiveness is expected to be €1 in the Central tonnage scenario. When considering the lower and upper bounds of all three tonnage scenarios the cost-effectiveness ranges from €0.1 to €8.

For waxes, polishes and air care products, the cost-effectiveness is expected to be €1 in the Central tonnage scenario. When considering the lower and upper bounds of all three tonnage scenarios the cost-effectiveness ranges from €0.1 to €2.

The cost-effectiveness for polymeric fragrance encapsulates are clearly higher than the cost-effectiveness for the other products. Nevertheless, the cost-effectiveness is comparable to, or lower, than previous REACH restrictions on environmental pollutants.

Table 80: Cost-effectiveness of the proposed restriction (€/kg)

		Low tonnage scenario	**Central tonnage scenario**	**High tonnage scenario**
Polymeric fragrance encapsulates (5-year TP)	Lower	€147	€96	€71
	Central	€244	€173	€137
	Upper	€337	€244	€197
Polymeric fragrance encapsulates (8-year TP)	Lower	€184-	€120	€89
	Central	€196	€128	€95
	Upper	€329	€242	€198
Other microplastics cointained in detergents	Lower	€0.4	€0.4	€0.4
	Central	€1	€1	€1
	Upper	€9	€8	€8
Waxes, polishes and air care products	Lower	€0.1	€0.1	€0.1
	Central	€1	€1	€1
	Upper	€2	€2	€2

Another way of looking at the proportionality of the restriction is to assess the restriction cost per kilogram of microplastics used. For polymeric fragrance encapsulates, this is estimated to be:

- Under a 5-year transition period: €543 – €2 588/kg, with €1 316/kg as the central estimate.

- Under an 8-year transition period: €543 – €2 019/kg, with €782/kg as the central estimate.

For other microplastics contained in detergents the estimated cost is €3€67/kg used with €9/kg as the central estimate. For waxes, polishes and air care products the estimated cost is €1 - €15/kg used with €5/kg as the central estimate. As the proposed restriction is expected to lead to small costs per kilogram of microplastics used, significant price increases are not expected. Therefore, the proposed regulatory actions are expected to be affordable to the impacted supply chains.

In summary, on the basis of cost-effectiveness and affordability considerations, the proposed restriction on detergents and maintenance products is proportionate to risk.

D.6.9. Transition periods

For the specific case of polymeric fragrance encapsulates, based on a comparison of the costs and proportionality under a 5 versus an 8-year transition period, it can be concluded that:

- The central total costs in the central tonnage scenario would be 68% higher under a 5-year transition period as compared with an 8-year transition period.
- The central cost per kg of emission in the central tonnage scenario would be 34% higher under a 5-year transition period as compared with an 8-year transition period.
- The central cost per kg used in the central scenario would be 68% higher under a 5 year transition period as compared to an 8-year transition period.
- The differences are smaller when comparing the lower and upper ranges in all of the tonnage scenarios.
- A 5 year transition period is expected to result in totally 610 tonnes (400 tonnes – 830 tonnes) less releases of microplastic to the environment as compared to an 8 year transition period.

It should be noted that the costs for polymeric fragrance encapsulates do not take into account other impacts that have not been possible to monetise, such as the environmental impact of increased perfume usage and a lower level of product performance for consumers in case industry is not able to develop alternatives before the restriction enters into effect. To illustrate, IFRA (#2421) claims that if alternatives could not be implemented before the end of the transitional period, industry experts believe that approximately 2-3% of all washes would be redone, equating to around 1 billion additional washes per year. Since no further evidence was provided to substantiate this claim, the Dossier Submitter is not able to conclude on whether this is a realistic assumption. Nevertheless, the Dossier Submitter believes that the risk of additional washes would be higher under a 5 year transition period.

Based on the information provided by industry in the consultation (#2421, #2239 and #2160), the Dossier Submitter considers that a transition period longer than 5 years is more clearly justified than what it was during the preparation of the Annex XV report. Nevertheless, the Dossier Submitter considers the proposed restriction proportional for this product category both under a 5 and an 8 year transitional period. Ultimately, the decision on what transition period is given depends on how much weight is given to the reduction of microplastic releases to the environment as compared to the associated

societal costs.

The Dossier Submitter also notes that, based on the information from the consultation (#2382), for the product categories of 'other microplastics contained in detergents' and 'waxes, polishes and air care products' the estimated costs of the ban have been reduced. The main costs argued by A.I.S.E. seem to be associated with the 'instructions for use' and reporting requirements, rather than with the ban itself. Therefore, there may be merits in shortening the transition periods for these two product categories, while looking into whether the 'instructions for use' and reporting requirements could be better targeted.

D.6.10. Uncertainties and sensitivity analysis

Uncertainties are discussed in the relevant sections above. Their impact on the conclusions of the analysis is tested in the tables presenting total costs and cost-effectiveness for the various scenarios and sensitivity ranges. Since the Annex XV report, the wide ranges used for tonnages and number of affected formulations have been narrowed down. Although it is not known what the most realistic costs will be, the Central tonnage scenario is expected to give an order of magnitude estimate of the anticipated impacts of the proposed restriction on detergents and maintenance products.

The results of the additional sensitivity analysis of the potential costs of the 'instructions for use' and reporting requirements have been outlined in a separate table above. As previously stated, the Dossier Submitter considers that the assumptions used in the sensitivity analysis are likely to highly over-estimate the costs of these requirements. In any case, when adding the costs of the sensitivity analysis to the total costs of the ban on the sector as a whole, the total cost in the central tonnage scenario is €1 181.9 million with a 5 year transition period for polymeric fragrance encapsulates and €968.3 million with an 8 year transition period for polymeric fragrance encapsulates. The cost-effectiveness for the sector as a whole calculated based on these costs and the emissions reduced from the ban (i.e. ignoring any further emission reductions due to the instructions for use and reporting requirements) is €9/kg with a 5 year transition period for fragrance encapsulates and €8/kg with an 8 year transition period for fragrance encapsulates. Based on the upper ranges in the high tonnage scenario, the cost-effectiveness would be €26/kg. Therefore, the Dossier Submitter would consider the proposed restriction proportional also if the full costs argued by industry for the instructions for use and the reporting requirements were included.

D.6.11. Impact of scope variations on proportionality to risk

Microplastics with no dimension greater than 1 mm:

Based on the information received in the Call for evidence, it seems that the vast majority of microplastics used in detergents and maintenance products are smaller than 1 mm. However, the proportion of any microplastics above 1 mm is uncertain. Therefore, separate cost-effectiveness for a restriction on microplastics with no dimension greater than 1 mm cannot be estimated.

Microplastics with film-forming functions are included in the scope:

Film-forming is an essential function of microplastics in many waxes and polishes. Therefore, should microplastics with film-forming functions be included in the scope of the restriction, the tonnages and number of required reformulations would be higher for

waxes and polishes. Therefore, the costs would most likely also be higher. However, the share of microplastics added for film-forming purposes in waxes and polishes is unknown.

Impact of change to 100 nm lower limit or no lower limit:

According to A.I.S.E. (#2382), the particle size distribution significantly varies depending on the type and size of the specific polymer/copolymer used. While it is known from the development of the Annex XV report that an increase of the lower limit in the microplastics definition would reduce costs for industry, the Dossier Submitter does not have sufficient information to assess the impacts of a reduced limit or of having no lower limit. Nevertheless, it should be noted that if there was a change to the 100 nm lower limit or if there was to be no lower limit, this could affect the tonnages and the number of affected formulations in the sector, thereby also affecting the costs to the sector.

D.7. *In vitro* diagnostic devices (IVDs)

In vitro diagnostics devices (IVDs) are non-invasive tests performed on biological samples (for example blood, urine or tissues).

IVDs are used by healthcare professionals in hospitals and laboratories in order to monitor, treat patients or improve their health conditions. They also help in providing reliable diagnostic test results to diagnose or exclude a disease, perform risk stratification, screening and therapeutic monitoring. IVDs provide valuable information about how the body is functioning and its state of health.

In addition to human health applications, IVDs are also used for veterinary applications. IVDs are used by animal healthcare professionals in clinics, and laboratories in order to diagnose, monitor, and improve the health conditions of animals (companion animals, breeders, food producers of livestock, poultry and dairy). IVDs are also used by competent authorities for preventing and controlling Transboundary Animal Diseases (TADs) at borders, and also in the frame of EU and national animal health programmes (e.g. surveillance, eradication programmes, outbreak containment plans, food products residue limits testing etc.).

The synergies between the IVDs for human health and the ones for veterinary health are important: IVDs often use the same instrument/technology, the suppliers of polymeric microspheres (the microplastic substrates used in many IVD assays) might be the same, and the working environments are very similar in term of personnel qualifications, equipment, quality assurance, etc.

D.7.1. Existing regulatory framework

IVD for human health:

In vitro diagnostic medical devices for human health are regulated by EU Regulation (EU) 2017/746 (aka IVDR). This EU regulation will repeal the existing directive on IVD (IVDD) from 26 May 2022. Due to transitional arrangements established in the IVDR, some IVD devices, with certificates issued under the IVDD, may continue to be placed on the market until 27 May 2024 and made available until 27 May 2025.

The IVDR brings significant changes in term of Vigilance, Post-market Surveillance and communication on safe use (label, and instructions for use-IFU). For example, it will grant Notified Bodies increased post-market surveillance authority. Unannounced audits, along with sample checks and testing will strengthen EU enforcement and help to reduce

risks from unsafe devices. Annual safety and performance reporting by IVD manufacturers will also be required in many cases: e.g. Periodic Safety Update Reports (PSUR)[100], and reporting to a central database named EUDAMED.

The IVDR does not explicitly require environmental risks to be assessed. Nevertheless, according to the legislator (source: DG GROW), "The definition of risk is broad enough to encompass also the harm to the environment. So the obligatory benefit-risk assessment of any device can be considered appropriate to deal with the issue". This interpretation is not shared by some Authorities (#2162, and 2714) who consider that environment assessment is not covered by the IVDR.

IVD for veterinary health:

Contrary to the human health application*, in vitro* diagnostic devices for veterinary applications are not regulated under EU legislation. Veterinary IVDs are subject to marketing authorisation granted by member state competent authorities for animal health. There is no EU harmonisation, nor coordination or mutual recognition of market authorisations. The requirements for a market authorisation vary from one country to another.

IVD for research:

In vitro diagnostic devices are also used for research and development activities, including PPORD activities. When IVDs are intended to be used for research purposes, without any medical objective, then such IVDs are also not covered by the IVDR.

IVD for research activities are often referred as RUO (Research Use Only), and do not have CE marking.

D.7.2. Uses and functions

Microplastics (in the form of polymeric microsphere) are widely used in medical and biological IVD applications; essentially as carriers, such as in immunoassays and cell separation, in nuclear medicine for diagnostic imaging, in studying the phagocytic process, in affinity separation of biological entities, etc. Microplastics are also used in assays undertaken to ensure compatible blood transfusion.

The essential property of microplastics is to be able to maintain a stable state during a potentially long shelf life, and to endure challenging use conditions (e.g. strong acid or basic pH, temperature, pressure). As a consequence of their specific density, refractive index and associated scattering properties, the use of microplastics have become fundamental to the functioning and reproducibility of the tests carried out on IVD instruments.

IVD for human health:

The uses of microplastics in IVDs for human health consists essentially of two main applications: (i) IVD reagents, assays and calibrator and (ii) analytical and purification chemistry for IVD applications.

[100] As part of the market surveillance, companies placing on the market MD and IVD should prepare and make available to the relevant competent authorities every two years a periodic safety update report (PSUR) which include updated information on the labelling.

According to MedTech Europe (CfE #726, and ECHA AI 2018 #31-311) and several companies placing IVDs on the market (CfE #652, #677 #746), various microplastics are used in *in vitro* diagnostic medical devices. The identity and properties of some of the microplastics used in IVD, as well as their technical function, are summarised in the Table 81 below.

During the consultation, some intentional uses of microplastics have also been reported for consumer home-based self-tests (#2434) without further details.

Table 81: Example of microplastics used in human health IVD applications (professional uses)

Type of microplastic	Function	Example of application
Nanocrystals/quantum dots (polymer coated cores of CdSe or CdTe stabilised with ZnS; 10-20 nm) Concentration in aqueous suspensions: <0.1%	Reagent and assays: Biochemically reactive fluorescent tags used to detect proteins, protein motifs, nucleic acids and other molecules	Anti-bodies detection
[super]paramagnetic porous polystyrene particles (particles comprised of iron oxide and polystyrene coated with various polymers e.g. epoxy, polyurethane, silane; 1 – 5 µm) Concentration in aqueous suspensions: 0.025-0.2%	Reagent and assays: These particles serve as solid support where one of the reaction components is attached to the particle surface. Following the reaction with the other components, the particles and all bound reactants are removed from the mixture with a magnet and then washed to remove the unreacted species and ultimately exposed to the signal generating components to visualise the bound species of interest (e.g. antigens, proteins, antibodies etc.).	Used for various biochemical, medical and R&D applications, including over 100 IVD immunoassays across 14 major health areas (toxoplasmosis and rubella infection, HIV, hepatitis, oncology, thyroid, fertility, cardiac, hormones, inflammation, brain damage, pregnancy, immunosuppressant drug monitoring, anaemia and bone).
Polystyrene or polystyrene copolymer particles (synthetic latex particles) [plain or carboxylated; non-magnetic] - 0.02 to 30 µm Concentration in aqueous suspensions: 0.02–4.6%	Reagent and assays: Reactive particles variously coated with antigens, proteins, anti-bodies, nucleic acids or as constituents of dry film reagents. Added to IVD assay to act as molecular sieve, binding agent or to control reflectance.	Blood testing/screening cartridge. IVD assay (e.g. infectious diseases, cancer, cardiac disease, blood screening, etc.)
Polystyrene latex for instrument calibration (0.1 - 100 µm). Concentration in aqueous suspensions: 0.001–10%	Calibration: referential system to study different biological parameters	Calibration and accuracy control of cytometer, haemocytometer, urinary analyser etc.
Silicon-based particles – ca.4 µm, e.g. polysiloxane	Anti-foaming	Mitigate foaming in IVD reagents
Polyvinyl alcohol (PVA) coated particles – magnetic particles based on cross-linked PVA (with iron oxide) with modified surface chemistry (carboxy group, amino group, silanized, N-hydroxy succinimid) – 1-3 µm diameter	Reagent and assays	DNA/RNA purification IVD products

Type of microplastic	Function	Example of application
Ion Exchange Resins (Size 1-300 µm) - solid, water insoluble, and non-degradable polymeric microsphere (cross-linked or not) containing ionic groups. e.g. polystyrene or divinylbenzene (DVB) particles (non-magnetic), Polyvinyl Ether, Methacrylate, etc. Formulated in analytical or purification chromatography columns.	Analytical and purification chemistry for IVD	Solid phase extraction (SPE): a methodology widely used in bioanalytical sample preparation e.g. biopharma, toxicology, drug abuse screening, environmental monitoring (e.g. pesticide residues). Anti-body purification using liquid chromatography. Purification of oligonucleotide intermediates in R&D (no resin in final product).
Sodium polyacrylate, polyacrylamide	Purification chemistry for IVD (absorption of 'waste' substance)	Waste bags in blood gas monitoring
Polymeric microsphere (no other details) Concentration: 0.001–1%	Reagents/Purification chemistry for IVD	Blood grouping in automated IVD (used to ensure compatible blood transfusion)

Source: MedTech Europe (CfE #726, and ECHA AI 2018 #31-311), companies placing IVDs on the market (CfE #652, #677 #746) and consultation (#2700)

IVD for veterinary applications:

As far as the veterinary IVDs are concerned, microplastics have three main applications: (i) reagents, (ii) ELISA tests (enzyme-linked immunosorbent assay that detects and measures antibodies in blood samples), and (iii) haematology analysers.

According to Diagnostics for Animals (D4A), the sector association representing the veterinary diagnostic and reagents industry, veterinary IVDs are highly dependent on the technological instruments and supply chain of the human health sector (#2412).

Table 82 below gives an overview of the identity and properties of some microplastic materials used in veterinary IVDs, as well as their technical function.

Table 82: Example of microplastics used in veterinary applications (professional uses)

Type of microplastic	Function	Example of application
Plain polystyrene or latex (particles are coated with proteins or small molecules and deposited into a porous plastic matrix – added to a device for testing) Particle size: 0.4-1.4 µm (specific to products Concentration in aqueous suspensions: 0.0003 - 0.2 %	IVD assays: the particle composition provides the right density, so when they are coated with Ab or Ag, they stay in suspension for depositing the right measured amount to control a specified sensitivity (concentration of Ab or Ag).	Used for infectious diseases, cardiac, immunoassay and clinical chemistry assays
Functionalized polystyrene or carboxyl particles (particles are either covalently or passively coated with conjugate antibody or proprietary material) Particle size: 0.3 – 0.5 µm Concentration in aqueous	IVD assays: the particle composition provides the right density, so when they are coated with Ab or Ag, they stay in suspension for depositing the right measured amount to control a specified sensitivity (concentration of Ab or Ag).	Used for infectious diseases, cardiac, immunoassay and clinical chemistry assays

Type of microplastic	Function	Example of application
suspensions: 0.002 - 0.00007 %		
Epoxy resin (cross-linked agarose particles, chemically modified to bind proteins) Particle size: 70 x 30 x 5 µm (the particle size is defined by photolithography. Population size diversity is not a factor Concentration in aqueous suspensions: 0.0022 - 0.0027 % Note that biodegradability testing have been initiated for this type of use	IVD assays: the surface activity of the particles is specific to the mass of the protein, in order to be bound to increase the efficiency of the particles. They must be the right density to stay in suspension during dispense and transport but then dense enough to settle out of suspension to not be aspirated with the sample – unique property	Used for infectious diseases, cardiac, immunoassay and clinical chemistry assays
IMAC (Immobilized Metal Affinity Chromatography) – magnetic crosslinked agarose particles, complexed with metal ion (e.g. Zn+2, Ni+2) using non-soluble linkers. Particle size: 20 - 100 µm Concentration in aqueous suspensions: 0.1 – 0.2%	IVD reagents and assays: 'Wafer' technology needs thin material for coating. Fluid resin hardens and allows for amino carboxyl material to be placed on the bead, which identifies the specific marker. Technology exists only with this material – single source of existing material to date	Added to IVD reagents for immunoassay and clinical chemistry assays to label and detect important diseases in animal health some of which also affect human health through various mechanisms of zoonosis
Methacrylate spherical beads Particle size: 1 - 8 µm	Cell based Haematology control and calibration material: the particles provide the necessary refractive index and associated scattering properties	Calibration and accuracy control
Polystyrene spherical beads Particle size: <4 µm	Cell based Haematology control and calibration material: the particles provide the necessary refractive index and associated scattering properties	Calibration and accuracy control
Iron oxide polymer coated magnetic beads in suspension	The design of the particle provides a relatively high surface area-to-volume ratio for extraction, while retaining the low flow resistance commensurate with open channels – unknown feasibility to replace (purchased technology).	PCR (Polymerase Chain Reaction) extraction material, or Protein purification This is a minor use.

Source: D4A (#2412)

Other types of IVD:

Although focussed on IVD uses by professionals, the uses indicated in Table 81 can be considered generic (in particular the analytical and purification chemistry ones). There are numerous applications of IVD in industrial settings (Purolite, 2012) such as:

- Life-sciences, medical and biotechnology research, development and manufacturing of biological API
- (Chromatographic) Extraction, isolation and purification in pharmaceutical and biotechnological industrial applications (e.g. production of antibiotics, extraction of enzymes, opium alkaloids, monoclonal antibodies (mAbs), insulin manufacturing, etc.)

- Adsorbent for blood treatment
- Demineralisation of water (industrial, professional and consumer uses)
- Metals removal
- Food industry: e.g. removal of the bitterness in orange juice manufacturing

D.7.3. Baseline – tonnage used and releases

Current uses and releases:

According to the information received from sector associations such as MedTech Europe (CfE #726, and ECHA AI 2018 #31-311), or D4A (#2412), and several companies placing MDs and IVDs on the market (CfE #652, #677 #746), the professional uses of microplastics in these fields is limited in term of quantity.

As far as Ion Exchange Resins are concerned (analytical and purification chemistry for IVD), the resin is usually contained in equipment/devices/articles without direct release to the aquatic environment. At the end of life, the resins are incinerated and treated as a biological hazardous waste: this has been confirmed by a survey made by a producer of the ion exchange resins towards its customers (essentially biotech/pharmaceutical companies and academia).

With regard to the other uses in IVD (reagents, assays and calibration), microplastics are in general contained in equipment or cartridge without direct release to the aquatic environment. Releases of microplastics to the environment from the IVD applications may occur but are limited to a few applications where the microplastics are disposed down the drain as part of the liquid waste. MedTech Europe indicated that at the end of life:

- Solid waste containing microplastics are usually disposed as infectious/biohazardous waste (and incinerated if specified by the local Regulations) as they also contain biological materials: e.g. reagents in immuno- and other IVD assays
- Concentrated liquid waste may be collected into a separate container: e.g. during calibration, flow cytometer analysis
- A small proportion of liquid waste might end up in wastewater and then directed to a municipal WWTP: e.g. rinsing water after calibration or use.

Once in the wastewater, treatments will remove most of the microplastics from the influents (cf. Section 1.4.2 in the Background Document). Microplastics will predominantly partition to the sludge phase (and might eventually be applied to agricultural soils, depending on the sludge-disposal practice of specific Member States). However, microplastics will potentially still be releases in small quantities in treated effluents resulting in direct releases to surface waters. The residues remaining after wastewater treatment depend on the type of polymer, wastewater treatment process and initial concentration in the influent. The potential for releases of microplastics from uses in IVDs are summarised in Table 83.

Table 83: Estimated amounts and releases of microplastics particles from IVD uses

Use	**Amount of microplastics intentionally added and placed on the market** **[EU tonnes/year]**	**Disposal assumption[1]**	**Estimated release of microplastics to environment** **[EU tonnes/year] [2]**
Analytical and purification chemistry for IVD for human health applications	Ca. 100 tonnes	Likely that microplastics are contained by physical means throughout their whole life cycle. Wastes typically treated as biohazardous waste and incinerated	Negligible
Reagents, assays and calibration standards for human health applications	Estimated <5 tonnes	Likely that microplastics are contained in cartridges during use. Solid waste typically treated as biohazardous waste and incinerated (standard practice) ~14% of microplastics (i.e. 0.7 tonnes) would be discarded as solid waste and sent to municipal solid waste (where incineration or land fill could happen). ~ 10% of microplastics (i.e. 0.5 tonnes) would be discarded as liquid waste (e.g. rinsing water). *(source: ECHA AI 2018 #31-311)*	0.25 -0.29 tonnes (0.27 tonnes as a median value) Predominantly to the terrestrial compartment (main source = liquid waste)
Reagents, assays and calibration standards for veterinary applications	Estimated <0.005 tonnes (i.e. <5 kg)	Likely that wastes are treated as biohazardous waste and incinerated. Solid Waste typically treated as biohazardous waste and incinerated (standard practice) ~ 15-20% of microplastics (i.e. 0.75-1 kg) would be discarded as solid waste sent to municipal solid waste (where incineration or landfill could happen) ~ 15-20% of microplastics (i.e. 0.75-1 kg) would be discarded as liquid waste (e.g. rinsing water).*(source: #2412)*	Negligible (0.39 – 0.51 kg) Predominantly to the terrestrial compartment (main source = liquid waste)

Sources: [1] : MedTech Europe (ECHA AI 2018 #31-311), D4A (#2412), and [2]: Dossier Submitter's modelling as described in section 1.4.2 of the Background Document

According to the information provided by the sector, professional uses of microplastics in IVD would therefore appear to result in relatively minor quantity of releases to the environment. Those releases would occur if microplastic containing wastes are not disposed of properly, and/or are discarded down the drain.

D.7.4. Alternatives and technical solutions to minimise releases to the environment

D.7.4.1. Alternatives

For *in vitro* diagnostic devices relying on microplastics (such as some IVD reagents, assays and calibration standards, analytical and purification chemistry for IVD), sector associations such as MedTech (CfE #726), or D4A (#2412), as well as several IVD suppliers (CfE #652, #677 #746 and consultations #2056, #2491, #2505) have indicated that there are currently no alternatives available.

Alternatives to microplastic would have to be physically and chemically stable under demanding use conditions (e.g. strong acid or basic pH), which often conflicts with the property of biodegradability. In addition, alternatives would need to have the same density as the current microplastics microsphere to stay in suspension during the various IVD assays steps. Other technical functions such as refractive index specifications would also have to be fulfilled (#2412). The Dossier Submitter is not aware of any readily available alternative to microplastics for IVD applications.

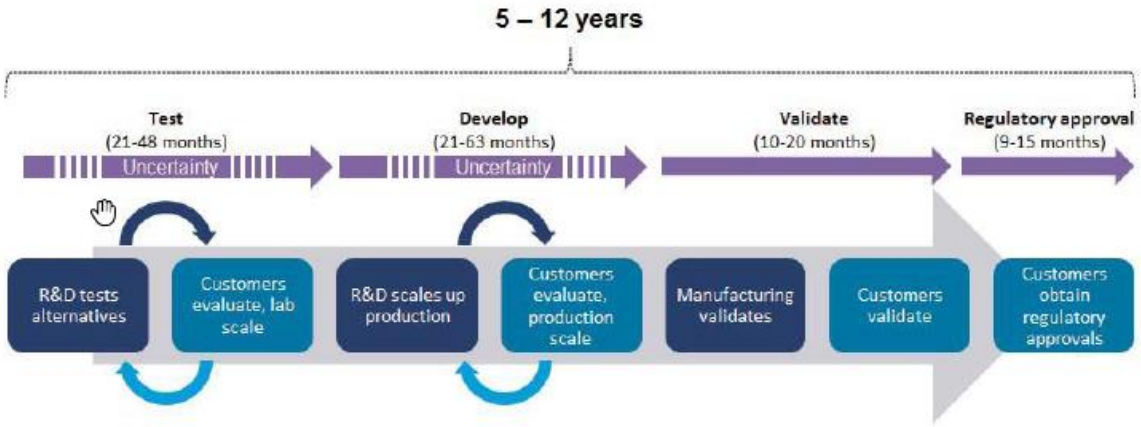
Replacing microplastics in IVD applications is likely to take many years of research to identify potential candidates and then a further period to manufacture, validate and certify them.

Alternatives would have to be recertified/reapproved by competent authorities in Europe and worldwide before an IVD containing them could be placed on the market. MedTech Europe, in their submission to the consultation, estimate that it might take between 5 and 12 years per application to substitute microplastics on the market in IVDs as shown by Figure 7. D4A claimed that between 12 and 15 years would be needed to find alternatives to microplastics in IVDs for veterinary applications, justifying this period by the sector's dependency on human health IVD technology.

With regard to costs, the replacement of microplastics in IVD assays is estimated by MedTech to be $5 million (about €4.5 million) per product. Some companies have up to 250 products microplastics. Based on this information, and the number of actors on the market, the Dossier Submitter estimates that between 1 000 and 5 000 different microplastic containing products are available on the market that would need to be replaced by a suitable alternative. The Dossier Submitter estimated the cost of reformulation of the existing reagents over a period of 20 years to range from €2.5bn to €12.5bn (PV).[101]

Figure 7: Timeline for IVD and MD development

[101] Reformulation cost calculations assume that annually 5% of existing reagents containing microplastics would be reformulated until all of them have been replaced.



Source: MedTech

It should also be noted that in the event that novel IVD products based on alternatives to microplastic would be available and approved by the competent regulatory authority, the continued use of microplastics would likely to be required in legacy *in vitro* diagnostic instruments that are currently in use. Any change in IVD reagents (frequently referred to as kits) could well necessitate redesigning the structure of the IVD-analyser and the accompanying software system, resulting in substantial costs for redevelopment and recertification by regulatory agencies and notified bodies. Also, some standards or reference testing/procedures such as the ones issued by the OECD, ICH, etc. would have to be revised or replaced by new standards based on the use of alternatives to microplastics.

D.7.4.2. Technical solutions to minimise releases to the environment

Microplastics used in IVDs are intended to come into contact with, or collect, biological specimens (e.g. blood, urine, saliva, tissue) that are to be analysed. Microplastic particles that were in contact with biological specimens are typically considered as hazardous biological waste, requiring appropriate disposal such as via incineration or via autoclaving/sterilisation before disposal (with subsequent landfill or incineration as solid waste).

The handling and disposal requirements for (biological) hazardous waste are usually set via local permits and vary between one Member State and another (or even across regions within one Member State) and is done in accordance with the Waste Framework Directive (WFD) (2008/98/EC).

It is important to note that the handling and disposal of (biological) hazardous waste is often dictated by the presence (or absence) of suitable incineration capacity in proximity of the source of the hazardous waste. The Final Draft (December 2018) of the Best Available Techniques Reference Document on waste incineration, Chapter 1.2, gives an overview of existing waste incineration capacity in Europe and shows that the use of incineration as a waste management measure varies greatly across the EU-28.

Table 84: Geographical distribution and capacity of incineration plants in the EU-28 for municipal (MSW) and hazardous waste (HW)

Country	Total number of MSW incinerators	Capacity (MT/year)	Total number of HW incinerators	Capacity (MT/year)
Austria	12	2.5	2	0.1
Belgium	16	2.7	3	0.3
Czech republic	3	0.65	NI	NI
Denmark	29 (1)	4.8 (1)	3	0.26
Estonia	NI	0.25	NI	NI
Finland	9	1.7	1	0.2
France	127	14.4	48 (2)	2.03 (3)
Germany	89	22.8	31 (4)	1.5
Hungary	1	0.38	NI	NI
Ireland	1	0.22	11	NI
Italy	44	7.3	NI	NI
Lithuania	NI	0.23	NI	NI
Luxembourg	1	0.15	0	0
Netherlands	13	7.6	1	0.1
Norway	15	1.6	NI	NI
Poland	NI	0.04	NI	NI
Portugal	3	1.2	5	NI
Slovakia	2	0.17	NI	NI
Slovenia	NI	0.004	NI	NI
Spain	10	2.64	1	0.038
Sweden (5)	34	6.6	1	0.1 (6)
Switzerland	29	3.29	11	2
United Kingdom	NI	6.18	3	0.12
EU-28	470	NI	NI	NI

Source: Best Available Techniques (BAT) (2018)

Note: NI: No information provided

MSW stands for 'Municipal Solid Waste', and HW stands for 'Hazardous waste'

(1) includes all incineration and co-incineration plants mainly treating non-hazardous solid waste. The

[16, Wilts et al. 2017] estimate for MSW alone is 3.3 Mt/yr

(2) Includes 28 dedicated commercial sites and 20 in-house plants (2015 data).

(3) 1.51 for commercial sites and 0.52 for in-house plants (2015 data).

(4) Figure includes installations used in the chemical industry.

(5) A total of 54 WI lines (boilers) are in operation at the 34 installations. 14 of the 34 installations are permitted for the incineration of HW too.

(6) Additionally, the incineration of 0.56 Mt/yr is permitted at the 14 MSWIs referred to in footnote (5).

Sources: UBA (2001), TWG (2003), TWG (2018), Bogdanovic et al. (2017), ISWA (2012)

IVDs generate both solid and liquid wastes. Solid waste is generally considered as biological hazardous waste and thus contained for proper disposal (often incinerated).

Liquid waste, composed essentially of purified water from the cleaning/rinsing of equipment, is often considered as non-hazardous and discharged down-the-drain (#2412 and #2714). Depending on the type of IVD instrument, liquid waste may be (i) contained by nature of the design of the instrument and collected in a storage tank / vessel before subsequent disposal (either via incineration, disposal down-the-drain or pre-treatment (chemical, sterilisation) prior to down-the-drain disposal), or (ii) disposed directly via a permanent connection to the waste water system. During the consultation, it was confirmed by the sector associations that incinerating liquid waste is not common practice.

Based on the information received during the consultation, technical and organisational solutions could be put in place to minimise the releases of microplastics from IVD applications; these include for example:

- Systematic incineration of solid wastes (instead of disposal in (municipal) solid waste landfill after autoclaving);
- Collection of all liquid wastes for incineration, or capture of microplastic from the liquid waste (in order to only incinerate the microplastics from the liquid waste, and not all liquid waste).

However, it is important to note that should technical solutions be considered to be feasible on a theoretical basis, they would have to be implemented for up to 60 000 IVD instruments that are already in use in the EU.

Alternatively, existing IVD instruments could be retrofitted or instruments redesigned so that microplastics in liquid waste could be separated for appropriate disposal; for example:

(i) Retrofitting an existing installation to separate the microplastics from the liquid waste:

- Microplastics could be removed from the liquid waste before they reach the wastewater system. This could be done by adding a filtration system to the liquid waste pipe in order to separate the microplastics from the liquid before it is discharged to the wastewater system.
- Due to the small size of microplastics and the presence of other materials in the liquid waste (e.g. lipids, wash solution), there are issues relating to filter saturation and blockage.
- The current design and installation of the IVD instruments might not always allow retrofitting (e.g. due to lack of space in the lab).
- Testing, validation, and regulatory approval of the changes would be needed before adapting the existing IVD instruments. MedTech Europe and D4A estimate that 5 to 12 years would be needed to develop and implement such solutions. According to D4A, the containment of microplastics is not feasible with the current IVD instrument for the liquid based assays. This statement is nevertheless not supported by any details.

(ii) Retrofitting existing installation to collect all liquid waste before sending them for incineration:

- In practice this option could mean (i) either modifying the existing wastewater system in order to connect it to a centralised collection tank located outside the laboratory, or (ii) install single collection tank or IBC to each IVD instrument

- This option would apply only to IVD instruments that have a direct connection to the wastewater system as certain types of IVD instruments already have a collection tank to collect liquid waste.
- Some IVD instruments can generate more than 200 litres of liquid waste per day, requiring sufficiently large storing tanks or frequent replacement of tanks as they become full.
- Testing and validation might be needed before adapting the existing IVD instruments.

(iii) Design and development of new IVD instruments to capture all microplastics (liquid and solid):

- According to MedTech, the development, testing and validation of new IVD equipment would require a period of 5 to 12 years. This information is supported by D4A, who estimates that 5 years would be needed for the veterinary applications.
- Both sector associations found it difficult to estimate the development costs: MedTech indicated that, based on experience, the development of new IVD instruments can cost up to €370 million over 20 years.

In conclusion, where collection and containment of liquid waste containing microplastics is not part of the initial design of an IVD instrument, it may be technically and organisationally challenging and expensive to retrofit existing installations. Developing integrated solutions to limit the release of microplastics in liquid waste would require considerable research and development by instrument manufactures that would take significant time (from feasibility to implementation) and resources; whist also requiring regulatory re-approval.

D.7.5. Proposed action

Releases of microplastics to the environment should be minimised. Although the quantity of microplastics released are low compared to other sources, *In vitro* diagnostic devices currently contribute to the release of microplastics to the environment. These releases occur as a result of the disposal of liquid waste down the drain. These releases could be minimised.

D.7.5.1. Baseline scenario

The baseline scenario adopted for the analysis is that, in the absence of restriction, microplastics will continue to be used as reagent / assays / calibration in IVDs. The Dossier Submitter assumes that the demand for microplastics in IVDs will remain stable during the study period (20 years).

The forecasted use of microplastics takes into account the following opposing assumptions:

- Increased use of microplastics as a result of increased use of IVDs which are an essential part of today's healthcare (human and veterinary). Indeed, according to a MedTech annual survey MedTechEurope (2017), the stagnation in EU revenues from sales of IVDs do not necessarily reflect changes in test volumes; there is

evidence in many countries that test volumes have increased without increased revenues.
- Downward trend in use due to growing public awareness and concern with microplastics emissions to the environment, and possibly from voluntary substitution from the sector.
- Potential impact of REACH authorisation outcome for IVD kits containing OPE/NPE.[102]

D.7.5.2. Restriction options

In term of restriction options, the Dossier Submitter has considered the following options:

- RO1: A ban on the placing on the market of microplastics for IVD uses with no transitional period after entry into force
- RO2: A derogation for IVD uses conditional on an obligation for downstream users to collect microplastic containing solid waste and send this for incineration
- RO3: A derogation for IVD uses conditional on an obligation for downstream users to contain the microplastics throughout their use, and incinerate them (i.e. solid and liquid waste) at the end of their life-cycle
- RO4: A ban on the placing on the market of microplastics for IVD use but with a transitional period long enough to allow the IVD sector suppliers to minimise the releases of microplastics to the environment
- RO5: Derogation for IVD uses conditional on including 'instructions for use and disposal' and an annual reporting requirement.

RO2 and RO3 target the downstream users of IVDs, while RO4 and RO5 primarily target suppliers and companies placing IVD analysers, reagents, assays and calibration standards on the market.

D.7.5.2.1. RO1: A ban on the placing on the market of microplastics for IVD uses with no transitional period after entry into force

In practice, this restriction option would mean that no microplastics would be available on the market as IVD assays, reagents or for calibration of IVD analysers once the restriction enters into force.

A ban on microplastics in IVD applications, without any transitional period, would have an immediate and wide-ranging impact on the provision of diagnostic capability across human and veterinary healthcare systems in general. Diagnostic tools that support human and animal health would become suddenly unavailable, with significant consequences. Such a ban could also have an impact outside of the EU/EEA, such as in IVD applications used for the prevention and control of transboundary animal diseases.

[102] At this stage of the process is not possible to predict the exact outcome and impact of the authorisation procedure. Nevertheless, if measures are put in place to minimise the releases of OPE/NPE contained in IVD kits, this might indirectly affect the releases of microplastics as some IVD kits contain both microplastics and OPE/NPE.

D.7.5.2.2. RO2: A derogation for IVD uses conditional on an obligation for downstream users to collect microplastic containing solid waste and send this for incineration

In practice, this restriction option would mean that (i) microplastics would remain available on the market for use in IVD assays, reagents or for the calibration of IVD analysers, and that (ii) downstream users would have an obligation to collect and incinerate all solid waste containing microplastics. This restriction option would affect only those downstream users that are currently autoclaving solid waste before disposal as (municipal) solid waste.

In terms of emission reduction, this option would have limited efficiency as releases of microplastics to the environment via solid waste are minor compared to the releases from liquid waste (cf. D.7.3).

In addition, as the treatment of solid waste is determined by the relevant EU, national and even local legislation, and due to the limited hazardous waste incineration capacity in different Member States (cf. D.7.4.2) this restriction option might result in cross-border transportation of waste and could generate other externalities, such as increased carbon dioxide from transportation or dioxin emissions when old incinerators are used.

D.7.5.2.3. RO3: A derogation for IVD uses conditional on an obligation for downstream users to contain the microplastics throughout their use and incinerate them (i.e. solid and liquid waste) at the end of their life-cycle

During the preparation of the Annex XV report, stakeholders reported that containment of microplastics was a standard practice in the IVD sector. The Dossier Submitter tested this contention when drafting the Annex XV report by proposing a ban on uses of microplastics where they are not contained throughout their use, and incinerated or disposed as hazardous [clinical] waste at the end of their life-cycle'. This was implemented via the derogation proposed in paragraph 5(a) of the conditions of the restriction in combination with the proposal for transitional arrangements of 24 months for *in vitro* diagnostic medical devices (paragraph 6.b in the Annex XV proposal).

In response to the consultation, industry associations and stakeholders provided additional information on the practical implications and costs of compliance with the proposed restriction. The Dossier Submitter has reviewed and assessed the information provided during the consultation.

As the retrofitting of filters to installed IVD equipment in order to capture microplastics from liquid effluents might not be possible at all downstream user sites (cf. D.7.4.2), the assumption is that in order for downstream users to comply with the restriction, liquid and solid wastes from IVD equipment (and containing microplastics) would be collected by downstream users and sent for incineration.

In practice, this would require that downstream users (hospitals, clinics, doctors, laboratories…) would have to modify some of their installations in order to collect the liquid waste that is currently discarded down the drain, and then incinerate (and not only autoclave) their solid and liquid waste generated from the IVD equipment.

Based on the information provided in the consultation, which was not available for the preparation of the Annex XV report, the Dossier Submitter has estimated that the total

cost of RO3 is between €0.8 and €3.2 billion[103] (based on transitional periods of between 2 and 12 years), with an associated cost effectiveness of between €0.3 and €1 million per kg of avoided release. The costs estimated by the Dossier Submitter are within the same order of magnitude as the €8.3 billion made by MedTech for a two year transitional period (#2714). The cost effectiveness of RO3 is several orders of magnitude less efficient than reported for any previous restriction adopted under REACH. Although there are no formally adopted benchmarks for acceptable cost-effectiveness when identifying appropriate REACH restrictions the Dosser Submitter concludes that the inefficiency of the cost effectiveness is highly likely to result in RO3 being a disproportionate restriction option, which should therefore be discarded.

Table 85: Overview of costs estimates for RO3

	MedTech (#2714) **TP - 2 years**	**Dossier Submitter assumptions** **TP - 2 years**	**Dossier Submitter assumptions** **TP - 5 years**	**Dossier Submitter assumptions** **TP - 12 years**
Total cost	€8.3 billion	€1.4 – 3.2 billion	€1.3 – 2.9 billion	€0.8 – 2.1 billion
Cost effectiveness (€/kg of release avoided)	-	€0.3 – 0.7 million	€0.3 – 0.7 million	€0.1 – 1.0 million

Note: based on the assumptions listed in Table 86 – TP stands for transitional period

The analysis of the economic costs, and cost effectiveness of the proposed RO3 relies on the assumptions which are detailed in Table 86. These assumptions were adopted in the absence of more appropriate information but are assumed to be plausible. RO3 scenario is tested with different transitional period, and compared to the cost estimates provided by MedTech (#2714) as a sensitivity analysis.

The Dossier Submitter has also considered the availability and capacity of incinerators in EU Member States. The Dossier Submitter also recognises that the classification of a waste as hazardous is a specific activity, based on specific criteria, which is of the responsibility of the waste producer. Therefore, the initially proposed wording 'A ban for the uses where microplastics are not contained throughout their use, and incinerated or disposed as hazardous [clinical] waste at the end of their life-cycle' was therefore not strictly appropriate. The wording should have just referred to incineration without reference to the term 'hazardous waste', or to refer to disposal 'as though it were hazardous waste'.

Table 86: Key assumptions for RO3 cost estimates

Assumptions on microplastic use and releases: Dossier Submitter assumptions: - Ca. 60 000 IVD instruments are currently on the market in Europe (#2714) - No information was provided by stakeholders on the number of use locations. The Dossier Submitter has therefore made an attempt to calculate this number. Considering that, in 2014, there were reported to be 2.9 hospitals for 100 000 inhabitants in the EU-28[104]. This suggests that there are roughly 15 000 hospitals in the EU-28. Considering that in France there is a ratio of two

[103] NPV – 20 years

[104] http://www.hope.be/wp-content/uploads/2018/07/2018_Hospitals-in-EU-28-Synthesis-final-for-publication-002.pdf

hospitals per laboratory[105], and applying the same ratio to EU, we would assume 7 500 IVD laboratories in the EU. Therefore, in total, the Dossier Submitter estimated that there are ca. 23 000 use locations in Europe of IVD equipment (hospitals + laboratories).
- 270 kg of microplastic releases to the environment annually from IVD applications. The Dossier Submitter has assumed that the annual release remains the same during the study period.

Assumptions on solid waste:

Dossier Submitter assumptions:

- Solid waste from IVD equipment are already collected for further treatment as hazardous waste: incineration or autoclave/sterilisation and then disposed as (municipal) solid waste (60% landfill). The later represents 14% of the microplastics used as reagent/assay/calibration beads in IVD application: i.e. 0.7 tonnes per year (Source: Table 83)
- Microplastics cannot be separated from the rest of solid waste (i.e. containers, plastic cuvette, pipette etc…), so the quantity currently not incinerated is not the microplastics quantity only: it is more important. The Dossier Submitter estimates that about 1 tonne of solid waste per year/per customer would need to be incinerated instead of autoclaved/sterilised.
- According to Medtech, ca. 10 000 users of IVD instruments are currently autoclaving their solid waste before disposal as solid waste. This number seems to be overestimated considering the total number of IVD instruments (60 000) currently installed in Europe. It seems to assume that each customer has one IVD instrument only, and that 14% of the users are currently autoclaving their waste (60 000*14%= ca 10 000). The Dossier Submitter is assumed that a user of microplastics might have more than one IVD instrument installed in its premises (this is confirmed by some confidential comments), and would apply the same type of treatment to all the solid waste generated in its premises. The Dossier Submitter has also assumed that there are 23 000 use locations in Europe (cf. above): 23 000*14% = ca. 3 000 users that are currently autoclaving their solid waste.
- The Dossier Submitter estimates that incinerating 1 kg of solid waste costs €25. This cost is below the upper value received via the consultation.

Information on cost received during the consultation:

MedTech estimates that each customer which is currently autoclaving his solid waste would have to send it to incineration, MedTech estimates that the additional cost for incineration of solid waste would be €4.08 billion over 20 years for the 10 000 users.

Assumptions on liquid waste:

Dossier Submitter assumptions:

- Microplastics disposed as part of the liquid waste: ca. 0.5 tonnes per year (Source: Table 83).
- Standard handling of liquid waste: down the drain.
- In some cases, the liquid waste is already collected in a separate container. The Dossier Submitter has assumed that ca. 50% of the existing analysers are already collecting liquid waste in a separate container and that 50% of the existing installations would need to have their piping modified in order to collect the liquid waste from the IVD in a separate container. The Dossier Submitter estimates that this modification at a DU site would cost between 10 000 and 50 000 € per impacted IVD analyser and that all necessary modification would be completed before the entry into effect of RO3.
- On average, one analyser can generate up to 20 L liquid waste per day (8-hour shift) – some analysers can generate much more. MedTech has estimated that 350 million L per year of liquid waste are generated from IVD instruments, and would need to be incinerated. On the other hand, based on an average 20 L daily liquid waste, the Dossier submitter estimates that between 1 000 and 4 400 L are generated yearly per IVD instruments, which corresponds to 264 million L per year of liquid waste are generated from the 60 000 IVD instruments installed in the EU.
- Based on a benchmark review, the Dossier Submitter estimates that incinerating 1 L of liquid waste costs €0.5. This cost is also within the range of incineration costs received via the consultation.

Information on costs received during the consultation:

MedTech estimates that 350 million L per year of liquid waste are generated from IVD instruments. MedTech estimates also that the cost for incineration of liquid waste would be approximately €4.23 billion over 20 years.

[105] https://solidarites-sante.gouv.fr/IMG/pdf/dgos_cc_2018_02_16_a_web_pages_hd.pdf

Other assumptions:

Dossier Submitter assumptions:

- Entry into force of the restriction: 2022
- Entry into effect of RO3: 2022 + TP (transitional period)
- Study period: 2022 – 2041
- Discount rate: 4% yearly
- Costs: 20 years – NPV
- Total cost (20 years – NPV) = Cost to incinerate solid waste + Cost to revamp piping at DU site to collect liquid waste + Cost to incinerate liquid waste + Enforcement cost (55 000€/year)

D.7.5.2.4. RO4: A ban on the placing on the market of microplastics for IVD use but with a transitional period long enough to allow the IVD sector suppliers to minimise the releases of microplastics to the environment.

Contrary to RO2 and RO3, this restriction option would target primarily the actors in the supply chain placing on the market microplastics for IVD applications, and/or the suppliers of IVD analysers/equipment.

A very long transition period (8 to 15 years) would allow the upstream actors in the supply chain to (i) either substitute the microplastic beads with an alternative, (ii) or design, and place on the market new IVD analysers that would capture (via a filtration system for example) and contain microplastics throughout their use. By doing so, the collection and incineration of large volumes of aqueous waste would not be needed. This RO indeed does not entail any obligations for the downstream users to incinerate additional solid waste, nor the liquid waste exempt from microplastics thanks to the filtration system.

The Dossier Submitter has therefore tested this RO4 using several transition periods: 8, 12 and 15 years.

A transition period of 8 years would, most probably, not allow the sector to replace all microplastics with alternatives or replace existing equipment with new models equipped with a filter. A transition period of 12 to 15 years for a restriction is not considered to be realistic. The risk of failure to find alternatives or technical solutions is also very high, considering the complexity and the high number of different applications and microspheres/equipment affected.

. The Dossier Submitter has estimated the total cost of RO4 to be between €0.1 and €12.5 billion[106] (for 12 and 15 transitional period, and depending on the proportion of substitution vs new design of IVD equipment). The cost effectiveness would be greater than 50 000 € per kilo of avoided release. Although there are no formally adopted benchmarks for acceptable cost-effectiveness when identifying appropriate REACH restrictions the Dossier Submitter concludes that the inefficiency of the cost effectiveness is highly likely to result in RO3 being a disproportionate restriction option, which should therefore be discarded.

Table 87: Overview of cost estimates for RO4

[106] NPV – 20 years

	MedTech (#2714)	**Dossier Submitter assumptions** **TP - 8 years**	**Dossier Submitter assumptions** **TP - 12 years**	**Dossier Submitter assumptions** **TP - 15 years**
Total cost if microplastics replaced by alternative	-	€1.5 – 7.6 billion !!: Due to the TP, max 40% of microplastics could be replaced by alternative	€2.1 – 10.6 billion !!: Due to the TP, max 60% of microplastics could be replaced by alternative	€2.5 – 12.5 billion !!: Due to the TP, max 75% of microplastics could be replaced by alternative
Total cost if new IVD equipment placed on the market are equipped with a filter to collect the microplastics from the liquid waste	€373 million	€50 – 110 million !!: Due to the TP, max 30% of IVD equipment could be replaced by new one	€100 – 200 million !!: Due to the TP, max 70% of IVD equipment could be replaced by new one	€100 – 300 million !!: Due to the TP, all IVD equipment could be replaced by new one

Note: based on the assumptions listed in Table 86 – TP stands for transitional period

The analysis of the economic costs, and cost effectiveness of the proposed RO4 relies on assumptions which are detailed in Table 88. These assumptions were adopted in the absence of better information but are considered to be plausible. The RO4 scenario was tested with different transitional periods, and compared to the cost estimates provided by MedTech (#2714) as a sensitivity analysis.

Table 88: Key assumptions for RO4 costs estimates

Assumptions on the replacement of microplastics by alternative:

Dossier Submitter assumptions:

- Between 1 000 and 5 000 different reagents/assays/calibration products would need to be replaced by alternatives that did not contain microplastics.
- 5 to 15 years required for replacement with an alternative (cf. relevant section on alternatives)
- Annual reformulation estimated to be 5% (similar to other sector)
- Reformulation cost (material + R&D) for one assay: €4.5 million (source: CfE)
- No profit loss accounted for as the replacement by alternative could be coupled with the design of new equipment.
- Enforcement cost (55 000€/year)

Assumptions on the design of new IVD analysers that would capture (via a filtration system) and contain microplastics throughout their use:

Dossier Submitter assumptions:

- 5 to 12 year needed to design and place on the market new IVD equipment (cf relevant section on technical solutions). The Dossier Submitter therefore assumed that the first newly designed IVD equipment could arrive on the market not earlier than 5 years after the EiF of the restriction, i.e. in 2027.
- R&D costs associated to the development of the new design: the Dossier Submitter assumed that the normal R&D activity of the sector would be deviated to comply with the Restriction Option. So no additional R&D cost is accounted for.
- MedTech indicated that the development of new IVD instruments would cost approximately €373 million fixed cost over 20 years (design and installation of new filter). The Dossier Submitter has assumed that the additional cost to install a filter on the newly installed equipment would be between €6 000 and €10 000 per new IVD equipment.
- Assuming a 10 year amortisation period, it is assumed that 6 000 new instruments could be introduced on the market each year. No earlier replacement of equipment is assumed by the Dossier Submitter. It means that not all equipment might be replaced by the moment the RO4 enter into effect.

Other assumptions:

Dossier Submitter assumptions:

- Entry into force of the restriction: 2022
- First new designed equipment arriving on the market: 2027
- Entry into effect of RO4: 2022 + TP (transitional period)
- Study period: 2022 – 2041
- Discount rate: 4% yearly
- Costs: 20 years – NPV
- No additional incineration cost – it is assumed that the solid wastes remain treated as they are today => releases are further minimised (not reduced to zero)
- Total cost (20 years – NPV) for replacement by alternative = Reformulation cost + Enforcement cost (55 000€/year)
- Total cost (20 years – NPV) for placing on the market new designed IVD equipment = Cost of new technical solution (add a filter) + Enforcement cost (55 000€/year)

D.7.5.2.5. RO5: A derogation for IVD uses conditional on including 'instructions for use and disposal' and an annual reporting requirement.

Under this restriction option, it is foreseen to derogate the use of microplastics in *in vitro* diagnostic applications, and to accompany this derogation with 'instructions for use and disposal' and 'reporting' requirements as already proposed for other derogated uses of microplastics

Despite the recent adoption of the IVDR for human health applications, there is currently no harmonised legislation at EU level that deals with all the IVD applications (e.g. veterinary or RUO - (Research Use Only)). An 'Instructions for use and disposal' requirement at EU level for all IVD applications could therefore be considered as a restriction option. Such requirement could feasibly address, without necessarily solving, the problem of releases occurring via inappropriate disposal of microplastics wastes from IVD applications. The requirement would raise the awareness of the end-users on the proper handling and disposal of the IVD reagents/assays and calibrators containing microplastics.

The Dossier Submitter is therefore proposing an obligation to indicate on the labels, SDS, and/or Instructions for Use (IFU), sufficient instructions to avoid releases to the environment (both during use and at the end of their life-cycle). It could be a way also to alert the users of microplastics of their impact on the environment.

In addition to the 'instructions for use and disposal', this restriction option also includes a reporting requirement. The reporting requirement aims at monitoring the uses and releases to the environment that might arise both from the downstream uses, but also from the industrial uses (cf. section on use and function) including the formulation of the IVD kits, or calibration kits.

The reporting requirement will help the European Commission to gather more systematic information on the use and release of microplastics. This action also sends a signal that substitution of microplastics or implementation of containment measures (cf. RO4) can be sought and encouraged without disrupting access to IVDs. This could be made via 'voluntary' actions from the sector. The information gathered via the reporting would reveal the effectiveness of any voluntary measures put in place by the sector to progressively reduce the release of microplastics into the environment. If low effectiveness was apparent further regulatory action under REACH could be initiated.

This restriction option would entail additional costs for industry, but they are assumed to be minor compared to the other restriction options. The costs of the 'instructions for use

and disposal' requirement could, for example, be covered by the normal review and update cycles of the labelling/SDS/IFU, while the costs of the reporting could be covered by already existing administrative costs.

It is also proposed to grant a transitional period long enough to allow the SDS/label/IFU requirement to be implemented as part of the regular label/IFU updates for the majority of IVD as well as to minimise any costs related to SDS/label/IFU-stocks and the replacement of old SDS/labels/IFU for products already on the market. The transition period should also be long enough to not interfere with the transition period sets in the IVDR[107].

D.7.5.2.6. Restriction option analysis

There are many ways of ranking these five restriction options. In Table 89, the Dossier Submitter presents its restriction option analysis scoring the ROs on five key dimensions from best (•••••) to poorest (•) based on the assessment presented in the previous sections. The unweighted score count favours RO1 (A full ban at entry into force) and RO5 (Information for use and reporting requirements) over the other three options. One may consider that the key dimension of a restriction on intentionally used microplastics should be to achieve emission avoidance. Correspondingly, one may wish to give twice as much weight to this dimension. A weighted score count favours RO01 (A full ban at entry into force) over the other four options. The conclusion that may be drawn from this analysis is that unless one favours emission reduction much more than the other dimensions, RO5 is likely to emerge as the best restriction option.

Table 89: Restriction option analysis for IVDs

	RO1	**RO2**	**RO3**	**RO4**	**RO5**
Emission reduction	•••••	•	••••	•••	••
Other environmental impact[1]	•••••	••	•	•••	•••
Investment costs	•••••	•••	•	••	••••
Opportunity cost[2]	•	•••	••	••••	•••••
Public acceptance	•	••	••	•••	•••
Unweighted score count	17	11	10	15	17
Weighted score count	22	12	14	18	19

[1]: environmental impact considering also the impact on the environment of the RO. For example the impact on the environment of the incineration required in RO2 and RO3.

[107] IVD devices, with certificates issued under the IVDD, may continue to be placed on the market until 27 May 2024 and made available until 27 May 2025

[2]: By opportunity cost: we mean here the impact of the RO on health care systems (e.g. in terms of compliance costs)

D.7.5.3. Conclusion – proposed restriction

Even though IVD for human and veterinary health applications contribute to the release of microplastics into the environment, these releases represent a minor fraction of the intentionally added microplastics released into the environment (270 kg per year, i.e ca. 0.25% of the total use of microplastics in IVD applications). The Dossier Submitter concludes that the best course of action is to propose the following restriction options accompanied with a transition period: RO5, i.e. Instructions for use and disposal, and reporting requirement.

Ideally, this restriction should be accompanied by 'voluntary' actions from the sector (upstream suppliers) to minimise, as much as technically and practically possible, the use and releases of microplastics to the environment.

The following points were taken into consideration in the decision whether to propose to restrict these uses under the REACH Regulation:

- Target and risk reduction: microplastics are essentially used in contained cartridge or equipment. *In vitro* diagnostic devices contribute to a minor fraction of the release of microplastics into the environment (270 kg per year): releases to the environment occur as a result of the disposal of liquid waste down the drain. A labelling/SDS/IFU requirement with relevant instructions for use and disposal to avoid releases of microplastics in the environment is expected to slightly reduce emissions to the environment. Rather than imposing conditions to the downstream users, the restriction should seek to motivate voluntary actions from the suppliers of IVD equipment and IVD polymeric microspheres for the development and implementation of either alternatives to microplastics, or technical means where microplastics would be contained throughout their use. The effectiveness of the voluntary actions could be monitored via the reporting requirement.
- Restriction cost and cost effectiveness: the proposed restriction associated with a transition time are expected to allow the SDS/label/IFU and the reporting requirement to be implemented as part of the regular SDS/label/IFU updates and administrative work. The proposed transition time should also minimise any costs related to SDS/label/IFU-stocks and their replacements for products already on the market. If the use of microplastics in IVD would be fully banned (RO1), or if downstream users would be obliged to collect and incinerate their solid and liquid waste (RO2, RO3), the total restriction costs and the cost effectiveness of the restriction would be extremely high with regard to the level of emissions. In addition, a restriction that would target only the downstream users (e.g. hospitals, clinics, laboratories…) and might also have an indirect impact on public health expenditure and quality of care, as the extra costs associated to the containment and treatment of waste would be transferred to the health care systems, and ultimately to the patients and taxpayers.
- Socio-economic impact: IVD containing intentionally added microplastic particles have a high societal value. They are used by professionals in hospitals, clinics and laboratories in order to treat patients, animals and provide reliable diagnostic test results. In some cases, IVD containing intentionally added microplastics can also

be used as home-based self-tests by consumers. Progress made in IVDs during the last 50 years has had very positive impacts on society in improving the health of the general population (earlier diagnostic and/or prevention of diseases), and avoiding the spreading of pests and infections. A ban (RO1), or a transition period that is too short (i.e. <12 years) to allow the suppliers to find alternatives or technical solutions to contain microplastics (RO4) could affect the availability of key IVD equipment, particularly as there are no readily available alternatives, nor readily available technical solutions for the uses concerned.

- Other socio-economic impact: the IVD sector is driven by research and development: approximately 1 billion euros per year is reinvested in R&D MedTechEurope (2017). The proposed restriction, even if not imposing a deadline for replacing microplastics with alternative or revamping the IVD equipment, is expected to have a positive impact on innovation. Giving the time and the opportunity for the sector to find technical solutions or alternatives, will also give industry the possibility to gain new potential markets in Europe and globally. The restriction proposal will impact the SMEs, that represent 95% of the companies operating in this sector in Europe, but moderately compared to a ban.
- Practicality, enforceability and monitorability: on one hand, there is a sector-specific EU regulation (IVDR) that already governs the placing on the market and the market-safety surveillance of IVD for human health. On the other hand, no common EU legislation exists for all other IVD applications such as veterinary IVD, or RUO (Research Use Only). Regulating the use of microplastics in IVD applications (without referring to any specific regulation) under REACH may bring some consistency and clarity for the actors in these different supply chains (both users and suppliers). Monitorability, and enforceability of the proposed measure should also be feasible and easier for inspectors as the same type of equipment and mixtures (reagents/assays/microsphere for calibration) would have the same requirement whatever their application domain (e.g. human health, veterinary, RUO or other).

In conclusion, the proposed restriction could be seen as a way of complementing the sector-specific regulations including the IVDR, and is considered as an effective, practical and monitorable measure to address the main source of emissions from *in vitro* diagnostic medical devices. The proposed restriction is also an incentive for innovation, and should be accompanied by 'voluntary' actions from the sector to either avoid the releases of microplastics from the new IVD equipment, and/or replace the polymeric microspheres by a more sustainable alternative.

D.7.6. Impact of scope variations on the proportionality to risk

Scope variation 1: Microplastics with no dimension greater than 1 mm

According to the information collected, the microplastics used in IVD applications have their dimensions smaller than 1 mm. So a change in the upper dimension specifications would have no impact on the restriction.

Scope variation 2: Variations in lower size limit of the microplastic definition

During the dossier development and the opinion-making process, the Dossier Submitter considered a number of variations in the lower limit of microplastics, i.e. no lower limit and a lower limit of 100 nm.

According to the information collected, the microplastics used in IVD applications may have dimensions lower than 1 µm. So a change in the lower dimension specifications would have an impact on the restriction. It would reduce the number of reagents and assays affected by the proposed restriction. It is nevertheless not possible to estimate the impact quantitatively as the Dossier Submitter does not have detailed information on the volumes of microplastics per beads size. Developing and implementing technical solutions to capture microplastics where no smaller dimension would be defined might also be problematic.

Scope variation 3: Microplastics with film-forming functions are included in the scope

Not applicable for the IVDs.

Scope variation 4: Microplastic with concentration in mixture above 0.1%

As indicated previously, the concentration of microplastics in mixtures placed on the market with reagents, assays, and calibration functionalities might vary from 0.001 to 10%. Therefore, an increase in the concentration specifications would have an impact on the restriction, and would reduce the number of reagents and assays affected by the proposed restriction. Unfortunately, the scale of the impact cannot be predicted due to a lack of information on this specific issue.

D.7.7. Uncertainties

Uncertainties have been indicated in the relevant sections above. They are essentially related to the scale of the issue, in particular the tonnage and type/number IVD affected by the restriction proposal, and the quantity of solid waste and liquid waste that are currently not incinerated. Based on the information provided by MedTech Europe, and several suppliers of IVDs, the Dossier Submitter has also assumed that most of the microplastics are used in contained equipment or cartridge and are handled as biohazard waste and incinerated at their end of life. This assumption has not been confirmed by a global survey targeting the end-users of IVDs.

Another uncertainty concerns the feasibility and practicalities to contain microplastics throughout their use in order to not discard them with municipal waste water at the end of their life-cycle.

D.8. Medical devices

Medical devices (MD) are mixture or equipment (complex articles) intended generally for a medical purpose. They can be used in prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the intended action of a medical device is not achieved by pharmacological, immunological or metabolic means.

D.8.1. Existing regulatory framework

Medical devices are regulated by the EU Regulation (EU) 2017/745 on Medical Devices (aka MDR). This EU regulation repeals the existing directives on MD, and AIMD[108] and will be applicable from 26 May 2020. Due to some transition period set in the new Regulation, some devices with certificates issued under the 'old' Directives (MDD and

[108] AIMD stands for Active Implantable Medical Devices.

AIMDD) may continue to be placed on the market until 27 May 2024 and made available until 27 May 2025.

The MDR recognises the existence of (substance-based) medical devices: 'medical devices that are composed of substances or combinations of substances that are to be introduced into the human body through a natural orifice or applied to the skin and that are absorbed by or locally dispersed in the human body' (classification rule 21 as set in Annex VIII to the MDR).

It is important to note that it is not easy, at first sight, to distinguish a (substance-based) Medical Device from a medicinal product, a cosmetic or a food supplement. For example:

- the main criterion for distinguishing between SB-MD and medicinal products is the product's mode of action, namely the issue of whether or not the intended purpose is achieved by a pharmacological, immunological or metabolic mode of action.
- the main criterion for distinguishing between (substance-based) medical devices and cosmetic or food supplement is if it is intended to improve the health condition or not.

In addition, national regulations for example on pharmaceuticals and medical devices may differ considerably. Thus, it is, especially for mixtures, often up to the formulator to decide, and prove, if the mixture is registered as a cosmetic product, a food supplement, a medical device or a medicinal product. The registration type for a same mixture/brand might also differ from one Member State to another depending on national regulations. For example, the same product (or type of product) might be classified in different Member States as either a medical device, a registered medicine, an over the counter (OTC) product or a cosmetic (e.g. toothpaste, mixture for topical applications, head-lice treatment…). The new MDR intends to address this topic of 'borderline cases' in Article 4(3), and in recital (7), (8) and (9), where the Commission can decide on a case-by-case basis whether a product falls within the scope of the EU MDR or not.

The MDR brings also significant changes in term of Vigilance, Post-market Surveillance and communication on safe use (label, and instructions for use-IFU). For example, it will grant Notified Bodies increased post-market surveillance authority. Unannounced audits, along with sample checks and testing will strengthen the EU's enforcement regime and help to reduce risks from unsafe devices. Annual safety and performance reporting by MD manufacturers will also be required in many cases: e.g. Periodic Safety Update Reports (PSUR)[109], and reporting to a central database named EUDAMED.

Last but not least, as any other MD, SB-MD must now be assigned a risk class (IIa, IIb, III). This is done according to the place where the SB-MD performs its action (i.e.in or on the human body), where it is introduced or applied, and whether a systemic absorption of the substances (or the result of its metabolism in the body) occurs. Compared to the former legislation, the main consequence is that SB-MD applied on the skin (or cavities) have to be classified according to classification rule 21 or rule 4, and can no longer be

[109] As part of the market surveillance, companies placing on the market MD should prepare, and make available to the relevant competent authorities every two years a periodic safety update report (PSUR) which include updated information on the labelling.

classified as a Class I MD (low risk MD). This implies that before placing such a SB-MD on the market, a conformity assessment by a Notified Body is required.

The MDR does not explicitly require environmental concerns to be assessed. Nevertheless according to the legislator (source: DG GROW), 'the definition of risk is broad enough to encompass also the harm to the environment. So the obligatory benefit-risk assessment of any device can be considered appropriate to deal with the issue'.

D.8.2. Uses and functions

Medical Devices (MDs) containing intentionally added microplastic particles are used by healthcare professionals in hospitals, and laboratories in order to monitor, treat patients or improve their health conditions. MDs are also used by consumers at home. According to MedTech Europe (CfE #726, and ECHA AI 2018 #31-311), intentionally added microplastics are present in the following medical devices:

- **Polymeric filters**, e.g. Ion Exchange Resins in water treatment or purification for medical uses) – (ca. 1 tonne per year)
- **Adsorber and absorber granulates for blood treatment** in critical and intensive care (below 10 tonnes per year for the professional uses)
- **Ultrasound transducers** (microplastics are typically used to alter the material properties of device components to obtain properties that would not be available with a single material e.g. velocity, impedance, thermal conductivity, acoustic attenuation. These are all critical factors in developing high quality medical transducers).

The above mentioned medical devices have only industrial or professional applications. There is no consumer uses.

During the consultation, different sectors associations (e.g Federation of the European Dental Industry, Association for the European Self-Medication Industry, Council of European Dentists), as well as competent authorities, and individual companies indicated the presence of intentionally added microplastics in various type of **(substance-based) medical devices**, and medical devices for health-care professionals and consumers. This is summarised in Table 90.

Table 90: Example of (substance-based) MD and MD containing microplastics

Type of use	Example of application	Information on the microplastics (type and function)
Oral health (Dental) – SB-MD	Uses by professional: -Dental filling material -Denture adhesives -Powders for dental crowns and bridges Uses by consumers: -Denture adhesives -Denture cleansing materials -Tooth paste -Formulation for gum disease protection	Based on the information provided during the consultation, it seems that some microplastics intentionally added would fall under the proposed derogation 5b.

Type of use	Example of application	Information on the microplastics (type and function)
Other oral health – SB-MD	Uses by consumers: -Tablets to treat gastro oesophageal reflux symptoms	Function: film coating, binder or disintegrant (similar function in medicinal products). The solid particulate form might be lost after ingestion (similar to medicinal applications).
Nasal health – SB-MD	Uses by consumers: -Nasal wash containing saline solution	Based on the information provided during the consultation, it seems that the microplastics intentionally added would fall under the proposed derogation 5b.
Skin health – SB-MD	Uses by consumers: -Cream for topical application -Vaginal gels -Sun protection[110]	Function: gel forming agent, emulsifiers, film forming, thickening. Functions, and ingredients are similar to the one reported in cosmetics. Based on the information provided during the consultation, it seems that some microplastics intentionally added would fall under the proposed derogation 5b.
Eye health – SB-MD	Uses by consumers: -Drops for eyes moistening	Based on the information provided during the consultation, it seems that the microplastics intentionally added would fall under the proposed derogation 5b.
Absorbance products - MD	Use by consumers and professionals: -Incontinence products (e.g. incontinence layer)	Based on the information provided during the consultation, it seems that the microplastics intentionally added would fall under the proposed derogation 5a.

Source: Consultation: Oral health (#2267, 2432, 2434), Nasal health (#2434), Skin health (#2267, 2115), Eye health (#2267), Absorbance products (#2162)

It should be noted that as the SB-MD share the same galenic formulation with medicinal products (e.g. topical and oral formulation, drops), and cosmetics (e.g. leave-on and wash-off), the same type of microplastics are used in these different sectors.

D.8.3. Baseline – tonnage used and releases

With regard to the MD applications (other than SB-MD), the releases of microplastics to the environment seem to be limited, because the microplastics are either industrial (not dispersive), or contained in equipment without direct release to the environment. At the

[110] This includes sun protection products that do not claim SPF (sun protection factor) protection on their label, and can justify to treat or prevent a medical condition according to the MDR regulation.

Sunscreen under the EU Cosmetics regulation is "any preparation intended to be placed in contact with the human skin with a view exclusively or mainly to protecting it from UV radiation by absorbing, scattering or reflecting radiation". SPF should be indicated on the label of cosmetic sunscreen.

end of life, the microplastics, together with the other waste generated are disposed as clinical waste. In the specific case of the electric/electronic devices containing microplastics (such as the ultrasound transducers), the MDs are subject to the Waste Electrical and Electronic Equipment Directive (WEEE Directive 2012/19/EU), and are therefore collected in Business to Business scheme at their end of life. Releases of microplastics from these applications would therefore occur essentially if the microplastics are not disposed properly, and/or discarded down the drain.

As far as the (substance-based) Medical Devices is concerned, their modes of release are expected to be similar to the one from cosmetic products: i.e. essentially down-the-drain releases for the SB-MD that are similar to wash-off cosmetics, and essentially trash-disposal for the SB-MD that are similar to leave-on cosmetics.

Based on the information received during the consultation, some microplastics intentionally added to SB-MD might also lose their particulate form during use and would therefore not contribute to the microplastic concern. Other microplastics might be released in the environment. Unfortunately, the quantity of intentionally added microplastics that would contribute to the environment concern cannot be extrapolated from the information received. Therefore, only a qualitative evaluation is possible.

An overview of the information received re. releases of microplastics is summarised in Table 91.

Table 91: Estimated amounts and releases of microplastics particles from MD

Use	**Amount of microplastics intentionally added and placed on the market** **[EU tonnes/year]**	**Disposal assumption**	**Estimated release of microplastics to environment** **[EU tonnes/year]**
Medical devices (other than SB-MD) e.g. polymeric filters, adsorber and absorber granulates for blood treatment in critical and intensive care, and ultrasound transducers	Ca. 10 tonnes	Used in closed systems. Treated as clinical waste or disposed of via B2B[111] scheme	Negligible (essentially due to wrong disposal)
(Substance-based) medical devices (SB-MD)	No information received via the consultation. AESG only refers to a 'significant amount of SB-MD' affected by the restriction proposal.	Disposal similar to cosmetics: down the drain, and trash disposal. Some microplastics will lose their solid particle form during use.	No information available

Sources: MedTech Europe (ECHA AI 2018 #31-311), Consultation

Industrial uses are de facto outside the scope of the current restriction proposal, nevertheless the Dossier Submitter has gathered some information during the Restriction proposal preparation, and would like to mention the following potential sources of

[111] B2B: business to business

microplastic emissions to the environment from industrial uses:

- As indicated earlier, Ion Exchange Resins (IER) can be used in closed systems in various industrial setting (biotechnology and pharmaceutical industry, food industry, demineralisation of water, metal removal etc.). The microplastics are tightly packed between several layers of foils and filters in a tube/column and are not released during their use. Suppliers of these resins have indicated that in some cases, the microplastics can be supplied in bulk to the customers for them to load in their own manufacturing facilities (chromatography columns for example) (source CfE#652 and 746, consultations #2118, 2056). Some releases might occur during this loading/unloading phase in industrial settings.
- Manufacturing of IER: Microplastics could be released to the environment during the manufacture of IER.
- Production of bioresorbable implants, and other bioresorbable MD (#2158)

D.8.4. Alternatives

As for cosmetics, or medicinal products, replacing intentionally added microplastics by alternative ingredients in SB-MDs would require reformulation effort. A one to one alternative might not always be available (#2267, 2126). Alternatives would have also to be reassessed before the MD is placed on the market. For the SB-MD, this entails finding alternatives with the same functionalities, and the same absorption, and human health safety profile for example.

In addition to alternative ingredients, alternative formulations with the same purpose could also be sought and could be readily available either as medical device, medicinal product or cosmetic (no medical purpose claim).

For medical devices (polymeric filter, adsorber and absorber granulates, and ultrasound devices) MedTech (CfE#726) and several MD suppliers (CfE #652, #677 #746) have indicated that there is currently no alternative available.

During the consultation, stakeholders from the various sectors (#2126, #2432 for the dental health sector, #2098, #2267 for over-the-counter SB-MD) indicated that a transition period of 6 years after EiF, similar to the one proposed for leave-on cosmetics, would be needed for reformulation, and that a cost of €0.6 to €1.1[112] million would be required per reformulation.

Other stakeholders (#2267) have highlighted the challenges in reformulating oral dosage form (e.g. tablets to treat gastro oesophageal reflux symptoms): these challenges being the same as the one encountered by Medicinal Products (cf. relevant section).

D.8.5. Proposed action

Because microplastics are extremely persistent in the environment, their emissions should be minimised.

Medical devices, and more particularly (substance-based) medical devices, contribute to the release of microplastics into the environment.

On one hand, in Medical Devices (other than SB-MD), microplastics are essentially used

[112] €1.1 million in case clinical tests would be needed (class III MD only)

in contained cartridge or equipment. They contribute to a minor fraction of the release of microplastics into the environment: releases to the environment occur as a result of the disposal of liquid waste down the drain. A labelling/SDS/IFU requirement with relevant instructions for use and disposal to avoid releases of microplastics in the environment is expected to further reduce emissions to the environment.

On the other hand, due to the nature of their uses (similar to wash-off and leave-on cosmetics), the releases from SB-MD cannot be minimised via technical measures, therefore an EU wide action is needed.

(Substance-based) medical devices containing intentionally added microplastics have a lot of similarities in term of (i) applicability domains with cosmetics (e.g. toothpaste, mouthwash, cream, gel) and (ii) galenic formulation with medicinal products (e.g. solid oral formulation). A common approach seems therefore appropriate to avoid the potential reclassification of certain cosmetics as substance-based medical device (e.g. toothpaste).

Despite the limited set of information submitted during the consultation, the Dossier Submitter concludes that the best course of action is to restrict the placing on the market of (substance-based) medical devices. To take into account the time needed to reformulate SB-MD, the Dossier Submitter is also proposing a transition period (6 years), similar to the one that is proposed for leave-on cosmetics. This transition period was also recommended by some actors in the sector.

The following points were taken into consideration in the decision whether to propose to restrict SB-MD under the REACH Regulation:

- Target and risk reduction: due to the way they are used, which are very similar to leave-on (with down-the-drain disposal) and wash-off cosmetics, SB-MD are inevitably released to the environment down-the-drain during or after use.
- Restriction cost: to find alternative to microplastics, development and reformulation costs (including MD market application costs) might occur, but the sector might benefit from the experience gained in the reformulation of cosmetics, especially if a sufficient transitional period is granted. This is why a transition time similar to the one for leave-on cosmetics is proposed.
- Other socio-economic impact: SB-MD are used by healthcare professionals and by consumers in order to prevent diseases or treat patients with health conditions. Some SB-MD, for example in the field of dental applications, have a high societal value as they contribute to health-care dental prevention and treatment. In some specific cases, the purchase of some SB-MD might also be subsidised in certain member states (but this is not harmonised at EU level). Progress made in medical devices during the last 50 years has had very positive impacts on society in improving the health of the general population. A ban, without transition period, on the use of microplastics in SB-MD could affect the availability of some SB-MD such as self-treatment or prevention/curing of various diseases (e.g. dental diseases). In addition, a restriction with no transition time might also have an impact on public health expenditure and quality of care. Indeed, a number of SB-MD contribute to potential health care-saving by empowering citizens for self-treatment/self-prevention and avoiding in the long term longer and more expensive treatments. Rather, the restriction seeks to push for the development of alternatives; either alternative ingredients or alternative formulations.

- Practicality, enforcability and monitorability: Given the uncertainty related to the uses and availability of alternatives, the proposed restriction accompanied by a transition period similar to leave-on cosmetics is a practical proposal as this sector could benefit from the reformulation made in other sector for similar type of products. Hence, the practicality for industry actor should be feasible. Re. the authority side, despite "being broad enough to encompass also the risk for the environment" (source DG-GROW), some member states indicate that the MDR does not require environmental concerns to be assessed (#2162, and 2714). Therefore restricting microplastics in SB-MD would ensure an equal and practical treatment for all SB-MD placed on the market in Europe. Enforcability and monitorability of the proposed measure should also be feasible via the instruments put in place by the MDR regulation.

Finally, as some releases of microplastics to the environment might arise from industrial use, the Dossier Submitter is proposing to monitor the microplastics uses and releases in these applications and is therefore proposing a reporting requirement for the industrial uses.

In conclusion, the proposed restriction could be seen as a way of complementing, in term of environment risk management, the new sector-specific regulation MDR that will become applicable in 2020 and fully rolled-out by 2025. The proposed restriction is considered as an effective, practical and monitorable measure to address the main source of emissions from medical devices.

D.8.6. Impact of scope variations on the proportionality to risk

Scope variation 1: Microplastics with no dimension greater than 1 mm

According to the information collected, the microplastics used in MD applications have their dimensions less than 1 mm. So a change in the dimension specifications would have no impact on the restriction.

Scope variation 2: Variations in lower size limit of the microplastic definition

During the dossier development and the opinion-making process, the Dossier Submitter considered a number of variations in the lower limit of microplastics, i.e. no lower limit and a lower limit of 100 nm.

Limited impact expected on the SB-MD based on the assessment made for the leave-on cosmetic products.

Scope variation 3: Microplastics with film-forming functions are included in the scope

Some SB-MD might be affected (but no detailed information received on the function of microplastics in SB-MD)

Scope variation 4: Microplastic with concentration in mixture above 0.1%

No impact expected.

D.8.7. Uncertainties

Uncertainties have been indicated in the relevant sections above. They are essentially related to the scale of the issue, in particular the tonnage and type/number of MD (including SB-MD) affected by the restriction proposal, as well as the releases.

Also the enforceability of the proposed reduction especially at end-user sites (e.g. hospitals, laboratory) remains uncertain.

D.9. Medicinal products for human and veterinary use

D.9.1. Uses and functions: microplastics as pharmaceutical excipient or active substance

Over the past decades, and thanks to their water-insoluble, inert, biocompatibility properties, polymers including some microplastics have become the backbone of many medicinal formulations, including 'controlled-release' (CR)medicines.

In contrast to immediate release (IR – to be understood as immediate release in the stomach), the CR formulations can deliver drugs with a delay after administration (i.e. delayed release), or for a prolonged period of time (e.g. extended release ER, extra release XR, extra long release XL, long acting LA, sustained release SR), or to a specific target organ in the body (targeted release dosage, enteric coating). CR mechanisms allow to protect the active substance from the physiological environment (e.g. enzymes, pH), and to control its release at a specific predetermined rate in specific location/organ (Debotton and Dahan, 2017). They therefore offer a significant advancement over IR drugs.

In particular, CR medicines provide the following main advantages to the patients:

- Maintain a constant, optimum level of drug concentration in the body, and increase the duration of the therapeutic effect
- Increase the solubility of active substances to enable their absorption and action
- Reduce the frequency of taking medications (e.g. once a day to once a month instead of 3 to 4 times per day)
- Minimise the peaks of drugs in the body
- Minimise the side-effects of drugs (e.g. protect the GI tract from irritating ingredients)
- Improve the compliance and observance of the treatment by the patient (less medicines to ingest daily, and easier to swallow).
- Provide taste masking for drugs with unpleasant (bitter) taste

On the other hand, it should be noted that the development of new drug delivery systems for existing drugs, such as CR formulations, offers pharmaceutical companies a possibility to extend the patent life of those drugs whose patent protection are expiring (Wen and Park, 2011). Beyond the convenience and advantages for the patients, and the patent protection for industry, CR formulations provides also important sales revenue expansion for the pharmaceutical industry through product line extension via the CR dose forms. By extrapolation with US market data, it is assumed that in 2004, about 10% of the top 200 drugs by sales volume in Europe were CR dosage forms (Curtiss, 2005) (Xue et al., 2006). Overall, this creates an incentive for the pharmaceutical sector to use CR technologies even in applications where IR formulations were used before.

CR mechanisms used in medicinal products are very similar to the ones used in the agricultural and horticultural sector discussed in Section D.4, and in the food additive Sector discussed in Section D.10. Table 92 below gives an overview of the CR mechanisms and required polymer properties for medicinal product applications.

Table 92: Overview of controlled-released mechanisms versus polymer properties in

pharmaceuticals

Controlled-release mechanism	Description	Polymer properties
Dissolution (matrix system)	The drug is homogeneously distributed throughout the polymer matrix. As the polymer matrix dissolves, drug molecules are released, also called 'erosion controlled release'.	Polymer soluble in water such as HPMC
Dissolution (reservoir system)	The drug release is determined by the thickness and the dissolution rate of the polymer membrane surrounding the drug core. Once the coated polymer membrane dissolves, all the drug will release like immediate release formulation.	
Diffusion (matrix system)	The drug is distributed through the polymer matrix, and the drug molecules have to diffuse through the matrix to be released.	Lipophilic polymer insoluble in water
Diffusion (reservoir system)	The drug is surrounded by a polymer membrane, and the drug molecules have to diffuse through a polymer membrane to be released.	
Ion exchange	Selective and stoichiometric exchange of mobile ions of like charges between the Ion Exchange Resin polymer and the external fluids surrounding them in the body.	Cross-linked resins
Osmotic control	Via solid reservoir system	Semi-permeable membranes

Source:(Wen and Park, 2011), (Singh et al., 2007)

Polymers that are 'soluble' in water are not a concern for the environment as the 'solid particulate' form does not exist in presence of water. Therefore, microplastic particles have been identified in the following types of CR mechanisms:

- Diffusion through a polymer matrix or a polymer membrane
- Ion exchange via cross-linked resins also known as Ion Exchange Resins
- Osmotic control via semi-permeable membranes

These CR mechanisms are further described below, together with additional information on the type of microplastics involved.

It is important to note that the uses in CR formulations are deemed relevant to the restriction of intentionally added microplastic particles as far as the polymer placed on the market fall also under the microplastic definition. For instance, coated tablets, encapsulation membranes, or osmotic systems can be recognised as microplastics as long as the 'end product' which is consumed/ingested lies within the targeted size range of a microplastic definition (cf. section B.1.3).

Additional information were also received during the consultation, indicating that microplastics were not only intentionally added in controlled release formulation but also in immediate release formulation, where they can play the function of binder, filler, or disintegrant.

D.9.1.1. Diffusion controlled release formulation

In diffusion CR, the release of the active drug follows the principle of diffusion, with the flow of a solute (active drug) going from a higher to a lower concentration. To achieve this; the active drug is either uniformly embedded in a matrix (monolithic matrix), or is

contained in a reservoir (tablet, granule or capsule) surrounded by **water insoluble polymer** which acts as a semipermeable membrane (e.g. tablet coating) (Wen and Park, 2011).

Different kinds of matrixes and polymers are commercially available for the purpose of CR drug manufacturing. Diffusion may use swellable hydrophilic and/or nonswellable hydrophobic polymers(Tsung and Burgess, 2012): swellable polymers rapidly absorb fluids and swell on coming into contact with gastro-intestinal fluids, producing a protective gelatinous membrane around the active drug]. The surrounding gelatinous layer controls the rate at which water enters its core and the amount of drug being released. In this system, both dissolution and diffusion take place. On the other hand, nonswellable hydrophobic polymers neither dissolve nor swell, consequently diffusion through the pores and erosion of the matrix/coating in the gastro-intestinal fluids govern the delayed release of the drug (i.e. the dissolving drug must find its way out through the matrix pores or macromolecular structure of the polymer). The polymers are not absorbed from the digestive system during uptake and distribution of the medicine in the patient's body. They pass through the digestive tract and are intentionally excreted via the faeces by the patients.

Depending on their substance identity, their degree of polymerisation, their type (hydrophobic, cross-linked) and the various properties of the different part of the gastrointestinal tract (pH, enzymes, transit time, etc.), the polymers (bio)degradability level in the body might vary from one formulation to another. This means also that polymers used in the formulation of medicines can be fully, or partially excreted in the feaces as microplastic. This will have to be assessed on a case by case.

In diffusion CR formulations, polymers fulfilling the definition of microplastics may have the following technical functions:

- Film coating
- Binder, filler

The polymers listed in Table 93 is an attempt to list examples of polymers potentially fulfilling the definition criteria of a microplastic in term of morphology, state, dimensions, non-(bio)degradability and non-water solubility criteria. This list is based on information gathered during the preparation of the Annex XV restriction proposal where the definition of microplastic published on ECHA website was slightly different than the one finally proposed in this dossier. The list has been updated after the consultation. Water soluble and/or (bio)-degradable polymers are not indicated in the table as they do not contribute to the microplastic concern. On the contrary, polymers that swells after ingestion are listed in the table, because there is no certainty about the potential for reversibility/irreversibility to a solid form after ingestion. The unpredictable behaviour of swelling polymers in different pH, and or temperature conditions has been highlighted in some comments (e.g. #2675), it might also lead to a phenomena known as 'ghost tablet' by general practitioners.

The Dossier Submitter has therefore taken a pragmatic approach which is to assess the swellable polymers against the microplastic definition based on their original physical state when placed on the market, and therefore include this type of polymers in the Table 93. Further details are available in Section B.1.3.8.4 of this document regarding this approach.

It should be noted that the table contains also a number of chemically modified natural polymers, identified by EFPIA as potential microplastics (ECHA AI 2018 #10-101), for which their biodegradability against the criteria laid out in the proposed restriction has not been assessed for the purpose of this analysis (e.g. ethylcellulose).

In addition, with regard to the polymers with a film forming function, which is a key function of microplastic in the pharmaceutical industry, the microplastic particles are intended to form a continuous polymeric film coating during the manufacturing process of the medicine, i.e., the microplastic particles coalesce to become a 'particle containing solid polymer''. As per the definition in the Annex XV restriction proposal, the core/tablet/granules/pellet/encapsulated medicine etc. placed on the market for consumer use would be considered as a microplastic only if its max dimension would be ≤ 5 mm. It should be noted that granules, pellets, tablets (aka 'mini-tab') with a diameter ≤ 5 mm are essentially used for elderly and youth people who might have difficulties to swallow a medicine.

Table 93: Example of potential microplastics used in the formulation of diffusion controlled release medicines

Chemical name	**Function(s)**	**Concentration range**	**Comment**
Polymethacrylates	Film coating for CR tablets/granules/beads	Concentration: 1-5% w/w in the formulation	Microplastics at point of use by consumer only if dimension of the coated core is ≤ 5 mm
Polymethacrylates	Binders for CR in wet granulation[113] formulation processes	Concentration: 5-20% w/w in the formulation	
Polymethacrylates	Binders for CR in dry granulation (aka direct compression) formulation process	Concentration: 10-50% w/w in the formulation	
Polymethacrylates	CR agent in gel formulation for rectal application		
Carbomer polymers (high-molecular-weight polymer of acrylic acid crosslinked with allyl ethers of polyalcohols)	Binders for CR in wet granulation formulation process	Concentration: 5-10% w/w in the formulation	Most of the carbomers swells, but not all of them are soluble in water
Carbomer polymers (high-molecular-weight polymer of acrylic acid crosslinked with allyl ethers of polyalcohols)	Binders for CR in dry granulation (aka direct compression) formulation process	Concentration: 15-30% w/w in the formulation	

[113] Granulation consists of powder particles enlargement by agglomeration technique using a solvent (wet granulation), or not (dry granulation), it is one of the most significant steps in the production of pharmaceutical dosage forms, mostly tablets and capsules. Granulation process transforms fine powders into free-flowing, dust-free granules that are easy to compress, or to feed into capsules, sachets, or other delivery systems.

Chemical name	Function(s)	Concentration range	Comment
Ethylcellulose	Film coating for CR tablets/granules/beads	Concentration: 3-20% w/w in the formulation	1)Ethylcellulose is a chemically modified natural polymer for which no (bio)degradability information was provided 2)Film coating function: Microplastics at point of use by consumer only if dimension of the coated core is ≤ 5 mm
Ethylcellulose	Microencapsulation	Concentration: 10-20% w/w in the formulation	
Ethylcellulose	Binder for CR in granulation formulation process	Concentration: 1-3% w/w in the formulation	
Polyvinyl acetate phtalate	Film coating for CR tablets/granules/beads (enteric)	Concentration: 9-10% w/w in the formulation	
Polyethylenevinyl acetate	Film coating for CR tablets/granules/beads		
Poly(ε-caprolactone)	Film coating for CR tablets/granules/beads		
Cellulose acetate (phtalate)	Film coating for CR tablets/granules/beads		

Source: Pharmaceutical unit operations Coating (Avis et al., 1998), Handbook of pharmaceutical Excipients (Rowe et al., 2006), Pharmaceutical Manufacturing Handbook (Gad, 2008), Fundamentals and applications of controlled release drug delivery (Tsung and Burgess, 2012) EFPIA (ECHA AI 2018 #10-101), Individual companies (ECHA AI 2018 #16-161 and #16-162), Lubrizol website (Lubrizol-LifeSciences, 2018)

Usually these polymers are marketed in pre-mix blends ready to be used by the pharmaceutical companies to manufacture the drugs.

Some examples of therapeutic areas where diffusion controlled release are included in the table below.

Table 94: Example of therapeutic area

Disease	Coating functionality
Gastro-intestinal diseases (e.g. chronic pancreatitis, stomach ulcers, duodenal ulcers)	Gastro resistance, drug protection. The microplastics prevents the drug to be degraded or inactivated in the stomach.
Colon related diseases (e.g. Crohn, ulcerative colitis)	Colon targeting. The microplastics allows the drug to reach the target organ (colon).
Bacterial and viral diseases (e.g. antibiotics, HIV)	Gastro resistance, drug protection. The microplastics prevents the drug to be degraded or inactivated in the stomach.
Bacterial and viral diseases (e.g. pediatric HIV)	Taste masking for orally dissolvable dosage forms of antiretroviral.
Heart diseases (e.g. antiplateles)	Stomach protection.

Disease	Coating functionality
	The microplastics prevents severe side effects.
Heart diseases (e.g. hypertension, angina pectoris)	Sustained release. The microplastics allows to reach a steady state plasma level without peaks. Severe side effects are also prevented.
Central Nervous System (CNS) diseases (e.g. depression, epilepsy, migraine)	Stomach protection. The microplastics prevents severe side effects, or the drug to be degraded or inactivated in the stomach.
Central Nervous System (CNS) diseases (e.g. epilepsy)	Sustained release. The microplastics allows to reach a steady state plasma level without peaks. Severe side effects are also prevented.
Bone and joint diseases (e.g. sclerosis, pain, arthritis)	Stomach protection. The microplastics prevents severe side effects

D.9.1.2. Immediate release formulations

During the Annex XV restriction proposal preparation, and based on the information received during the call for evidence, the Dossier Submitter recognised that polymers are a backbone in the majority of solid oral dosage forms (both IR, and CR). Nevertheless, considering that polymers used in IR formulation (e.g. for film-forming, binding, taste masking or disintegrant function) aim by definition at quickly dissolving (when in contact with water or in slightly acidic conditions) in order for the API in the core to be released quickly/immediately ; the Dossier Submitter has assumed that IR formulations would not contain polymers that would fall under the scope of this restriction (because they would be water soluble or would be (bio)-degradable).

During the consultation, various stakeholders confirmed the use of polymers in the majority of solid oral dosage forms including immediate release formulations (#2153, #2194, #2237, #2267), but indicated as well that many polymers (falling under the definition of microplastics) used for example as binders, taste making agent in CR formulation were also used in immediate release (IR) formulation. Ethylcellulose was for example indicated, by some respondents, as a commonly used excipient as film coating or disintegrant in IR formulation. Nevertheless, the comments received did not specify if the ethylcellulose used in IR formulation would be water soluble or (bio)-degradable and would therefore be excluded from the scope of the proposed restriction.

It remains therefore unclear to which extend microplastics could be present in IR formulations.

In IR formulations, polymers fulfilling the definition of microplastics, and falling under the scope of the proposed restriction, may therefore have the following technical functions:

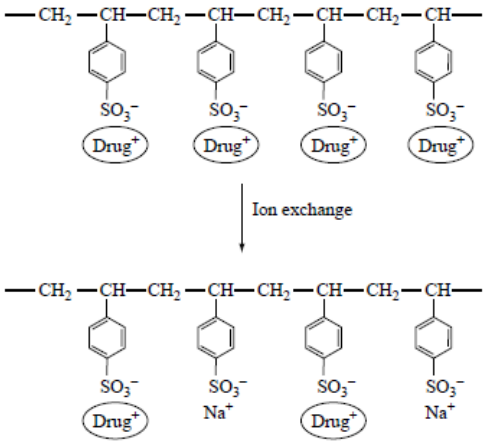
- Film coating
- Binder or filling agent
- Disintegrant

D.9.1.3. Ion exchange based controlled release formulations

Ion exchange based CR use a type of polymer called ‘ion exchange resins (IER)’.

Ion exchange resins are **crossed-linked**, **solid**, **water insoluble, non degradable,** polymeric materials containing ionic groups (Wen and Park, 2011), (Mahore et al., 2010), (Singh et al., 2007). Drug molecules can attach onto the ionic groups with opposite charge through electrostatic interaction. Thus, the drug molecules can be replaced with other ions with the same charge and released from the ion-exchange resin, as shown in Figure 8. The drug release from ion-exchange systems depends on replacement of the drug molecules by other electrolytes. To have a more predictable drug release, the ion-exchange resins can be coated with water-insoluble polymers such as ethylcellulose (EC) to provide diffusion controlled drug release (Wen and Park, 2011).

Figure 8: Ion exchange controlled-release mode of action



Source: (Wen and Park, 2011)

IER formulated in CR pharmaceutical formulations are fine powder particles (<200 micron). Being high molecular weight water insoluble and non-degradable polymers, the resins are not absorbed by the body and are therefore fully excreted via faeces (Mahore et al., 2010). This information was also confirmed by a producer of IER, and is clearly stated in the SmPC (Summary of Product Characteristics) of medicines containing IER[114].

The table below provides examples of IER available in Europe.

Table 95: Example of ion exchange resins used in the formulation of medicinal products

Chemical name	Function(s)	Example of application	Comments
Calcium polystyrene sulfonate	API Carrier for sustained release	Used in the treatment of hyperpotassemia	Posology: up to 60 g/day/patient Concentration: ca. 70% to 90% w/w in the formulation (powder)
Cholestyramine/ Colestiramine Colestyramin/ (EC: 234-270-8 CAS: 11041-12-6)	API and Excipient Carrier for sustained release Taste masking	Prescription drugs Used: - for cholesterol reduction, to treat bile acid diarrhoea, *clostridum difficile*	Posology: up to 24 g/day/patient (e.g. Questran®) Concentration: ca. 70% w/w in the formulation (powder)

[114] Cf. SmPC (section 5.2) of Resonium A® which contains Sodium polystyrene sulfonate as active substance: https://www.medicines.org.uk/emc/product/1461/smPC #PHARMACOKINETIC_PROPS

Chemical name	Function(s)	Example of application	Comments
		- in combination with non-steroidal anti-inflammatory drugs (NSAIDs) (German market) - in ointments for diaper rashes. - after cancer treatment to clean the liver. - in the "wash out" procedure in patients taking leflunomide or teriflunomide to aid drug elimination in the case of drug discontinuation due to severe side effects caused by leflunomide or teriflunomide.	
Hydrogen polystyrene sulfonate	Excipient Carrier for sustained release Taste masking Stabilization of final dosage	Used in the treatment of hyperkalemia (chronic kidney disease)	
Methacrylic acid with divinylbenzene	Excipient Taste masking		
Polacrilex (a copolymer of methacrylic acid with divinylbenzene)	Excipient Carrier for sustained release	Used to create the "Nicotine Resinate" described in the European Pharmacopoeia ((Ph. Eur.)), and incorporated into nicotine gums for smoking cessation (e.g. Nicorette gums® which might be registered as a medicine or not)	Posology: up to 300 mg/day/patients 18% of Nicotine Gums formulation
Polacrilin potassium	Excipient High-performance tablet and capsule disintegrant		Concentration: 2-10% w/w in tablet formulation
Sodium polystyrene sulfonate	API Carrier for sustained release Taste masking Stabilization of final dosage	Used in the treatment of hyperpotassemia	Posology: up to 60 g/day/patient Concentration: up to 99% w/w in formulation
Sodium polystyrene sulfonate	Excipient Carrier for sustained release of other API	e.g. complexed with codeine, chlorpheniramine for controlled-release	Posology: up to 60 g/day/patient

Sources: Handbook of pharmaceutical Excipients (Rowe et al., 2006), Individual companies (ECHA AI 2018 #07-071) and various publications (Mahore et al., 2010), (Purolite, 2012), (Bilandi and Kanta Mishra, 2013), emc website (search API only: https://www.medicines.org.uk/emc/browse-ingredients)

Depending on the pharmaceutical application, IER are used either as an excipient[115], or an active pharmaceutical ingredient (API).

D.9.1.4. Osmotic systems formulations

Osmotic release systems have a number of major advantages over other CR mechanisms. They are significantly less affected by factors such as pH, food intake, GI motility, and differing intestinal environments. Using an osmotic pump to deliver drugs has additional inherent advantages regarding control over drug delivery rates. This allows for much more precise drug delivery over an extended period of time, which results in much more predictable pharmacokinetics. However, osmotic release systems are relatively complicated, somewhat difficult to manufacture, and may cause irritation or even blockage of the gastro-intestinal tract due to prolonged release of irritating drugs from the non-deformable tablet.

Osmotic CR oral delivery systems (OROS) have the form of a rigid tablet with a semi-permeable outer membrane and one or more small laser drilled holes in it. As the tablet passes through the body, water is absorbed through the semipermeable membrane via osmosis, and the resulting osmotic pressure is used to push the active drug through the opening(s) in the tablet.

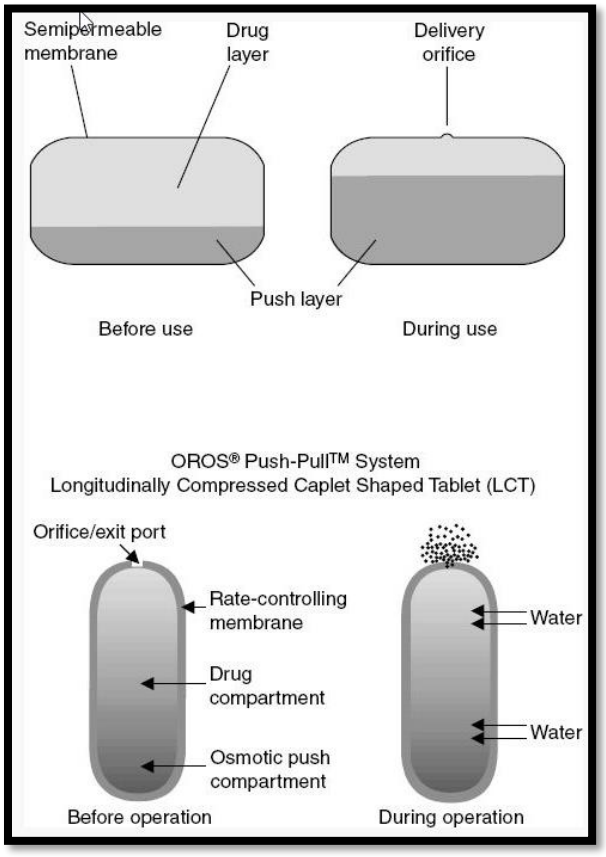
Being a 'solid' shell, the osmotic tablets are not absorbed by the body and are therefore fully excreted via faeces.

OROS are usually big, and their dimensions might exceed 5 mm. Nevertheless some OROS have dimensions below 5 mm that would fall under the microplastic definition. This is the case of Volmax[116] (salbutamol [albuterol] sulphate – to treat asthma), and potentially some paediatric formulations.

Figure 9: Osmotic drug delivery technology - cross-sections of bilayer and trilayer tablets before and during use

[115] Pharmaceutical excipients can be defined as non-active ingredients that are mixed with therapeutically active compounds to form medicines.

[116] The Dossier Submitter could not confirm if this medicine is placed on the market in Europe. It is given as an example of potential OROS having a size ≤ 5 mm.



Source: (Bass et al., 2002)

D.9.2. Baseline – tonnage used and releases

With regard to pharmaceutical/medicinal applications, AMEC Foster Wheeler study (AMEC, 2017b) indicates that even though microplastics are reported to be increasingly used in medicines as vectors for drugs (Cole et al., 2011), the associations of the pharmaceutical and self-medication industries have indicated in their responses to the AMEC consultation that 'they believe microplastics are not used within their sectors in the EU'. In addition, limited information on the applications of microplastics in human and veterinary medicines was provided in the call for evidence potentially as the implications of REACH in these sectors is not immediately well known and understood.

On the other hand, literature searches and direct contacts with various actors from the pharmaceutical industry supply chain (experts, and suppliers of polymers for the formulation of medicines, food supplements, and medical food) done during the preparation of this Annex XV restriction proposal, indicate that the use of microplastics is a reality in Europe, with potentially non-negligible quantities.

Exhaustive and comprehensive information about list of microplastics and quantities used and released are unfortunately not available. The information presented in Table 96, and in particular the amount of microplastics used in this sector might be under estimated as the data presented is based on the information provided by few companies on a limited number of microplastics only. The information received during the consultation did not allow the Dossier Submitter to refine the assumptions and estimates below. The Dossier submitter has made the following assumptions for estimating the used tonnages:

Diffusion controlled system:

Microplastics used in the formulation of diffusion controlled systems would still meet the definition of microplastics once placed on the market, if they fulfil at that stage all the definition criteria of a microplastic as set in the Background Document, in practice this means:

- If the microplastic has a **film forming function**:
    - Microplastic at formulation stage (industrial use – out of scope of the current proposal)
    - Microplastic when placed on the market for consumer and professional only if the core/granule/tablet all dimensions are ≤ 5 mm (aka 'mini-tablets' or pellets)
    - Not a microplastic when placed on the market as a medicine for consumer (patient) and professional if the core/granule/tablet all dimensions are > 5 mm
- If the microplastic has **any other function** (e.g. taste masking, binder, disintegrant, diluent, lubricant function, etc.):
    - Microplastic at formulation stage (industrial use – out of scope of the current proposal)
    - Microplastic when placed on the market as a medicine for consumer (patient) and professional

The Dossier Submitter has not received nor found consolidated information re. the tonnages used for different microplastics in the pharmaceutical industry, nor the splits of tonnage between the different functions of the solid polymers, nor the split of tonnage between core/granule/tablet sizes for the film coating function. It remains also unclear which polymers would fall under the microplastics definition. Therefore, the following assumptions have been made for estimating the quantities of microplastics used in diffusion controlled system:

- Tonnage lower band: considering the European consumption of 150 g API/capita/year, considering an EU population of 511.8 Million people in 2017 (Eurostat), considering that 90% of the API are delivered using a solid oral dosage form (Gad, 2008), and that 10% of the oral dosage forms would contain microplastic (Curtiss, 2005) assuming only film forming formulation, considering that microplastics contributes to a weight gain of ca. 5% in CR film coated formulations. This leads to an estimation of ca 500 tonnes.
- Tonnage upper band: the pharmaceutical applications of one specific type of polymer that could fall under the definition of microplastic has been reported to be ca 2 700 tonnes per year in Europe (ECHA AI 2018 #16-162). This quantity does not distinguish between the different functions of the microplastic (binder vs film forming), nor the size of the core/tablets/granules for the film forming function. So the tonnage might be over-estimated for a single microplastic, but under estimated if considering that diffusion controlled release medicines are using more than one type of microplastic. Therefore, having no other information, the Dossier Submitter has used this value as the upper tonnage band.

Immediate release formulations

The information received during the Consultation did not allow the Dossier Submitter to

estimate the tonnage used and released.

Ion exchange based controlled system:

In the contrary of the polymers used in diffusion controlled release, there is a clear case to conclude that all the IER (Ions Exchange Resins) used in the formulation of CR medicines fulfil the definition of microplastics. The tonnage band for the use of IER has been estimated using the following assumptions:

- A company placing on the market IER, indicated that a minimum of 300 tpa of IER are used for the formulation of controlled-release medicines in Europe (ECHA AI 2018 #07-071)
- Cholestyramine, alone, has been REACH pre-registered by nineteen (19) companies between 2008 and May 2017, including by two (2) pharmaceutical companies. One of them is placing on the European market prescription medicines that are a combination of cholestyramine and non-steroidal anti-inflammatory drugs (NSAIDs). The pre-registered tonnage of Cholestyramine for these two pharmaceutical companies was between 100 and 1 000 tpa (consolidated tonnages).

Osmotic systems:

According to EMA, OROS represents a niche market in Europe. No information on tonnage is available, but the uses of microplastics in OROS are assumed to be negligible.

Table 96: Estimated amounts and releases of microplastics particles from medicinal and medical uses (professional and consumer uses)

Use	**Amount of microplastics used [EU tonnes/year]**	**Release assumption**	**Estimated release of microplastics to environment [EU tonnes/year]**
Diffusion controlled system	500-2 700 tonnes (1 600 tonnes as a median value)	95% of the medicines placed on the market are consumed by patients: the microplastics are 100% excreted via faeces after consumption (down the drain releases). 5% of medicines are non-used, and not collected via special scheme (municipal solid waste landfill and incineration)	300 – 1 300 tonnes (800 tonnes as a median value)
Immediate release	Not estimated		Not estimated
Ion exchange based controlled system	300-1 000 tonnes (700 tonnes as a median value)		100 - 500 tonnes (300 tonnes as a median value)
Osmotic systems	Negligible		Negligible

Releases estimation:

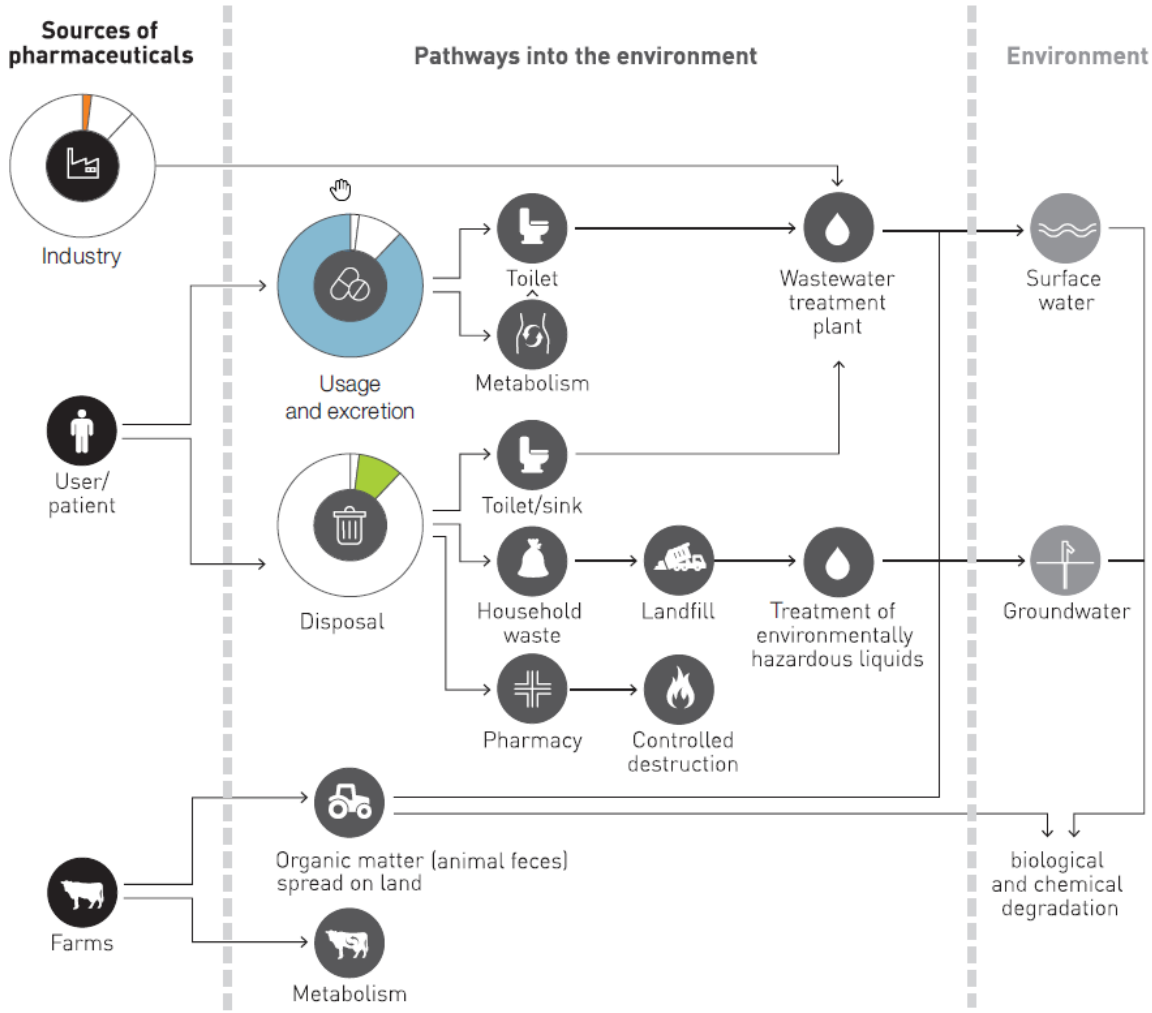
The key steps (from an environmental perspective) in the life cycle of a medicinal product are manufacturing, consumption by patients/use by professional and waste management. In our case, the consumption phase is considered to be the largest contributor to the emissions of medicinal products into the environment, notably through excretions (i.e. when patients take medicines and then excrete them or the remnants of the capsules/tablets the medicines were contained in), and incorrect disposal of unused medicines through sinks, or toilets. The Figure 10 summarises the sources of

microplastics in medicinal products and their pathways into the environment.

Considering that microplastics in CR medicines are expected to be inert and to not react with the body, and without specific studies on the topic, the same assumption has been made for the microplastics excreted via the faeces: i.e. 100% of ingested microplastics are excreted from the body through the faeces.

Once in the wastewater, treatment will remove most of the microplastics (cf. relevant section of the report), but microplastics will potentially still be detectable in effluents as well as in the receiving surface and groundwaters. The residues remaining after wastewater treatment depend on the type of polymer, wastewater treatment process, and initial concentrations in the influent. Without information on these parameters, only assumptions, and trends can be made. This is summarised in Table 96.

In addition, the Dossier Submitter has considered that in the majority of EU Member States, a large share of unused human medicinal products (50% on average) is not collected and some EU Member States do not implement take-back schemes (EFPIA, 2017). This might results in higher releases to the environment.



Source: EFPIA (EFPIA, 2017)

Figure 10: Sources and pathways into the environment of microplastics used in the formulation of medicinal products

D.9.3. Alternatives

Excipients with similar functions and properties (e.g. film coating, binder, filler, controlled release, taste masking) are available but limited and might not be compatible with all API (e.g. due to the water sensitivity of some ingredients), nor allow the same medicine specifications in term of thickness, size, hardness, disintegration or release profile for tablets for example.

Polymers that would be digested after ingestion could be analogous to the derogation outlined in paragraph 5b of the proposal. The derogation for (bio)degradable or natural occurring polymers may also be applicable to some polymers authorised as excipients. Nevertheless the issue of disposal of unused medicines down the drain would still remain

Alternatives could also be considered among the existing excipients that are water soluble polymers as this type of polymer does not present a concern for the environment (the 'particulate' form is lost in presence of water either after ingestion or direct release into the environment). Nevertheless, some respondents have highlighted in their

comments to the Consultation that the functionality of many pharmaceutical excipients is directly linked to their physicochemical properties and in particular their polymeric nature and insolubility in water (#2163).

Developing new excipients (aka 'Novel Excipients') with the same technical functionalities, same safety profile, and same bioavailability of the API is a challenging effort that might require as well 10 to 15 years of development and approval by the health authorities before being used in pharmaceutical formulations (#2163)

During the consultation, both sector associations and individual companies have also confirmed that the reformulation of a medicinal product is not straightforward: a one to one substitution of ingredients is not possible (e.g. #2153, #2194, #2237, #2267, #2550). Several factors such as the active ingredient concentration, physico-chemical properties, solubilities, degradation mode, but also the size or composition of the medicine, play an important role in the formulation, and in particular in the drug release rate in controlled-release formulations. In addition, for oral formulations, the various properties of the different parts of the gastrointestinal tract (pH, enzymes, transit time, etc.) make the reformulations rather difficult and the choice of alternative not straight forward (Wen and Park, 2011). For some technical functions, such as targeted organ release or sustained releases, EFPIA and suppliers of microplastics have indicated that no alternative solution currently exist on the market.

The Table 97 lists some examples of potential alternatives, and their limitations.

Table 97: Example of potential alternatives (non exhaustive list)

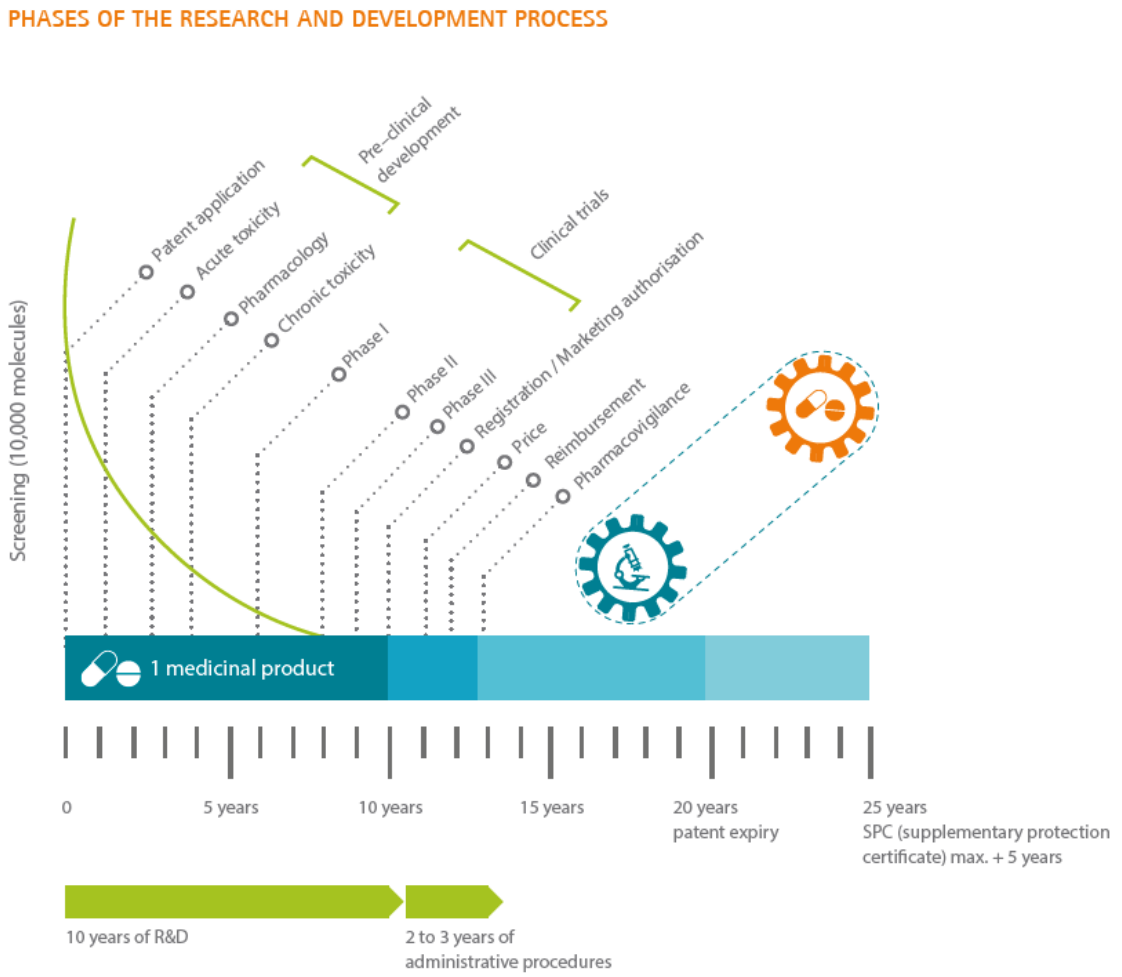
Alternative	**Technical function**	**Comment**
Maize starch	Disintegrant	Limitations: less effective than a synthetic polymer. Volume of the tablet would be increased (product too big to be swallowed). Formulation would be also more sensitive to humidity.
Shellac	Controlled Release	Limitations: naturally produced polymer from insect. Quality is variable – does not meet the current pharmaceutical standards
Lipid based excipients	Diffusion Controlled Release (matrix)	Limitations: limited API release rate
Microcrystalline cellulose	Binder	
Cellulose based material (if not microplastics)	Taste masking	Limitations: limited taste masking functionality as these substances are soluble in saliva.
Starches and sugar	Binder in tablets	Limitations: less effective than a synthetic polymer. Volume of the tablet would be increased. Formulation would be also more sensitive to humidity and less stable. Formulations tends to be sugar free for health reasons.

Alternative	Technical function	Comment
Lactose	Filler	Limitations: patients might be intolerant to lactose. Lactose is not compatible with all API or other excipients. Poor binding properties might be problematic for the formulation.
Povidone	Binder in tablets	Polymer soluble both in water and alcohol. Good alternative as a binder for the active substances that degrade in presence of water. 2 to 3% w/w suffice in a formulation
HYDROXYPROPYL CELLULOSE (HPC)	Binder in tablets	Soluble in water and ethanol Water solubility depends on moles of substitution. Also authorised as food additive (E 463)
hydroxypropyl methyl cellulose, hypromellose (HPMC)	Binder in tablets, controlled-release, film coating, viscosity modifier, ophtalmic formulations	Soluble in water and biodegradable. Alternative to animal gelatine Also authorised as food additive (E 464)
Polyethylene Glycol (PEG)	Microencapsulation (CR)	Used in parenteral formulation for example

Source: EFPIA (ECHA AI 2018 #10-101), AESGP (#2267), EFPIA (#2237), other sources

Last but not least, similarly to the food additives, and *in vitro* diagnostic devices, even if an alternative to microplastic would be available for medicinal products, the substitution would require most probably a major product re-formulation, including (bio)equivalence and stability studies to demonstrate the same specifications of the medicine (e.g. dissolution, friability, stability over time etc), clinical tests to verify and prove the effectiveness, performance, and safety of the alternatives. In addition, the market authorisation would have to be updated with potentially major variations for pharmaceutical products (variation type II[117] according to the European Regulations). Overall, the redevelopment, revalidation and reauthorisation of the products would require multiple years and an important financial investment. In some cases, the market authorisation holder might decide to withdrawn from the EU market the medicinal product which might leave some patients without treatments.

[117] Type II is a variation that is not an extension of the marketing authorisation (line extension) and that may have a significant impact on the quality, safety or efficacy of a medicinal product.



Source: EFPIA (EFPIA, 2017)

Figure 11: Development phases of a medicine

The European Medicines Agency (EMA) indicated as well some concerns that a REACH restriction could affect the availability of medicines, particularly as it was not clear if there were alternatives available for the uses, or for the medicines themselves.

Looking at the alternative questions from a broader perspective, one may argue that other galenic formulations (e.g. syrup, spray, drops, injection etc…) exist in the same therapeutic areas, and could substitute the solid oral formulation containing microplastics; again this would need to be investigated on a case by case situation especially where microplastics are used for paediatric or elderly people formulations.

D.9.4. Existing regulatory framework and other union-wide risk management measures

D.9.4.1. Sector-specific regulations

Medicinal products for veterinary and human health use are regulated by the EU Directive

2001/82/EC[118] and Directive 2001/83/EC respectively. They provide the legal framework for the market authorisation, manufacture and distribution of medicines in the EU. The centralised authorisation procedure for human and veterinary medicines is based on Regulation (EC) No 726/2004, which established the European Medicines Agency (EMA).

According to these Regulations, all medicines must be authorised before they can be placed on the market and made available to patients. In Europe, there are two main routes for authorising medicines: a centralised route (via the European Medicines Agency - EMA) and a national route. As part of the authorisation process, the authorities (either NA or EMA's committees depending on the authorisation route) perform a human-health benefit-risk analysis of the application, and give a recommendation on whether the medicine should be marketed or not.

Environmental risk assessment (ERA) in the market authorisation process:

For veterinary medicinal products, an ERA is required and mandatory for all types of marketing authorisation applications, including for new medicinal products, generics, variations and extensions. The ERA is taken into account in the risk-benefit analysis in view of the authorisation.

With regard to human health medicinal products, since October 2005, an ERA is required for new products to be placed on the market, but the ERA results in this specific case cannot lead to denying a market authorisation, even if some Risk Mitigation Measures (RMM) can be required when considered necessary.

A study performed in 2013 on behalf of the Executive Agency for Health and Consumer (Service, 2013) has listed the weaknesses of the current ERA in the human medicinal products market authorisation process:

- Many new medicines do not have ERA because the assessment of medicines fulfilling specific criteria stop after a first step
- ERA is based on the use of the product and the physicochemical, ecotoxicological, and fate properties of its active substance only. The excipients properties are ignored.
- ERA is build on confidential finished medicinal product information that cannot be reused from one dossier to another even if it concerns the same API
- ERA is not based on real API volumes emitted in the environment (only on individual company information)
- ERA is often incomplete or totally absent from some market authorisation applications
- The body in charge of the evaluation of human medicinal products (CHMP in centralised procedure, and national agency in case of national procedure) does not necessarily have an environmental expert able to understand the ERA content.

The same report has also pointed out that for both for human and veterinary medicines:

- No specific guidance is available on how to include a PBT assessment in the ERA, nor the consequences on the market authorisation

[118] Note that EU Directive 2001/82/EC on medicinal products for veterinary use will be repealed by Regulation (EU) 2019/6

- The PBT assessment is not considered in the risk benefit analysis

Summary of product characteristics (SmPC):

The SmPC is a legal document approved as part of the marketing authorisation of each medicine. The information contained in the SmPC is updated throughout the life-cycle of the product as new data or relevant information emerge e.g.: following safety communication updates, or when new adverse reactions have been observed during the marketing of the product.

The SmPC is the basis of information for healthcare professionals on what the medicinal product is and contains, and how it should be used. The Package Leaflet (PL) of the medicines "shall be drawn up in accordance with the SmPC" (Article 59 of Directive 2001/82 and 2001/83).

According to the EMA guidance on the drafting of the SmPC (EMA, 2009), section 6.6 (*6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product*) of the SmPC should contain any instructions for disposal, if appropriate for the medicinal product. The conclusions on the environmental risk assessment (ERA) of the product should also be included in this section.

Here are some examples of sentences that could be included in the SmPC and the PL (EMA, 2009):

- 'Any unused product or waste material should be disposed of in accordance with local requirements'
- 'Any unused medicines should be returned to the pharmacy, or disposed according to the local Regulation. Unused medicines should not be flushed down the toilet nor placed in liquid waste disposal systems.'

Outer packaging and Package Leaflet (PL):

Title V of Directive 2001/83 for Human medicines, and Title V of Directive 2001/82 for veterinary medicines, lay down the obligations in term of labelling, outer-packaging and package leaflet.

In particular, Articles 54(j)[119] in both Directives mention the obligation to include **"where appropriate"** instructions for the disposal of (unused) medicines "**on the outer packaging"** of the medicinal products for both human and veterinary medicines.

The Package Leaflet (PL) is also approved as part of the marketing authorisation of each medicine. According to Article 59 in both Directives, the PL "shall be drawn in accordance with the SmPC" (which includes instructions for disposal – cf previous chapter), and shall contain the minimum information listed in Article 59 (i.e legally binding information). The minimum legally binding set of information to be specified on the PL does not include the instructions for disposal.

[119] According to Articles 54(j) in both Directive 2001/82 and 2001/83, "the following information shall appear on the outer packaging: specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products, where appropriate, as well as reference to any appropriate collection system in place".

D.9.4.2. Strategic approach to water pollution from pharmaceutical substances

Article 8c of Directive 2008/105/EC aka Water Framework Directive (amended by Directive 2013/39/EU) obliges the European Commission to develop a strategic approach to water pollution from pharmaceutical substances. It is also required to follow up, where appropriate, with proposals for measures to be taken at EU and/or national level, to address the possible environmental impact.

The European Union Strategic Approach to Pharmaceuticals in the Environment was adopted in March 2019[120]. It focusses on a life cycle approach with over 30 actions spreading over key areas including awareness raising, greener manufacturing, Environmental Risk Assessments, management of waste, and environmental monitoring. It is a collective approach between all concerned Directorate Generals working together on this important issue.

D.9.5. Proposed action

Microplastics are intentionally added in the formulation of medicinal products for human and veterinary uses, essentially as film-forming agent, binder, filler and disintegrant. They play a key role in controlled-release formulations, and offer many advantages for the patients (better safety profile, better observance due to less frequent medicine intake etc…). These microplastics are 100% excreted from the body and released to the environment either as a microplastic or secondary microplastic. In addition, a proportion of microplastics can be released to the environment because of disposal of unused medicines down the drain. As these releases could potentially be further minimised through targeted measures, there is a need for an EU wide action.

In term of risk management option, a ban of microplastics in medicinal products was considered but dismissed, for the following main reasons: there are sector-specific EU regulations that already govern the placing on the market, the benefit-risk analysis (on human health) and the market-safety surveillance of medicinal products for human and veterinary uses. Regulating the use of microplastics under REACH in addition to the existing regulations may result in a lack of clarity for the actors in these two supply chains. In addition a restriction on these already heavily-regulated uses could affect the availability of medicines, particularly as there is no readily available alternative to microplastics, and it is also not clear if there are alternatives medicines (i.e. without microplastics) available for the pathologies where microplastic is used either as an excipient or an active substance. Medicinal products have also a high societal value, and a ban on microplastics in medicinal products will affect the availability of the majority of the solid dosage forms.

Nevertheless, the Dossier Submitters notes that the current risk assessment system of medicines (benefit/risk analysis) under the medicinal products Regulation is not an efficient way to addressing the issue of the microplastics: the benefit risk/analysis is focusing essentially on human health and safety, and does not take into account (even if it should) the risks for the environment when granting a market authorisation.

[120] https://ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF

Even though medicinal products contribute to the release of microplastics into the environment, it is concluded that the best course of action is for the moment to propose the following restriction option:

1. Reporting requirement: in order to gather more systematic information on the use of microplastics, in order to decide which EU action (e.g. REACH, Medicinal product regulation, other) would be the most efficient to address this issue, and avoid potentially double regulation.
2. 'Instructions for use and disposal' requirement with a transition period: in order to address already now the problem of the releases via inappropriate disposal of unused medicines, the Dossier Submitter is proposing to complement the existing medicinal product regulations with the obligation to indicate on the package leaflet (PL) of the medicines, sufficient instructions for the patients to dispose properly the unused medicines. The instructions should be in accordance with the EMA templates (EMA QRD template), guidance and standard phrases to be used on SmPC and packaging leaflet (EMA, 2009). For example: "Any unused medicines should be returned to the pharmacy, or disposed according to the local Regulation. Unused medicines should not be flushed down the toilet nor placed in liquid waste disposal systems".

The following points were taken into consideration in the decision to propose a labelling and reporting requirement:

- Target and risk reduction: as indicated in the previous chapters, microplastics could be released to the environment via the disposal of the unconsumed medicines down the drain. There is currently no legal obligation to inform about the proper disposal of medicines on the packaging leaflet, therefore an 'information for use' requirement with relevant instructions in the PL for proper disposal of unused medicines is expected to contribute to the reduction of emissions to the environment.
- Restriction cost: the costs re. reporting and labelling updates is estimated to be manageable for the pharmaceutical industry which is already well-organised to report on regular basis drug safety information, including SmPC, and PL's update to the authorities worldwide. This sector is also well organised to handle the re-labelling or repacking of its products. In addition, thanks to the proposed transition period associated to the labelling requirement, a large part of the additional costs are expected to be absorbed within the normal product re-labelling/repacking cycle. This is expected to allow the PL requirement to be implemented as part of the regular PL updates for the majority of products as well as to minimise any costs related to PL-stocks and the replacement of old PL for products already on the market. Some respondents indicated as well that the instructions for disposal are already part of the PL, and would therefore not need to take additional action with regard to the 'instructions for use and disposal' requirement (e.g. #2098, #2153, #2194, #2219, #2237).
- Other socio-economic impact: human and veterinary medicines containing microplastic particles are used to treat life-threatening diseases such as HIV, CNS, heart diseases, etc. Microplastics are also present in smoking cessation gums, and are also used in CR medicines specifically targeted to paediatric and elderly

populations. A ban on the use of microplastics in medicines could affect the availability of key medicines, particularly as it is not clear if there are alternatives available for the uses, and medicines concerned. More information needs therefore to be gathered via the reporting.

- Practicality and monitorability: the reporting requirement is considered implementable and manageable for the pharmaceutical sector as long as a central/common receiving system is put in place on the authority side. The PL changes can be monitored using the existing drug surveillance tools already in place in the pharmaceutical industry (e.g. SmPC and PL update).
  Another important issue for pharmaceutical industry associations and the EMA relates to the potential thread of double regulation and the establishment of diverging requirements. The Dossier Submitter agrees that these would be undesirable outcomes. This is why the proposed actions (reporting and PL update) aims essentially at complementing existing sector-specific regulations, and making the presence of disposal instruction (as instructed in the EMA QRD templates, guidance and standard phrases (EMA, 2009)) compulsory in the PL in case of presence of microplastics. The potential issue of retrospective changes of approved PL or packaging could be dealt with by way of derogation for previously approved medicines for example. Making the 'instructions for use and disposal' applicable and enforceable only for newly authorised or marketed medicines.

The proposed actions (reporting and PL update) are considered as effective, practical and monitorable measures to address one source of emissions from medicinal products, and gather more information in order to ultimately decide the best legislative route to handle the microplastics concern.

The practicality will also be ensured if sufficient transition period (TP) is provided. The TP should take into account the shell-life of medicines (3 to 5 years) especially considering that due to the Falsified medicine directive requirements (now embedded in Directive 2001/82/EC and 2001/83/EC), leaflet cannot be replaced in all existing medicines packaging without breaking the seals in place on the packaging. The Dossier Submitter would therefore consider that a TP of 2 to 3 years after the EiF would be sufficient for the sector to adapt.

The proposal highlights also the urgency for the legislator (the European Commission) to clarify the 'Strategic approach to pharmaceuticals in the environment', and in particular to coordinate between the regulatory actions proposed in this restriction and other relevant regulations. The overarching objectives should be to address the presence of environmental hazardous ingredients (including microplastics) in medicinal products and avoid diverging regulatory requirements, whilst closing regulatory loopholes: ensuring for example that an environmental risk assessment of the medicines including their ingredients is properly factored in the marketing authorisation and review process (i.e. address the limitations of the current ERA as indicated in section D.9.4.1).

Finally, the Dossier Submitter recognises that it is often up to the formulator, or company placing a product on the market to decide, and prove, if a product should be registered as a cosmetic product, a food supplement, a medical device or a medicinal product. This leads to different regulatory regimes being applied on the exact same products (and sometimes even same brand/formulation) in different EU Member States, and also within the same Member State. The Dossier Submitter considers that the proposed restriction

will not make worst (nor improve) the existing 'market distortion' situation, and highlights the need for the legislator to harmonise the definition and qualification of these different categories of products within the EU-28.

D.9.6. Impact of scope variations on the proportionality to risk

Scope variation 1: Microplastics with no dimension greater than 1 mm

According to the information collected, the polymers used in ion exchange based controlled release formulation have their dimensions less than 1 mm. So this use would not be affected by a change in the restriction scope. On the other hand, osmotic systems, and all coated CRF tablets would be excluded.

Scope variation 2: Variations in lower size limit of the microplastic definition

Same impact expected.

Scope variation 3: Microplastics with film-forming functions are included in the scope

Same impact. The film forming function (scope 5b in the restriction proposal) is already included in both the labelling and reporting requirement.

Scope variation 4: Microplastic with concentration in mixture above 0.1%

As indicated previously, the concentration of microplastics in medicines placed on the market might vary from 3 to 90% depending of the microplastic function in the medicine.

Therefore, an increase in the concentration specifications would have no impact on the labelling and reporting requirements.

D.9.7. Uncertainties

The issues presented in the previous sections, in particular the identification of polymers that would fall under the definition of a microplastic, is the biggest uncertainty. While, it is clear that the Ion Exchange Resins (IER) polymers would fall under the definition of microplastic, it is at the moment not possible to be 100% sure of the scale of the issue for the polymers used in solid dose formulations such as matrix and film diffusion (CR and immediate releases).

The availabilities of alternatives are also subject to uncertainties.

In general, very few information has been submitted by the pharmaceutical industry. This might be explained by a lack of awareness of REACH duties and impacts in this sector: the pharmaceutical industry is already regulated by other EU legislations on human and veterinary medicines, and quite often industry does not realise that the uses of substances in medicinal products can be restricted under REACH if they pose an unacceptable risk to human health or the environment.

For the medicinal products, it is worth noticing also that the available data on EU consumption is relatively scattered. Also, sales data is often confidential and it is particularly difficult to obtain data on medicinal products prescribed, sold over the counter (OTC) or via the internet. Similarly, detailed knowledge regarding the degradability of certain type of microplastics/polymers after ingestion (e.g. uses in controlled-release matrix and reservoir systems) is currently missing.

D.10. Food additives (in food supplements and medical food)

According to Article 3(2) of the EU Regulation (EC) No 1333/2008, a 'food additive' is any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food. Food additives are, by definition, intentionally added to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results. Food additives are present in the final food placed on the market.

D.10.1. Existing regulatory provisions

Despite being already regulated by another piece of legislation, food additives can also be restricted under REACH.

Food additives are indeed regulated by the EU Regulation (EC) No 1333/2008 which provides the legal framework for the use of food additives in foods in the EU. The purpose of this Regulation is to ensure an 'effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests and fair practices in food trade, taking into account, where appropriate, the protection of the environment'.

In addition, in order to ensure harmonisation, the risk assessment and approval of food additives should be carried out in accordance with the procedure laid down in Regulation (EC) No 1331/2008. According to recital 12 of this Regulation, "the authorisation to place substances on the market must be preceded by an independent scientific assessment, of the highest possible standard, of the **risks that they pose to human health**."

This regulation therefore does not specifically foresee an environmental risk assessment to be performed prior placing on the market a food additives, but also recognises that "in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account, including societal, economic, traditional, ethical and environmental factors and the feasibility of controls" (Recital 14 of Regulation (EC) No 1331/2008).

According to the Recital 14 of the EU Regulation (EC) No 1333/2008, "Food additives should be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information. Where necessary, the Commission together with the Member States should consider appropriate action."

Food additives remain also subject to the general labelling obligations as provided for in Directive 2000/13/EC.

D.10.2. Uses and function

In the course of the Annex XV report preparation, companies supplying microplastics to the pharmaceutical industry indicated that they were supplying the same microplastics as

food additive to the food for Specific Groups[121] (including food for special medical purposes) and food supplement[122] industries.

During the Consultation, three different sectors associations (VCI, Food supplements Europe and AESGP), and one company confirmed the use of microplastics as food additive in food for Specific Groups and food supplement (#2103, #2234, #2267 and#2675). There has been no information received to confirm the use of microplastics in other type of food or feed supplements, but this cannot be totally excluded by the Dossier Submitter.

The polymers fulfilling the microplastics definition have similar technical functions and benefits to the microplastics used as excipients in medicinal products (cf. section D.9 for additional details), i.e.:

- **Film coating**: this is a key function for controlled released (e.g. sustained release of vitamin C or caffeine, or targeted release to the colon of probiotics), protection of the main ingredients (e.g. vitamins, fish oil, garlic oil), protection of the GI tract in case of aggressive ingredient, improved swallowing of the tablet and taste masking
- **Binder or filler**: this is a key function for the processability during the manufacturing of tablets (e.g. tabletting step, moisturing control) and to insure consistent tablets specifications (tablet thickness, disintegration rate, dissolution rate). Binder can also be used for controlled released in matrix based CR formulation, and to improve the solubility of active ingredients by enabling their absorption and action
- **Disintegrant**

Some examples of polymers that could fulfil the microplastic definition, and fall under the restriction scope, are listed in Table 98. They are all authorised as food additives under the EU Regulation (EC) No 1333/2008 for use in food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable. They are also authorised for use in the same form in medical food (i.e. Food for specific groups regulated by Regulation (EU) N 609/2013). They are usually present in the formulation in a concentration between 2 and 3%.

In a similar way as in medicinal products, polymers (fulfilling the definition of microplastic) can be used either (i) as a functional coating, for example on tablets, pellets, granules, and/or (ii) within the solid dosage form itself (i.e. matrix).

Table 98: Example (non-exhaustive list) of authorised food additives that could fall under the definition of microplastics

[121] Food for specific groups is regulated by Regulation (EU) N 609/2013. It aims at protecting specific vulnerable groups of consumers (infants and young children, people with specific medical conditions and people undertaking energy-restricted diets to lose weight) by regulating the content and marketing of food products specifically created for and marketed to them.

[122] Food supplements are defined in Directive 2002/46 as foodstuffs containing nutrients and other substances presented in dose form and intended to be consumed in small unit dose.

E number	Additive name	Specifications according to Annex II to EU Regulation (1333/2008)	Function
E 462	Ethyl cellulose[1]		emulsifiers, film-coating (protection from water) Authorised also in all types of food
E 468	Cross-linked sodium carboxy methyl cellulose, cross linked cellulose gum, croscarmellose		Film coating (CR), binder, controlled-release Authorised also in table-top sweetener in tablet or powder forms
E 1202	Polyvinylpolypyrrolidone (crosspovidone)		Film coating (CR), binder, controlled-release
E 1205	Basic methacrylate copolymer	Maximum limit: 100 000 mg/kg Authorised since: ?	Film coating (CR)
E 1206	Neutral Methacrylate Copolymer	Maximum limit: 200 000 mg/kg Authorised since: 2013	Film coating (CR)
E 1207	Anionic Methacrylate Copolymer	Maximum limit: 100 000 mg/kg Authorised since: 2013	Film coating (CR)

Note: [1]: Depending on the degree of substation, molecular weight etc the fate properties of EC might vary. The Dossier Submitter has not assess the (bio)-degradability of this substance.

Source: Consultation (PC #2234, 2713, 2599), Regulation (EU) No 231/2012, EFSA ANS Panel (2018), EU food additive database available at https://webgate.ec.europa.eu/foods_system/main/?event=substances.search&substances.pagination=1

D.10.3. Baseline – tonnage used and releases

The scale of the intentional use of microplastics as food additive in food remains unclear: some submissions received during the consultation indicate a 'limited number' of microplastics among the approved food additives (#2103 and #2234), while other submissions (such as #2267) indicates that half of the food supplements placed on the market in Europe would contain microplastics.

Only scarce data from individual companies are available: Food Supplements Europe (#2713) indicates that one of his member is using 1 tpa of E 468, and another member less than 50 kg of E 468 but 3 tpa of E1202. Considering that there are 2 000 companies on the food supplement market in Europe (#2713), this leads to a potential important quantity of microplastics released from food supplement applications. One could assume releases estimates similar to the one from medicinal products.

It is important to note that not all polymers authorised as food-additive would fall under the scope of the proposed restriction. For example, Polymers that are 'soluble' in water are not a concern for the environment as the 'particulate' form does not exist in presence of water. In addition, polymers that would be digested after ingestion could be analogous to the derogation outlined in paragraph 5b of the proposal. The derogation for (bio)degradable or natural occurring polymers may also be applicable to some polymers authorised as food additive. Unfortunately little data is currently available on the

degradation of microplastics after ingestion (# 2713). A recent reassessment of cellulosic food additives made by EFSA concludes that modified celluloses (e.g. E 468) are not absorbed, not fermented and are excreted intact via the faeces EFSA ANS Panel (2018).

Releases estimation:

The Dossier Submitter has not been able to quantify the releases of microplastics from the food additive sector due to scarce data on used tonnage. Nevertheless, the use and releases paths of microplastics as food additives in food supplement, and medical food is very similar to the one in the medicinal products. Therefore, the releases pathways identified for the medicinal products are also valid for this sector, i.e.:

- release through excretions (i.e. when patients take medicines and then excrete them or the remnants of the capsules/tablets the medicines were contained in), and
- incorrect disposal of unused medicines through sinks, or toilets

Considering that microplastics as food additives are expected to be inert and to not react with the body, and without specific studies on the topic (except the recent one from EFSA on cellulosic compounds EFSA ANS Panel (2018)), the same assumption, as the one for medicinal products, has been made for the microplastics excreted via the faeces: i.e. 100% of ingested microplastics are excreted from the body through the faeces.

D.10.4. Alternatives

According to the information received via the consultation, already approved food additives with similar function (i.e. film coating, binder, controlled release and taste masking) are available but limited, and might not be compatible with all 'active ingredients' (e.g. water sensitive ingredients such as vitamins), nor allow the same tablets specifications in term of thickness, size, disintegration or release profile.

Those alternatives could be polymers, or other substances already authorised as food additive that are water soluble and/or biodegradable (e.g. E 463, E 464, E1201, E1203, E1208, E1209) according to the specification set in regulations (EC) 231/2012, 264/2014 and 685/2014. Those polymers would not represent a microplastic concern for the environment, but would have the same limitations as the one listed in Table 97.

Assuming that alternatives to microplastics are available, reformulation of existing food supplement is estimated to last between 2 and 5 years (#2267, #2713), and to cost between €45 000 and €200 000 per reformulation (#2713). A notification to the relevant MS competent authorities of the new formulation will also be needed in most of the EU countries. In addition, in case the reformulation is intended to be exported as well, new stability studies might be needed.

In case new food additive would have to be developed, AESGP (Association for the European Self-Medication Industry - #2267, and #2550) and Food Supplement Europe (#2234, #2713) indicates that it could cost approximately €1.4 million per new development, and could last 7 to 15 years. An approval from EFSA would also be needed before the alternative food additive could be placed on the market.

Some stakeholders indicate that a transition period similar or longer to the one proposed for the cosmetics would allow time to find alternatives and avoid potentially market disruption (#2234, #2713).

Alternatives could also be seen as 'alternative formulation' rather than 'alternative substance'. Food Supplements Europe has indicated in its submission to the consultation, that food supplements are available on the EEA market in various form (e.g. solid form containing microplastics but also syrups, sprays, ampoules, and drops). Alternative food supplements (i.e. formulation without microplastics) might therefore be available for some or all indications. Nevertheless it should be noted that the solid formulations (tablets and capsules) represents 60% of the market share, and that switching from one formulation type to another will have consequences on the type of industrial equipment used to manufacture food supplement (switch from tabletting process to liquid or capsule filling technology) including capacity issues.

D.10.5. Proposed action

Because microplastics are extremely persistent in the environment, their emissions should be minimised.

Microplastics are authorised food additives intentionally added in the formulation of food supplements and medical food for human uses, essentially as controlled-release agent, taste-masking agent and/or binders. These microplastics are assumed to be 100% excreted from the body and released to the environment either as a microplastic or secondary microplastic. In addition, a proportion of microplastics can be released to the environment because of disposal of unused packaging's content down the drain. As these releases could potentially be further minimised through targeted measures, there is a need for an EU wide action.

In the initial Annex XV restriction proposal, the Dossier Submitter tested the following restriction option: 'A ban with no transitional period'. In responses to the consultation on the Annex XV proposal, industry associations and stakeholders provided additional information on the practical impacts and costs of such a restriction. The Dossier Submitter has reviewed and assessed the information provided.

In term of risk management option, a ban of microplastics in food additives with a sufficient transition period (e.g. 5 years) was considered but finally dismissed, for the following main reasons: there is a sector-specific EU regulation that already govern the authorisation for placing on the market, and the benefit-risk analysis (on human health only) of food additives. Regulating the use of microplastics under REACH in addition to the existing regulation may result in a lack of clarity for the actors in this supply chain. In addition, a restriction on these type of applications (i.e. food additives used in food supplement and medical food) could affect the availability of the same polymers, used as excipients in medicines, particularly as there is no readily available alternative to all microplastics. Indeed there is a strong synergy between the food supplement, medical food and medicinal formulations as they are sharing the same type of formulation (tablets, capsules) and excipients/additives functional needs.

Even if in Europe, "an adequate and varied diet could, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life (…)" (Directive 2002/46 recital 3), some food supplements and medical food have a high societal value for specific group of population (e.g. children, pregnant women) or specific countries. Food supplement and medical food might be recommended by national authorities for certain populations, and might also be part of national reimbursement schemes (e.g. supplemental folic acid for pregnant women, supplemental vitamin D for

the Finnish population, supplemental vitamins and nutrients for people after gastric by-pass surgery, malabsorption of nutrients after chemotherapy….).

From a regulatory point of view, the Dossier Submitter recognises also that there is no harmonised practice neither in Europe nor within the same Member State regarding the classification of a product as a food supplement, as a medical food or as a medicine. It is often up to the formulator, or company placing a product on the market to decide, and prove, if a product should be registered as a food supplement, a medical food or a medicinal product. This leads to different regulatory regimes being applied on the exact same products (and sometimes even same brand/formulation) in different EU Member States. In addition, depending on the dosage of the main ingredient, a product might fall under one or the other Regulation. For example, tablets containing <2 mg of melatonin are sold as food supplement, while tablets containing >2 mg of melatonin are sold as medicine. Restricting food supplement differently than the medicinal products could end up in a market distortion.

Based on all these arguments, and unless one favours emission reduction much more than the health benefit for the society and the risk of market distortion, a restriction option similar as the one proposed for the medicinal products is likely to emerge as the best option. It is therefore concluded that the best course of action is for the moment to propose the following restriction option:

1. Reporting requirement: in order to gather more systematic information on the use of microplastics, in order to decide which EU action (e.g. REACH, Food additive authorisation scheme) would be the most efficient to address this issue, and avoid potentially double regulation.
2. 'Instructions for use and disposal' requirement with a transition period: in order to address already now the problem of the releases via inappropriate disposal of unused food supplement and medical food, the Dossier Submitter is proposing the obligation to indicate on the package leaflet or on the packaging, sufficient instructions for the patients to dispose properly the unused products.

The following points were taken into consideration in the decision to propose a labelling and reporting requirement:

- Target and risk reduction: as indicated in the previous chapters, microplastics could be released to the environment via the disposal of the unconsumed products down the drain. There is currently no obligation to provide relevant instructions on/in the packaging for proper disposal of unused products, Such a proposal is expected to contribute to the reduction of emissions to the environment.
- Restriction cost: the costs re. reporting and 'instructions for use and disposal' updates is estimated to be manageable by the sector if sufficient transition time is given. The restriction proposal is also the one which represent the lower cost for the sector. Industry placing on the market food supplement and medical food are often also active in the medicinal product market, therefore those companies (even if not all) can benefit from synergy by using a common reporting system, and therefore lower the implementation costs.
- Socio-economic impact: the sector is comprised primarily of small companies: 95% are SMEs (#2234). Nevertheless, as the same requirement will apply to all actors placing on the EU market food additives in consumer products, these

companies (EU and non-EU) will probably pass through any regulatory extra cost to their customers.

- Practicality and monitorability: the reporting requirement is considered implementable and manageable for the sector as long as a central/common receiving system is put in place on the authority side. The 'instructions for use and disposal' requirement is considered implementable is a sufficient transition period is granted to the sector to apply the changes.

The proposed actions (reporting and PL update) are considered as effective, practical and monitorable measures to address one source of emissions from food additives, and gather more information in order to ultimately decide the best legislative route to handle the microplastics concern.

There is a sector-specific EU regulation that already govern the use of food additives in foods including food supplements. This Regulation aims at ensuring the protection of human health and consumer, taking into account, where appropriate the protection of the environment. The Dossier Submitter would like therefore to highlight the possibility for the legislator (the European Commission) to consider the use of the Recital 14 of the EU Regulation (EC) No 1333/2008, which indicates that "Food additives should be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information. Where necessary, the Commission together with the Member States should consider appropriate action."

Finally, the Dossier Submitter considers that the proposed restriction will not make worst (nor improve) the existing 'market distortion' situation with re. to food supplement, medical food or medicinal product, and highlights the need for the legislator to harmonise the definition and qualification of these three different categories of products within the EU-28.

D.10.6. Impact of scope variations on the proportionality to risk

Cf. section D.9.6on medicinal products.

D.10.7. Uncertainties

The issues presented in the previous sections, in particular the identification of polymers that would fall under the definition of a microplastic, is the biggest uncertainty. As a consequence, it is at the moment not possible to be 100% sure of the scale of the issue.

The availabilities of alternatives are also subject to uncertainties.

Detailed knowledge regarding the degradability of certain type of microplastics after ingestion (e.g. uses in controlled-release matrix and reservoir systems) is currently missing.

D.11. Oil & gas

D.11.1. Uses

Microplastics use in the oil & gas sector is an example of industrial use of the substances. Microplastics can be integral to oil & gas operations and using them prevents other serious risks from occurring. According to industry, some of the chemical products containing microplastics could be considered as safety critical products, e.g., they ensure oil well integrity, limit corrosion, maximise oil & gas recovery, minimise oil release into

the environment,[123] reduce energy use (regulated),[124] contribute directly or indirectly to overall safety, among others. They fulfil these functions by, for example, preventing build up in pipelines, support in separation efforts ensuring that less oil is discharged to the marine environment, increase the impermeable properties of certain matrices while maintaining flexibility, e.g., cement.

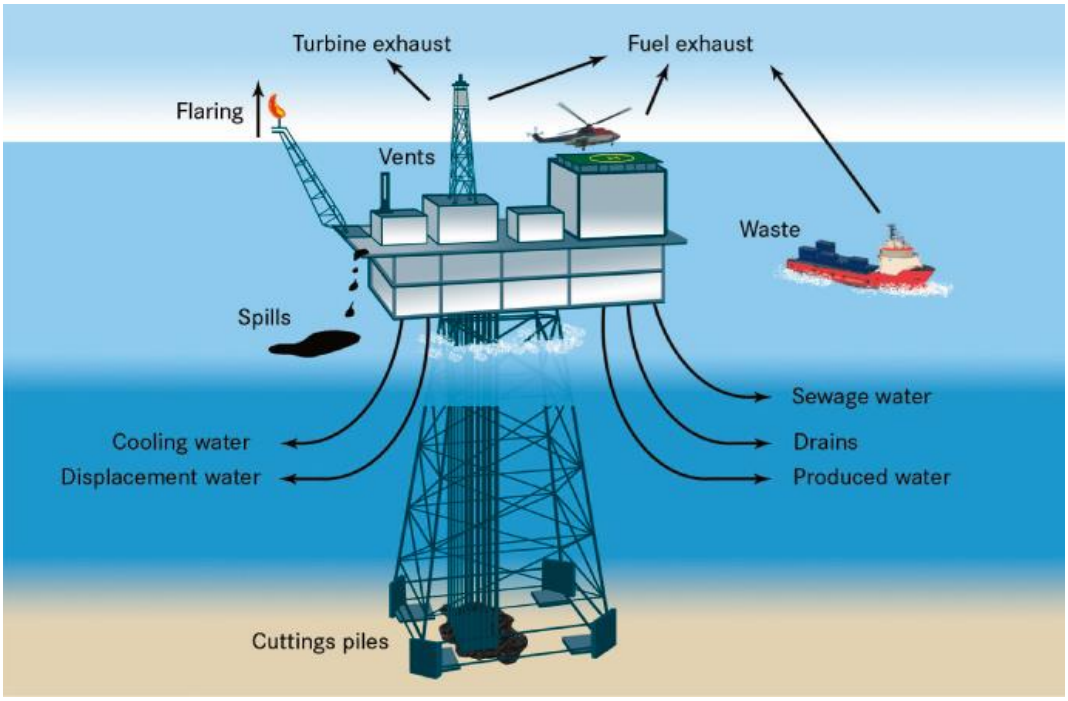
The microplastics used can be beads, fibres or of irregular shape. Their dimensions range from less than 100 µm to larger than 5 mm (i.e., the upper limit of the proposed definition for the purpose of this restriction dossier). The dimensions and other characteristics of the microplastics are proprietary information. They are selected after extensive testing to meet performance criteria under certain temperature and pressure conditions of the downhole oil well environment (ECHA CfE 2018, several entries). Further information in the CfE indicate that microplastics are generally present at low concentrations. Microplastics used in oil & gas applications may be discharged to the environment via produced water, deposited in the formation (proppants[125]), incorporated into a matrix (e.g., cement or coalescing into a plastic film), or via accidental emissions during production, drilling or transportation of oil & gas (e.g., emissions during casting of cement or re-opening of an old well). Some of these emission pathways for offshore oil & gas are shown on Figure 12.

Similar to other sectors, the microplastics used in oil & gas applications have low biodegradability, are solid and non-soluble in water. However, some microplastics are used in conditions which may lead to their degradation in other mediums such as hydrocarbon solvents or be retained or partitioned in the oil phase. Therefore, similar to other sectors, while a diverse range of polymers is used in oil & gas applications, it is difficult to say, based on the available information, whether these uses meet the criteria for microplastics at the point of use or point of release, whether they contribute secondary microplastics or whether their intentional addition does not lead to microplastic emissions to the environment.

[123] According to OSPAR Recommendation 2001/1 for the management of produced water in offshore applications "no individual offshore installation should exceed a performance standard for dispersed oil of 30 mg/l for produced water discharged into sea" as a monthly average of at least 16 samples per month. The goal is for each Contracting Party to accomplish a reduction of min 15% annually from 2000 levels of oil in produced water and new offshore operations (after 2001) should take as a point of departure minimisation of discharges and where appropriate, zero discharges (OSPAR, 2001).

[124] The European Commission co-sponsored AESOP project, "Assessment of Energy Saving Oil Pipelines" (2000-2003) which determined that a reduction of more than 25% in the energy required for ton-km of the base products is realised by using drag reducing agents (DRAs). The tests, conducted in an 84 km pipeline, demonstrated a reduction of 0.03 kWh per ton-km. Applying these results to current LSPI products and with additional modelling, reductions of 55-142 tonnes CO2-equivalent per tonne of DRA injected at 20 ppm is realized. (AESOP 2005: "Assessment of Energy Saving Oil Pipelines" (2000-2003) https://cordis.europa.eu/project/rcn/52372_en.html

[125] Proppants are particles mixed with fracturing fluid to hold fractures open after a hydraulic fracturing treatment. In addition to naturally occurring sand grains, man-made or specially engineered proppants, such as resin-coated sand or high-strength ceramic materials like sintered bauxite, may also be used. Proppant materials are carefully sorted for size and sphericity to provide an efficient conduit for production of fluid from the reservoir to the wellbore (Schlumberger, 2019)



Source: OSPAR[126]

Figure 12: Discharge of hazardous substances in the offshore oil and gas industry

D.11.1.1. Functions & baseline

Detailed information on the use of polymers and microplastics is available for offshore applications. This is due to the extensive reporting requirements developed under OSPAR and the concerted action under the OSPAR OIC (Offshore Industry Committee) on limiting plastic marine litter dating earlier than 2013. (See next section for further information.) According EOSCA (European Oilfield Specialty Chemical Association),[127] 115 products may contain microplastics and of those 82 were discharged to the environment. These discharged products represent less than 0.05% of the chemicals used and 0.16% of total discharges (ECHA WS 2018).

An EOSCA review of 2016 data found that in 14 out of the 59 OSPAR definitions of product functions, microplastics can be used. Table 99 shows that about 1 800 tonnes of microplastics may be used in offshore oil & gas operations and about one-third of them are reported as discharged to the environment in the course of a year (ECHA WS 2018). Earlier work by Cefas, estimated additional 7 500 tonnes of possible plastics (Cefas 2013).

As shown in Table 99, the largest uses and emissions are associated with the use in demulsifies, antifoam agents, corrosion and wax inhibitors. Industry have expressed opinions that these polymer uses do not fully meet the criteria for microplastics at the point or use or release, as they may not be particles, may be dissolved in organic solvent

[126] https://www.ospar.org/work-areas/oic/chemicals

[127] EOSCA is comprised of 42 members – chemical suppliers and service companies – which collectively represent more than 85% of products used in the North Sea (ECHA WS 2018).

which will partition to the hydrocarbon phase (ECHA CfE 2018, #671, 771; ECHA WS 2018; ECHA AI 2018, #12, 20; pers. comm.). The Dossier Submitter was not able to confirm this based on the information provided by industry. Furthermore, the work of EOSCA uncovered divergence in the reporting of demulsifier emissions by oilfield operators, ranging from 0 to 100%. Furthermore, for several of the remaining emissions, no intended discharge is specified as for example for pipeline applications the polymers are added to the exported oil (processed subsequently on shore) or for drilling fluid applications the microplastics remain in the formation indefinitely. For the latter in particular, it can be assumed some unintentional release occurs during drilling activities.

Table 99: Possible microplastics use & emissions by function: offshore oil & gas applications (2016 data, tonnes)

OSPAR Function	Definition	Used	Discharged
Demulsifier	Additives to produced fluids to accelerate the separation of the hydrocarbon and water phases	1 086	384.8
Wax inhibitor	Chemical injected into the wellbore to prevent or minimise wax deposition which can choke the production lines and can lead to reducing the oil production to uneconomic levels. The effectiveness of wax inhibitors is dependent on crude oil composition. Wax inhibitors are introduced into the oil before it cools to its cloud point.	160	20.9
Other chemicals	Various	135	2.0
Corrosion inhibitors	Additives to injection water or produced fluids to protect the installation from corrosion.	95	30.5
Antifoam (hydrocarbons)	Added to produced oil to speed up the removal of gas bubbles	67	42.4
Lost Circulation Material	Solid material intentionally introduced into a mud system to reduce and eventually prevent the flow of drilling fluid into a weak, fractured or vugular formation. It is generally fibrous or plate-like in nature, e.g., ground peanut shells, mica, cellophane, walnut shells, calcium carbonate, plant fibres, cottonseed hulls, ground rubber, polymeric materials and other low-cost waste products from the food processing or chemical manufacturing industries.	70	0.1
Drilling lubricants	A mud additive for lowering torque (rotary friction) and drag (axial friction) in the wellbore and to lubricate bit bearings if not sealed. Lubricants may be solids, such as plastic beads, glass beads, nut hulls and graphite, or liquids, such as oils, synthetic fluids, glycols, modified vegetable oils, fatty-acid soaps and surfactants.	46	0.1
Defoamer	Mud additive used to lower interfacial tension so that trapped gas readily escapes. Octyl alcohol, aluminium stearate, various glycols, silicones and sulfonated hydrocarbons are used	37	2.3
Fluid loss control chemical	Mud additives designed to lower the volume of filtrate that passes through a filter medium	30	-
Asphaltene inhibitor	Used to remove asphaltenes from crude oil, i.e., impurities found in crude oil that can choke refining equipment if not removed	25	0.1
Friction reducing agent	An additive, generally in slurry or liquid form, used to reduce the friction forces experienced by tools and tubulars in the wellbore	17	2.5

OSPAR Function	Definition	Used	Discharged
Viscosifier	A type of rheology modifier, an additive for oil- and synthetic-base muds that provides high viscosity at low shear rates, which is useful when drilling high-angle and horizontal wells and can be critical for cuttings carrying and to prevent sag and settling of weighting material. Products used include dimeric and trimeric fatty acids, imidazolines, amides and synthetic polymerse. E.g., HEC[128], imidazoline and amide based products[129], etc.	15	-
Cement/Cement additive	Chemicals & materials added to a cement slurry to modify the characteristics of the slurry or set cement. Cement additives may be categorised as accelerators, retarders, fluid-loss additives, dispersants, extenders, weighting agents, lost circulation additives and special additives designed for specific operating conditions. Cement additives are commonly available in powder or liquid form. Cement additives such as microplastics are used to hold well casting in place and prevent fluid migration from the subsurface. Microplastics are selected to withstand high temperature/ pressure conditions to impart better zonal insolation, improved well integrity, long functional life, etc. with the main being flexibility (critical due to changing conditions in the system). E.g., lignosulphonates and cellulosics; sugars and superplasticizing agents (~ 1960s), polyamine/imine (~1970s); SB Latex (~ 1980s); co/ter-polymers AMPS (~ 1980s); biopolymers (~ 1990s, not based on Xanthan gum)	12	0.9
Total		**1 795**	**486.6**

Source: Corrosionpedia (2019), ECHA WS 2018, ECHA CfE 2018 (#722), OGISPME 2016[130], Piot (2009), Schlumberger (2019)

The information in Table 99 does not reflect onshore activities. There is less aggregated information on the use and emissions of microplastics from onshore activities. Statistics about oil & gas operations in the EEA as well as information about industry practices can help with the estimation of the total use and emissions of microplastics in the EEA.

Today, over 90% of oil and over 60% of gas produced in the EU and Norway comes from offshore operations (EC 2017[131]). EuroStat 2016 oil production data in the EEA shows that the majority originates from bordering the North Sea (and North Atlantic) basin (i.e., in regions managed by the OSPAR Convention), and primarily in Norway (55%) and the UK (35%). The remaining Member States each account to less than 5% of EEA production. Natural gas production is geographically more diversified, with Norway (50%), the Netherlands (18%) and the UK (17%) accounting for the largest share. Industry reports that in general many of the oil & gas products find applications in both on- and off-shore applications. Onshore oil operations, however, tend to be less

[128] HEC is a non-ionic cellulose derivative with hydroxyethyl groups attached to the polymer structure. HEC is used as a viscosifier in brines and saline fracturing fluids, workover fluids, completion fluids and drill-in fluids. It gives pseudoplastic rheology but essentially no gel strength development. HEC offers little fluid-loss control, other than its rheological effects. HEC is seldom used in drilling fluids. Cellulose fibres are reacted with caustic soda and ethylene oxide to form HEC. Hydroxyethyl groups attach to the OH groups of the polysaccharide structure by ether linkages. A high degree of substitution (from 1.5 to 2.5 out of 3 maximum) gives HEC superior solubility in water and various brines. Being non-ionic, it is not precipitated by hardness ions and disperses well at high salinity. HEC is not degraded by common bacteria (Schlumberger, 2019).

[129] CRODA, https://www.crodaoilandgas.com/en-gb/discovery-zone/functions/viscosifiers

[130] To what extent is the oil and gas industry a source of plastics and microplastics in the marine environment: https://www.slideshare.net/TimGibson23/microplastics-report-64879266

[131] http://europa.eu/rapid/press-release_IP-11-1260_en.htm

chemically intensive than offshore. Gas operations in general tend to be less chemically intensive than oil operations (pers. comm.).

Taking into account the uncertainties related to the type of polymer applications that may fall within the scope, potential problems with emissions reporting and the estimated microplastic uses in onshore operations, it can be estimated that the use of microplastics in the EEA oil & gas sector is between 300 to 2 000 tonnes annually. Emissions from these uses as a result may be negligible (primarily due to non-intentional releases) to up to 550 tonnes per annum. For the purpose of this analysis, the central values will be taken: respectively 1 150 tonnes of microplastics use and 270 tonnes emissions.

D.11.1.2. Future use and emissions

Future use and emissions will depend on the overall demand for oil & gas and subsequently the demand for oil & gas chemicals supporting exploration, production and transportation of oil & gas.

The volume of chemicals in the UK for example has been fairly stable since 2010 (ECHA CfE 2018, #671), potentially due to the level of oil & gas activities in the last years in response also to world energy demand. From that perspective, in the short to medium term, the volume of chemicals (including microplastics used) may remain the same or even decline in the event of a global recession. Long-term trends to transition to more sustainable energy may lead to further decline in oil & gas operations. On the other hand, as more aging (depleting) and challenging (in terms of oil & gas recovery) oilfields are being explored, oil & gas activities are expected to be more chemically intensive. From that perspective, microplastics use in the sector may increase in the future, although this conclusion does not take into account future R&D activities that may lead to their replacement.

It is also uncertain how the emissions from microplastics in the future would be addressed under the current regulatory regimes. Newly built offshore oil facilities operate on the reinjection principle, reducing the emissions of production water (and any residuals) in the environment. Furthermore, many Member States and supranational organisations (e.g., OSPAR) have provisions to ensure the gradual decrease of oil & gas discharges of hazardous substances (OSPAR/NO).

Given the substantial uncertainties with the projection of future volumes of microplastics in oil & gas, for the purpose of the analysis, it is assumed that the 2016 level of estimated use and emissions will continue for the remainder of the study period.

D.11.2. Alternatives

In principle, there are non-microplastic containing oil & gas products for every function shown in Table 99. Some examples are shown in the table.

In the event any release of microplastics is unacceptable, reformulation of the microplastic-containing products would be required. The most likely candidates for substitution are substances considered to "pose little or no risk to the environment" or the so-called PLONOR list substances. The OSPAR Agreement 2013-06 specifies that substances in the PLONOR list (e.g., naturally occurring substances, soluble organic, or insoluble organic man-made substances as well as minerals and substances on Annex IV and Annex V of REACH) are subject to expert judgement as they do not normally need to be strongly regulated as, from assessment of their intrinsic properties, the OSPAR

Commission considers that they pose minimal risk to the environment (OSPAR, 2018a). There are a number of chemically modified natural polymers that are included in the list and may be used in the functions described in Table 99; however, their biodegradability against the criteria laid out in the proposed restriction has not been assessed for the purpose of this analysis. Examples of those are:

- Carboxy methyl hydroxy ethyl cellulose (CAS# 9004-30-2)
- Cellulase (CAS# 9012-54-8, EC# 232-734-4)
- Hydroxyethyl cellulose, 2-Hydroxyethyl ether cellulose (CAS# 9004-62-0, EC# 618-387-5)
- Sodium carboxymethylcellulose (CAS# 9004-32-4)
- High MW hydroxy ethyl cellulose polymer (CAS# 9004-62-0)
- Hydroxypropylated cross-linked corn starch

Many of these alternatives, however, may not be appropriate for all geological formations. It is important to note that oil & gas drilling and production chemicals are selected to address specific well characteristics, and many natural or biodegradable alternatives may not be able to perform their intended function in high temperature and high pressure environments. The variation within the installation design, well-flows, and the oil product means that a chemical that fulfils its function in one installation may not work elsewhere (ECHA CfE 2018, #723). During the ECHA CfE, information from in excess of 15 oil & gas chemicals was provided indicating that there are no alternatives with similar performance and that the microplastic particles are selected after extensive testing to meet performance criteria under certain temperature and pressure conditions of the downhole oil well environment. Many high pressure and high temperature applications may be lost, meaning that the risk of failure for more demanding drilling projects may increase significantly. (ECHA CfE 2018, #607, 623, 631, 632, 634, 639, 641, 650, 653, 654, 658, 660, 661, 662, 664, 665, 670; ECHA AI 2018, #12). Industry reports that many microplastics/polymers were introduced to reduce health and environmental risks, improve performance of new technologies and eliminate substances with higher hazards (ECHA AI, #12, 20).

Oil & gas drilling and production chemical are selected to meet the exact requirements of the formation to maximise human health and safety, reduce impacts on the environment, maximise oil & gas recovery, among others. Each installation needs to trial and test alternatives to ensure that they work in situ. For example, micron size leaks within a cement sheath in an oil well can lead to serious problems. The problems can range from a minor oil well leak to losing a well completely. A high risk to human life and oil spill are points of serious concerns with high socio-economic impacts. Well blowouts are not uncommon (although they are more frequent but of lower duration for gas vs oil wells) and according to EC 2011, the annual oil well blowout costs can range €140-€850 million (2010 values), primarily consisting of oil spill clean-up costs. Adding to this property losses of less costly but more common major accidents leads to an annual direct tangible costs of offshore accidents in Europe of €205-€915 million in 2010 values (EC 2011).

The transition to less effective demulsifies would result in a greater discharge of oil in water overboard or increased CO_2 emissions from the transport of produced water back to shore for waste treatment. The transition to less effective corrosion inhibitors would result in a loss in asset integrity, with degradation of the steel pipework and infrastructure occurring more rapidly. This could lead to a loss of hydrocarbons to the

marine environment and/or greater maintenance and more chemical use to protect or coat the pipework, including production downtime for these treatments. Larger CO_2 impacts are can also be expected due to transport of more chemicals and replacement of steel-work to offshore installations (ECHA AI 2018, #12). The European oil & gas extraction sector is open to international competition via the global oil and gas markets. The high level of operational standards applied by the European industry allows it to be 30% less carbon-intensive than the global industry average. This environmental performance is achieved at a cost, already making the European oil & gas sector's sensitive to global competition (ECHA AI 2018, #20).

DRA impacts

Overall, it is unknown whether these impacts and their magnitude can be associated with substituting microplastic-containing oil & gas chemicals with their next best alternatives. Based on currently available information, the Dossier Submitter is unable to assess the technical feasibility and the effectiveness of microplastic-containing chemical products used in the oil & gas industry and their next-best alternatives.

Furthermore, the efforts required finding alternatives is very much application dependent, with considerable costs. Examples of straightforward substitution (e.g., demulsifier) suggest reformulation cycle of about four years consisting of laboratory-based bottle testing, field optimisation and trial, test preparation and trial, full plant trial with injection, field trial of reformulated product). This reformulation period is consistent with results of the examination of the progress of substituting hazardous chemical in the 2007 UK National Plan.[132] The study showed that Level 1 substances (organic substances that are highly persistent, bioaccumulating and toxic) were eliminated within four years. Level 2 substances (moderately persistent, bioaccumulating and toxic) were largely phased out within six years, although substitution of corrosion inhibitors is particularly difficult (La Védrine et al., 2015). This is consistent with information for onshore operations in Germany, where industry reports that the development of currently used corrosion inhibitor for sourgas wells took about 20 years to full performance. Five to ten years was suggested as a typical timeframe for reformulation, in particularly for the development of an entirely different product with comparable performance, as it may be required for some applications (ECHA AI 2018, #12, 20).

Microplastic-free products that demonstrate similar effectiveness with lower environmental impacts would likely command higher price considering the demonstrated impacts of microplastics to the environment. Price is not the leading factor for product selections: as explained above other factors are leading and their relative cost in comparison to the overall cost of oil & gas operations and production is minimal (pers. comm.).

The costs per reformulation of oil & gas production and drilling chemicals has been reported from several million to exceeding €1 billion (ECHA AI 2018, #12, 20) but the more substantial costs may be as a result of production loss, e.g., until the knowledge is built up for their optimal use, risk of a major accident, efficiency losses, etc. (see above).

[132] In 2006, OSPAR Recommendation 2006/3 recommended to Contracting Parties to prepare national plans with established timeframes for potential cessation of the discharge from offshore installations of substances marked for substitution. In response, the UK National Plan was published in 2007 (La Védrine et al., 2015).

D.11.3. Proposed action

Microplastics are extremely persistent. They accumulate in the environment leading to potentially high environmental consequences in the long run. Therefore, microplastic emissions to the environment should be minimised to the extent possible to prevent further addition to the substantial macro and microplastic stock currently in the environment. Given the transboundary nature of microplastic pollution, an EU-wide action is necessary.

Recognising the critical role of oil & gas applications that may contain microplastics for human safety, reduced environmental damage, lower externalities due to energy inefficiencies, improved oil & gas recovery rates, etc., a process that encourages further substitution without compromising these critical aspects would be considered most appropriate. Steps need to be taken to recognise the negative effects of microplastics to the environment and to develop appropriate tools to assess their risks due to oil & gas uses (recognising that the PEC/PNEL approach cannot fully capture their risks) in order to select appropriate risk management measures.

The following sections discuss how this could be achieved via an improvement on existing provisions or via a REACH restriction. The final section concludes on their pros and cons and outlines the proposed action under REACH: reporting and labelling requirements.

D.11.4. Existing provisions

Member States have control over oil and gas deposits and activities on their territories. Overarching rules, ensuring fair and transparent procedures for the exploitation of oil & gas resources in the EU, are set out in Directive 94/22/EC of 30 May 1994 on the conditions for granting and using authorisations for the prospections, exploration and production of hydrocarbons. Article 6.2 in the Directive specifies that Member States can impose additional requirements on the basis of issues such as the protection of the environment (along with national security, public safety, public health, security of transport, the protection of biological resources, the planned management of hydrocarbon resources or the need to secure tax revenue). All Member States impose rules, through national legislation, on the use and emissions of chemicals in the oil & gas activities. Many Member States adopt agreed upon rules in international conventions such as the Convention for the protection of the marine environment in the North-East

Atlantic (OSPAR),[133] the Helsinki Convention,[134] the Barcelona Convention (UNEP-MAP),[135] and the Bucharest Convention.[136] The EU Marine Directive[137] requires that, in developing their marine strategies, Member States use existing regional cooperation structures to co-ordinate among themselves and with third countries in the same region or sub-region. The EU is a (Contracting) party to the first three conventions and as such has the right to vote and recommend initiatives similar to other parties of the conventions (European Commission, 2016).

D.11.4.1. OSPAR Convention

The OSPAR Convention (OC) is the legal instrument guiding international cooperation for the protection of the marine environment of the North-East Atlantic. More than 90% crude oil and natural gas production in the EEA in 2016 (Eurostat, 2018f) originated in Contracting parties of the OSPAR convention (EU Member States only, excluding the EU as a whole). Through decisions, recommendations, agreements, strategies and guidance documents, OSPAR has developed a comprehensive framework for the monitoring and the status of the marine environment, as well as the use and emissions of chemicals in the offshore industry. OSPAR's decisions (legally binding) and recommendations (with an implementation period, although OSPAR as an organisation does not have a compliance

[133] The OSPAR Convention entered into force in 1992. It has been signed and ratified by all of the Contracting Parties to the original Oslo or Paris Conventions (1972 and 1974): Belgium, Denmark, the European Union, Finland, France, Germany, Iceland, Ireland, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom of Great Britain and Northern Ireland, along with Luxembourg and Switzerland https://www.ospar.org/.

[134] The Contracting Parties of the Convention on the Protection of the Marine Environment of the Baltic Sea Area, known as the Helsinki Convention established in 1974, are: Denmark, Estonia, the European Union, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden. HELCOM (Baltic Marine Environment Protection Commission - Helsinki Commission) is the governing body of the Helsinki Convention whose aim is to protect the marine environment of the Baltic Sea from all sources of pollution through intergovernmental cooperation. http://www.helcom.fi

[135] The Contracting parties of the Barcelona Convention (i.e., Convention for the Protection of Marine Environment and the Coastal Region of the Mediterranean or the) are: Albania, Algeria, Bosnia and Herzegovina, Croatia, Cyprus, Egypt, the European Community, France, Greece, Israel, Italy, Lebanon, Libya, Malta, Monaco, Montenegro, Morocco, Slovenia, Spain, Syria, Tunisia, Turkey. The regional collaboration began in 1976 and today there are six protocols, two of which are relevant for the impacts offshore activities on the marine environment: the Offshore Protocol (pollution from exploration and exploitation) and the Hazardous Wastes Protocol. http://ec.europa.eu/environment/marine/international-cooperation/regional-sea-conventions/barcelona-convention/index_en.htm.

[136] *The Bucharest Convention (i.e., the Convention on the protection of the Black Sea against pollution) was signed in 1992. Its parties are: Russia, Turkey, Ukraine, Georgia, Bulgaria and Romania. http://www.blacksea-commission.org/main.asp.*

[137] The EU Marine Directive (Directive 2008/56/EC establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) aims to achieve Good Environmental Status (GES) of EU's marine waters by 2020 and to protect the resource base upon which marine-related economic and social activities depend. It contains the explicit regulatory objective that "biodiversity is maintained by 2020", as the cornerstone for achieving GES. The Directive takes the ecosystem approach to the management of human activities having an impact on the marine environment, integrating the concepts of environmental protection and sustainable use. In order to achieve its goal, the Directive establishes four European marine regions – the Baltic Sea, the North-east Atlantic Ocean, the Mediterranean Sea and the Black Sea – located within the geographical boundaries of the existing Regional Sea Conventions.

committee or other structured compliance control mechanisms for its measures) are normally the minimum requirements for offshore operations which Contacting Parties are expected to implement in their national legislation, policies and procedures.[138] OSPAR's fundamental goals include prevention and elimination of pollution from offshore sources (Article 5 of OC) and ensuring that use and discharges of offshore chemicals are subject to authorisation (Article 4 of Annex III of OC). This is accomplished via the following:

- establishment of a mandatory permitting system for use and discharges of offshore chemicals
- requirement to notify (register) all chemical prior to their use could be authorised in offshore applications
- requirement to gradually reduce emissions via produced water to the environment
- establishment of harmonised pre-screening with the objective of the identification of substances for substitution to promote the continued shift towards the use of less hazardous substances (or preferably non-hazardous substances), etc.

All these OSPAR provisions can be used to address risks from microplastics. These provisions are briefly discussed below.

OSPAR Decision 2000/2 on a Harmonised Mandatory Control System (HMCS) for the Use and Reduction of the Discharge of Offshore Chemicals (as amended by OSPAR Decision 2005/1) states that any use and discharge of offshore chemicals shall be permitted by the competent authorities of the Contracting Parties (OSPAR, 2000, OSPAR, 2005). As a result a system is established where any discharges to sea must be permitted by the Contacting Parties in advance, and only registered chemicals that have been assessed and registered are allowed for use or discharge. As part of the registration with the Contracting Parties, a chemical supplier is required to complete and submit a registration form – (based on) HOCNF – providing information on the composition and test data on the constituent substances in the chemical product. A chemical is registered for a particular OSPAR function category, relevant to offshore oil and gas operations.

Once a chemical product is registered, an offshore operator can apply for a permit to use and discharge the product. The chemical permit application includes a risk assessment for all the products that will be discharged to the marine environment for the individual installation. Operators applying for permits are also required to review their chemical use and to substitute chemicals marked for substitution for less environmentally harmful alternatives. Where an operator intends to use and discharge a chemical marked for substitution, a justification needs to be provided on the basis of technical limitations and risk (ECHA CfE 2018, #714, 722, 723, OSPAR (2006), pers. comm.).

OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF) outlines the information and data that needs to be submitted (REACH registration data, if available, or the HOCNF form) as part of the registration of chemical products for use and discharge offshore to enable authorities to make a permitting decision. The HOCNF form requires detailed information on the composition of the

[138] Article 2.5 of OC states that the Contracting Parties are not prevented from taking more stringent measures more stringent requirements.

chemical product and for each of its constituents, the chemical supplier is required to provide information on the substance identity, as well as information necessary to determine the hazard and risks associated with use and discharge of the substance, e.g., information to determine bioaccumulation and biodegradability, among others. The supplier is also requested to specify (section 1.6.b) whether the substance is on the OSPAR List of Chemicals for Priority Action (LCPA), OSPAR List of substances of possible concern (LSPC),[139] REACH Annex XIV or XVII, surfactant, heavy metals or compounds, organo-halogen compounds, or radioactive substance (OSPAR, 2010). The overall purpose of the HOCNF is to provide authorities with information to help with the assessment of the hazards and risks of the substances in the chemical product being registered to facilitate their pre-screening (as specified by OSPAR 2000/2).

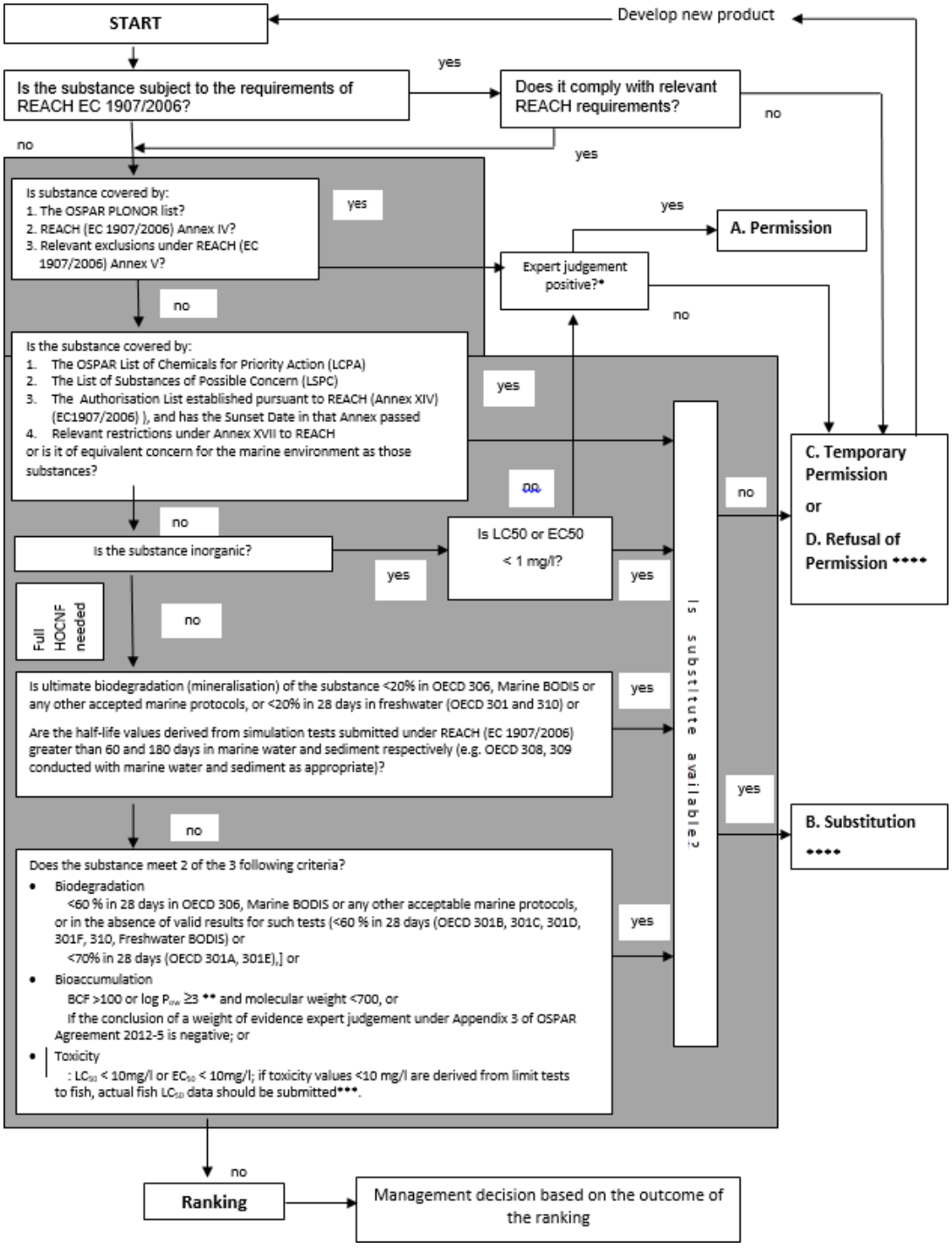
OSPAR 2006/3 recommends that by 2017, Contracting Parties have phased out the discharge of offshore chemicals that are, or contain substances that are, identified as candidates for substitution. An exception is made for those chemicals where, despite considerable efforts, it is demonstrated that substitution is not feasible due to technical or safety reasons. Demonstration of those reasons needs to include a description of the efforts made (OSPAR, 2006). Authorities review the justifications provided by the offshore operator and determine, given the specificities of the offshore operation, whether a permit to use and discharge these substances can be granted (pers. comm.). Contracting Parties develop and present National Plans for the phasing out of these chemicals and exchange information on the progress of reaching the goal of OSPAR 2006/3 and on the practicability, efficacy, cost and environmental impact of the proposed alternatives (OSPAR, 2006).

Candidates for substitution are identified via a pre-screening process conducted by Contracting Parties. Pre-screening is the first part of the overall regulatory process which requires information on bioaccumulation potential, biodegradation, and acute toxicity of substances and mixtures and may use expert judgement. The pre-screening process was laid out in OSPAR decision 2000/2, which was later developed in several recommendations (2000/4 as amended by OSPAR Recommendations 2008/1, 2010/4, and 2016/4, culminating into OSPAR Recommendation 2017/1. Its aim is to substitute, and ultimately phase out, those substances which are hazardous and to regulate the remaining substances, where necessary. The principle of the pre-screening process is described in Figure 13. OSPAR (2017) states that chemicals should be substituted if they are covered by points 1-4 or they meet the biodegradation, bioaccumulation or toxicity criteria listed in the figure and they have an alternative. According to discussions with industry and authorities, microplastics (except potentially natural polymers) should be identified as substances for substitution as at a minimum they meet criterion 3.2.g. of

[139] The OSPAR List of Chemicals for Priority Action (LCPA) was established in 2002 (https://www.ospar.org/work-areas/hasec/chemicals/priority-action). OSPAR 2005A/02 recommends to authorities not to issue new authorisations for the discharge of these chemicals unless those offshore chemicals have already been notified (in accordance with OSPAR Recommendation 2000/5) for offshore use prior to this recommendation taking effect. By 2010, the Contracting Parties should have phased out the discharge of these substances. The addition of new chemicals on the LCPA has slowed down (the latest addition to the list was in 2011), due to the stepped up evaluation of chemicals under REACH and the Water Framework Directive, although some substances from the LSPC have been moved to the LCPA (OSPAR 2018e). Work on the LSPC, also established in 2002, has progressed similarly (https://www.ospar.org/work-areas/hasec/chemicals/possible-concern).

OSPAR 2017/1 (OSPAR, 2017) and potentially others depending on their exact composition: i.e., an ultimate biodegradation (mineralisation) of less than 20% in OECD 306, Marine BODIS or any other accepted marine protocols; or less than 20% in 28 days in freshwater (OECD 301 and 310). However, according to ECHA CfE 2018 (#722) and OSPAR (2018b), only about 50% of offshore products identified as containing microplastics are marked for substitution. This could potentially be due to a concern raised by representatives of some authorities that the presence of a solvent in the mixture of microplastics subjected to testing masks the poor biodegradability of the microplastics in the mixture (OSPAR, 2018b). This could potentially result in some microplastic-containing products not being identified as substances for substitution.

An interesting aspect of the pre-screening criteria is point 4 in Figure 13, which suggests that substances can be marked for substitution if its offshore use is subject to a restriction under REACH Annex XVII or an equivalent concern for the marine environment. It is uncertain to what extent this is applied by Contracting Parties in their pre-screening activities.



Source: OSPAR (2017)

Notes: * In accordance with the precautionary principle, expert judgement on a PLONOR/Annex IV/Annex V substance should take into account sensitive areas, where the discharge of certain amounts of the substance may have unacceptable effects on the receiving environment, or any relevant REACH restrictions.**The figure ≥3 means the result of an OECD 107 test or the highest reported log P_{ow} from the range of values in an OECD 117 test. ***For further guidance on fish toxicity testing, please refer to OSPAR Guidelines for Completing the HOCNF.****CHARM (Chemical Hazard Assessment and Risk Management Model) may be used as a decision supporting tool and expert judgement.

Figure 13: Harmonised pre-screening scheme (shaded) as part of the Harmonised Mandatory Control System for Offshore substances set out in OSPAR decision 2000/2

Furthermore, OSPAR Recommendation 2001/1 (amended by OSPAR 2006/4 and 2011/8) set the 2020 goal (also set out in the OSPAR Hazardous Substances Strategy) for a continuous reduction in discharges of hazardous substances via produced water with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close to zero for man-made synthetic substances (OSPAR, 2001). OSPAR Recommendation 2012/5 guides Contracting Parties in the application of a risk-based approach to assess the environmental risk posed by produced water discharges including naturally occurring substances (OSPAR, 2012). The objective is that by 2020 all offshore installations with produced water are assessed to determine the level of the risk and that, where appropriate, measures are taken to reduce the risk posed by the most hazardous substances. The method used to undertake the risk-based approach should be based on the determination of PEC/PNEC ratios (or the fraction of species potentially affected). It is meant to assist Contracting Parties in identifying, prioritising and adopting measures that will reduce risks to the environment from discharges of produced water. However, as pointed out in the restriction report, section 3, the PEC/PNEC approach does not fully capture all risks from microplastics to the environment.[140]

D.11.4.2. OSPAR activities on microplastics

The OSPAR Offshore Industry Committee (OIC) first discussed the issue of plastics (microplastics) in 2013 in response of concern with the use and discharge during offshore drilling operations of Loss Circulation Materials (LCMs) containing plastic substances. At OIC 2018, Contracting Parties agreed in principle to a definition of plastic substances (solid synthetic polymers insoluble in water) for the purpose of the OSPAR HMCS. It was discussed that a reference to the size of the particles is unnecessary as all plastics degrade to microplastics but that a supplement to the definition can be adopted to identify microplastics. It was also agreed that additional information is requested at the chemical registration stage (HOCNF, section 1.6b) to ensure that any chemical products containing plastic or microplastic substances are identified, and to subsequently enable Contracting Parties to quantify the scale of use and discharge of plastics and microplastics in the OSPAR region. In addition, the United Kingdom reported that it had reviewed the effectiveness of the existing HMCS pre-screening scheme to identify chemicals that contained plastics as candidates for substitution and concluded that under half of the plastic substances discharged carried substitution warnings. Many of the others included solvents, and the solvent biodegradability may mask the persistence of the plastic substances. The United Kingdom reported that it had decided not to accept biodegradability data that may be affected by the presence of solvents, and recommended that the HOCNF Guidelines be amended (OSPAR (2018b); ECHA CfE 2017, #714).

D.11.4.3. Conclusion

OSPAR has an established chemical substitution process (HMCS) which creates a driver

[140] Differences have been identified between CHARM and REACH recommended assessment factors (AF) for the predicted no effect concentration (PNEC), with the REACH recommended AF resulting in more precautionary PNEC than the OSPAR ones. However, it should be noted that REACH R10 Guidance already makes provision for use of alternative AF, provided these are scientifically justified on a case by case basis.

to replace substances that are persistent such as microplastics, without unnecessary disruption to production, threat to regulatory compliance (e.g., discharged oil, energy efficiency), safety and other environmental pollution due to, e.g., major industrial accident. Another advantage of OSPAR is that the UK is one of the Contracting Parties. The UK currently accounts for about one-third of produced crude oil & natural gas in the EEA (Eurostat, 2018f). An action under OSPAR ensures UK's future compliance regardless of its future status in the EU/EEA.

Several provisions can be strengthened to more adequately address risks from microplastics:

- ensure the poor biodegradability of microplastics is recognised by providing guidance to measuring their biodegradability, including when present in solvent-based mixtures
- reduce ambiguity with respect to discharges from demulsifiers by reducing the variation in the reported discharges
- ensure PLONOR substances do not contain substances meeting the definition of microplastics as defined by this restriction proposal
- consider whether microplastics are of equivalent concern in accordance with OSPAR (2017), point 3.2.e. (in the event of a possible decision to amend Annex XVII as a result of this restriction proposal)
- when taking a risk-based approach for identifying, prioritising and adopting measures to reduce risks to the environment from discharges of produced water, recognise that the PEC/PNEC approach does not fully address risks from microplastics
- consider other avenue to identify microplastic-containing substances for substitution, e.g., via inclusion in the LCPA
- consider aligning OSPAR definition for micro/plastics with the definition emerging from the proposed EU-wide action as a result of this restriction proposal.

The main disadvantages of action under OSPAR is that it is time consuming[141] and that it does not impact the EEA as a whole. While other regional sea conventions currently account for less than 10% of the produced natural gas and crude oil (Eurostat, 2018f) according to latest statistics, given recent developments, e.g. in the Mediterranean, their share of production may increase in the future.

D.11.5. Analysis of a potential restriction on use under REACH

The following section evaluates the effectiveness, practicality and monitorability of an action to address the risks form microplastics under REACH.

D.11.5.1. Effectiveness

Targeted at and capable of reducing risk

As concluded in the restriction report, section 3, microplastics are extremely persistent. They accumulate in the environment leading to potentially high environmental

[141] Considering three years are necessary to gather essential information on the scale of the problem (as chemical notifications are filed every three years, pers. comm.) and the time needed for a decision (one year) and reformulation (5-10 years), full phase out may not be expected earlier than 2029.

consequences in the long run. Therefore, microplastic emissions to the environment should be minimised to the extent possible to prevent further addition to the substantial macro and microplastic stock currently in the environment. A restriction under REACH on the concentration of microplastics in oil & gas chemicals discharged in the environment, e.g., via produced water, will reduce emissions to the environment and will reduce the concentrations of microplastics in the environment.

Proportional to risk

Emissions from oil & gas are estimated at approximately 270 tonnes per annum (currently estimated to range between minimal to 550 tonnes) although the estimates are uncertain. The costs to reduce these emissions will be several billions annually. To comply with the restriction, industry would have to reformulate critical chemical mixtures, which are primarily intended to work in difficult formations, in high temperature and high pressure environment. This will require time (ranging from four to over 10 years for some microplastics functions) and investment to reformulate more than 100 chemical mixtures. Costs per reformulation has been reported from several million to exceeding €1 billion (ECHA AI 2018, #12, 20) but the more substantial costs may be as a result of production loss (until the knowledge is built up the optimal use of the alternative), risk of a major accident (estimated at €205-€915 million in 2010 values (EC 2011)), efficiency losses, etc. These costs would likely be shared among chemical suppliers side, from the oil and gas service providers side, and from oil and gas operators side.

Not allowing sufficient time to reformulate, could introduce additional socio-economic costs (e.g., loss of profit, reduction in the global competitiveness of the EEA oil & gas sector, increased dependency on foreign energy sources) and can increase the magnitude and the likelihood of these societal costs occurring, particularly with respect to major accidents and production losses. The proposed restriction may be affordable for the oil & gas industry, whose profits also tend to be in the billions, however, an overall conclusion on the proportionality is not possible. The Dossier Submitter does not have detailed information on the availability of alternatives for all critical functions of microplastics in oil & gas chemicals and cannot assess the impacts of the proposed restriction on the basis of their next best alternative. Despite the substantial efforts by industry, offshore in particular, further information needs to be gathered on the substitutes of microplastic-containing products for all critical applications.

D.11.5.2. Practicality and monitorability

The main advantage under REACH is that it is EEA-wide. The industry is well regulated (under the regional sea conventions or national legislation), which among others includes details provisions for monitoring and reporting. These provisions can assist with the enforcement and monitoring of the risk reduction as a result of the proposed restriction.

D.11.5.3. Conclusion on restriction on microplastics use in oil & gas under REACH

While a restriction on the use of microplastics in oil & gas applications under REACH is targeted to the risk, capable at reducing the risk, practical and monitorable, its proportionality to the risk cannot be concluded on the basis of currently available information. Important information on the use of microplastics and their substitutes for all critical applications needs to be gathered in order to be able to conclude on the

magnitude of the anticipated impacts of a restriction and the overall proportionality. A restriction with a long transitional period of 5-10 years after EiF (assumed 2022) could lead to billions of euro in annual societal costs to reduce about 270 tonnes of emissions per annum, resulting in a cost-effectiveness which surpasses the cost-effectiveness in absolute number of previous restriction measures on environmental pollutants. However, the tonnes of microplastics emitted itself is subject to considerable uncertainty due to the lack of detailed knowledge on the microplastics used in oil & gas products to ascertain whether they fall within the scope of the proposed definition the Dossier Submitter.

D.11.6. Conclusion on proposed action for microplastic use in oil & gas

Taking into considerations the possible actions under existing provisions (e.g., OSPAR) and the effectiveness, practicality and monitorability of a possible restriction on the use of microplastics in oil & gas applications, the Dossier Submitter is proposing reporting & labelling requirements to oil & gas downstream users and importers of such products. This will help the European Commission gather necessary data on the use of microplastics in oil & gas and to monitor annual progress. The proposed action sends a signal that substitution of microplastics is desirable and such substitution can be sought and encouraged under existing measures without disruption to production and other unintended consequences for human safety, environmental protection, externalities due to energy inefficiencies,. In the event, the data reveals that that existing measure do not lead to progressive reduction of microplastic emissions from oil & gas uses, further action under REACH can be initiated.

Table 100: Summary of impacts of proposed action

Impacts/Sectors	**Oil & Gas**
Proposed action	Reporting & labelling/ SDS requirements
Justification for action	Microplastics are used and emitted. However, there's considerable uncertainty related to the microplastic use within scope and the available substitutes for critical uses.
Sector characteristics	
Product description	Microplastics are used in cement/cement additives, viscosifiers, lost circulation materials, drilling lubricants, defoamers, fluid loss control chemicals, Asphaltene inhibitors, friction reducing agents and other drilling, production or pipeline applications
Tonnes used	1 150 (300 – 2 000) tonnes
Alternatives	Microplastic-free products are available for all applications; however, alternatives may not be available for critical uses, e.g., in high temperature/ high pressure environments
Effectiveness & Proportionality	
Targeted at risk/ capable to reduce risk (or Risk reduction capacity)	Based on current information, emissions are estimated at 270 tonnes (from min to 550). Further action under REACH can be initiated in the event emissions are not reduced under existing measures (e.g., OSPAR & other regional sea conventions).
Additional sector specific benefits	

Cost-effectiveness & affordability	Resources required for meeting the reporting requirements will likely be minimal, and therefore affordable, as already actions are taken to identify microplastic-containing chemicals mixtures (e.g., under OSRAP)
Practicality	Given the uncertainty related to the uses and availability of alternatives for critical applications, the proposed measure is a practical approach to gather information for possible further action.
Monitorability	The proposed measure has a monitoring element, which will enable the EC to monitor whether emissions are declining under existing measures or further action under REACH is required.
Impact of scope modifications	
- All dimensions < 1mm	Some microplastics reported are larger and can exceed the 1 mm upper bound. Microplastic characteristics, including their dimensions, are proprietary information. They are selected to deliver specific performance required by e.g., the well/formation characteristics.
Main Uncertainties (impact on Proportionality conclusions)	The following uncertainties are an impediment for a use restriction under REACH but are anticipated to be addressed via the proposed action: - Polymer uses in scope which impacts tonnes used & emitted - Availability of alternatives for critical applications - The impacts associated with next best alternatives.

Notes: 2017 values, 2022 – assumed entry into force (EiF – entry into force), annual data.

D.12. Paints and coatings

Paints and coatings provide a decorative and/or protective layer to a surface. The solids in the paint, which will form the protective film, need to be thinned so that the paint can be applied in layers on the surface. There are three types of delivery systems of paints: powder coatings, solvent-based paints and water-based paints. Normally, a coating formulation consist of the categories of material described below.

- **Binders**, which bind together the other components into a paint film through a hardening process during the drying phase.
- **Pigments**, i.e. small particle powders that are insoluble in water or organic solvents, which give the coating a colour and hiding power. Some pigments may also provide other properties, such as UV-protection or corrosion resistance.
- **Dyes**, i.e. materials that are soluble in the carrier phase and that have no or very low ability to hide the previous colour layer or the surface itself. The following three groups of substances are most commonly used as dyes in coatings: metal-complex dyes, anionic-dyes and azo-dyes.
- **Carrier phase**, which is typically a liquid, such as water, an organic solvent or a mixture of these, which evaporates after application, thereby enabling the film formation.
- **Extenders/fillers**, which are typically inorganic products providing bulking at a relatively low cost. They contribute properties such as sheen, scrub resistance, exterior colour retention, rheology and others. Examples of commonly used extenders include aluminium silicates (clay), diatomaceous silica, calcium carbonate, talc and lime.

- **Additives** to improve the stability, handling and application of the formulation, as well as to provide the desired properties of the final coating. (OECD, 2009)

Coating systems

Powder coating is normally applied electrostatically on the surface as a free-flowing, dry powder and is cured by heat. The polymer can either be a thermoplastic or thermoset. Most powder coatings have a particle size in the range of 2-50 µm. Normally, powder coating is used in industry and not by individual consumers or SMEs, due to the cost of investment. It is assumed that handling of any spillage of the powder is done in a professional way, so only unintentional release of the powder would be expected.

Solvent-based paints may contain up to 80% solid content. However, the information received in the call for evidence suggests that solvent-based paint is an insignificant source of microplastics to the environment, as the used brushes or rollers are not cleaned by water.

Water-based paints are either emulsions (colloid dispersion) or water soluble (true solution). Water-based paints have a solid content in the range of 30 to 60 %. The solid content consists of binders and a variety of additives. The polymer particles in the dispersion is typically sub-micrometer, 0.1-0.5 µm, and fuse together by coalescence and evaporation of the solvent (water and small amounts of solvent) to form a film. (CoalitionCleanBaltic, 2017)

Of the different coating systems described above, only water-based paints and coatings are of relevance for potential release of primary microplastic particles to the environment. Hence, powder coating and solvent-based paints are not addressed further in this report.

Common polymers use in polymer dispersions

Organic binders are polymer or silicon resin emulsions with an average molecular mass between 500 and 3 000. High molecular mass products include cellulose nitrate, polyacrylate and vinyl chloride copolymers. Low molecular mass products are alkyd resins, polyisocyanates and epoxy resins. A list of common polymers used in dispersions can be seen in Table 101, including types that are out of scope in this study. Low molecular mass monomers or prepolymers that crosslink to form a film, i.e. alkyd coatings, polyurethane coatings and epoxy are out of scope as well as mineral-based coatings based on silicon. (CoalitionCleanBaltic, 2017).

Table 101: Examples of common polymers used in dispersions.

Type	Area of use
Chlorinate rubber coatings	Underwater coatings on ships
Vinyl coatings including polyolefins	Polishing agents, weather resistant coatings
Coatings with Thermoplastic Fluoropolymers	Binder for indoor and outdoor paints and textured finishes
Polystyrene and Styrene Copolymers	Exterior-use paints, paints for concrete and road-marking

Acrylic coatings	Emulsion paints for ceilings, walls and building fronts
Alkyd coatings	Corrosion protection and decoration in almost all sectors
Polyurethane coatings	Surface coatings in almost all sectors
Silicon coatings	Surface coatings
Epoxy	Surface coatings

Source: (CoalitionCleanBaltic, 2017)

D.12.1. Use of microplastics in paints and coatings

Microplastic particles in paints and coatings can have both film-forming properties or be used as additives for a multitude of functions.

D.12.1.1. Film forming - binder

The main ingredient of the paint is the binder, a polymer (resin), also known as the film-forming component. The binder is always present whether the system is water-based, solvent-based, or a powder coating. Binders are responsible for the adhesion of the coating to a surface and when the binder fuses by coalescence into a film, it will include any other functional additives, e.g. intentionally added microplastics, which will be distributed throughout the coating.

Limited information on binders in paints was submitted by industry in the call for evidence. One company indicated that synthetic dispersions can be used as binders in coatings and that these may contain 35-40% of plastic particles. In general, limited information on polymer use in water- or solvent-based paints was provided in the call for evidence, as industry considered that there was no emission route to the environment. According to the Swedish industry association for the paint and adhesives industry, SVEFF, the average binder content in paint is 20% by weight and may vary between 5-30 % by weight depending on the type of paint (SVEFF, 2018). According to #2040 and 2216, the share of binders can be up to 80% in powder coatings and printing inks.

D.12.1.2. Intentionally added microplastics to get a specific function other than film-forming

In addition to the film-forming particles in water-based emulsions, polymeric spheres/beads or fibres in the micro- and nano-scale may be used as additives in paints and coatings to obtain certain properties.

The addition of microparticles may give various properties to the final coating, depending on the polymer type, the particle size and the concentration of the microplastic particles in the formulated products.

The two most important forms of microplastic particles in uses other than film-forming are microbeads and microfibers. Microbeads, in the form of polyacrylates, are used for weight reduction, to facilitate application of the paint, to increase elasticity of the film and for scratch resistance. Microfibres, in the form of polyacrylates, polyamide and polyacrylonitrile, are used for wear resistance, concealing cracks and increased thixotropy of the wet paint.

Irrespective of the physical form, the total number of functions identified for microplastics in paints and coatings are:

- Weight reduction of the paint contents (ergonomic reasons)
- Abrasion resistance
- Scratch, mar and wear resistance
- Impact resistance
- Flexibility and anti-cracking
- Anti-slip effects
- Soil resistance/ easy-to-clean surfaces
- Friction reduction
- Matting/delustering effects, side sheen control
- Surface texture
- Tactile effects such as "soft feel" or "coarse feel"
- TiO_2 dispersion/improved hiding, TiO_2-substitute
- Glitter effects
- Insulating properties (heat, sound dampening)
- Anti-blocking
- Corrosion resistance
- Lubrication
- Improved applicability
- Increased thixotropy of the wet paint

In a report by Amec Foster Wheeler, contracted by the European Commission, less than 1% of water-based building paints were reported to contain microplastics (AMEC, 2017a). In accordance with this data, SVEFF also reports that few water-borne building paints on the Swedish market include microplastics (<1 %). In paints that contain microplastics, the concentration is typically around 1.6% - 2 %, with the lower limit reported in the Amec Foster Wheeler study and the higher limit reported by the Danish EPA (Lassen and Pernille; Nielsen, 2015). However, the concentration is application-dependant and certain paints may contain up to 30% of microplastics. According to #2040, paints, coatings and printing inks may contain polymer-based additives at a concentration of 2% - 10%. #2073 states that in waterborne paints a minimum of 5% of solid polymer dispersion is needed to achieve e.g. properties of adhesion. According to #2148, the minimum concentration varies between 1% and 30%, depending on whether it's a wax or a synthetic polymer dispersion.

It is expected that microplastics could be used in paints for walls and ceilings. In Denmark, the main application for microplastics in coatings are as building paints, including floor lacquers (Lassen and Pernille; Nielsen, 2015). According to SVEFF (2018), microplastics is however not common in floor lacquers in Sweden, as inorganic microparticles are the additives of choice for floors in Sweden. It is possible that there is a variation between countries regarding the use of microplastics in different applications. However, this could not be determined from the available information. Further information from industry is needed to understand to what extent microplastics are used in other applications apart from building paint and floor lacquers.

Certain microplastic particles may be either film-forming or non-film forming depending on application. Polymer powder coatings for example, with a particle size of < 5 mm, form a continuous film when used in hot-melt applications. However, the same polymer

powder may also be used as an additive in liquid paints and coatings. It is not always clear from technical data sheets or marketing material, which is the application of choice. This may provide some uncertainty on why a certain microplastic has been added to a paint product.

D.12.1.3. Size range of intentionally added microplastics in functions other than film-forming

In the call for evidence, industry representatives indicated that they use the following polymer particles in their products (size < 1 mm):

- Polyacrylic (beads: 5-80 µm, fibres: 4-6 µm long, diameter 30 µm)
- Polyamide (fibres: 4-50 µm long, diameter 10 µm)
- Polyacrylonitrile (fibres: 0.5 mm long, diameter 30 µm)

One company indicated that the particle size distributions could vary from 10 to 100 nm for some products. Other microplastic particles with variable size distributions were identified in literature searches. Most of these are thermoplastic polymers, but also thermoset polymers such as polyurethane and melamine-formaldehyde resins were used as microparticles. The indicated size range varies between 250 nm and 500 µm (Table 102:).

Table 102: Microplastic particles in paints and coatings with functions other than film-forming

Type	Size (μm)	Function	Application	Shape/formulation	Brand names	Producer	Source
PMMA	5-50	Resistance to temperature and solvents, scratch resistance, haptic "soft feel". flow- and dispersing properties, matting/delustering agent, antiblocking.	Paints and coatings (inkl. leather)	Spherical, coffee bean, hemisphere	Copobeads PMMA	Coating Products OHZ e.K.	https://www.coating-products.com/additives.htm#wachse
	5-200	Haptic "coarse feel", scrub-resistance, matting, UV-resistance, anti-dirt-pick-up.	Coatings for furniture, wood floors, walls, consumer electronics and general anti-slip coating for floors	spherical, water and solvent-based	Decosilk® Art	MicrocheM	http://microchem-online.com/en/produkttypen.html
	6-40	For super matte paints, even for dark colours. Side sheen control, scratch resistance, durablility, "easy to clean", surface texture. Flop control of metallics.	Decorative and exterior paints, clear wood coatings, varnishes, metallic paints, flooring and panelling lacquers.	Spherical	Spheromers ® CA	Microbeads AS Norway	http://www.micro-beads.com/Applications.aspx
	2-12	Matting effect, antislip and antiblocking.	Coatings	Powder	Epostar MA	Nippon Shokubai	https://www.shokubai.co.jp/en/products/functionality/epokara.html
	0.01-0.4	Antislip and antiblocking.	Coatings	Emulsion	Epostar MX	Nippon Shokubai	https://www.shokubai.co.jp/en/products/functionality/epokara.html
	1-50	Light diffusion, delustering properties. Heat, solvent, scratch and weather resistance.	Paint, inks, pigments	Spherical	Techpolymer MBX	Sekisui Japan	http://www.tech-p.com/en/application/paintandink.html
PBMA	4-6	Scratch resistance, haptic "soft feel", surface texture, anti-slip,	Paints and coatings (inkl. leather)	Spherical?	Copobeads PBMA	Coating Products	https://www.coating-products.com/additives.htm#

		delustering agent.				OHZ e.K.	wachse
	5-12	Soft feel texture.	Baked coating and precoat metal coating fields	Spherical	Techpolymer BMX	Sekisui Japan	http://www.tech-p.com/en/application/paintandink.html
Acrylic polymer 40-50 %		Dispersion of TiO2 for better hiding, corrosion resistance over ferrous metal, tannin resistance on wood coatings, cleanability on house-hold coatings	Paints (polymer composite paint)	Waterborne emulsion	Evoque®	Dow Chemicals	https://www.dow.com/en-us/products/EVOQUEPreCompositePolymers
Polyacrylic ester	8-30	Light diffusion, delustering properties, abraision and scratch resistance, soft feel, elastic coating.	Paint, inks, pigments	Spherical	Techpolymer ABX/AFX	Sekisui Japan	http://www.tech-p.com/en/application/paintandink.html
Styrene/ acrylic copolymer		Dirt-pickup resistance, tint retention, film durability, burnish and scratch resistance, gloss retention, TiO2-substitute, gloss and opacity.	interior and exterior architectural coatings (paints), paper coatings	Solvent and waterborne	Ropaque®	Dow Chemicals	https://www.dow.com/en-us/products/ROPAQUEOpaquePolymers
Polystyrene	6-40	To obtain super matte paints, even for dark colours, combined with excellent side sheen control, good scratch resistance and a surface film which is durable and easy to clean. Surface texture.	Decorative and exterior paints, clear wood coatings, varnishes, metallic paints, flooring and panelling lacquers.	Spherical	Spheromers ® CS	Microbeads AS Norway	http://www.micro-beads.com/Applications.aspx
Polyolefin	≥ 10	Satin and matting effect, anti-scratch, anti-slip and anti-chip effect, abrasion and impact resistance. Structural effects. Low weight makes the particles "float" on the surface.	Paints and varnishes. Typical applications are: Road markings, structured paint, vehicle body parts, wood & metal furniture coatings, metal casings, electrical box coatings, marine	Powder	Coathylene	Akxalta Coating Systems	http://www.axaltacs.com/content/dam/EMEA/Polymer%20Powders/EN/Public/Documents/polymer-powder-additives/Axalta-Coathylene-Paint-and-Varnishes-Flyer.pdf

			coatings, ship decking, swimming pools, heavy duty industrial flooring				
Polyamide	Ultra fine powder	Abrasion, scratch resistance, soft feel texture, coating flexibility and dry lubrication.	Rheological and texture additive in decorative paints and metal coatings. Surface modifier in inks, wood and plastic coatings. Main applications are coil, can and industrial coatings, wood finish flooring and graphic arts.	Water based, UV and solvent based	Orgasol®	Arkema	https://www.orgasolpowders.com/export/sites/orgasolpowders/.content/medias/downloads/literature/orgasol-rilsan-coating-additives-brochure-2014.pdf
	Fine powder	Abrasion, corrosion and impact resistance. Even texture, good coverage and uniform colour effects.	Rheological and texture additive in decorative paints and metal coatings. Powder resin in metal coatings. Main applications in liquid paint, thermoplastic powder coating in automotive and appliances.	Liquid paint or powder coating	Rilsan®	Arkema	https://www.orgasolpowders.com/export/sites/orgasolpowders/.content/medias/downloads/literature/orgasol-rilsan-coating-additives-brochure-2014.pdf
		Matting effect, texture effect, abrasion resistance, reduced friction, reduced soiling, increased elasticity.	Metal, coil and structural coatings (hot and cold melt applications), Wood lacquers	Powder: Melted during application!	Vestosint®	Evonik Resource efficiency GmbH	https://www.vestosint.com/product/peek-industrial/downloads/vestosint-polyamide-12-coating-powders-en.pdf
PTFE	3-15	Improve slip and abrasion resistance, reduce friction, increase antibacking and scratch resistance.	Inks, coatings		Copo PTFE	Coating Products OHZ e.K.	https://www.coating-products.com/additives.htm#wachse
	0,25 - 500	Non-stick, friction and wear-reduction, high corrosion resistance, lubrication.	Marine, industrial and extreme environment coating. Non-	Granules, powder, spherical in aquose or	Ultraflon, Marzon	Laurel Products	http://laurelproducts.com/additives-for-coatings/

			stick/multiple release coatings for kitchen ware.	isopropyl dispersions			
Acetic acid ethenyl ester. Dichloreth ene & 2-propenenit rile	5-40 (unexp anded), ~10-100 (expan ded)	Soft-touch, matting effects, anti-slip, sound-dampening, chip-resistance, low weight, higher water vapour permea-bility, improve applicability.	Underbody coatings, artificial leather and wallpaper,	Expandable thermoplastic spheres as powder, slurries	Expancel®	Akzo Nobel	https://expancel.nouryon.com/
? (non-film-forming polymer)	0.4 ± 0.05	Partial replacement of TiO2 and other extenders.	Paints (polymer composite paint)	Emulsion that forms hollow air filled particles when dried	Orgawhite 2000	Organik Kimya	https://www.scribd.com/document/360556078/Orgawhite-2000-pdf
PUR	7-30	Enhance matting efficiency, scratch resistance, slip control and absence of polishing.	Industrial coatings, inks	Decosphaera® (powder), Sphaerawet® (wet powder) and Adimatt® (water dispersion)	Decosphera ®, spherawet®, afimatt®	Lamberti S.p.A. Italy	http://www.lamberti.com/products/coatings.cfm
PUR	7-60	Matting effect, scrub, UV and chemical resistance.	Coatings for leather, wood/cork, vinyl floors, interior automotive, walls	spherical, water and solventbased	Decosoft®	MicrocheM	http://microchem-online.com/en/produkttypen.html
Benzoguan amine/mel amine - formaldehy de resin		Light diffusion, antislip, antiblocking, modifier in paints. Control of electrification in toners.	Paints, inks/toners	Powder	Epostar	Nippon Shokubai	https://www.shokubai.co.jp/en/products/functionality/epokara.html
Wax	micronized	Antiblocking, slip, mar and scratch resistance, matting and increasing hydrophobic character.	Inks, coatings		Copo wax	Coating Products OHZ e.K.	https://www.coating-products.com/additives.htm#wachse

PTFE wax	< 8	Same as PTFE (?)			Copo wax	Coating Products OHZ e.K.	https://www.coating-products.com/additives.htm#wachse

D.12.2. Baseline – tonnages used & emitted

The binder in paints and coatings is included for film-forming purposes. It is assumed that these microplastic particles will coalesce to become an integral part of the coating once the paint has dried (as such they will cease to be microplastics). Other types of non film-forming microplastics are also used in paint/coating formulations, such as rheology modifiers or pigment extenders. Dispersed microplastic particles (prior to coalescence) may be released when brushes, rollers and other equipment are washed after use. Releases to the environment can therefore occur under reasonable foreseeable conditions of use. Although there will be loss of a portion of the film to the environment during the useful life of the coating after it has dried, these would be most appropriately considered to be secondary microplastics, as such they are outside of the scope of this analysis. However, non film-forming particles can be assumed to retain their original particle form in a film and any release to the environment from the film during the useful life of the coating would be relevant to consider in this analysis.

Therefore, both film-forming particles and particles with functions other than film-forming are considered relevant in this report. Referring to film-formers, they are polymer-based particles with a typical size range of 0.1-0.5 µm. It is recognised that the polymer particles come in various shapes and forms, and depending on substance identity and degree of polymerisation, the state of the particles may vary from potentially semi-solid to solid. Many of these polymer particles are however described as droplets of solid material dispersed in water and the morphology can often be observed using e.g. transmission electron microscopy. The particles *(perhaps not all)* are therefore considered to fulfil the CLP definition for solid and therefore to be within the scope of the definition in this report.

Microplastic particles - functions other than film-forming

The information on uses in the call for evidence was mainly focused on microplastic particles with functions other than film-forming. While this information is presented in this section, it should be noted that the film-forming function is also considered relevant, as explained above. As a response to a consultation from the European industry association for the paint, printing ink and artists' colours industry (CEPE), Amec Foster Wheeler reported on the total use of microplastics (other than film-forming) in water-based paints and coatings (AMEC, 2017a). The volumes were reported based on the following definition of microplastics:

"A solid non-biodegradable polymeric particle with physical dimensions between 1µm – 5 mm originating from anthropogenic sources."

Accounting for less than 1% of water-based building paints containing microplastics particles, with an average microplastics content of 1-2%, it was estimated by CEPE that 220 tonnes of microplastics are used in water-based paints and coatings in the EU.(CEPE, 2017) With an estimated emission release factor of 1% (OECD, 2009), the amounts of microplastics particles to waste water amounts to 2-3 tonnes per annum (see Table 103).

Amec Foster Wheeler also reports on total uses of microplastics in Denmark in paints, varnishes and similar coatings, printing ink and mastics, with the volumes estimated by the Danish Environmental Protection Agency. The volumes reported are 200 - 350 tonnes and corresponds to intentionally added microplastic particles with functions other than film forming. Extrapolating the Danish data to the European market implies that

22 000 – 38 000 tonnes of microplastics in paint would be used in the EU, much higher than the data reported by CEPE. Amec Foster Wheeler further reports on estimates by RIVM on releases of microplastics in paints in the building and shipping sector in the Netherlands. The volumes reported amounts to 330 tonnes. When extrapolating to the European market, the results imply that 9 000 tonnes of microplastic particles would be released to surface waters in the EU. The RIVM definition of microplastic particles is somewhat wider than the definition used by CEPE and the Danish EPA. It is not clear if the data from Denmark and the Netherlands refers to other product groups than water-based paints. Amec Foster Wheeler reports that the only reliable quantitative estimate of intentionally added microplastic particles with functions other than film forming is the volume reported by CEPE but that the volumes may be considerable higher based on other sources.

Table 103: Reported amounts and releases of microplastics particles with functions other than film forming

	Water-based building paint (EU-level, tonnes)	Amounts of microplastics (EU level, tonnes)	Estimated release (EU level, tonnes)
CEPE	14 000	220	2-3
Danish EPA	Not reported	22 000 – 38 000[1]	220 - 380[2]
RIVM	Not reported	900 000[2]	9 000

1. Calculated from national data by extrapolating to European level
2. Not reported in (AMEC, 2017a), calculated based on an estimated emission release of 1%.

Microplastic particles – film-forming function

Volumes of the total use of film-forming particles in water-based paints is estimated based on paint demand in Europe. According to Eunomia (2018), the total demand for paints in the EU-28 + NO, CH (excl. Cyprus, Luxemburg and Malta) is 6 796 000 tonnes per year. Of the different sectors reported, Architectural/Decorative is considered the most relevant for water-based paints with an estimated volume of 4 213 520 tonnes. The polymer content in paints is assumed to be 20%, although according to #2073 the content of "solid polymer" is typically 7% in interior wall paints and 10% in exterior wall paints. Eunomia (2018) further assumes that the sector is split between interior/exterior paint and consumer/professional paints as presented in Table 104.

Table 104: Decorative Paints Market Segmentation

Market	Proportion	Paint sales (tonnes)
Interior	73%	3 160 140
Professional	59%	1 870 743
Consumer	41%	1 289 397
Exterior	27%	1 137 650
Professional	59%	673 468

Market	Proportion	Paint sales (tonnes)
Consumer	41%	464 183
Total		4 213 520

Source: (Eunomia, 2018)

The releases to wastewater for the above tonnages can be estimated in accordance with the OECD (2009) Emission Scenario Document on Coating industry, as follows:

- For consumer paints, OECD (2009) assumes that 25% of the initial coating will be left unused in paint cans. It further assumes that 2% of the remaining solids (i.e. 1.5% of the initial solid fraction) will be lost as brush residues.
- For professional paints, OECD (2009) assumes that 3% of the initial coating will remain unused in paint cans. 1% of the remaining solids (i.e. about 0.97% of the initial solid fraction) will be lost as brush residues but will be properly disposed of by the painter. While OECD thereby does not anticipate any releases to water from professional paints, the brush residues are presented in the table below in brackets.

Table 105: Emissions from decorative paints

Market	Paint tonnage	Polymer content	Release factor	Releases to wastewater
Interior - professional	1 870 743	20%	0.97%	(3 629)
Interior - consumer	1 289 397	20%	1.5%	3 868
Exterior - professional	673 468	20%	0.97%	(1 307)
Exterior - consumer	464 183	20%	1.5%	1 393
Total	4 213 520	842 704		5 261 (10 197 with professional paints included)

Additionally, OECD (2009) assumes that 3% of the coating will be lost to land during the useful life of the coating product. This accounts for 2% of the initial solid fraction. As this would not include the film-forming function, the releases can be based on the tonnage of microplastics reported by CEPE, i.e. 220 tonnes. That would mean a further 9 tonnes of releases to industrial soil. Taken together with the above releases to water means that an estimated 2 673 tonnes of emitted polymers from paints and coatings end up in the environment annually (up to 5 182 if professional paints are included too).

Marine paints is a segment of paints that have protective and/or anti-fouling properties. The market share of marine paints is about 2%, in comparison to architectural/decorative coatings with a market share of 62%. The market share seems small, but it is likely that the direct emissions of uncured paint during application may be

a larger source for microplastics than weathering for the marine segment. Eunomia has estimated that the emissions from uncured paint directly into the marine environment, during application, amounts to 1 993 - 4 525 tonnes. It is not clear what fraction of this volume is related to water-based paints containing microplastic particles.

An estimation of releases of film-forming particles (film-forming and non-film forming) from water-based paints, inks and coatings on a European level was also done based on data from the Swedish Product Registry hosted by the Swedish Chemicals Agency. Statistical data from 2016 for the sector "Manufacturing of paints, lacquer, printing inks" estimates that the total amount of binders[142] produced for the Swedish market amounts to 40 000 – 50 000 tonnes (Table 106). With an estimated emission release of 1% (OECD, 2009), the amount of microplastic release was estimated. The method proposed by Magnusson *et al,* based on the number of inhabitants was used for the extrapolation to EU conditions (Table 106). The total volume of estimated emissions of film forming microplastic particles on the European market amounts to 20 400 – 25 600 tonnes. Both film forming particles and microplastic particles with functions other than film forming are included as these could not be separated in the analysis. The major share of the volumes are expected to have film forming functions. In contrast to the data reported by Eunomia (2018), the volumes estimated from the Swedish product register data is not divided into sub-sectors. The calculated emissions on a European level, estimated from the Swedish data, is of the same order of magnitude as the volumes estimated by Eunomia for the architectural/decorative and marine sectors.

Table 106: Estimates for release of binders due to wash of paint brushes and rollers (Magnusson et al., 2016)

Amount of produced binder according to the Swedish Product Registry (Sweden 2018)	40 000 – 50 000 tonnes
Assumed loss rate (AMEC, 2017a, SVEFF, 2018)	1 %
Population in Sweden 2017	9.995 million inhabitants
Potential discharge of microplastics in the form of binder (Sweden)	0.04-0.05 kg/inhabitant
Population in EU 2017	511.8 million inhabitants
Potential discharge of microplastics in the form of binder in the EU before entering any Wastewater Treatment Plants (WWTP)	20 400 – 25 600 tonnes
Potential retention of particles in the WWTP were not calculated due to uncertainty in the retention data	• 98% (if particles above 300 µm in diameter, only data from households) • Average retention rate in Europe 53-84% (by number rather than mass) (Eunomia, 2018)

In conclusion, it will be assumed that 2 673 tonnes of polymers from a total of 842 704

[142] Only emulsion polymer binders that coalescence into a film were considered. Binders that form a film by chemical crosslinking were not included. It was not possible to identify polymers with other functions than film-forming.

tonnes of polymers in decorative paints and coatings end up in the environment annually (up to 5 182 if professional paints are included too). To put these emissions into context, it is estimated that the total European paints, coatings and printing inks market had a turnover of approximately €41 billion in 2016 (Eurostat, 2018d). Assuming that the share of the architectural/decorative sector can be scaled according to tonnage, the turnover of this sector is estimated to be €25 billion.[143]

D.12.3. Alternatives

It would be easy to conclude that the addition of microplastics should be reduced at the source, so they will not end up in the sewer. However, some of the functions of those microplastics could be of great value, because the protective layer will last longer, add specific anti-fouling properties, etc. Therefore, it is important to make an evaluation of the consequences, from a life cycle perspective, of reducing the amount of microplastics in paint applications.

There are some alternatives to synthetic polymers, although they may not be applicable for all uses. Inorganic binding agents have a mineral basis and do not form a film, but reacts chemically with the substrate forming an indissoluble bond between the paint and the underlying substrate (silification). Pure silicate paint is another alternative for exteriors, and is already used for the renovation of historical buildings. It forms a resistant and UV-stable bond with permanently integrated mineral pigments, resulting in longer paint vibrancy.

According to CEPE, glass beads and cellulose-based beads are possible substitutes for microbeads (polyacrylic polymers).

Glass beads are already used in paints, particularly in road markings due to its reflective effects, making them visible in the dark. According to Amec (2017), other performance characteristics of glass beads include controlled thickness and scratch resistance. However, it seems glass beads cannot replicate other specific characteristics of microbeads, such as elasticity. Therefore, they would most likely only be a possible alternative for certain paint products. A search for publicly available sources found prices of €250 - €890/tonne for glass beads intended for paints.

Cellulose-based beads are already used as alternatives to exfoliating/cleansing beads in the cosmetics sector. However, there is no specific information available regarding the technical feasibility of using them as an alternative to microbeads in the paints and coating sector.

For microfibres (polyacrylic, polyamide and polyacrylonitrile polymers), both CEPE and a company operating in the paints and coatings sector said that microfibres could be replaced by natural materials, such as cotton fibres, onyx jojoba beads, olive stone, kahl wax or pistachio shells. However, these are only theoretical alternatives at this stage and must still be further developed.

Regardless of the alternative, the products in question would need to be reformulated, tested and customer evaluated. According to CEPE, this process would typically take approximately two years until the products could be introduced on the market. Given the specific uses and alternatives, several respondents to the call for evidence considered it

[143] 4 213 520 tonnes / 6 796 000 tonnes = 62%

unlikely that the alternatives would cover the spectrum of properties offered by microplastics. CEPE considered that the alternatives would require more maintenance cycles (and thereby more paint), to compensate for the properties of microplastics (e.g. scratch resistance and toughness of the applied coating). If the alternatives could not meet the technical specifications, the products in question would need to be discontinued.

A potential ban on the film-forming emulsion paints could mean that there would be a need to revert to old technologies with their pros and cons, such as:

- Solvent borne paints with health risks in terms of volatile organic emissions (VOC) for the painters from the organic solvent
- Distemper paint is easy to work with, but is not suitable for all surfaces and the level of protection needed for some applications
- Linseed oil based paints where there is a handling risk, due to self-ignition of the linseed oil
- Egg tempera is more of an artistic painting technique today, but there is a risk of egg allergy and the depletion of resources (eggs).

D.12.4. Proposed action

As discussed above, the intentional uses of microplastics include film-forming and the use of certain microbeads and microfibers that give specific performance characteristics in the final applied film. Releases of microplastics to the environment mainly come from the cleaning of painting equipment and through the improper disposal of waste. As these releases could potentially be reduced through targeted measures, there is a need for EU wide action.

An instructions for use requirement regarding the correct disposal of paint and coating waste as well as the cleaning of equipment is proposed to minimise releases to the environment from products containing microplastics. The instructions for use shall be clearly visible and easily understandable. The instructions for use should be written in the official language(s) of the Member State(s) where the product is placed on the market, unless the Member State(s) concerned provide(s) otherwise. The instructions for use may involve pictograms, if these are able to convey how to correctly dispose of the paint and clean the equipment.

In proposing such an instructions for use requirement, the option of restricting the use of microplastics in paints and coatings was also considered but dismissed. There are few known alternatives to microplastics in paints and coatings, meaning that some products would likely be discontinued if they could not contain microplastics. Since the key emissions are limited to the disposal of waste and cleaning of equipment, a measure addressing these specific uses was considered to be more beneficial to society overall. The option of amending existing regulations regarding paint disposal/collection was also considered but since no such EU-wide legislation seems to exist, this option was dismissed too.

In terms of introducing the proposed instructions for use requirement, the Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008) was also considered but dismissed. One possibility could be to add a new EUH phrase to Annex II of the CLP Regulation, which would make it possible to request a certain hazard statement based on specific criteria. However, since the hazard statements are intended for use in very

specific circumstances, a labelling requirement under this restriction was considered more appropriate.

Furthermore, a reporting requirement is also proposed. This will help the European Commission gather data on the use of microplastics in the paints and coatings sector and to monitor any changes. In the event that the data reveals any concerns for the sector, further actions under REACH can be initiated.

The following was taken into consideration in the decision to propose an instructions for use and reporting requirement:

- Targeting and risk reduction: There is currently no obligation for paint and coating producers to include information on how to properly dispose of waste and how to clean painting equipment. Therefore, an instructions for use requirement is expected to reduce emissions to the environment related to the disposal of left-overs and the cleaning of equipment, such as brushes and rollers. The reporting requirement will help to monitor whether there are any changes to emissions, including from the instructions for use requirement.
- Costs and other socio-economic impacts: Product labels are often updated on a regular basis, both due to regulatory requirements and due to changes in trends and demands. A new instructions for use requirement would imply some additional costs in terms of designing and modifying labels. However, with the proposed transition period, a large part of the additional costs are expected to be absorbed within the normal product re-labelling cycle. This is expected to allow the new instructions for use requirement to be implemented as part of the regular label updates for the majority of products as well as to minimise any costs related to label-stocks and the replacement of old labels for products already on the market. If any new pictograms were to be introduced due to the instructions for use requirement, there would be some additional costs related to the development of the pictogram as well as public awareness campaigns, if these were deemed to be needed. There will also be some additional costs related to collecting data for the reporting requirement. However, since the collection of data and completion of the electronic format is not likely to require much time, the cost is expected to be small. The costs related to the instructions for use and the reporting requirements are discussed further in the main report.
- Cost-effectiveness and benefit-cost comparison: Numerous studies have been undertaken on the effectiveness of labels/instructions for use, showing that there are several factors that influence whether a user who reads a product label will follow the instructions on that label. The factor that seems to have the largest influence on user behaviour is familiarity with the product – users familiar with a product are less likely to notice the label/instructions for use, believe the information on it and comply with the instructions. The perceived hazard also has an impact - users are more likely to pay attention to and read labels/instructions for use on products perceived to be more toxic or potentially harmful. (USEPA, 2016) Since paints and coatings are not everyday consumer items and there is likely to be some perceived risk related to them, it is assumed that consumers would be likely to read and comply with the instructions for use, thereby reducing emissions from the disposal of waste and cleaning of equipment. Considering that the costs are expected to be relatively low, the instructions for use requirement is considered cost-effective for consumer products. While the emissions from

professional paints are likely to be lower than from consumer paints, the instructions for use requirement is considered sufficiently inexpensive to be cost-effective also for professional products. Similarly, the reporting requirement is expected to be a relatively inexpensive way of monitoring changes in use and can therefore be considered cost-effective.

- Practicality and monitorability: Paints and coatings are already subject to labelling requirements under the CLP Regulation. While the proposed instructions for use requirement would force producers to modify existing labels, these are nevertheless updated on a regular basis both due to other regulatory requirements and market demand. Given the similarity with existing requirements under the CLP Regulation, the proposed instructions for use requirement should be practical and monitorable. The proposed reporting requirement is a practical approach to gather information for possible further action.

In conclusion, the instructions for use and reporting requirement is considered an effective, practical and monitorable measure to address the main source of emissions from paints and coatings containing microplastics. In addition to the proposed instructions for use and reporting requirement, the Dossier Submitter notes that some sort of extended producer responsibility could also be considered further. For example, producers could be responsible for providing disposable tray liners to be inserted into the reusable trays.

D.13. Polymeric infill material for synthetic turf sports fields

D.13.1. Introduction

During the preparation of the Annex XV report proposing a restriction on intentional uses of microplastics, the Dossier Submitter identified that the polymeric granular infill (e.g. produced from end-of-life (ELT) tyres or other synthetic elastomers) used on synthetic sports fields would be consistent with the proposed definition of an intentionally-added microplastic.

No information of any kind on this use (e.g. releases or impacts) was received from relevant stakeholders during the preparation of the Annex XV report (e.g. in the call for evidence). Therefore, no specific impact assessment for this use was undertaken by the Dossier Submitter. As the proposed conditions of the restriction are generic the restriction, as currently proposed, would therefore apply to this use from the entry into force date of the restrictions (i.e. no transitional period for the use is foreseen).

As clarified by ECHA during the consultation process, the use of existing pitches containing polymeric infill would not be immediately affected by the proposed restriction as playing on these pitches could continue, without hindrance, until the operator's stock of polymeric infill was exhausted; impacts would accrue from this point onwards.

The Annex XV report noted that the impacts of restricting the use of polymeric infill (as microplastic) could be partially understood based on the impact assessment reported in the Background Document for the recent proposal to restrict PAHs in polymeric infill.[144] Moreover, the Annex XV report highlighted that it would be beneficial to obtain information on the impacts of a restriction on polymeric granular infill (as microplastics)

[144] See https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e181d5746d

from stakeholders during the consultation on the restriction proposal; notably as polymeric alternatives to ELT granules would also be subject to the proposed restriction. To this end, a specific question was included in the consultation to gather information on the impacts of the proposed restriction on this use.

The questions also sought information on the appropriateness and effectiveness of risk management (mitigation) measures to prevent the release of polymeric granular infill material to the environment. The Dossier Submitter has assessed the potential for risk management measures to be used instead of a ban on placing polymeric granular infill on the EU market.

This Annex was added to the Background Document during the opinion-development phase of the proposal and is informed by the information submitted in the consultation. It pertains to both the possible emissions and to the impacts of a restriction on the use of polymeric infill material and should serve to guide discussions the appropriateness of different risk management options (including transitional periods, derogations or use conditions such as technical emission control measures) for the use of polymeric granular infill on synthetic sports pitches.[145]

D.13.2. Uses and functions

D.13.2.1. Introduction

Many sports including football, rugby, American football, lacrosse and Gaelic sports are increasingly played on synthetic sports fields (ECHA 2017; RIVM 2018; EUNOMIA 2018). The newest (3rd) generation synthetic sports fields use pile heights ranging from 35 to 65 mm (with many systems being based on 60 mm carpets) and a mixed ballast layer composed of different types of infill (ECHA 2017; Figure 14).

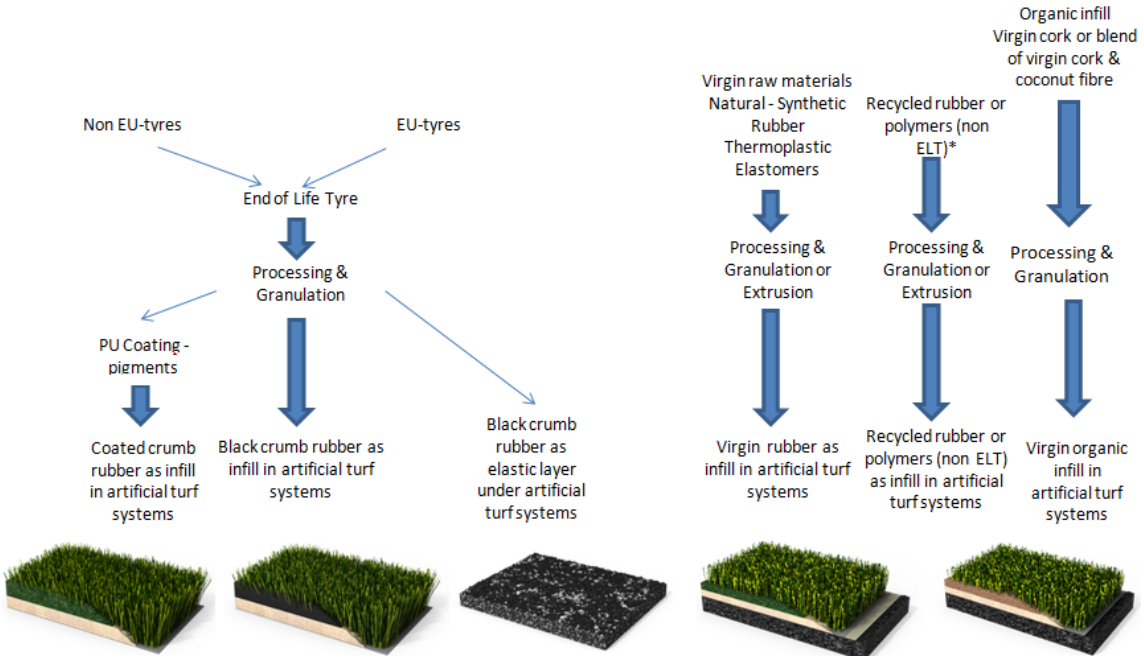


Figure 14: Schematic of 3rd generation artificial turf systems; based on information

[145] Other uses of polymeric granules may be in scope of the restriction. However, the analysis in this Annex focusses on its use as infill material on sports pitches as this is the most relevant use of such materials.

provided by ETRMA and ESTO (2016).

According to information from industry, football is by far the largest sport played on long pile synthetic turf fields in the EU. This was confirmed by submissions to the consultation by the Union of European Football Association (UEFA) and national football associations from several large EU member states.

D.13.2.2. Types of infill

Infill material in synthetic sports fields is used to absorb impacts in order to help prevent injuries and to mimic the feel of natural turf. The most common infill material consists of polymeric particles <5mm in size (thus meeting the definition of microplastic under the proposed restriction), which are distributed throughout the turf surface just below the artificial grass pile (EUNOMIA 2018). Alternatively, non-polymeric infill and natural polymer-based infill are used. However, to date they are less common because of their price and/or properties relative to polymeric granular infill. Alternatives are discussed in more detail in Section 0.

D.13.2.2.1. End-of-Life Tyre (ELT)-derived infill

According to reports by ECHA (2017) and RIVM (2018), 90-95% of the artificial turf pitches in the EU use infill made from ELT rubber granules produced from recycled tyres, which is also referred to as styrene-butadiene rubber (SBR) (EUNOMIA 2018). Whilst ELT-derived infill is used EU-wide, it is less common in some Member States (e.g. Germany and Norway) and more common in others (Denmark and the Netherlands).

D.13.2.2.2. Other polymeric infill materials

Other types of polymeric infill used in the EU are (ECHA 2017; RIVM 2018):

- EPDM rubbers: market share of ~4%;[146]
- Thermoplastic elastomers/thermoplastic rubbers (TPE): market share of ~4%;
- Polyethylene (PE) or polypropylene (PP): market share unknown.

For example, in Germany, ~50% of the infill material used on artificial turf pitches is made from ethylene propylene diene monomer (EPDM) rubber or thermoplastic elastomer (TPE) rubbers.[147]

The majority of these alternative polymeric infills are expected to be virgin material. However, some may be from recycled materials (RIVM 2018). For example, ECHA (2017) noted that a Polish company had reported that infill material can be produced using recycled SBR, EPDM and TPE from mats, belts, sleeves, spouts and gaskets. This company appeared to supply infill material predominantly to customers in Poland, Lithuania, Estonia, Latvia and Finland (ECHA 2017). The use of recycled materials appears to have a limited market share in the EU but is expected to grow (RIVM 2018).

In the consultation on the restriction proposal on intentionally-added microplastics, one response was received from a producer of virgin TPE material (TPE, inorganic and

[146] According to industry information, EPDM rubber material is produced from both recycled EPDM and virgin EPDM infill material (ECHA 2017).

[147] Consultation, comment #2364. ELT-derived material is sometimes coated with polyurethane-based coatings (ECHA 2017), making a clear distinction between recyclate and virgin material difficult.

organic additives) that will, according to the producer, fall under scope of the proposed restriction.

D.13.3. Baseline

D.13.3.1. Tonnages used

D.13.3.1.1. Number of pitches

Based on information provided by the European Synthetic Turf Organisation (ESTO), around 13 000 full-sized synthetic turf pitches and 47 000 so-called mini pitches were used for football in the EU in 2016 (ECHA 2017; EUNOMIA 2018). The number of synthetic sports pitches is expected to continue to grow; by 2020 the number of football fields with synthetic turf is expected to be about 21 000 and the number of mini pitches around 72 000 (ESTO Market Report Vision 2020). According to the EMEA Synthetic Turf Council (ESTC)[148], there are currently more than 17 700 full-sized synthetic turf pitches installed in 11 Member States.[149] For other Member States, no verifiable public records exist. However, given these numbers and the projected annual growth rate of installations of pitches, it seems not unlikely that by the end of 2020 the total number of installed full-sized pitches may be even greater than the ESTO's estimate of 21 000. In Germany alone, there are more than 5 000 full-sized artificial pitches (as reported by multiple German Football Associations during the consultation).

If the number of pitches were to reach 21 000 by 2020, and the number of mini pitches around 70 000, this would correspond to an annual growth rate of about 6% for football pitches and mini pitches. Based on this information, the Dossier Submitter estimates the number of full-sized synthetic turf pitches to be around 34 000 in 2028, and the number of mini pitches to be around 110 000. These estimates are for newly installed pitches only. Assuming an average 10-year service life for synthetic turf pitches (as indicated by UEFA), the Dossier Submitter assumes that ~10% of existing pitches are refurbished in each given year. Hence, the total number of full pitch (re-)installations between 2018 and 2028 will be on average 4 200 and the total number of mini pitch (re-)installations will be on average around 6 600 annually (RIVM 2018).

An estimate for installed rugby pitches was also provided in the ESTO report for Europe as a whole. Although artificial turf use in rugby is growing fast, it currently only represents 2% by surface area installed (EUNOMIA 2018). The number of pitches exclusively dedicated to other sports is considerably smaller. Rugby Europe reported the total number of installed rugby synthetic rugby pitches in the EU to be 558 in 2016, whereas the number is thought to have exceeded 660 in 2018 as reported by World Rugby in the Annex XV report consultation. The number of pitches on which Gaelic sports are played is even lower. For Lacrosse, the exact number of installed artificial turf pitches in the EU is unknown but are estimated to be less than that for rugby (RIVM 2018).

ESTO estimates that more than 95% of all synthetic turf installations are outdoors (ECHA 2017) and hence subject to material loss. As most artificial turf pitches are football pitches and as football is by far the largest sport in the EU, the baseline estimates

[148] Consultation, comment #2140.

[149] Belgium, Denmark, France, Germany, Ireland, Italy, Netherlands, Norway, Spain, Sweden, UK.

provided below focus on football pitches and mini pitches.

D.13.3.1.2. Quantities of infill material used

The amount of polymeric granular infill material used on synthetic turf pitches depends on the height of the pile and the performance required. In general, mini pitches have a lower quantity of infill per square metre as most mini pitches have a short pile height. If the system incorporates a shock pad (elastomeric layer underneath the turf), the pile height may be lower, and the required quantity of infill will also be lower (ECHA 2017). Systems that use non-ELT infill material often have shock pads and short pile heights and require lower quantities of infill to balance the higher price of the infill material (RIVM 2018).

The sizes of football pitches vary somewhat but are generally between 100 and 120 metres long and between 64 and 75 metres wide. The assumed standard surface area of a full-size football pitch is 7 600 m^2. Sizes of mini pitches vary largely in size. Following RIVM (2018), the Dossier Submitter assumes that the area of a mini pitch is 1 400 m^2. Based on these surface areas and the number of installations, refurbishments and maintenance, RIVM (2018) estimated that the total annual use tonnage of ELT-derived infill material would grow from 350 kilotonnes in 2016, to 390 kilotonnes in 2018, to 550 kilotonnes in 2028 in the baseline situation (RIVM 2018).[150]

Based on industry estimates (ETRMA 2016), the quantity of ELT rubber infill used on EU sport fields is 80-130 kilotonnes per year. EUNOMIA (2018) estimated a total of 51 616 pitches in the EU with a corresponding surface area of 112 million square meters. Using an infill density of 16.1 kg/m^2, EUNOMIA estimated that around 120 tonnes of SBR would be required to fill a full-size pitch. The total infill material estimated to be currently in use in the EU is 1.8 million tonnes.

However, the reliability of these estimates has been questioned by several stakeholders contributing to the consultation on intentionally added microplastics. One German company[151] argued that the infill density in artificial turf pitches installed in Germany is on average 3.5 kg/m². This would result in significantly lower quantities of infill material used per pitch. Another stakeholder[152] who responded to the consultation suggested that an infill density of 6 kg/m² would be a far more realistic estimate. In the restriction on PAHs in rubber granules[2], RIVM used 15 kg/m² as best estimate for the infill demand per pitch without shock pad. However, RIVM noted that most modern pitches have a shock pad and hence require significantly less infill material.

One of the key factors that drives the use volume of infill material is the filament height. The French Agency ANSES confirmed that, in France, the most commonly used filament

[150] The Dutch industry association of tyre and wheel (VACO) estimated the annual volume of infill material used in the EU to be in the range of 80-200 kilotonnes. The total production volume of rubber granules in the EU, on the other hand, is 900 kilotonnes per year (VACO, 2015). The Dossier Submitter made calculations on infill required based on the available information on number of pitches and required amounts of performance infill per type of artificial pitch. The results of these calculations differ from the estimates by VACO. The difference may be caused by a difference in scope of the two sources. The estimate of the Dossier Submitter covers use of infill for newly installed pitches, refurbished pitches and pitch maintenance. It is unclear whether the estimate of VACO also includes refurbishment and maintenance.

[151] Consultation, comment #2364.

[152] Consultation, comment #2021.

height is 60 mm, which usually requires 110 to 120 tonnes of infill on a full-sized football pitch. However, ANSES also indicated that, if the pitch had a shock pad, the pile height could be lower, and the infill volume could be only 40 tonnes. The European Recycling Industries' Confederation (EURIC)[153] claimed that the average volumes of ELT infill material used on artificial turf pitches in Denmark and Netherlands are 90 tonnes and 100 tonnes, respectively.

Given the reported variance of infill density in different EU member states (as summarised in Table 107), it does not seem justifiable to assume that an infill density of 16.1 kg/m^2 as assumed by EUNOMIA (2018) would be representative of the EU-wide situation. The Dossier Submitter notes that the required infill density depends on the infill material used and whether a field has a shock pad installed.

Table 107: Overview of average quantities of ELT infill needed per full pitch, annual refill quantities, and fraction of existing and new pitches that use ELT infill.

Country	Average ELT infill (tonnes/full-sized pitch)	Annual refill (tonnes/year)	Fraction of existing pitches using ELT infill (%)	Fraction of new pitches using ELT infill (%)
EUNOMIA study	120	1.2-4	--	--
France	40-120	--	--	--
Germany	24-42	0.25-5	30%	10%
Denmark	90	1-2	90%	90%
Netherlands	100	2.2	90%	50%

Sources: a) EURIC; b) various European football associations, installers and manufacturers who submitted information during the consultation.

Based on the information received, one can expect a typical full-sized artificial pitch in the EU to use infill material in the range of 40 to 120 tonnes. In the restriction on PAHs in rubber granules, RIVM assumed that the market share of ELT infill for newly installed pitches (new installations and re-installations) would gradually reduce from 90% in 2018 to 70% in 2028 under their baseline scenario. This estimate was based on information received from stakeholders during a workshop held on 24 November 2017 in support of the preparation of the restriction proposal on PAHs in rubber granules. This would mean that the share of ELT-derived granules on all synthetic turf pitches in operation in 2028 would be ~78%, whereas EPDM and TPE infill would account for ~18% and cork would account for ~4% of infill material used (RIVM 2018).

D.13.4. Emissions

Polymeric infill can be inadvertently removed from pitches by players (attached to their clothing or footwear) or through maintenance activities, such as snow clearance. It may then enter drains, soil, surface water or be removed as part of waste collection.

EUNOMIA (2018) estimated that between 18-72 kilotonnes of infill material would be lost

[153] Consultation, comment #2535.

into the EU environment per year. This corresponds to a loss rate of 1-4% of the total infill material or 1.5 to 5 tonnes per year from each pitch, assuming there are about 120 tonnes of infill in each full-sized pitch. Whilst this loss rate correlates with the amount of infill top-up that was commonly reported by turf manufacturers—typically around 3% per year—the absolute volume lost into the environment depends on the estimated use volumes per field as well as on the prevailing compaction rate and the technical measures at a specific pitch and could hence be much lower than indicated by EUNOMIA (2018).

If one applied the lower bound estimate of 40 tonnes of polymeric infill material per full-sized pitch (with shock pad), the annual infill consumption per pitch would fall to 400-1 600 kg (i.e. 1-4% of the total infill volume), corresponding to an overall annual consumption of polymeric infill material in the EU of 15-62 kilotonnes per year. Similarly, if one applied the upper bound estimate of 120 tonnes of polymeric infill material per full-sized pitch, the infill consumption per pitch would be 1 200-4 800 kg, corresponding to an overall annual consumption of polymeric infill material in the EU of 46-185 kilotonnes per year.

These calculations rely on the projections of ESTO that there would be 21 000 full-sized and 72 000 small-sized pitches by 2020 in the EU, as well as on the assumption that on average one full-sized pitch would be equivalent to four small-sized pitches in terms of size. Presuming that compaction effects account for 65-85% of the consumption of infill material (Løkkegaard et al. 2018), actual emissions are significantly lower.[154]

Indeed, the consumption range of 15-185 kilotonnes per year reported above corresponds to losses of 2-65 kilotonnes per year. Adjusting for sports fields that either use alternative infill materials or have already emission control measures in place results in a grand average estimate of approximately 16 kilotonnes of polymeric infill material lost into the environment each year.[155] The Dossier Submitter's central emission

[154] Multiple stakeholders indicated in the consultation that a good fraction of infill consumption is due to the compaction resulting from use and other mechanical load occurring during maintenance work (e.g. snow ploughing). In their report EUNOMIA (2018) disregarded this objection arguing that decompaction maintenance such as raking would revert such compaction effects. Reviewing the available knowledge on the effects of decompaction maintenance on the infill state and play performance, Fleming et al. (2015) concluded that "at present, little is understood about either the science of the infill compaction process or the efficacy of decompaction maintenance". Under laboratory conditions, they found that compaction effects could be almost entirely reversed by decompaction maintenance. Yet measurements on real fields did not result in the same decompaction efficacy. Moreover, it is unclear how frequently such decompaction maintenance is undertaken on artificial pitches across EU. The Dossier Submitter can therefore not establish the efficacy of raking and other decompaction maintenance in slowing down or reversing the compaction effect.

[155] Assume that an average full-sized pitch uses 80 tonnes of infill material and 2.5% of infill material per year would have to be refilled. This corresponds to an annual consumption of 2 tonnes per average full-sized pitch. Consider that 75% (1.5 tonnes) of the consumption are due to compaction. The actual loss per full-sized pitch would be 500 kg per year. On average, four mini pitches fit into a full-sized pitch and, hence, 72 000 mini pitches correspond to 18 000 full-sized pitches (https://www.discountfootballkits.com/blog/football-pitch-size-guide). Add that to the forecasted 21 000 full-sized pitches to obtain an estimate of full-sized pitch equivalents of 39 000; account for fields that either use already alternative infill material (~5% of all pitches) or have emission control measures in place (~15% of all pitches); multiply the resulting 32 000 pitches that are releasing microplastics by 500 kg per full-sized pitch to arrive at 16 kt of forecasted losses of infill material. As this calculation relies on the fraction of full-sized pitch equivalents using polymeric infill material, it may be used to test other assumptions by up- or down-scaling.

estimate is well aligned with emission estimates from artificial turf fields in France[156] and can be triangulated with a recent study on microplastics emissions from tyre use in Switzerland (Sieber et al. 2019).[157]

This estimate is further supported by information received in the consultation. Drawing on studies from Sweden, the Netherlands and Denmark, the EMEA Synthetic Turf Council claims that the volumes of infill released to the environment via different pathways are very limited.[158] Similarly, the European Recycling Industries' Confederation (EURIC) stated in the consultation that the actual loss of infill material from pitches to the environment is very limited and the necessity to refill a pitch is largely attributable to the compaction of infill material.[159]

EURIC cited a recent study from Bergavik's IP (Sweden), which found that the potential spread of infill from artificial turf may be overestimated by up to a factor of 50. Relying upon data collected by the Swedish Environmental Research Institute, the following transport routes for infill material were considered relevant:

- Quantity of infill added within first two months of operation of the sports pitch: 1 000-2 000 kg per year;
- Compacting effect: 200 to 1 000 kg per year;
- Quantity of infill inadvertently removed by players: 40 kg per year;
- Loss through snow ploughing and other maintenance: 500 kg per year;
- Loss through draining water and ground water: up to 34 kg per year;
- Loss through wind dispersion: considered not to be relevant due to the weight of polymeric infill material.

The main routes for spreading of microplastics from artificial turf pitches are summarised in Figure 15.

[156] The consultation, comment #2493.

[157] The study estimates that over the last 30 years microplastics emissions from tyres in Switzerland have amounted to 200 mt. They purport that ~3% of these emissions are attributable to ELT infill material. Thus, in an average year, 200 tonnes of ELT infill material have been lost into the environment. There are currently 8.6m people living in Switzerland. Hence the per capita microplastics emission attributable to ELT is ~23kg per year. Scaling this up to the current EU28 population of 513.5m results in a grand total of 12 kt of infill lost into the environment each year. If one adjusts for the fact that the Swiss population has been growing over the last 30 years and that virgin polymeric infill materials are not accounted for in the study, one arrives at emission estimates in the ballpark of 16 kt per year.

[158] The consultation, comment #2140.

[159] The consultation, comment #2535.

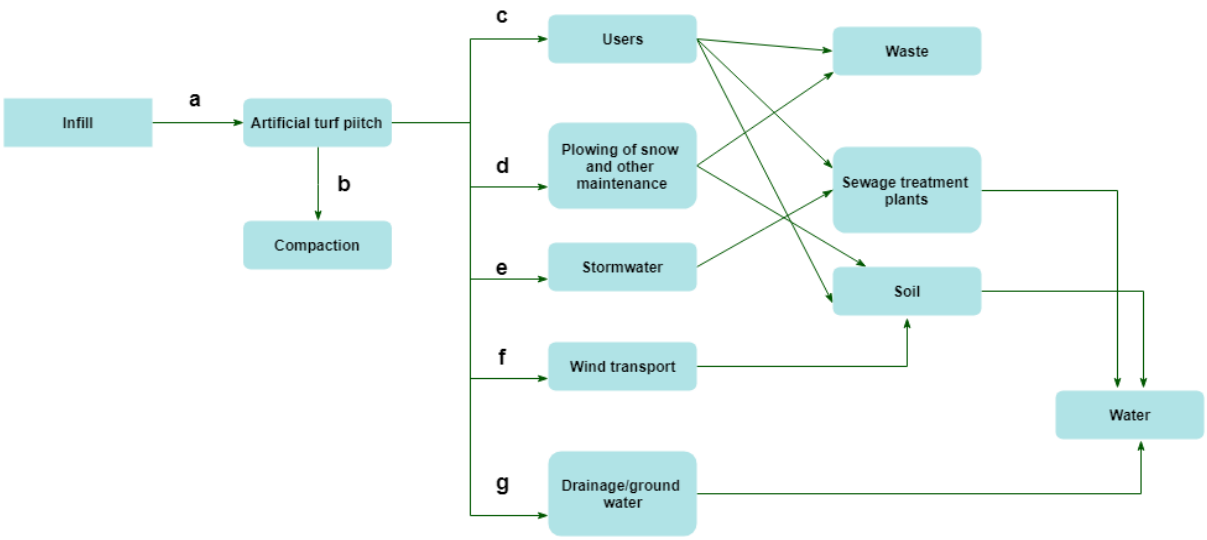


Figure 15: Summary of the main route of spread of microplastics from a synthetic turf (Krång et al. 2019).

Another major study carried out by the Weijer and Knol 2017 (BSNC), found that 250-325 kg of infill material per year is lost to the surrounding environment, particularly grass and pavements within the perimeter of two metres around the field. During renovation or maintenance work on these fields, it was considered relatively easy to collect this dispersed infill material as well as to install preventive measures that would minimise any further dispersion. Similarly, one submission[160] in the consultation suggested that relatively simple technical measures are available that could limit the loss of infill material to insignificant amounts. The results of the Dutch study as regards the loss flows per field are summarised in the Table 108.

Table 108: Loss flows per field (rounded) (Weijer and Knol, 2017).

Field (infill material)	Socks & shoes	Sweeping	Wastewater	Surface water	Grass	Pavement
	kg/year	kg/year	kg/year	kg/year	kg/year	kg/year
Rotterdam (SBR)	12	20	0.9	--	260	1
Amsterdam (SBR)	12	9	--	10	240	60
Hoogeveen (SBR)	12	0	0.3	6	240	40
Utrecht (TPE)	12	5	--	100	15	2
The Hague (Cork)	12	40	--	--	4	3

The Danish Technological Institute (DTI) also assessed migration of rubber granules from synthetic turf pitches to the aquatic environment and concluded that discharges to the aquatic environment are limited. It concluded that the main reason behind the periodic top-dressing of an artificial turf pitch is to compensate for compaction of the

[160] The consultation, comment #2364.

infill material. More specifically, their results suggested that 1.5-1.9 tonnes (about 65-85%) out of 2.2 tonnes of infill material consumed annually per pitch were actually related to compaction, while 250 kg of infill material migrated to the ground and paved areas, 40 kg were transferred via clothes and shoes of players, up to 240 kg per year were lost through snow removal, and 10-200 kg were lost through water discharge, see Figure 16.

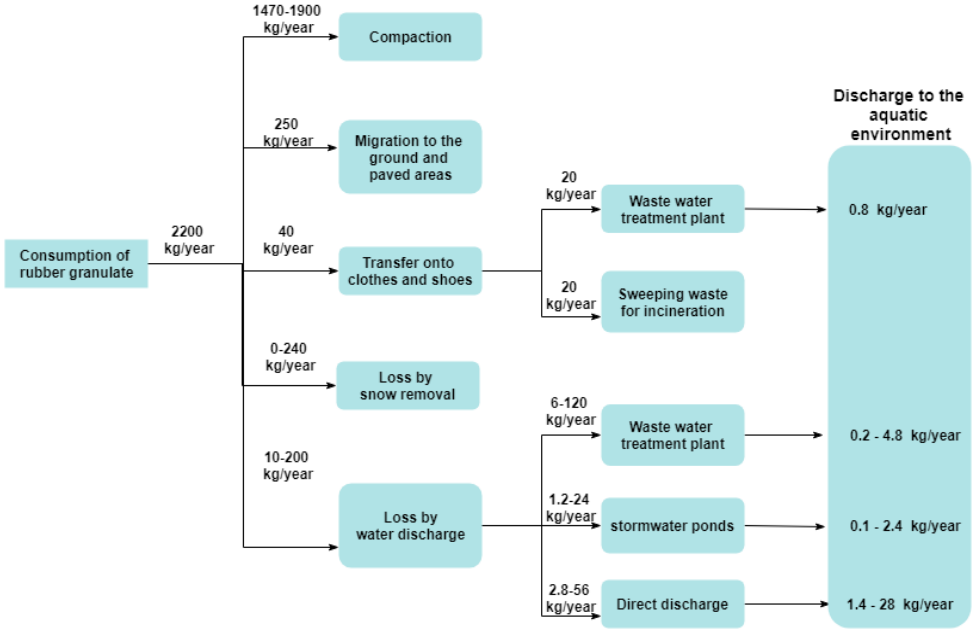


Figure 16: Different pathways for loss of rubber infill (Løkkegaard et al. 2018).

In addition to these experimental studies, EUNOMIA (2018) mentioned one study which attempted to create a mass balance for infill material used on artificial turf. This study looked at three local pitches containing SBR infill and one containing TPE infill. The results of the study were inconclusive, and may not be representative, but their indicative results were as follows. Transport by players was estimated to be around 4% of the total loss of infill material, releases to surface water were typically around 2-3% (with one notable exception where surface water discharge accounted for 75% of the loss). In Northern and Eastern EU Member States an important source of loss of infill material is snow removal. This is relevant as these Member States account for approximately 15% of the installed turf pitches (EUNOMIA 2018).

To the Dossier Submitter, the information presented above indicates that estimating the overall infill material loss in the EU is subject to significant uncertainties and will have to be based on assumptions. Based on the aforementioned calculations, and taking into account the various pieces of information received during the consultation, the Dossier Submitter assumes an average loss per pitch of ~500 kg per year, corresponding to an overall annual infill material loss in the EU in the range of 16 kilotonnes per year. On any given pitch, this amount may be significantly reduced by technical measures to minimise the loss of infill material (see section D.13.4.1).

D.13.4.1. Examples of technical measures to minimise emissions

Releases of infill material can be minimised by means of various technical measures and design solutions. There is an expanding range of design solutions available on the EU market for the containment of infill migration, most of which have been brought to the

attention of the Dossier Submitter during the consultation on the Annex XV report. The diverse set of technical measures are specifically targeted at different pathways of granular infill migration; namely, migration to the ground and paved areas, transfer via players' clothes and shoes, loss by snow removal, and loss through water discharge.

Examples of technical measures for minimising emissions of granular infill from artificial turf pitches for each of these pathways are presented in Figure 17-Figure 19. Meanwhile, FIFA (the Fédération Internationale de Football Association), UEFA (the Union of European Football Associations) and World Rugby are producing their own quality standards for infill material used on synthetic sports pitches (see ECHA 2017 for details).

The FIFA quality standards include some hazard-based criteria for infill material. Specifically, 'The manufacturer should be asked to supply to the purchaser an assurance that the sports surface together with its supporting layers, does not contain in its finished state any substance which is known to be toxic, mutagenic, teratogenic or carcinogenic when in contact with the skin. Furthermore, that no such substances will be released as a vapour or dust during normal use.'

FIFA has also established the FIFA Quality Programme for Football Turf, which certifies final installations are subject to a testing procedure. However, the number of fields in the EU that fulfil the FIFA quality programme is unknown (ECHA 2017). Similarly, some Member States have specific control systems in place. For example, the French Football Federation notes that the owners of the fields are municipalities, which may require laboratory reports showing that the infill material used on their pitch is compliant with the national standard (NF P 90112), which sets up limits on heavy metals.

There are several other technical standards applicable to rubber granules (ECHA 2017):

- EN 15330-1 (2013): Surfaces for sports areas. Synthetic turf and needle-punched surfaces primarily designed for outdoor use.
- EN 933-1 (2012): tests for geometrical properties of aggregates part 1: determination of particle size distribution – sieving method.
- EN 14955 (2005): surfaces for sport areas – determination of composition and particle shape of unbound mineral surfaces for outdoor sport areas.
- EN 1097-3 (1998): tests for mechanical and physical properties of aggregates – part 3: determination of loose bulk density and voids.
- EN 14836 (2005): synthetic surfaces for outdoor sport areas. Exposure to artificial weathering.
- DIN 18035-7:2002-06: Sports Grounds Part 7: Synthetic Turf Areas, Determination of Environmental Compatibility
- NF P90-112: Sports grounds - Unbound mineral surfaces for outdoor sport areas - Specifications for construction.

Figure 17: Examples of infill containment and entrapment. Source: ESTC (2019).

Figure 18: Brush station for players and other users. Source: ETRMA (2019).

Figure 19: Footwear with integrated socks, entrance with player-cleaning-area, special drains with filters/interceptors. Source: BIR Tyre & Rubber Com (2019).

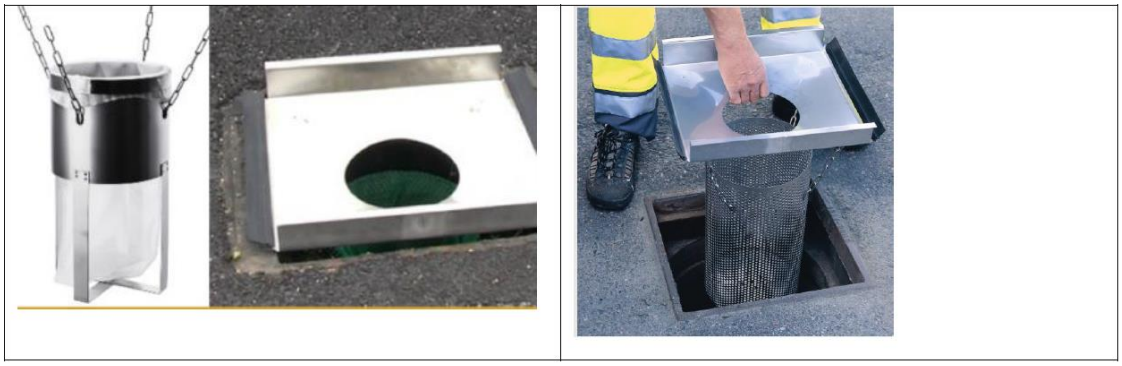


Figure 20: Granules traps and filters in drainage system to minimise the risk of granules entering watercourse. Source: ETRMA (2019).

Figure 21: Example of a field with fences to avoid dispersion from visitors and a dedicated area for cleaning maintenance machinery. Source: ETRMA (2019).

Figure 22: Example of snow dumping area. After snow melts, the granules are recovered and returned to the pitch. Source: ETRMA (2019).

The potential for the polymeric infill material from artificial sports turf to contribute to microplastics emissions has been a relatively recent issue. Best practice measures can

be taken to minimise the loss of infill from individual pitches (EUNOMIA 2018). The ESTC, one of the respondents in the consultation, published guidance on controlling infill migration in 2017. This guidance provides an overview of procedures and mechanisms for preventing the migration of the infill beyond the footprint of the synthetic turf pitch. It also provides examples of infill containment and entrapment by means of designing catchment gates and grids at pitch entrances as well as constructing fenced migration barriers and implementing surface water interception drains and filters.

The ESTC claims that by implementing effective artificial turf pitch designs and proper maintenance procedures, the infill migration would be significantly minimised, thereby rendering a ban on the use of polymeric infill material unnecessary.

Over a dozen of German regional football federations too have reported in the consultation that targeted risk management measures would significantly reduce the release of infill into the environment, obviating the need to ban the placing on the market of polymeric infill material. In the same vein, the Dutch industry association of tyre and wheel (VACO) has argued in the consultation that proper compliance with the duty of care can largely prevent the spread of polymeric infill material to the surrounding environment. VACO also referred to a closed system design of an artificial turf sports field that has been successfully implemented and tested in Kalmar, Sweden. One of the outcomes of implementing the closed system design has been the drafting of clear maintenance and usage guidelines, with a practical explanation of the need to prevent the spread of microplastics.

Furthermore, several technical solutions can be used to contain the infill material. Artificial sports fields can be surrounded by boarding with one entry-and-exit point, where visitors can wipe the infill material from their shoes. Outside the pitch polymeric infill material should be vacuum-cleaned and disposed.

Another efficient measure is the use of settling bins near the field. These measures may reduce leakage through water pipes. Other measures that can be taken include the performance of leaf blowing from the outside to the inside of the field, the performance of maintenance activities under dry weather conditions and the installation of a brush station for players.

The European Recycling Industries' Confederation (EURIC) outlined in their contribution to the consultation a list of risk management measures that would significantly reduce the releases of infill to the environment.[161] These measures include:

- Installation of boards and retaining walls around the fields to prevent the migration of infill;
- Installation of 'catch areas' where any infill that migrated from the field can be collected and then reused in the same field;
- Installation of drains with filters/interceptors where infill can be easily collected. Implementation of such a system would eliminate any releases to water;

[161] The consultation, comment #2535.

- Fences around the field with only a few entrances. Each entrance should have a brushing station/player cleaning area with the ability to collect the infill that was brushed/cleaned off from their clothes and shoes;
- During maintenance work special brushes should be used, which would be kept close to the pitch;
- Players should wear football shoes that with integrated socks that would ensure that no granules are stuck between shoes and socks;
- Installation of special mats that catch the rubber after players leave the field;
- When cleaning the field of leaves using a blower, it has to be ensured that blowing is done toward the centre of the field, where the leaves would be collected manually. This would minimise migration of infill to the environment.

Ragn Sells (Sweden) carried out a one-year study on a synthetic turf pitch installed in Kalmar, Sweden, where the following risk management measures were applied:

- Surface water and drainage water were separated;
- Sealing layer under the plan was installed to collect all drainage water;
- Granular traps (200 µm) were installed in all stormwater wells around the plan;
- Granular filters (100 µm) were installed for both surface and drainage water;
- Winter lining was set to lay snow on the ground instead of hardened surface;
- Brushing station and information plate were installed for players at the entrance/exit points;
- Operating personnel brushes of vehicles after operation / maintenance.

Preliminary results of this one-year study showed that the migration of microplastics from the artificial pitch to the environment, given the introduced RMMs, amounted to about 0.3 kg/year.

There is still a lack of awareness among pitch operators that loss of infill can contribute to the microplastic concern and there is no regulatory of reputational driver for pitches to prevent loss of polymeric infill material or to use alternatives (EUNOMIA 2018). VACO has argued that increasing awareness is fundamental to fostering human behavioural patterns that would lead to the enhancement of the benefits for the environment.

Mitigation measures are potentially simple to achieve if implemented during the design and construction of the field. These are similar to those employed at factories as part of Operation Clean Sweep (OCS) for pellet loss mitigation; traps for drains both inside and out, good housekeeping with spills regularly cleaned up and a site designed to prevent infill from migrating outside of the pitch area, are all simple but effective measures (EUNOMIA 2018).

The European Recycling Industries' Confederation (EURIC) suggested there is a great country-to-country variance in terms of costs of implementing operational conditions (OCs) and risk management measures (RMMs). In the consultation some information about such costs were received. They can be summarised as follows:

- Sweden: Implementation of best practices would result in the extra costs of €29 000 per pitch. The key cost drivers would be closed water system,

underlying construction, extra wells and filters, special entrance with a brushing station as well as a grid and an asphalt border with a retaining wall.

- Germany: The cost of implementing targeted risk management measures has been estimated by the German Football Association[162] to be in the range of €3 000 to €10 000 per pitch.
- Netherlands: The extra cost for a closer boarding around one pitch is estimated at €10 000 when a surrounding fence is already planned. Extra costs for maintenance are thought to be negligible.
- UK: If special drains and retaining walls are already in place, the installation of timber edging would cost about €22 000. The costs of preventive measures are being explored.
- Norway: Implementation of best practices would result in the additional cost of €21 000.

Whereas the average implementation cost of RMMs has been estimated to be in the range of €3 000 (Germany) to €29 000 (Sweden) per pitch (and may be higher in Nordic countries, see the comment by the Norwegian Competent Authority in the consultation[163]), the complete resurfacing of the existing artificial pitches containing polymeric infill material would result in much higher costs. The Belgian Olympic and Interfederal Committee (BOIC), Sports Flanders Agency, ISB and VSF[164] have estimated the replacement investments costs to be in the vicinity of €100 000 per pitch, excluding transport, storage and processing costs, whereas the EMEA Synthetic Turf Council estimated the cost to be closer to €200 000 per pitch. The German Football Association25 estimated that the replacement of existing polymeric infill material on its members' 5 000 artificial turf pitches would cost around €90 million in material cost alone (i.e. notwithstanding any changes in the artificial turf systems).

As for the effectiveness of RMMs in limiting emissions of polymeric infill material, it has to be considered that emission reductions to levels as low as measured at the Kalmar test site (<1 kg per year) are unlikely to be achieved on an artificial turf pitch with standard RMMs implemented. Yet various comments received during the consultation suggest that, if properly implemented, such measures can reduce emissions to quantities well below 100 kg per year.[165] Based on this information, the Dossier Submitter assumed in its quantitative analysis conducted in Section D.13.6.2.5 that the implementation of a comprehensive set of RMMs will generally limit the annual emissions of polymeric infill material from a pitch to about 50 kg, corresponding to an effectiveness in limiting emissions of 90%. In special cases, the residual emission could be more or less but given the emission pathways described in Section D.13.4 it is clear that effective measures are available to address major emission sources.

[162] The consultation, comment #2048.

[163] The consultation, comment #2139.

[164] The consultation, comment #2676.

[165] The consultation, comments PC#2021, 2042, 2045, 2051, 2119, 2139, 2140, 2147, 2156, 2369, 2439, 2440.

D.13.5. Alternatives

In addition to polymeric infill material, several non-polymeric infill materials can be produced from organic alternatives such as cork and coconut husk (ECHA 2017; RIVM 2018; EUNOMIA 2018) and timber granulate (ESTC; consultation). In this section, the Dossier Submitter summarises the information gathered during the consultation on the pros and cons of specific alternatives. However, a detailed technical verification of specific technical information is beyond the scope of this proposal.

To start with, the European Synthetic Turf Association (ESTA) informed in the consultation that it is not possible to simply remove a polymeric infill material and replace it with an organic one since many artificial turf pitches meet sports performance or player welfare regulation requirements because of the elastic properties of the polymeric infill material used.

Where organic infills such as coconut fibres or nut shells have little or no impact attenuation properties, it is essential that such a system includes an impact absorbing shock pad laid beneath the synthetic turf carpet. In practice, this means that existing artificial turf pitches would need to be fully resurfaced, not just have the infill changed. The expected cost per pitch was estimated by ESTA is close to €200 000.

The best-known alternatives to polymeric infill materials for use in synthetic turf are cork and coconut husk (TURI 2016; RIVM 2018; EUNOMIA 2018) and, on 2nd generation artificial turf pitches, sand (PlanMiljø ApS, 2017). According to (EUNOMIA 2017), these alternative materials are currently used in less than 3% of the artificial turf pitches in the EU. However, their use has been reported to be increasing, partly in response to issues surrounding the PAH content of ELT infill material. Accordingly, RIVM (2018) estimated in the recent Annex XV restriction proposal on PAHs in rubber granules that the use volume of cork and other organic materials would double by 2028.

All these alternatives were comprehensively reviewed in a study conducted for the Norwegian Environmental Agency (PlanMiljø ApS 2017), which is succinctly summarized in Table 109. In the following sections, the most relevant aspects of alternative infill materials are further discussed.

Table 109: Overview of artificial turf options (Source: PlanMiljø ApS 2017, prices converted into 2019 €).

Type	Variation	Material properties	Usability	Availability	Costs	Health aspects	Manufacturing	Use	Waste treatment
SBR	Crumb Rubber SBR	Crumb rubber is derived from scrap car and truck tires that are ground up and recycled. The rubber's scientific name, styrene-butadiene rubber (SBR), covers a general-purpose synthetic rubber, produced from a copolymer of styrene and butadiene.	The most widely used infill product worldwide. High durability. Many different sizes. The infill can reach very high temperatures, but only in countries with warmer climate. Only comes in black colour, which can be an aesthetic issue and has a distinct odour.	Very high availability	190-250 €/t; the amount of refilling of infill needed depends on maintenance.	The preponderance of studies show no negative health effects associated with crumb rubber in outside fields but some studies found the rubber causing a considerable impact on the indoor environment. Many studies recognize the need for further scientific study of the topic – and many comprehensive study programs have been initiated during the last years.	The material stems from shredded car tires that would alternatively either be recycled as rubber powder and granulates for other purposes; incinerated with heat extraction; or deposited at landfills (not allowed within the EU).	An artificial turf field requires annual supplement of 0-5 tons rubber granulate, depending mainly on the winter maintenance procedures (in cold and snowy regions more rubber is removed during maintenance). The rubber supplement substitutes removed/migrated rubber granules that may contribute to micro plastic pollution. The turf does not require water, fertilizers, pesticides or other chemicals for maintenance.	The traditional waste handling has been incineration or landfilling. Recycling of SBR can be difficult because the infill is contaminated with sand. Recycling of the complete turf is now possible with 99% recycling of the turf materials. If recycling is not possible it is unsure whether a secondary market for a lower quality product exists. If the crumb rubber field is cut into smaller sections there is little change for it to be reused. Instead it will presumably end up in incineration
	Coated SBR	A reticulated SBR polymer, encapsulated with polyurethane (PU) film to enhance its durability and eliminate the unwanted effects typical of traditional black rubber. Equilibrated and heterogeneous granules between 0,5 – 2,5 mm.	Coated SBR provides additional aesthetic appeal (different colours), can reduce dust and splash on the field. Advertised as having high use durability: Excellent resistance against UV, ageing, and wearing trample, and high stability. 10-year warranty on the coating. Stakeholders states that the coating may vanish over time.	Medium availability	500 €/t; advertised as needing 10% less infill than SBR	Can reduce discharge of chemicals and metals (compared to traditional SBR) if encapsulation of the rubber particle is not deteriorated during the lifespan.	Rubber materials as above. A long list of coating agents are being used, depending on the supplier; no environmental review has been identified and the impact from manufacturing processes is unknown.	As for SBR. The coating reduces spreading/ leaking/emission of rubber, micro plastics, and chemical substances during use. No reference on environmental pollution caused by the coating materials has been identified, but coating materials are to a certain extent emitted during use. Spreading of micro plastic could be less than from uncoated SBR rubber because of the equilibrated and heterogeneous fragments.	As above. If incinerated the total greenhouse gas emissions from the coated SBR is higher than from the non-coated SBR.
TPE		Crosslink of plastic and rubber, can be virgin or recycled. Can be shaped like SBR crumb rubber or any other shapes; pellet shaped, cylindrical, hollow inside.	Good weather resistance and long lasting if UV stabilizers are used and available in a variety of colours that should resist fading. Less warm to play on than SBR. Good quality TPE creates a soft surface playing field. Poor quality TPE can harden over time and melt at high temperatures.	Limited availability however if demand increases more can be manufactured.	1 500-1 700 €/t; approximately 7-10 kg/m2 granules are necessary if a shock pad is used (50-70 tonnes for a standard field). Refilling is estimated to be between 6-8% a year	Chemical composition is very unlike SBR rubber, generates less pollution. Advertised as free of lead, zinc, and other toxic metals and materials, but not all is in fact according to studies (see appendix). The emission of chemical substances from TPE is predicted to be limited, because no vulcanisation chemicals are used as is the case for rubber	The product is produced from virgin fossil materials and therefore has a relatively higher environmental impact (use of virgin fossil materials as compared to recycling of tyre materials) than the products based on reused rubber	As for SBR	A thermoplastic that can be re-melted. Recyclable and reusable as infill.
EPDM	Recycled	EPDM has the same grain size as SBR crumb rubber. Can be virgin or recycled. EPDM is a generic term and the source, formulation, and quality of the material can vary greatly. Good quality EPDM is well suited for use in artificial turf, but some suppliers use a lot of chemical fillers or recycled EPDM, which can cause the rubber granulates to crumble, resulting in poor quality granulates. Only (expensive) testing of the granulate can show the quality.	A cleaner and cooler material with less odour compared to SBR. Many different colours available. Quality of EPDM granulates differs greatly. EPDM is by suppliers advertised as a polymer elastomer with high resistance to abrasion and wear and to resemble the surface of natural grass. Reports of premature aging and degradation due to high levels of chemical fillers. Several manufacturers in Europe have had to replace a	Limited availability however if demand increases more can be manufactured	700 €/t; approximately 7-10 kg/m2 granules are necessary if a shock pad is used (50-70 tonnes for a standard field). Refilling is estimated to be between 6-8% a year	There are insufficient data on chemical exposures due to limited studies that evaluate the composition, off gassing, leaching, and associated potential health effects. EPDM is in studies stated to be non-toxic, and more environmentally friendly than tire rubber. In the NFF analysis the EPDM product shows no content of the hormone disrupting phthalate (DEHP) but the highest emissions of volatile organic compounds to the	Less environmental impact than virgin EPDM.	As for SBR	EPDM is a thermoset plastic that cannot be melted into other products.

Type	Variation	Material properties	Usability	Availability	Costs	Health aspects	Manufacturing	Use	Waste treatment
			large number of EPDM-filled fields due to a reaction between the EPDM and the carpet fibre.			indoor environment.			
	Virgin	EPDM has the same grain size as SBR crumb rubber. Can be virgin or recycled. EPDM is a generic term and the source, formulation, and quality of the material can vary greatly. Good quality EPDM is well suited for use in artificial turf, but some suppliers use a lot of chemical fillers or recycled EPDM, which can cause the rubber granulates to crumble, resulting in poor quality granulates. Only (expensive) testing of the granulate can show the quality.	A cleaner and cooler material with less odour compared to SBR. Many different colours available. Quality of EPDM granulates differs greatly. EPDM is by suppliers advertised as a polymer elastomer with high resistance to abrasion and wear and to resemble the surface of natural grass. Reports of premature aging and degradation due to high levels of chemical fillers . Several manufacturers in Europe have had to replace a large number of EPDM-filled fields due to a reaction between the EPDM and the carpet fibre.	Limited availability however if demand increases more can be manufactured	1 200-1 500 €/t; approximately 7-10 kg/m2 granules are necessary if a shock pad is used (50-70 tonnes for a standard field). Refilling is estimated to be between 6-8% a year	There are insufficient data on chemical exposures due to limited studies that evaluate the composition, off gassing, leaching, and associated potential health effects. EPDM is in studies stated to be non-toxic, and more environmentally friendly than tire rubber. In the NFF analysis the EPDM product shows no content of the hormone disrupting phthalate (DEHP) but the highest emissions of volatile organic compounds to the indoor environment.	Higher environmental impact (total climate gas emission) than reused EPDM	Can have less leaking of chemicals than reused EPDM.	EPDM is a thermoset plastic that cannot be melted into other products.
Silica sand		One of the earliest alternative infilling materials. Silica sand is derived from quartz eroded by wind and water. Silica sand can be mixed with other types of sand in a 50/50 ratio, and a mixture of silica sand and rubber infill is known to provide a better playing surface than rubber alone, i.e., a better field safety and playability	Natural infill, with tan, off-tan, or white colour and round or sub-round in particle shape. Silica sand is abrasive and relatively hard, especially under cold or frozen conditions. Can be recommended for less intensive use.	High availability	Silica sand is inexpensive and easily found.	Risk of sand dust causing respiratory irritation if inhaled, some studies indicate that the dust from silica sand might cause silicosis or even cancer when inhaled.	Less energy and processing is required compared to materials based on fossil fuel. There is a risk of environmental impact from mining, groundwater removal, and processing of the virgin materials.	Silica sand is a heavy material that will only to a small extent be removed/spread from the artificial turf field during use and maintenance.	Silica sand can be recycled and resold for many purposes.
Organic	Mix	Several types of infills available with different organic components; Coconut fibre, coconut husk, coconut peat, cork, rice husks, walnut shells, etc. All are treated with an antimicrobial application to prevent deterioration of the infill	Weather can impact playability of turf filled with organic materials as the infill may become saturated and freeze. Less heat absorbing No track record for durability and there are concerns about break down of the organic material, insects, and compaction of the material over time	Limited availability	High material and maintenance costs	Favourable conditions for fungus can be created when wet. No studies about the problem.	Lower environmental impact than for polymer infills (natural fibre as opposed to material based on fossil fuels, lower total climate gas emission). Use of antimicrobial substances and flame retardants may affect the environmental performance negatively.	No references	Recycling with composting might be possible. However, the resources used on separation of the organic infill from the turf can outweigh the gain of using the infill as compost. If incinerated the organic infill has a better total lifecycle greenhouse gas emission picture than the polymer infill materials.
	Cork	Cork is the outer bark of the cork oak tree and the structure and composition of the membranes make it very strong and waterproof.	Cork is advertised to keep the turf cool because of the low thermal conductivity, have good shock absorbing properties, and being completely recyclable. Players are usually content with the cork infill however problem can arise with cold weather if the cork is poor quality. The durability of cork is less than rubber and the material must be replaced in 3-4 years. There is a risk that crumbled cork might seal the drain of the field.	May be of limited availability.	DOMO cork costs 1 900-2 400 €/t. Approximately 1.7-2 kg/m2 needed. Unisport's 'eCork' product is approximately 500 €/t.	Cork can be 100% natural with no additives only a boiling process. If not properly maintained the cork infill can compact and become hard which can affect safety. Favourable conditions for fungus can be created when wet. No studies about the problem.	Cork is a renewable source and the harvesting and processing is seen as sustainable. The forestry of cork has some environmental benefits because of a high biodiversity in the cork landscapes. Use of antimicrobial substances and flame retardants may affect the environmental performance negatively.	No environmental toxicity as cork contains and binds the pollutants because of its natural protective function for the cork oak. Because of a low bulk density cork may be unintentionally removed from the fields when raining, which will require refill. Can require irrigation.	As for organic
Non-infill		A yarn based, carpet like product. There are several different options. Can be	The non-infill field are generally harder to play on than infill fields and the ball	High availability	Approximately 16-29 €/m2; minimal	No available literature in health effects.	N/A	N/A	N/A

Type	Variation	Material properties	Usability	Availability	Costs	Health aspects	Manufacturing	Use	Waste treatment
		installed indoor and outdoor in different sizes.	will tend to roll faster. The non-infill can be used for professional use but they do not (yet) meet FIFA quality since they cannot pass the skin abbreviation tests.		maintenance required.				

D.13.5.1. Sand

Silica sand is commonly used as infill material on synthetic sports pitches. It is a very good stabiliser to keep the fibres standing but can get compacted when wet. However, silica sand needs to be replaced over time because it is removed by wind or play. Silica sand was widely used in 2nd generation artificial turf pitches (PlanMiljø ApS, 2017). For example, the German Federal State of Hamburg has successfully substituted polymeric infill material on public artificial sport pitches with quartz sand since 2011.[166]

Silica sand can be coated with different materials as standalone product or used in combination with traditional rubber granule systems. A mixture of silica sand and rubber infill is even suggested to provide a better playing surface than rubber infill alone (PlanMiljø ApS, 2017). Similarly, silica sand may be used in combination with cork infill material.

According to PlanMiljø ApS (2017), silica sand is the least expensive alternative infill material and easily sourced. However, no reliable cost estimates of the material were reported during the consultation.

A drawback of silica sand reported by some commentators in the consultation is that sand dust may cause respiratory irritation, silicosis or even cancer if inhaled. These commentators adduced that mining of silica sand can affect the ground water due to the use of heavy machinery, spills and leak of fuel, oil or chemicals, runoff from contaminated sources, or illegally dumped waste. The use of flocculants in the cleaning of the sand might also present a risk (PlanMiljø ApS 2017).

Overall, it needs to be considered that while sand is still used on very short pile pitches (used e.g. for field hockey) it is not used as performance infill material on 3rd generation artificial turf pitches that are used for football and rugby.

D.13.5.2. Cork

Cork is the outer bark of the cork oak tree and the structure and composition of the membranes make it very strong and waterproof. Since 2007, granulated and most often heat-treated leftover material from bottle cork production has been used as infill material in artificial turf systems (PlanMiljø ApS, 2017). Cork has good shock absorbing properties and is completely recyclable. Moreover, cork as infill has several positive properties such as low density, high strength, low wear, and low heat absorption when exposed to sunlight (PlanMiljø ApS, 2017).

Cork infill manufacturers have claimed that cork infill can significantly reduce maintenance costs, improve safety for athletes, and enhance their performance and comfort, by giving neutral odour and natural appearance and texture to the field (Amorim Cork Composites, 2018). It has been also suggested that cork infill allows the terrain surface temperature to be up to 30% lower than with other infill materials.

On the downside, cork infill tends to bind water by absorption; it may harden or be damaged by frost, and dry out and fragment during dry periods in the summer with resulting dust emissions, lack of elasticity and a tendency to stick to shoes and clothes

[166] https://taz.de/Fussballplaetze-vor-der-Sperrung/!5607225.

(PlanMiljø ApS, 2017). Expanded cork[167] is more freeze-resistant and does not absorb water as easily as untreated cork. The price of expanded cork infill is in the range of €500-1 000 per tonne (PlanMiljø ApS, 2017).

The Tyres and Rubber Committee of the Bureau of International Recycling (BIR) in its 2019 report[168] claims that cork is "a highly abrasive product with a very limited availability" and considers that its use would result in an increase of inhalable dust in the vicinity of the artificial pitch. In the same report BIR claims that cork has a much higher GHG footprint than SBR infill material and, should any restriction be placed on the use of ELT-derived infill material on artificial pitches, 35 hectares of cork forests would be needed to produce the infill material for one pitch. Whereas the Dossier Submitter has not scrutinised such claims in detail, they seem to be made based on the assumption that only cork infill would be available. The Dossier Submitter rejects this presumption as implausible.

There are many suppliers of cork granules operating in the EU. Yet stakeholders have claimed that the amount of high-quality cork is too limited to meet the EU demand (PlanMiljø ApS, 2017). Moreover, it takes a cork tree 25 years to grow to maturity, meaning that abrupt upscaling of the amount of cork is virtually impossible.[169] One Norwegian supplier informed that cork infill material costs approximately €1 900-2 400 per tonne (PlanMiljø ApS, 2017). The quantity needed is 1.7-2 kg/m^2 at a 15 mm infill height (plus a shock pad). The total price for the cork infill on a standard field (160 m^2) would hence be approximately €23k-29k. Another Norwegian supplier quoted approximately €500 per tonne of cork infill material. Yet another source claimed that the total cost of cork infill on a full-sized football pitch would amount to approximately €16k, whereas the costs for SBR, EPDM, and TPE infills would be €10k, €115k, and €111k, respectively (Kristin Johansson 2018).

A Dutch life-cycle assessment performed by Ecotest in 2015 compared different polymeric infill materials with cork. The study primarily looked at the global warming potential (GWP) and costs of the various infill materials and concluded that cork had the lowest GWP and the third highest overall costs of the tested alternatives (Ecotest 2015).

Table 110 provides a summary of the results.

Table 110: Summary of life cycle assessment of two end-of-life tyre applications: artificial turfs and asphalt rubber (Kristin Johansson, 2018).

Infill material	Amount of infill material needed per full-sized pitch	Durability	Relative amount of refilling per year
Cork	8.3 tonnes	4 years	10%
SBR/ELT	52 tonnes	10 years	6%

[167] Cork is boiled so that cork cells expand into a tight 'honeycomb' cell structure thereby turning them into a smoother and more pliable form.

[168] https://deutschland.iaks.sport/sites/default/files/downloads/Best%20practices/2019-07/BIR%20document%20microplastic%20restriction%20-%20BIR.pdf.

[169] The consultation, comment #2156.

EPDM	77 tonnes	10 years	6%
TPE	65 tonnes	10 years	6%

Multiple suppliers stated that cork generally has a lower overall cost than other organic infill materials considering the total cost of maintaining a pitch because of limited compaction and less need for irrigation. However, they also stated that cork will need to be maintained and refilled more often than other non-organic granules due to its lower density. Because of the low density (< 1 g/cm^3) cork will float on water and therefore the material will discharge more easily with water and wind (PlanMiljø ApS, 2017). If not frequently and properly maintained, even cork infill can compact and become hard, which will negatively affect field performance and players' safety. Contrary to industry claims, PlanMiljø ApS (2017) found the overall environmental impact of cork to be relatively low because of the sustainable production and straightforward processing of the material.

Whilst in principle cork infill is—just as other organic infill materials—treated with an anti-microbial application to prevent deterioration of the infill over time. However, there are some cork infills available on the EU market that are not treated with an anti-microbial application. For example, DOMO® NATURAFILL cork does not need to be treated as it is naturally resistant to microbes. Likewise, FieldTurf® PureFill is not needing additional anti-microbial coating because its suberin component already serves as anti-microbial and anti-allergenic agent. There are other instances of cork infill brands claiming to be free of any anti-microbial coating/spraying needs, but it can be expected that the majority of pitches using cork as infill material will require the use of anti-microbial coating/spraying.

D.13.5.3. Organic infills other than cork

There are several organic infill materials available. These include coconut fibre, coconut husk, coconut peat, rice husks, sugar cane, fully biodegradable Saltex BioFill™ [170], walnut shells, etc. The products are often treated with an antimicrobial application to prevent deterioration and moulding of the infill material. There seems to be little experience regarding the durability of these materials and some concerns about break down of the organic material, pests, and compaction of the material over time have been reported (PlanMiljø ApS, 2017).

Cold weather can also impair the playability of turf pitches filled with organic materials, as the infill may become water-saturated and freeze. Reports of early degradation under harsh weather conditions in Nordic countries are common.

Organic infill materials generally require irrigation and regular maintenance, including de-compaction twice a year and replacement of 10% of the infill every 2-3 years because of loss through decomposition and wind throw (albeit this seems to be a no larger issue than with polymeric infill material). The organic materials may harden and blow or float away, leading to migration and accumulation in waterways, reduced

[170] https://marketplace.chemsec.org/Alternative/Saltex-BioFill-a-100-natural-and-environmentally-friendly-infill-material-for-artificial-turf-200.

performance capability of the turf court, and higher potential for injury.

There is potential for weed and mould growth and decomposition if biocides are not used (PlanMiljø ApS, 2017)[171]. Moreover, when organic infill material gets wet, favourable conditions for fungi may lead to unexpected health risks. Otherwise, organic infill is non-toxic and has generally a lower environmental impact in terms of total GHG emissions than polymeric infill materials. This said, long transportation distances of some organic materials should be considered when looking at environmental impacts.

At the end of its life cycle the organic material can be recycled directly into the environment through composting but cannot be reused as infill for new artificial turf fields (PlanMiljø ApS, 2017). Moreover, the biocide/pesticide content of used material has to be considered before dispersing it into the environment.

The price of common organic infill materials is relatively low compared to other alternative infill namely EPDM and TPE. However, prices vary considerably across materials and producers. Reportedly there is limited availability of organic infill (PlanMiljø ApS 2017), but this may change with increasing demand for such materials.

D.13.5.4. Non-infill systems

There are alternative technologies to artificial sports pitches that do not require infill material. For example, a yarn-based, carpet-like product (PlanMiljø ApS, 2017). For some systems there may be a size issue, but several full-size artificial fields (64 x 100 meters) have been installed in Norway. Not all of the non-infill fields currently meet FIFA quality standards and it has been observed that they are generally more difficult to play on than infill fields (PlanMiljø ApS 2017). In particular, the fibres may lie down during play (since there is not enough support around the filament) causing the ball to roll too fast.

However, some FIFA certified non-infill systems are available in the EU. One example is 'GreenFields FT XP 32 NF', which uses advanced fibrillated tape fibre and claims to offer high durability and an enhanced playing experience.[172] Generally speaking, there is a shorter guarantee on these fields, depending on how frequent they are used and the extent of maintenance. The average lifespan of the field has been estimated to be five years compared with the 10-year lifespan of a standard artificial turf (PlanMiljø ApS, 2017). One cost advantage of a non-infill system is that it does not need to be replenished but may need raking in the spring when snow has melted.

Prices for non-infill systems quoted in the Norwegian study were 16-29 €/m^2, depending on the pile height (PlanMiljø ApS 2017). The Dossier Submitter notes that these prices seem relatively low compared to RIVM's estimate of the excess cost for installing an artificial turf pitch without infill in the restriction on PAHs in rubber granules. Indeed, compared to a pitch using ELT infill, RIVM assumed excess costs of about 16 €/m^2 or €120 000 per average-sized football pitch.

[171] Claims supported in the consultation, comment #2406.

[172] https://www.greenfields.eu/products/tufted/GreenFields-FT-XP-32-NF

D.13.5.5. Existing regulatory provisions

There is no legislation directly regulating the use of artificial turf pitches in the EU. REACH requires the infill material used (a mixture under REACH) to comply with, for example, entry 28-30 of Annex XVII of REACH related to concentrations of CMRs in the infill material. A specific restriction on PAHs in infill material has just been assessed by ECHA's scientific committees and a legal limit value of 20 mg/kg for a combination of eight PAHs has been recommended. ECHA is also assessing if further restrictions are needed because of other substances contained in the granules that may pose a risk to human health or the environment.

D.13.6. Proposed action

D.13.6.1. Introduction

Based on the above assessment, the Dossier Submitter assumes that polymeric infill material accounts for emissions of 16 kilotonnes of microplastics per year. Many stakeholders have agreed in the consultation that these releases can and should be minimised either through targeted technical measures or the use of alternative infill materials. This suggests there is a public acceptance of need for an EU-wide action.

Accordingly, the Dossier Submitter has assessed the following options for reducing the emissions from polymeric infill material:

- Implementation of suitable RMMs to prevent or minimise emissions;
- Restricting the placing on the market of polymeric infill material (with and without transitional arrangements);
- Requirement for labelling and instructions for use as well as for reporting.

These options are analysed in more detail below.

D.13.6.2. Restriction options

D.13.6.2.1. Restriction on placing on the market of polymeric infill at entry into force (RO1)

This restriction option would ban the placing on the market of polymeric infill material meeting the criteria of microplastics from the entry into force of the proposed restriction, presumably sometime in mid-2021. In practice, this would mean that no polymeric infill material, namely SBR, EPDM, TPE, PE and PP would be available for sale in the EU after that date, thereby rendering the refilling of many existing artificial turf pitches impossible and thus compromising their playability. Because of the unavailability of polymeric infill material, existing artificial turf pitches using polymeric infill would either need to be shut down gradually or completely resurfaced as it is not possible to merely replace polymeric infill material by organic infill material. The shutdown of the existing polymeric infill-based turf pitches will have severely negative consequences for public health and wellbeing, the economy and society at large.

In this regard, various football associations have used UEFA's GROW SROI model to

measure the social return on investment from football mass participation.[173] For example, estimates for Scotland suggest that since 2015 direct contributions to the Scottish economy as a result of playing football amounts to €242.3m, whereas the economic impact of social benefits and healthcare savings from football participation over the same period are estimated to correspond to €352m and €763m, respectively.[174] Using the same model, Sweden has received a social return on investment equivalent to €1.9bn, out of which health service savings account for more than €1bn.[175] For Italy, socio-economic and health-related benefits from football participation have exceeded €3.0bn in 2017-2018.[176] The German Football Association (and its regional members) informed in the consultation on intentionally added microplastics that they estimated the welfare-benefits derived from playing football in Germany to be close to €6.7bn. Likewise, the English Football Association informed that football in England, much of which is increasingly played on artificial pitches, generates £10.8bn annually for the UK economy of which £2.1bn is economic value and £8.0bn is a value reflecting social wellbeing.[177] Similar arguments were put forward by football associations and leagues from other EU Member States.

Further to these large social opportunity costs, the Dossier Submitter notes that a complete ban on the placing on the market of polymeric infill material would affect the installation of new artificial pitches after the entry into force. Essentially, all newly installed artificial pitches would have to fully rely on either organic alternatives or non-infill systems. The former option would pose significant challenges in terms of availability of organic infill material and the alleged decrease in performance and safety standards associated with the use of organic vs. polymeric material. The latter option would result in increased installation costs, and, possibly, reduction in performance and non-compliance with certain FIFA criteria. Replacing artificial turf pitches with natural grass pitches is not a preferable and in certain urban areas not even a viable option, because of the high maintenance costs, the unavailability of high-quality grass stock, the sensitivity to weather conditions (e.g. in Nordic countries), and the decreased playability (see RIVM 2018).

For these reasons, the English and the German football associations explicitly dismiss an immediate ban of polymeric infill as 'excessive' and 'disproportionate' to the problem arising from emissions to the environment and state that such emissions could be further minimised or prevented with appropriate risk management measures.

Furthermore, the Dossier Submitter observes that an outright ban on the placing on the

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[173] The UEFA GROW SROI model is part of the UEFA GROW programme, see https://www.uefa.com/insideuefa/football-development/grow/. Although UEFA's GROW SROI model measures the social return on investment from football activities taking place on all types of pitches (not only artificial), it has to be noted here that a large portion of these activities do occur on artificial turf pitches, and as such the presented figures per country provide a good indication of the social value derived from playing football on artificial turf pitches.

[174] https://www.scottishfa.co.uk/media/4460/scottish-fa-uefa-sroi-digital-version-2.pdf.

[175] https://www.uefa.com/insideuefa/news/newsid=2598488.html.

[176] https://www.figc.it/media/97433/2019_0240_rc_interni_ingl_bassa.pdf.

[177] The consultation, comment #2621.

market of polymeric infill material, which currently corresponds to around 80% of all infill material used, would mean that annually over 1.4 million tonnes[178] of end-of-life tyres would have to be either sent for incineration/energy recovery or used for alternative recycling means such as the manufacture of infill material for gardening purposes, flooring, surfaces, athletic tracks, road underpavings, etc. However, the market demand for such alternative recycling uses is still limited and would thus impose extra costs. While the practice of using ELT in form of polymeric infill material may not be a sustainable solution to the tyre recycling problem, it does prolong the use life of carbon-rich material. On the other hand, it seems fair to note that a full ban of putting polymeric infill material on the EU market would address environmental concerns related to hazardous substances found frequently in ELT-derived infill material and as such creates regulatory co-benefits.[179]

D.13.6.2.2. Restriction on placing on the market of polymeric infill with a 6-year transitional period (RO2)

In responses to the consultation, it was suggested by more than a dozen respondents (all from Germany) that, if the use of polymeric infill were to be restricted, a transitional period of at least six years from entry into force would be needed to transition to alternative infill materials or technology without disrupting sports activities on existing synthetic sport fields. This claim was echoed by UEFA, which called in the consultation for "*(i) sector-specific transitional arrangements to assist UEFA and other sports bodies in the process of converting the existing surfaces, and (ii) for postponement of the 'blanket ban' element of the restriction from the initial entry into force date (approximately 2022), to a later date, potentially the final entry into force date (EiF plus 6 years) as specifically regards synthetic turf. This transitional period would guarantee to protect the practice of physical activity and preserve the socio-economic benefits deriving from it. Furthermore, it would give local authorities, sports federations and the industry, time to find viable alternatives to existing ones if further studies shall provide evidence of the hazards and risks associated with infills used in synthetic turf surfaces for human beings and the environment*."

The commentators argued that the six-year transitional period would allow for a gradual move towards artificial turf systems that either use organic infill material or are infill-free. The presumption thus is that all artificial turf pitches to be installed or refurbished during the transitional period would need to rely either on organic infill material or a non-infill system.[180] A sufficiently long transitional period would allow industry to gradually increase the availability of alternative infill material and turf systems so that the disruption of sports activities and the resulting negative impact on wellbeing could be

[178] ETRMA claims that in 2017 about 1.76 mt of end-of-life tires went through the material recovery route. In an earlier ETRMA report (p.5), it was suggested that *rubber granulate and powder* account for ~80% of the material recovery, followed by *civil engineering applications and public works*, and *dock fenders, blasting mats and reducing agent in steel mills and foundries*. This would suggest that at the 2017 level of tyre retirement about 1.4 mt of end-of-life tyres would have to find alternative markets in case of a complete ban on the placing of polymeric infill material on the EU market.

[179] https://www.rivm.nl/bibliotheek/rapporten/2018-0072.pdf.

[180] As a ballpark estimate it can be assumed that roughly 4 000 full-sized pitch equivalents (~10% of the existing fields) would have to be refurbished every year as their service life comes to an end.

limited. It would also help in spreading out the societal costs of a ban over a longer time horizon thereby allowing communities and clubs to replace their field at the end of its foreseen lifespan.

Akin to RO1, this restriction option would eventually entail negative externalities for the environment as, if no other markets could be found for this material, 1.4 million tonnes[34] of end-of-life tyres per year would have to be either sent for incineration/energy recovery or used for other recycling means (in as far as there is demand for such uses). As remarked for RO1, it would eliminate concerns related to substances in ELT-derived infill material that is hazardous for the environment.

Overall, it stands to reason that RO2 would address most of the immediate, negative impacts of RO1. However, RO2 might not guarantee continuous play on all the affected synthetic sports fields across the EU and would likely result in the premature replacement of a limited number (perhaps 10-20%) of existing fields that could have otherwise been used some years longer.[181]

D.13.6.2.3. Instruction-for-use and reporting requirements (RO3)

Under this restriction option it is foreseen to derogate the use of polymeric infill on artificial turf pitches but impose appropriate operational conditions (OCs) and Risk Management Measures (RMMs) to be identified on product labels and in instructions for use (IFU) of polymeric infill material. Labelling and IFU requirements would ensure that users of polymeric infill material (e.g. sport centres) are well informed about conditions of use to minimise releases to the environment. Sports facilities, clubs, municipalities and other entities who use polymeric infill material on their artificial turf pitches would be responsible for implementing 'best practice' operational measures, including among other things a series of regular awareness-raising campaigns targeted toward players.

The requirement would entail additional costs for industry in terms of designing and modifying labels or enhancing use descriptions. However, since labels are typically updated on a regular basis due to both regulatory requirements and market demands, it is expected that with a sufficiently long transitional period, a large part of these costs could be absorbed within the normal re-labelling cycle.

The proposed restriction would also encompass reporting requirements on quantities of polymeric infill material used and thereby improving the monitorability of the effectiveness of the restriction. Furthermore, it would serve the purpose of providing necessary information for decision-makers and enforcement authorities to consider further action. The reporting requirements would entail the creation of a reporting format or software for submitting and processing the information to regulators. One option would be that the European Chemicals Agency received information electronically from downstream users (sports centres, clubs and other entities owning infill-based artificial turf pitches) on the used volumes of infill material, as well as on existing appropriate risk

[181] Presuming that there are 40 000 artificial turf pitches and the average lifespan of a pitch is 10 years, then each year ~4 000 pitches need to be refurbished. If pitch owners (sports clubs, communities, regions) would learn by mid-2020 that 6 years after EiF a full ban would apply to polymeric infill material in the EU, they would have more than 8 years to replace existing pitches that are near the end of their lifespan by pitches that do not use polymeric infill material.

management measures for minimisation of infill-related emissions. While the electronic format will need to be designed to enable appropriate reporting, it is foreseeable that it would bear resemblance to the electronic reporting system currently in use for downstream users to notify ECHA of their use of an Annex XIV substance for an authorised use (Article 66 notifications).

Whereas labelling requirements would concern manufacturers and importers that place polymeric infill material on the EU market, reporting requirements would be imposed upon downstream users of the infill material. This makes sense given that these downstream users would implement the recommended OCs and RMMs and monitor that emissions are sufficiently minimised. Whilst labelling costs are thought to be relatively minor—particularly if a sufficiently long transition period was granted—costs borne by downstream users for implementing OCs and RMMs and for reporting are considerably higher. Whilst no detailed information is available on what it may cost to have emission minimisation measures implemented on all artificial turf pitches in the EU that would continue using polymeric infill material, the Dossier Submitter attempts a ballpark estimate of the cost in the analysis of RO4 (see Section D.13.6.2.4).

D.13.6.2.4. Derogation conditional on technical risk management measures being implemented (RO4)

Under this restriction option the use of polymeric infill material on artificial sports fields would be derogated subject to the condition that recommended technical measures would be implemented to minimise or prevent emissions of microplastics to the environment. In the consultation on intentionally added microplastics, many stakeholders have argued that targeted risk management measures would sufficiently reduce the release of infill material to environment, thereby obviating the need for restriction.

A range of specific risk management measures that are already in place in some Member States and for some pitches have been suggested (and will be summarised in greater detail in Section D.13.6.2.5). Moreover, the ESTC together with the European Standards Committee (CEN) have advocated that *CEN/TC 217 – Surfaces for sports areas*[182] develop a CEN Technical Report to promote the design and maintenance features that will minimise or eliminate infill migration from sports fields. The Technical Report will support European Standard *EN 15330-1: Specification for Synthetic Turf Sports Surfaces*. The European Standards Committee is currently seeking approval of the National Standards Bodies to approve the new work item and intends to publish the technical report in 2020. At the same time, the ESTC is trying to secure support of FIFA and World Rugby for the containment measures proposed in the technical report, and more importantly, to have them incorporated in the two governing bodies' field certification programmes.[183] The Dossier Submitter considers this a positive spillover effect that may reduce emissions of polymeric infill material in other jurisdictions.

[182] Technical standardization body in the field of surfaces for indoor and outdoor sports areas with a special regard to safety and performance requirements, test methods and environmental aspects.

[183] The consultation, comment #2140.

Moreover, in 2017 the ESTC published a guidance document on the ways of controlling infill migration from synthetic turf surfaces and plans to update this guidance in 2019. Besides a series of useful instructions on minimising infill emissions to the environment, the guideline includes examples of good practice, some of which are:

- Use of raised perimeter edge details;
- Use of entrance mats and metal foot-grills to capture infill that escaped a field;
- Use of slit traps or special filter areas in the drainage devices around the boundaries of fields and in changing rooms, etc.;
- Use of synthetic turf systems that either have a lower potential for infill movement using yarn profiles and stich rates that are designed to restrict infill movement and or the use of synthetic turf systems that require less infill;
- Use of infills that are less prone to movement and migration.

The Dossier Submitter welcomes this effort and considers that, should the ESTC succeed in ensuring that these measures and good practices are adopted by FIFA and World Rugby and embedded in their respective field certification programmes, it will become considerably easier to encourage pitch owners to take them up. The costs of implementing these measures and good practices will vary depending various factors including, the age and type of a pitch and the financial resources of the owner. Some of the relatively modern and state-of-the-art existing artificial turf fields would only need marginal modifications in design as they have already several of the proposed measures in place, whereas others would need some major changes (or be replaced by new systems).

In the consultation the cost for retrofitting existing artificial sports fields were indicated in the range of €3 000 to €60 000 per pitch. EU-wide, an average cost of €40 000 per full-sized pitch may be incurred for implementing recommended risk management measures. Assuming that today around 5% of the existing ~40 000 full-size pitch equivalents do not use any of the polymeric infill materials and that a fraction of pitches in Nordic countries and Germany have already measures in place (say about 20% of artificial turf pitches using polymeric infill material), one may assume that some 32 000 pitches would require additional measures to be taken; and if those measures cost on average €40 000 per pitch, then the overall cost of this requirement would be in the order of €1.28bn. However, older pitches would have to be replaced anyway and with a sufficiently long transitional period granted the cost of retrofitting can be expected to be succinctly lower.

Notwithstanding the hefty costs of implementing proposed risk management measures across the EU, a rough cost-effectiveness analysis suggests that the cost of preventing polymeric infill emissions to the environment is relatively low. Similarly, the downtime for retrofitting is relatively limited. As discussed in Section D.13.4, it stands to reason that an average full-sized pitch loses around 500 kg per year. If that loss were to be reduced to, say, 50 kg per year at the one-off expense of €40 000, then the cost-effectiveness over an average remaining lifespan of 5 years (the midpoint of the 10-year life expectancy of a 3rd generation artificial sports field) would suggest an abatement cost of less than €10 per kg of emission avoided.

D.13.6.2.5. Restriction option analysis

There are many ways of ranking these four restriction options. In Table 111, the Dossier Submitter presents its restriction option analysis scoring the ROs on four key dimensions from best (••••) to poorest (•) based on the detailed assessment of these dimensions presented in Sections D.13.6.2.1 to D.13.6.2.4. These dimensions were established based on effectiveness and proportionality considerations. The Dossier Submitter considered that all but the first option are implementable, enforceable and manageable and the result of the implementation of the proposed restriction can be duly monitored. While most effective, RO1 will not be practical and therefore not proportionate as it gives pitch owners too little time for the replacement of their existing artificial turf pitches.

The unweighted score count favours RO4 (derogation with technical RMMs implemented) and RO3 (instruction-for-use and reporting requirements) over the other two options. One may object that the key dimension of a restriction on intentionally used microplastics should be emission avoidance. Correspondingly, one may wish to give more weight to this dimension. A weighted score count giving twice as much weight to emission avoidance still favours RO4 (derogation with technical measures implemented) over the other three options. The conclusion that may be drawn from this analysis is that unless one favours emission reduction much more than the other dimensions, RO4 is likely to emerge as the best option. If one does indeed favour emission reductions over the other dimensions, then RO2 appears a practical and effective option.

Table 111: Dossier Submitter's restriction option analysis.

	RO1 Immediate ban	RO2 Transitioned ban	RO3 Instruction-for-use and reporting	RO4 Technical RMMs
Emission reduction	••••	•••	•	••
Investment costs	•	••	••••	•••
Opportunity costs	•	••	••••	•••
Public acceptance	•	••	•••	••••
Unweighted score count	**7**	**9**	**12**	**12**
Weighted score count	**11**	**12**	**13**	**14**

Given this preliminary ranking of restriction options the Dossier Submitter assessed the implementation costs for options RO2 and RO4 in some more detail with the premise that a transition period for RO4 should allow limiting emissions over a 20-year analytical horizon to the same extend than RO2. As long as RMMs cannot fully abate emissions this can only be achieved if a transition period for RO4 is shorter than the 6 years after EIF foreseen for RO2. Based on this premise, the Dossier Submitter constructed a stylised comparison between RO2 and RO4 using the implementation cost estimates reported in Table 112. It should be stressed that whilst these assumptions are subject to some uncertainty (relating to their representativeness for all artificial turf pitches in the EU),

the general conclusions reached in terms of implementation cost vs emission abatement are perhaps surprisingly robust.

Table 112: Assumptions maintained for the investment cost comparison.

A simple model of implementation cost IC_i for option i may now be devised:

	Best estimate	Range	Unit
Maintenance cost	10 000	[6 000-12 000]	€/pitch and year
Emission control cost	40 000	[3 000-60 000]	€/pitch
Replacement cost	200 000	[100 000-200 000]	€/pitch
No. affected pitches in EU28	32 000	n/a	Pitches in EU
Lifetime of an average pitch	10	[10-15]	Years
No. pitches to be replaced in an average year	3 200	n/a	No. pitches per year
Baseline emissions per field	500	[250-1 000]	kg/pitch and year
Effectiveness of measures	90	[80-95]	per cent
Residual emissions per field	50	[25-200]	kg/pitch and year
Cost multiplier for non-polymeric field	150	[125-200]	per cent

$$IC_i = \sum_{t=1}^{20} \frac{(RC_{i,t}+MC_{i,t}+CC_{i,t})}{(1+r)^t} - \sum_{t=1}^{20} \frac{(RC_{0,t}+MC_{0,t}+CC_{0,t})}{(1+r)^t} \text{ for } i=\{RO2,RO4\}$$

$$\text{s.t.} \sum_{t=1}^{20} RE_{RO4,t} = \sum_{t=1}^{20} RE_{RO2,t}.$$

In words, the model sums up the differences between cost streams (RC=replacement cost, MC=maintenance cost, CC=control cost, r=social discount rate) accruing under business as usual and the respective restriction option subject to the constraint that both RO2 and RO4 would emit the same quantities of polymeric infill material (RE=restriction effectiveness). Given the assumptions on implementation costs reported in Table 112, and the fact that RO2 foresees a transition period of 6 years after EiF, RO4 would require the implementation of RMMs appropriate in reducing annual emissions to 10% within 3 years after EiF. This then permits to obtain cost-effectiveness ratios of 33.3 €/kg of emissions avoided for RO2 and 4.5 €/kg of emissions avoided for RO4, respectively. As the residual emissions over the analytical horizon of 20 years (80 000 tonnes) are required to be the same under both options, one may directly compare the present value of implementation costs which amounts to €9.6bn for RO2 and €1.3bn for RO4, respectively. This finding supports the Dossier Submitter's qualitative restriction option analysis (Table 111) and suggests that a swift implementation of technical RMMs may be the most proportionate restriction option.

D.13.6.3. Conclusions

The Dossier Submitter concludes that i) all restriction options analysed are practical and monitorable, and ii) RO4 is likely to emerge as the best option unless the decision maker

favours emission reduction much more than any of the other key dimensions in which case RO2 is the most proportional option.

D.13.7. Impact of scope variations on the proportionality to risk

Not relevant.

D.14. Other uses

During the consultation, stakeholders reported additional uses for which no detailed impact assessment has been performed due to scarce or very limited information provided. As a consequence, these uses will be banned from placing on the market at entry into force of the restriction.

The sectors affected will be invited to provide relevant information, and a socio-economic impact assessment of the proposed restriction during the SEAC draft opinion consultation. Such information will allow SEAC to consider the need or not for other restriction options than a ban from placing on the market at entry into force.

The reported uses are listed below:

- Bulk IER for purification of water
- Substance or mixture used as a toy or for arts and crafts activities
- Substance or mixture used for the transportation of glass sheet

D.15. Option value theory

D.15.1. Introduction

This section provides an economic underpinning for why regulatory action in face of an uncertain harm may be justified by expected learning over time. The model presented below parallels research on the emission of greenhouse gases (GHG), as these have several aspects in common with microplastics pollution:

- just as GHG, microplastics are emitted by a myriad of individual point sources;
- it is prohibitively expensive and impractical to clean up environments from plastic particles which are, by definition, on the micrometre scale;
- as their degradation takes several thousands of years, microplastic releases into the environment are irreversible and a pollution stock has been building up.

There are also several distinctive features of the microplastics problem:

- microplastics are often the product of unintended releases, e.g. through decay and/or abrasion of larger plastics;
- in several applications they are not the undesired by-product of a beneficial use, but have an intrinsic function that makes their use beneficial in the first place;
- microplastics are less volatile than GHG, making them more stationary in the terrestrial environment (although they are eventually transported to the oceans);
- terrestrial stationarity allows for unilaterally reducing emissions and thereby the growth of the pollution stock in the EU (whilst GHG emission schemes are prone to issues of by-standing and free-riding by third countries);
- the potential harm of microplastics to humans and the environment is not yet well understood, but ongoing research initiatives are likely to substantially improve our understanding of microplastic pollution within the next decade;

- because of the lack of understanding, economic metrics such as the social cost of carbon do not exist and monetisation of the damages associated with emissions of (micro-) plastics to the environment is therefore not possible.

To summarise, the emission of microplastics into the environment causes irreversible effects. Irreversibility poses a challenge to conventional policy analysis, especially if the long-term consequences are poorly understood and cannot be priced with some degree of certainty (Traeger, 2014). It has been shown that, in such situations, restricting an activity may be optimal even if the expected costs of regulation outweigh the direct benefits (Gollier et al., 2000).

To provide intuition for this result, one has to consider the shortcomings of conventional benefit-cost analysis (BCA) in the context of irreversibility and uncertainty, both of which create a so-called 'option value' (Arrow and Fisher, 1974, Henry, 1974, Graham, 1981).[184] Building on these early accounts, Hanemann (1989) formalised a quasi-option value, which captures the value of learning under precaution. Independently, Dixit and Pindyck (1994) proposed a real option value capturing the net value of precaution under learning. In the context of microplastics, the latter value is of most relevance.

D.15.2. Model

This section presents an abstract model that helps in finding the optimal regulatory strategy when one is anticipating learning under an irreversibility constraint. Based on the model, the social values from undertaking and postponing regulatory action on microplastics in the presence or absence of learning are defined.

The problem setting follows the classical paper by Hanemann (1989). Consider two periods, t_1 and t_2. In t_1, the decision maker faces a discrete decision between restricting of continuing the use of microplastics. Let e_1 denote the emissions that go along with the decision not to restrict the use in t_1. If the decision maker restricts the use in the first period, he has the option to keep or revoke the restriction in t_2. However, if the decision maker decides not to curb emissions in the first period, then the emissions from that period stay in the environment. In t_1, the decision maker is uncertain about the costs and benefits of his actions but expects that this uncertainty is (at least partially) resolved before the beginning of the second period.[185]

Formally, the welfare problem is characterised by the function: $v(e_1, e_2, \theta) = u_1(e_1) + u_2(e_1, e_2, \theta)$, where e_1 and e_2 denote emissions in period one and two, respectively. The random variable θ represents the uncertain component of the problem which relates to the potential harm from a growing stock $E = e_1 + e_2$ of microplastics in the environment. The uncertainty about the value of θ is assumed to shrink over time as new information

[184] In this context, the concept of *option value* is best understood as the value that is given to preserving nature in such a condition that it is unrestrictedly available for future use.

[185] Alternatively, the decision to restrict can be interpreted as a sunk investment determining an uncertain future payoff (Traeger 2014). The decision maker may or may not invest in t_1; if he has not invested in t_1, he can still do so in t_2.

is expected to become available between t_1 and t_2 (Gollier et al., 2000).

A sophisticated decision maker anticipates that any decision in the second period will be based on better information than in the first period. In the second period, he will therefore maximise $u_2(e_1, e_2, \theta)$ subject to a given e_1 and the received information θ. The irreversibility constraint restricts the second period choice variable to the set $\{e_1,E\}$: if $e_1 > 0$ these emissions cannot be undone.

Anticipating the second period action, the decision maker optimises the first-period expected payoff by choosing the e_1 that is welfare maximising:

[1] $$\max_{e_1} \mathbb{E} \max_{e_2 \in \{e_1,E\}} v(e_1,e_2,\theta) = \max_{e_1} u_1(e_1) + \mathbb{E} \max_{e_2 \in \{e_1,E\}} u_2(e_1,e_2,\theta),$$

The optimal decision strategy is thus to first maximise second-period welfare for every possible realisation of θ and e_1, and then take expectations and optimise over first-period emissions e_1.[186]

To define the option value associated with a strategy of "first act, then learn", one may consider a set of present values with different degrees of sophistication (Traeger, 2014). The value of restricting emissions to a decision maker who does expect to learn more about the harmfulness of microplastics is defined as $V^L(0)=u_1(0)+\mathbb{E} \max_{e_2 \in \{0,E\}} u_2(0,e_2,\theta)$.

Analogously, the value of no action in the first period, that is following a "learn first, then act" strategy, is given by $V^L(e_1)=u_1(e_1)+\mathbb{E} \max_{e_2 \in \{e_1,E\}} u_2(e_1,E,\theta)$. If no learning is expected, then restricting results in a delay $V^P(0)=u_1(0)+ \max_{e_2 \in \{0,E\}} \mathbb{E}u_2(0,e_2,\theta)$, whilst continuing the use implies $V^P(e_1)=u_1(e_1)+ \max_{e_2 \in \{e_1,E\}} \mathbb{E}u_2(e_1,E,\theta)$. Finally, one could conceive of a myopic decision maker (or one who realises that there is only a limited window of opportunity for regulatory actions). That decision maker would either restrict in the first period or never, implying values $V^N(0)=u_1(0)+\mathbb{E}u_2(0,0,\theta)$ and $V^N(e_1)=u_1(e_1)+\mathbb{E}u_2(e_1,E,\theta)$. Traeger (2014) demonstrates how decision rule [1] may be used to derive the option value:

[2] $$OV \equiv \max\{V^L(0),V^L(e_1)\} - \max\{V^N(0),V^N(e_1)\}.$$

Adapted to the context of this restriction proposal, the option value corresponds to the maximum value obtained from having the possibility to restrict now or wait until later when new information about the potential harm of emitting microplastics is expected to become available, minus the maximum value obtained from the possibility to restrict now or never. Thus, the option value is a net value resulting from the avoidance of irreversible emissions conditional on learning that they are actually harmful. Since, under plausible assumptions $V^L(e_1) \geq V^N(e_1)$ and $V^L(0) \geq V^N(0)$, the option value is non-negative confirming that learning has a positive value for decision-making as it reduces uncertainty about the extent of harm associated with the emission of microplastics.[187]

[186] This type of optimization problem is typically solved recursively.

[187] The plausibility of these assumptions rests on the fact that $\mathbb{E} \max_{e_2 \in \{e_1,E\}} u_2(e_1,E,\theta) > \mathbb{E}u_2(e_1,E,\theta)$, which captures that upon learning the decision maker will be able to choose the optimal amount e_2.

D.15.3. Conclusion

Given the research efforts on microplastics currently under way, one can reasonably expect learning to take place and uncertainties to shrink over the next decades. Intuitively, this progress in understanding is of value to the decision maker. If the uncertainty relates to the extent of harm—as is the case with microplastics—and the emissions are irreversible, then the option value measures the net value from restricting the use of microplastics based on precautionary motives. As discussed in Section D.15.2, this suggests that whenever learning about a possible harm is expected to happen, regulatory action may be justifiable based on the option value one receives from avoiding irreversible effects. This may thus be invoked as one reason to support a "first act, then learn" approach over a "first learn, then act" approach.

This has been recognised in previous restriction proposals, e.g. on D4/D5 in wash-off products, wherein the Dossier Submitter argued that *"As certainty surrounding potential damage increases, option value should change and WTP should react. It is expected that greater certainty of toxicity will raise WTP. Were a substance known to cause no problems, we might expect zero WTP to reduce accumulation."* Although in this restriction proposal, no attempt has been made to monetise the potential harm from microplastics emission, the same conclusion holds mutatis mutandis.

Annex E. Appendix D.1

Table 113: Polymers/Ingredients used as the basis for the 'High' scenario (520-polymer scenario)[188]

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
CARBOMER	20-25%	20-25%
POLYETHYLENE	10-15%	5-10%
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER	10-15%	10-15%
ACRYLATES COPOLYMER	10-15%	10-15%
NYLON-12	10-15%	< 0.5 %
STYRENE/ACRYLATES COPOLYMER	5%	15-20%
POLYBUTENE	5-10%	< 0.5 %
POLYQUATERNIUM-7	<1%	30-35%
TRIMETHYLSILOXYSILICATE	5-10%	< 0.5 %
POLYMETHYL METHACRYLATE	5%	< 0.5 %
SODIUM POLYACRYLATE	5-10%	<5%
POLYMETHYLSILSESQUIOXANE	5%	< 0.5 %
POLYETHYLENE TEREPHTHALATE	5%	< 0.5 %
PVP	<5%	<2%
METHYL METHACRYLATE CROSSPOLYMER	<5%	< 0.5 %
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER	5-10%	<5%
POLYACRYLAMIDE	3-5%	<2%
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER	<2%	< 0.05 %
OCTYLACRYLAMIDE/ACRYLATES/BUTYLAMINOETHYL METHACRYLATE COPOLYMER	<2%	< 0.5 %
POLYVINYL BUTYRAL	<2%	< 0.05 %

[188] This list of polymers is used as the starting point for the 'high' costs scenario used to investigate the potential costs of a restriction on microplastic in cosmetic products. Inclusion on this list does not imply that ECHA considers that these polymers/ingredients would meet the regulatory definition of a microplastic. Based on the information available to the Dossier Submitter, it is not currently possible to conclude that all of the listed ingredients would fulfil the regulatory definition of a microplastic . The INCI (International Nomenclature of Cosmetic Ingredients) name is often insufficient for this purpose, or the properties of the polymer were not known or communicated to the Dossier Submitter. The same INCI name can be used to describe substances in a variety of physical states. Therefore, liquid (non solid) polymers and water soluble polymers (>2 g/L) have not been excluded from the list. In addition, film forming polymers (that could be derogated from the ban on placing on the market on the basis of paragraph 5b and biodegradable polymer (that could be completely derogated from the restriction on the basis of paragraph 3b) have also not been excluded. Please see Section D.5. Cosmetics for assumptions and approach, including section on "state" in D.5.1. Use and functions.

[189] The estimated occurrences have been calculated from two different data sources (Que Choisir, 2018 and CosmEthics, 2018) with consistent results which are presented in the two last columns of the table.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER	<2%	< 0.5 %
ETHYLENE/PROPYLENE/STYRENE COPOLYMER	<2%	< 0.05 %
BUTYLENE/ETHYLENE/STYRENE COPOLYMER	<1%	< 0.05 %
POLYVINYL ALCOHOL	<1%	< 0.5 %
ACRYLATES/OCTYLACRYLAMIDE COPOLYMER	<1%	< 0.05 %
POLYURETHANE-11	<1%	< 0.05 %
ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER	<1%	< 0.5 %
ACRYLATES/DIMETHICONE COPOLYMER	<1%	< 0.05 %
POLYQUATERNIUM-6	< 0.5 %	<5%
SODIUM ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER	<1%	<1%
ETHYLENE/PROPYLENE COPOLYMER	<1%	< 0.05 %
HYDROGENATED STYRENE/METHYL STYRENE/INDENE COPOLYMER	<1%	< 0.5 %
GLYCERYL ACRYLATE/ACRYLIC ACID COPOLYMER	<1%	< 0.5 %
SODIUM ACRYLATES COPOLYMER	<1%	< 0.5 %
OXIDIZED POLYETHYLENE	<1%	< 0.5 %
ETHYLENE/ACRYLIC ACID COPOLYMER	<1%	N.A.
STYRENE/ACRYLATES/AMMONIUM METHACRYLATE COPOLYMER	<1%	N.A.
GLYCERYL POLYMETHACRYLATE	<1%	< 0.5 %
POLYACRYLATE-13	<1%	< 0.5 %
POLYBUTYLENE TEREPHTHALATE	<1%	< 0.05 %
VA/CROTONATES/VINYL NEODECANOATE COPOLYMER	<1%	< 0.05 %
POLYLACTIC ACID	< 0.5 %	0.58%
DIVINYLDIMETHICONE/DIMETHICONE COPOLYMER	< 0.5 %	<2%
NYLON-6	<1%	< 0.05 %
POLYACRYLATE-4	<1%	N.A.
ACRYLONITRILE/METHYL METHACRYLATE/VINYLIDENE CHLORIDE COPOLYMER	<1%	< 0.05 %
ETHYLENEDIAMINE/STEARYL DIMER DILINOLEATE COPOLYMER	<1%	N.A.
ETHYLENE/VA COPOLYMER	< 0.5 %	< 0.05 %
ACRYLATES/POLYTRIMETHYLSILOXYMETHACRYLATE COPOLYMER	< 0.5 %	N.A.
LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER	< 0.5 %	< 0.5 %
ACRYLATES/T-BUTYLACRYLAMIDE COPOLYMER	< 0.5 %	< 0.05 %
GLYCERYL POLYACRYLATE	< 0.5 %	< 0.5 %
POLYPROPYLENE	< 0.5 %	< 0.05 %
ACRYLATES/STEARETH-20 METHACRYLATE COPOLYMER	< 0.5 %	0.80%
ACRYLATES/STEARYL ACRYLATE/DIMETHICONE METHACRYLATE COPOLYMER	< 0.5 %	N.A.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
HYDROGENATED STYRENE/ISOPRENE COPOLYMER	< 0.5 %	< 0.05 %
POLY C10-30 ALKYL ACRYLATE	< 0.5 %	< 0.05 %
POLYACRYLATE CROSSPOLYMER-6	< 0.5 %	< 0.5 %
POLYURETHANE-33	< 0.5 %	< 0.05 %
VP/DMAPA ACRYLATES COPOLYMER	< 0.5 %	< 0.5 %
ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER	< 0.5 %	< 0.5 %
ACRYLATES/BEHENETH-25 METHACRYLATE COPOLYMER	< 0.5 %	< 0.5 %
STYRENE/ACRYLAMIDE COPOLYMER	< 0.5 %	0.51%
VP/DIMETHYLAMINOETHYLMETHACRYLATE COPOLYMER	< 0.5 %	< 0.5 %
SODIUM LANETH-40 MALEATE/STYRENE SULFONATE COPOLYMER	< 0.5 %	< 0.5 %
ACRYLATES CROSSPOLYMER-4	< 0.05 %	<1%
ETHYLENE/METHACRYLATE COPOLYMER	< 0.5 %	N.A.
SODIUM STYRENE/ACRYLATES COPOLYMER	< 0.5 %	<1%
ACRYLAMIDOPROPYLTRIMONIUM CHLORIDE/ACRYLATES COPOLYMER	< 0.05 %	<1%
ACRYLATES/C12-22 ALKYL METHACRYLATE COPOLYMER	< 0.5 %	< 0.05 %
HYDROGENATED STYRENE/BUTADIENE COPOLYMER	< 0.5 %	< 0.05 %
AMMONIUM ACRYLATES COPOLYMER	< 0.5 %	< 0.05 %
ACRYLATES/ETHYLHEXYL ACRYLATE COPOLYMER	< 0.5 %	< 0.05 %
AMP-ACRYLATES COPOLYMER	< 0.5 %	< 0.05 %
ACRYLATES/PALMETH-25 ACRYLATE COPOLYMER	< 0.5 %	< 0.5 %
SODIUM POLYACRYLATE STARCH	< 0.5 %	< 0.05 %
SODIUM POLYSTYRENE SULFONATE	< 0.5 %	< 0.5 %
SODIUM POLYMETHACRYLATE	< 0.5 %	N.A.
STYRENE/VP COPOLYMER	< 0.5 %	< 0.5 %
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER	< 0.5 %	< 0.05 %
AMP-ACRYLATES/ALLYL METHACRYLATE COPOLYMER	< 0.5 %	< 0.05 %
POLYURETHANE-14	< 0.5 %	< 0.05 %
BUTYL ESTER OF PVM/MA COPOLYMER	< 0.5 %	< 0.05 %
VP/METHACRYLAMIDE/VINYL IMIDAZOLE COPOLYMER	< 0.5 %	< 0.5 %
POLYIMIDE-1	< 0.5 %	< 0.5 %
POLYVINYL ACETATE	< 0.5 %	< 0.05 %
AMMONIUM POLYACRYLATE	< 0.5 %	< 0.05 %
POLYACRYLATE-1 CROSSPOLYMER	< 0.05 %	0.56%
ACRYLATES CROSSPOLYMER	< 0.5 %	< 0.5 %
SODIUM ACRYLATES CROSSPOLYMER-2	< 0.5 %	< 0.5 %
ACRYLATES/HYDROXYESTERS ACRYLATES COPOLYMER	< 0.5 %	< 0.05 %

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
AMMONIUM ACRYLOYLDIMETHYLTAURATE/BEHENETH-25 METHACRYLATE CROSSPOLYMER	< 0.5 %	< 0.05 %
POLYURETHANE-15	< 0.5 %	N.A.
HYDROXYETHYL ACRYLATE/IPDI/PPG-15 GLYCERYL ETHER COPOLYMER	< 0.5 %	< 0.05 %
POLYACRYLATE-3	< 0.5 %	N.A.
ACRYLATES/AMMONIUM METHACRYLATE COPOLYMER	< 0.5 %	< 0.5 %
POLYAMIDE-5	< 0.5 %	N.A.
ACRYLIC ACID/ISOBUTYL ACRYLATE/ISOBORNYL ACRYLATE COPOLYMER	< 0.5 %	N.A.
POLYVINYL LAURATE	< 0.5 %	N.A.
POLYVINYLALCOHOL CROSSPOLYMER	< 0.5 %	< 0.05 %
BEHENYL DIMETHICONE/BIS-VINYLDIMETHICONE CROSSPOLYMER	< 0.5 %	N.A.
LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE COPOLYMER	< 0.5 %	< 0.05 %
NYLON 6/12	< 0.5 %	< 0.05 %
ACRYLATES/ACRYLAMIDE COPOLYMER	< 0.5 %	< 0.05 %
ACRYLATES/AMINOACRYLATES/C10-30 ALKYL PEG-20 ITACONATE COPOLYMER	N.A.	< 0.5 %
NYLON-12 FLUORESCENT BRIGHTENER 230 SALT	< 0.5 %	< 0.05 %
POLYURETHANE-35	< 0.5 %	< 0.05 %
ACRYLAMIDE/AMMONIUM ACRYLATE COPOLYMER	< 0.5 %	< 0.05 %
POLYVINYLCAPROLACTAM	< 0.5 %	< 0.05 %
VP/ACRYLATES/LAURYL METHACRYLATE COPOLYMER	< 0.5 %	N.A.
ACRYLATES/STEARETH-20 METHACRYLATE CROSSPOLYMER	< 0.5 %	< 0.5 %
ALLYL STEARATE/VA COPOLYMER	< 0.5 %	N.A.
TRIMETHYLSILOXYSILICATE/DIMETHICONOL CROSSPOLYMER	< 0.5 %	< 0.05 %
BUTYL ACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER	< 0.5 %	N.A.
POLYURETHANE-39	< 0.05 %	< 0.5 %
ALLYL METHACRYLATES CROSSPOLYMER	< 0.5 %	< 0.05 %
ACRYLATES/VINYL NEODECANOATE CROSSPOLYMER	< 0.05 %	< 0.5 %
AMMONIUM ACRYLOYLDIMETHYLTAURATE/STEARETH-25 METHACRYLATE CROSSPOLYMER	< 0.5 %	< 0.05 %
POLYURETHANE-6	< 0.5 %	N.A.
BUTYL ACRYLATE/HYDROXYPROPYL DIMETHICONE ACRYLATE COPOLYMER	< 0.5 %	N.A.
ACRYLAMIDE/SODIUM ACRYLATE COPOLYMER	< 0.5 %	< 0.05 %
POLYACRYLATE-22	< 0.5 %	N.A.
ACRYLATES/ETHYLHEXYL ACRYLATE CROSSPOLYMER	< 0.5 %	< 0.05 %
ACRYLATES/CARBAMATE COPOLYMER	< 0.5 %	N.A.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
METHACRYLOYL ETHYL BETAINE/ACRYLATES COPOLYMER	< 0.5 %	< 0.05 %
POLYESTER-1	< 0.5 %	N.A.
POLYURETHANE-1	< 0.5 %	< 0.05 %
SODIUM ACRYLATE/ACRYLOYLDIMETHYLTAURATE/DIMETHYLACRYLAMIDE CROSSPOLYMER	< 0.5 %	< 0.05 %
SODIUM ACRYLATES/BEHENETH-25 METHACRYLATE CROSSPOLYMER	< 0.5 %	< 0.05 %
HYDROXYETHYL ACRYLATE/METHOXYETHYL ACRYLATE COPOLYMER	< 0.5 %	< 0.05 %
POLYURETHANE-34	< 0.5 %	< 0.05 %
ACRYLIC ACID/ACRYLAMIDOMETHYL PROPANE SULFONIC ACID COPOLYMER	< 0.05 %	< 0.5 %
ACRYLATES/C10-30 ALKYL METHACRYLATE COPOLYMER	< 0.05 %	< 0.05 %
ACRYLATES/C26-29 OLEFIN COPOLYMER	< 0.05 %	< 0.05 %
ACRYLATES/ETHYLHEXYL ACRYLATE/DIMETHICONE METHACRYLATE COPOLYMER	< 0.05 %	N.A.
C30-38 OLEFIN/ISOPROPYL MALEATE/MA COPOLYMER	< 0.05 %	N.A.
CROTONIC ACID/VINYL C8-12 ISOALKYL ESTERS/VA/BIS-VINYLDIMETHICONE CROSSPOLYMER	< 0.05 %	N.A.
ISOBUTYLMETHACRYLATE/BIS-HYDROXYPROPYL DIMETHICONE ACRYLATE COPOLYMER	< 0.05 %	N.A.
NYLON-6/12	< 0.05 %	N.A.
NYLON-11	< 0.05 %	< 0.5 %
POLYSTYRENE	< 0.05 %	< 0.05 %
ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE/ACRYLIC ACID COPOLYMER	< 0.05 %	< 0.05 %
ACRYLATES/PEG-10 MALEATE/STYRENE COPOLYMER	< 0.05 %	< 0.5 %
VP/VINYL CAPROLACTAM/DMAPA ACRYLATES COPOLYMER	< 0.05 %	N.A.
POLYMETHYL ACRYLATE	< 0.05 %	N.A.
ACRYLATES/STEARETH-20 ITACONATE COPOLYMER	< 0.05 %	< 0.05 %
DIVINYLDIMETHICONE/DIMETHICONE CROSSPOLYMER	< 0.05 %	< 0.05 %
POLYACRYLATE-33	< 0.05 %	< 0.5 %
POLYETHYLACRYLATE	< 0.05 %	< 0.05 %
BUTYLENE/ETHYLENE COPOLYMER	< 0.05 %	< 0.05 %
C8-22 ALKYL ACRYLATES/METHACRYLIC ACID CROSSPOLYMER	< 0.05 %	N.A.
POLYAMIDE-1	< 0.05 %	< 0.05 %
SODIUM ACRYLATE/ACRYLONITROGENS COPOLYMER	< 0.05 %	< 0.05 %
VA/BUTYL MALEATE/ISOBORNYL ACRYLATE COPOLYMER	< 0.05 %	N.A.
VA/VINYL BUTYL BENZOATE/CROTONATES COPOLYMER	< 0.05 %	N.A.
ACRYLATES CROSSPOLYMER-3	< 0.05 %	< 0.05 %

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
ACRYLATES/DIMETHYLAMINOETHYL METHACRYLATE COPOLYMER	< 0.05 %	N.A.
ETHYLENEDIAMINE/STEARYL DIMER TALLATE COPOLYMER	< 0.05 %	N.A.
POLYURETHANE CROSSPOLYMER-2	< 0.05 %	< 0.5 %
VINYL DIMETHICONE/LAURYL DIMETHICONE CROSSPOLYMER	< 0.05 %	< 0.05 %
ACRYLATES/STEARYL ACRYLATE/ETHYLAMINE OXIDE METHACRYLATE COPOLYMER	< 0.05 %	N.A.
ETHALKONIUM CHLORIDE ACRYLATE/HEMA/STYRENE COPOLYMER	N.A.	< 0.5 %
POLYACRYLATE CROSSPOLYMER-11	< 0.05 %	< 0.05 %
POLYURETHANE-2	< 0.05 %	N.A.
ACRYLATES/C1-2 SUCCINATES/HYDROXYACRYLATES COPOLYMER	< 0.05 %	< 0.05 %
ACRYLATES/CETETH-20 ITACONATE COPOLYMER	< 0.05 %	< 0.5 %
AMMONIUM ACRYLOYL DIMETHYLTAURATE/CARBOXYETHYL ACRYLATE CROSSPOLYMER	< 0.05 %	< 0.05 %
AMMONIUM ACRYLOYLDIMETHYLTAURATE/STEARETH-8 METHACRYLATE COPOLYMER	< 0.05 %	< 0.05 %
CETYL DIMETHICONE/BIS-VINYLDIMETHICONE CROSSPOLYMER	< 0.05 %	N.A.
ISOBUTYLENE/STYRENE COPOLYMER	< 0.05 %	< 0.05 %
POLYACRYLATE-14	< 0.05 %	N.A.
POLYACRYLATE-16	< 0.05 %	N.A.
POLYACRYLATE-2 CROSSPOLYMER	< 0.05 %	< 0.05 %
ACETOPHENONE/OXYMETHYLENE COPOLYMER	< 0.05 %	N.A.
DIMETHYL ACRYLAMIDE/HYDROXYETHYL ACRYLATE/METHOXYETHYL ACRYLATE COPOLYMER	< 0.05 %	N.A.
ISOBUTYLENE/SODIUM MALEATE COPOLYMER	< 0.05 %	N.A.
SODIUM ACRYLATES CROSSPOLYMER	< 0.05 %	< 0.05 %
STARCH/ACRYLATES/ACRYLAMIDE COPOLYMER	< 0.05 %	N.A.
STEARETH-10 ALLYL ETHER/ACRYLATES COPOLYMER	< 0.05 %	< 0.05 %
STYRENE/BUTADIENE COPOLYMER	< 0.05 %	< 0.05 %
ACRYLATES/C5-8 ALKYL ACRYLATE COPOLYMER	< 0.05 %	< 0.05 %
ACRYLATES/STEARYL METHACRYLATE COPOLYMER	< 0.05 %	< 0.05 %
ACRYLATES/TRIDECYL ACRYLATE/TRIETHOXYSILYLPROPYL METHACRYLATE/DIMETHICONE METHACRYLATE COPOLYMER	< 0.05 %	N.A.
AMMONIUM STYRENE/ACRYLATES COPOLYMER	< 0.05 %	< 0.05 %
DIMETHYLACRYLAMIDE/ETHYLTRIMONIUM CHLORIDE METHACRYLATE COPOLYMER	< 0.05 %	< 0.05 %
METHYLSTYRENE/VINYLTOLUENE COPOLYMER	< 0.05 %	N.A.
POLYPROPYLENE TEREPHTHALATE	< 0.05 %	< 0.05 %

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
POLYURETHANE-20	< 0.05 %	< 0.05 %
POTASSIUM ACRYLATES COPOLYMER	< 0.05 %	< 0.05 %
SODIUM METHOXY PEG-16 MALEATE/STYRENE SULFONATE COPOLYMER	< 0.05 %	N.A.
ACRYLATES/VA COPOLYMER	< 0.05 %	N.A.
ACRYLOYL DIMETHYL TAURATE/MELAMINE/PEG- METHACRYLATE CROSSPOLYMER	< 0.05 %	< 0.05 %
AMP-ACRYLATES/DIACETONEACRYLAMIDE COPOLYMER	< 0.05 %	N.A.
DEA-STYRENE/ACRYLATES/DVB COPOLYMER	< 0.05 %	N.A.
GLYCERYLAMIDOETHYL METHACRYLATE/STEARYL METHACRYLATE COPOLYMER	< 0.05 %	< 0.05 %
GLYCOL DIMETHACRYLATE CROSSPOLYMER	< 0.05 %	N.A.
HYDROGENATED BUTYLENE/ETHYLENE/STYRENE COPOLYMER	< 0.05 %	N.A.
HYDROGENATED ETHYLENE/PROPYLENE/STYRENE COPOLYMER	< 0.05 %	< 0.05 %
METHYL METHACRYLATE CROSSPOLYMER-2	< 0.05 %	< 0.05 %
POLYACRYLATE CROSSPOLYMER-7	< 0.05 %	< 0.05 %
POLYACRYLATE-1	< 0.05 %	N.A.
POLYISOBUTYL METHACRYLATE	< 0.05 %	N.A.
POTASSIUM ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER	< 0.05 %	< 0.05 %
STYRENE/STEARYL METHACRYLATE CROSSPOLYMER	< 0.05 %	< 0.05 %
ACRYLATES/DIMETHICONOL ACRYLATE COPOLYMER	< 0.05 %	< 0.05 %
BUTYL METHACRYLATE/DMAPA ACRYLATES/VINYLACETAMIDE CROSSPOLYMER	< 0.05 %	N.A.
BUTYLAMINOETHYL METHACRYLATE CROSSPOLYMER	< 0.05 %	< 0.05 %
BUTYLENE/ETHYLENE/PROPYLENE COPOLYMER	< 0.05 %	N.A.
CETEARYL DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER	< 0.05 %	N.A.
ETHYLENE/MA COPOLYMER	< 0.05 %	N.A.
ETHYLENE/SODIUM ACRYLATE COPOLYMER	< 0.05 %	< 0.05 %
ETHYLENEDIAMINE/HYDROGENATED DIMER DILINOLEATE COPOLYMER BIS-DI-C14-18 ALKYL AMIDE	< 0.05 %	N.A.
METHYL METHACRYLATE/PEG/PPG-4/3 METHACRYLATE CROSSPOLYMER	< 0.05 %	N.A.
NYLON 12	< 0.05 %	N.A.
POLYACRYLATE-32	N.A.	< 0.05 %
POLYPROPYLENE TEREPHTHALTE	N.A.	< 0.05 %
SODIUM ACRYLATE/VINYL ALCOHOL COPOLYMER	< 0.05 %	< 0.05 %
SODIUM STYRENE/MA COPOLYMER	< 0.05 %	N.A.
STYRENE/ACRYLATES/DIMETHICONE COPOLYMER	< 0.05 %	N.A.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
STYRENE/METHYLSTYRENE COPOLYMER	< 0.05 %	< 0.05 %
TRIMETHYLSILOXYSILICATE/DIMETHICONE CROSSPOLYMER	< 0.05 %	< 0.05 %
ACRYLATES/DIMETHICONE METHACRYLATE COPOLYMER	< 0.05 %	N.A.
ACRYLATES/METHACRYLAMIDE COPOLYMER	< 0.05 %	N.A.
ACRYLATES/PALMETH-25 ITACONATE COPOLYMER	< 0.05 %	< 0.05 %
ACRYLONITRILE/METHACRYLONITRILE/METHYL METHACRYLATE COPOLYMER	< 0.05 %	< 0.05 %
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VINYL FORMAMIDE COPOLYMER	< 0.05 %	N.A.
BUTYL ESTER OF ETHYLENE/MA COPOLYMER	< 0.05 %	N.A.
C5-6 OLEFIN/STYRENE COPOLYMER	< 0.05 %	< 0.05 %
DIMETHYLACRYLAMIDE/ACRYLIC ACID/POLYSTYRENE ETHYL METHACRYLATE COPOLYMER	< 0.05 %	N.A.
LAURYL ACRYLATE CROSSPOLYMER	< 0.05 %	N.A.
METHYL METHACRYLATE/ACRYLONITRILE COPOLYMER	< 0.05 %	N.A.
PEG/PPG-25/25 DIMETHICONE/ACRYLATES COPOLYMER	< 0.05 %	N.A.
POLYACRYLATE-15	< 0.05 %	< 0.05 %
POLYACRYLATE-2	< 0.05 %	N.A.
POLYETHYLENE ISOTEREPHTHALATE	< 0.05 %	N.A.
POLYETHYLMETHACRYLATE	< 0.05 %	N.A.
POLYSTYRENE/HYDROGENATED POLYISOPENTENE COPOLYMER	< 0.05 %	N.A.
POLYURETHANE-10	< 0.05 %	N.A.
POLYURETHANE-25	< 0.05 %	< 0.05 %
PVP/VA/VINYL PROPIONATE COPOLYMER	< 0.05 %	< 0.05 %
STYRENE/ACRYLATES/DIMETHICONE ACRYLATE CROSSPOLYMER	< 0.05 %	< 0.05 %
STYRENE/VA COPOLYMER	< 0.05 %	N.A.
VINYLDIMETHYL/TRIMETHYLSILOXYSILICATE STEARYL DIMETHICONE CROSSPOLYMER	< 0.05 %	N.A.
ACRYLATES/C12-13 ALKYL METHACRYLATES/METHOXYETHYL ACRYLATE CROSSPOLYMER	N.A.	< 0.05 %
ACRYLATES/DIETHYLAMINOETHYL METHACRYLATE/ETHYLHEXYL ACRYLATE COPOLYMER	< 0.05 %	N.A.
ACRYLATES/DIMETHICONE METHACRYLATE/ETHYLHEXYL ACRYLATE COPOLYMER	< 0.05 %	N.A.
ACRYLATES/ETHYLAMINE OXIDE METHACRYLATE COPOLYMER	< 0.05 %	N.A.
ACRYLATES/ETHYLHEXYL ACRYLATE/HEMA COPOLYMER	< 0.05 %	N.A.
ACRYLATES/ETHYLHEXYL ACRYLATE/HEMA/STYRENE COPOLYMER	< 0.05 %	N.A.
ACRYLATES/ETHYLHEXYL ACRYLATE/STYRENE COPOLYMER	< 0.05 %	N.A.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
ACRYLATES/LAURYL ACRYLATE/STEARYL ACRYLATE/ETHYLAMINE OXIDE METHACRYLATE COPOLYMER	< 0.05 %	N.A.
ACRYLATES/OCTYLACRYLAMIDE/DIPHENYL AMODIMETHICONE COPOLYMER	< 0.05 %	N.A.
ACRYLATES/VP COPOLYMER	< 0.05 %	N.A.
ACRYLIC ACID/ACRYLONITROGENS COPOLYMER	N.A.	< 0.05 %
ACRYLIC ACID/STEARYL ACRYLATE COPOLYMER	< 0.05 %	N.A.
ACRYLIC ACID/STEARYL METHACRYLATE/DIMETHICONE METHACRYLATE COPOLYMER	< 0.05 %	N.A.
AMMONIUM ACRYLATES/ACRYLONITROGENS COPOLYMER	< 0.05 %	N.A.
AMMONIUM VA/ACRYLATES COPOLYMER	< 0.05 %	N.A.
AMP-ACRYLATE/C1-18 ALKYL ACRYLATES/C1-8 ALKYL ACRYLAMIDE COPOLYMER	< 0.05 %	N.A.
AMP-ACRYLATES/C1-18 ALKYL ACRYLATE/C1-8 ALKYL ACRYLAMIDE COPOLYMER	< 0.05 %	N.A.
BEHENYL METHACRYLATE/T-BUTYL METHACRYLATE COPOLYMER	< 0.05 %	N.A.
BIS-VINYLDIMETHICONE CROSSPOLYMER	< 0.05 %	N.A.
BUTYL ACRYLATE/CYCLOHEXYL METHACRYLATE COPOLYMER	< 0.05 %	N.A.
BUTYL ACRYLATE/ETHYLTRIMONIUM CHLORIDE METHACRYLATE/STYRENE COPOLYMER	N.A.	< 0.05 %
BUTYL ACRYLATE/STYRENE COPOLYMER	< 0.05 %	N.A.
C12-22 ALKYL ACRYLATE/HYDROXYETHYLACRYLATE COPOLYMER	< 0.05 %	N.A.
C26-28 ALKYLDIMETHYLSILYL POLYPROPYLSILSESQUIOXANE	< 0.05 %	N.A.
C6-14 PERFLUOROALKYLETHYL ACRYLATE/HEMA COPOLYMER	< 0.05 %	N.A.
ETHYLENE/CALCIUM ACRYLATE COPOLYMER	< 0.05 %	N.A.
ETHYLENE/OCTENE COPOLYMER	N.A.	< 0.05 %
HYDROXYETHYL/METHOXYETHYL ACRYLATE/ BUTYL ACRYLATE COPOLYMER	< 0.05 %	N.A.
LAURYL METHACRYLATE/SODIUM METHACRYLATE CROSSPOLYMER	< 0.05 %	N.A.
METHACRYLIC ACID/STYRENE/VP COPOLYMER	< 0.05 %	N.A.
PHENOL/STYRENE/METHYLSTYRENE COPOLYMER	< 0.05 %	N.A.
POLYACRYLATE CROSSPOLYMER-4	< 0.05 %	N.A.
POLYACRYLATE-10	N.A.	< 0.05 %
POLYACRYLATE-11	< 0.05 %	N.A.
POLYACRYLATE-30	< 0.05 %	N.A.
POLYBUTYL METHACRYLATE	< 0.05 %	N.A.
POLYDIMETHYLAMINOETHYL METHACRYLATE	< 0.05 %	N.A.
POLYETHYLENE NAPHTHALATE	< 0.05 %	N.A.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
POLYHYDROXYETHYLMETHACRYLATE	< 0.05 %	N.A.
POLYPROPYL METHACRYLATE	< 0.05 %	N.A.
POLYURETHANE CROSSPOLYMER-1	< 0.05 %	N.A.
POLYURETHANE-17	< 0.05 %	N.A.
POLYURETHANE-7	N.A.	< 0.05 %
POLYVINYL CHLORIDE	N.A.	< 0.05 %
POLYVINYL STEARYL ETHER	< 0.05 %	N.A.
POTASSIUM ACRYLATES/ETHYLHEXYL ACRYLATE COPOLYMER	< 0.05 %	N.A.
SODIUM ACRYLATE/SODIUM ACRYLAMIDOMETHYLPROPANE SULFONATE COPOLYMER	< 0.05 %	N.A.
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE/ACRYLAMIDE COPOLYMER	< 0.05 %	N.A.
SODIUM ACRYLATES/ACROLEIN COPOLYMER	< 0.05 %	N.A.
SODIUM MA/DIISOBUTYLENE COPOLYMER	N.A.	< 0.05 %
STEARYL/LAURYL METHACRYLATE CROSSPOLYMER	< 0.05 %	N.A.
STYRENE/ACRYLATES COPOLYMER/POLYURETHANE	N.A.	< 0.05 %
STYRENE/METHYLSTYRENE/INDENE COPOLYMER	< 0.05 %	N.A.
TEA-ACRYLATES/ETHYLHEXYL ACRYLATE COPOLYMER	< 0.05 %	N.A.
VA/VINYL CHLORIDE COPOLYMER	< 0.05 %	N.A.
ACETYLENEDIUREA/FORMALDEHYDE/TOSYLAMIDE CROSSPOLYMER	N.A.	N.A.
ACROLEIN/ACRYLIC ACID COPOLYMER	N.A.	N.A.
ACRYLAMIDE/ETHALKONIUM CHLORIDE ACRYLATE COPOLYMER	N.A.	N.A.
ACRYLAMIDE/ETHYLTRIMONIUM CHLORIDE ACRYLATE/ETHALKONIUM CHLORIDE ACRYLATE COPOLYMER	N.A.	N.A.
ACRYLAMIDES/DMAPA ACRYLATES/METHOXY PEG METHACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/ACETOACETOXYETHYL METHACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/BEHENETH-25 METHACRYLATE/STEARETH-30 METHACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/BEHENYL ACRYLATE/DIMETHICONE METHACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/BEHENYL METHACRYLATE/DIMETHICONE METHACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/BIS-HYDROXYPROPYL DIMETHICONE CROSSPOLYMER	N.A.	N.A.
ACRYLATES/CETEARETH-20 METHACRYLATE CROSSPOLYMER	N.A.	N.A.
ACRYLATES/CETEARETH-25 METHACRYLATE/METHACRYLAMIDE CROSSPOLYMER	N.A.	N.A.
ACRYLATES/CETETH-20 METHACRYLATE COPOLYMER	N.A.	N.A.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
ACRYLATES/DIACETONEACRYLAMIDE COPOLYMER	N.A.	N.A.
ACRYLATES/ETHYLHEXYL ACRYLATE/GLYCIDYL METHACRYLATE CROSSPOLYMER	N.A.	N.A.
ACRYLATES/ETHYLHEXYLACRYLAMIDE COPOLYMER	N.A.	N.A.
ACRYLATES/HYDROXYETHYL ACRYLATE/LAURYL ACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/HYDROXYETHYL ACRYLATE/METHOXYETHYL ACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/LAURETH-25 METHACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/LAURYL METHACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/LAURYL METHACRYLATE/TRIDECYL METHACRYLATE CROSSPOLYMER	N.A.	N.A.
ACRYLATES/METHOXY PEG-15 METHACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/METHOXY PEG-23 METHACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/METHOXY PEG-23 METHACRYLATE/PERFLUOROOCTYL ETHYL ACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/METHOXY PEG-4 METHACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/PEG-4 DIMETHACRYLATE CROSSPOLYMER	N.A.	N.A.
ACRYLATES/PROPYL TRIMETHICONE METHACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/RHUS VERNICIFLUA SAP EXTRACT CROSSPOLYMER	N.A.	N.A.
ACRYLATES/STEARETH-30 METHACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/STEARETH-50 ACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/TDI/TRIMETHYLOLPROPANE COPOLYMER	N.A.	N.A.
ACRYLATES/TRIFLUOROPROPYLMETHACRYLATE/POLYTRIMETHYL SILOXYMETHACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/TRIS(TRIMETHYLSILOXY)SILYLPROPYL METHACRYLATE COPOLYMER	N.A.	N.A.
ACRYLATES/VA CROSSPOLYMER	N.A.	N.A.
ACRYLATES/VP/DIMETHYLAMINOETHYL METHACRYLATE/DIACETONE ACRYLAMIDE/HYDROXYPROPYL ACRYLATE COPOLYMER	N.A.	N.A.
ACRYLIC ACID/C12-22 ALKYL ACRYLATE COPOLYMER	N.A.	N.A.
ACRYLIC ACID/ISOBORNYL METHACRYLATE/ISOBUTYL METHACRYLATE COPOLYMER	N.A.	N.A.
ACRYLIC ACID/PHOSPHORYLCHOLINE GLYCOL ACRYLATE CROSSPOLYMER	N.A.	N.A.
ACRYLONITRILE/BUTADIENE/STYRENE COPOLYMER	N.A.	N.A.
ACRYLONITRILE/GLYCOL DIMETHACRYLATE CROSSPOLYMER	N.A.	N.A.
ACRYLOYL DIMETHYL TAURATE/MELAMINE/PEG-6 METHACRYLATE/PHLOROGLUCINOL CROSSPOLYMER	N.A.	N.A.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
ALLYL METHACRYLATE/GLYCOL DIMETHACRYATE CROSSPOLYMER	N.A.	N.A.
AMINOETHYLACRYLATE PHOSPHATE/ACRYLATES COPOLYMER	N.A.	N.A.
AMINOETHYLPROPANEDIOL-ACRYLATES/ACRYLAMIDE COPOLYMER	N.A.	N.A.
AMINOETHYLPROPANEDIOL-AMPD-ACRYLATES/DIACETONEACRYLAMIDE COPOLYMER	N.A.	N.A.
AMMONIUM ACRYLATES/ETHYLHEXYL ACRYLATE COPOLYMER	N.A.	N.A.
AMMONIUM ACRYLATES/METHYL STYRENE/STYRENE COPOLYMER	N.A.	N.A.
AMMONIUM ACRYLOYLDIMETHYLTAURATE/LAURETH-7 METHACRYLATE COPOLYMER	N.A.	N.A.
AMMONIUM STYRENE/ACRYLATES/ETHYLHEXYL ACRYLATE/LAURYL ACRYLATE COPOLYMER	N.A.	N.A.
AMP-ACRYLATES/C1-18 ALKYL ACRYLATE/C1-8 ALKYL ACRYLAMIDE/HYDROXYETHYLACRYLATE COPOLYMER	N.A.	N.A.
AMP-ACRYLATES/DIMETHYLAMINOETHYLMETHACRYLATE COPOLYMER	N.A.	N.A.
AMP-ACRYLATES/ETHYLHEXYL ACRYLATE COPOLYMER	N.A.	N.A.
AMPD-ACRYLATES/DIACETONEACRYLAMIDE COPOLYMER	N.A.	N.A.
BEHENYL METHACRYLATE/ETHYLAMINE OXIDE METHACRYLATE COPOLYMER	N.A.	N.A.
BEHENYL METHACRYLATE/PERFLUOROOCTYLETHYL METHACRYLATE COPOLYMER	N.A.	N.A.
BIS-HYDROXYETHYL ACRYLATE POLY(NEOPENTYL GLYCOL ADIPATE)/IPDI COPOLYMER	N.A.	N.A.
BIS-HYDROXYETHYL ACRYLATE POLYNEOPENTYL GLYCOL ADIPATE/TDI COPOLYMER	N.A.	N.A.
BIS-HYDROXYPROPYLMETHACRYLATE POLY(1,4-BUTANEDIOL)-9/IPDI COPOLYMER	N.A.	N.A.
BIS-PENTAERYTHRITYL DIACRYLATE/IPDI COPOLYMER	N.A.	N.A.
BIS-VINYL DIPHENYL DIMETHICONE	N.A.	N.A.
BUTENE/PROPYLENE COPOLYMER	N.A.	N.A.
BUTYL ACRYLATE/C6-14 PERFLUOROALKYLETHYL ACRYLATE/MERCAPTOPROPYL DIMETHICONE COPOLYMER	N.A.	N.A.
BUTYL ACRYLATE/ETHYLHEXYL METHACRYLATE COPOLYMER	N.A.	N.A.
BUTYL ACRYLATE/HYDROXYETHYL METHACRYLATE COPOLYMER	N.A.	N.A.
BUTYL ACRYLATE/ISOPROPYLACRYLAMIDE/PEG-18 DIMETHACRYLATE CROSSPOLYMER	N.A.	N.A.
BUTYL BENZOIC ACID/PHTHALIC ANHYDRIDE/TRIMETHYLOLETHANE COPOLYMER	N.A.	N.A.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
BUTYL DIMETHICONE ACRYLATE/CYCLOHEXYLMETHACRYLATE/ETHYLHEXYL ACRYLATE COPOLYMER	N.A.	N.A.
BUTYL POLYDIMETHYLSILOXYL ETHYLENE/PROPYLENE/VINYLNORBORNENE COPOLYMER	N.A.	N.A.
BUTYLDIMETHICONE METHACRYLATE/METHYL METHACRYLATE CROSSPOLYMER	N.A.	N.A.
C18-22 ALKYL PEG-25 METHACRYLATE/DIETHYLAMINOETHYL METHACRYLATE COPOLYMER	N.A.	N.A.
C20-24 OLEFIN/OLEYL ALCOHOL COPOLYMER	N.A.	N.A.
C4-6 OLEFIN/STYRENE COPOLYMER	N.A.	N.A.
C4-8 ALKYL ACRYLATE/HEMA COPOLYMER	N.A.	N.A.
C8-22 ALKYL ACRYLATE/BUTYL DIMETHICONE METHACRYLATE COPOLYMER	N.A.	N.A.
CETYL HEXACOSYL DIMETHICONE/BIS-VINYLDIMETHICONE CROSSPOLYMER	N.A.	N.A.
CORN STARCH/ACRYLAMIDE/SODIUM ACRYLATE COPOLYMER	N.A.	N.A.
CYCLOHEXYL METHACRYLATE/ETHYLHEXYL METHACRYLATE COPOLYMER	N.A.	N.A.
DICYCLOPENTADIENE/ISOPENTENE/ISOPRENE/STYRENE COPOLYMER	N.A.	N.A.
DIETHYLAMINOETHYL METHACRYLATE/HEMA/PERFLUOROHEXYLETHYL METHACRYLATE CROSSPOLYMER	N.A.	N.A.
DIMETHYLAMINOETHYLMETHACRYLATE/HEMA/LAURYL METHACRYLATE COPOLYMER	N.A.	N.A.
DMAPA ACRYLATES/ACRYLIC ACID/ACRYLONITROGENS COPOLYMER	N.A.	N.A.
DVB/ISOBORNYL METHACRYLATE/LAURYL METHACRYLATE COPOLYMER	N.A.	N.A.
ETHYLENE/ACRYLIC ACID/VA COPOLYMER	N.A.	N.A.
ETHYLENE/ETHYLIDENE NORBORNENE/PROPYLENE COPOLYMER	N.A.	N.A.
ETHYLENE/MAGNESIUM ACRYLATE COPOLYMER	N.A.	N.A.
ETHYLENE/MALEIC ANHYDRIDE/PROPYLENE COPOLYMER	N.A.	N.A.
ETHYLENE/POTASSIUM ACRYLATE COPOLYMER	N.A.	N.A.
ETHYLENE/SODIUM SULFOISOPHTHALATE/TEREPHTHALATE COPOLYMER	N.A.	N.A.
ETHYLENE/ZINC ACRYLATE COPOLYMER	N.A.	N.A.
ETHYLENEDIAMINE/DIMER TALLATE COPOLYMER BIS-HYDROGENATED TALLOW AMIDE	N.A.	N.A.
ETHYLHEXYL ACRYLATE/METHYL METHACRYLATE COPOLYMER	N.A.	N.A.
ETHYLHEXYL ACRYLATE/VP/DIMETHICONE METHACRYLATE COPOLYMER	N.A.	N.A.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
FIBROIN/PEG-16/SODIUM ACRYLATE COPOLYMER	N.A.	N.A.
GLYCOL DIMETHACRYLATE/VINYL ALCOHOL CROSSPOLYMER	N.A.	N.A.
HEXAFLUOROPROPYLENE/TETRAFLUOROETHYLENE COPOLYMER	N.A.	N.A.
HYDROGENATED BUTADIENE/ISOPRENE/STYRENE COPOLYMER	N.A.	N.A.
HYDROGENATED DICYCLOPENTADIENE/ISOPENTENE/ISOPRENE/STYRENE COPOLYMER	N.A.	N.A.
HYDROLYZED ETHYLENE/MA COPOLYMER	N.A.	N.A.
HYDROLYZED VA/VINYL ACETOACETATE COPOLYMER	N.A.	N.A.
HYDROXYETHYL/METHOXYETHYL ACRYLATE COPOLYMER	N.A.	N.A.
HYDROXYETHYL/METHOXYETHYL ACRYLATE/BUTYL ACRYLATE COPOLYMER	N.A.	N.A.
HYDROXYETHYLCELLULOSE/PHOSPHORYLCHOLINE GLYCOL ACRYLATE COPOLYMER	N.A.	N.A.
HYDROXYPROPYL DIMETHICONYLPROPYL ACRYLATES COPOLYMER	N.A.	N.A.
ISOBUTYL METHACRYLATE/TRIFLUOROETHYLMETHACRYLATE/BIS-HYDROXYPROPYL DIMETHICONE ACRYLATE COPOLYMER	N.A.	N.A.
ISOBUTYLENE/ISOPRENE COPOLYMER	N.A.	N.A.
ISOBUTYLENE/MA COPOLYMER	N.A.	N.A.
ISOBUTYLMETHACRYLATE/TRIFLUOROETHYLMETHACRYLATE/BIS-HYDROXYPROPYL DIMETHICONE ACRYLATE COPOLYMER	N.A.	N.A.
ISOPROPYLIDENEDIPHENYL BISOXYHYDROXYPROPYL METHACRYLATE/TMDI COPOLYMER	N.A.	N.A.
LAURYL ACRYLATE/VA COPOLYMER	N.A.	N.A.
LAURYL ACRYLATE/VA CROSSPOLYMER	N.A.	N.A.
LAURYL POLYDIMETHYLSILOXYETHYL DIMETHICONE/BIS-VINYLDIMETHICONE CROSSPOLYMER	N.A.	N.A.
MALEATED HEXENE/PROPYLENE COPOLYMER	N.A.	N.A.
METHYL ACRYLATE/METHYLENE DROMETRIZOLE METHACRYLATE COPOLYMER	N.A.	N.A.
METHYL METHACRYLATE/ETHYLHEXYL ACRYLATE/BUTYL DIMETHICONE PROPYL METHACRYLATE COPOLYMER	N.A.	N.A.
METHYL METHACRYLATE/TRIMETHOXYSILYLPROPYL METHACRYLATE CROSSPOLYMER	N.A.	N.A.
METHYLBUTENE/METHYLSTYRENE/PIPERYLENE COPOLYMER	N.A.	N.A.
'NYLON-11',	N.A.	N.A.
OXIDIZED POLYPROPYLENE	N.A.	N.A.
PEG/PPG/BUTYLENE/DIMETHICONE COPOLYMER (JPN)	N.A.	N.A.
PEG/PPG-5/2 METHACRYLATE/METHACRYLIC ACID CROSSPOLYMER	N.A.	N.A.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
PEG-800/POLYVINYL ALCOHOL COPOLYMER	N.A.	N.A.
POLY(METHOXY PEG-9 METHACRYLATE)	N.A.	N.A.
POLY[OXYMETHYLENE MELAMINE ACRYLATES/ACRYLAMIDE]	N.A.	N.A.
POLYACRYLATE CROSSPOLYMER-3	N.A.	N.A.
POLYACRYLATE CROSSPOLYMER-5	N.A.	N.A.
POLYACRYLATE CROSSPOLYMER-8	N.A.	N.A.
POLYACRYLATE-12	N.A.	N.A.
POLYACRYLATE-17	N.A.	N.A.
POLYACRYLATE-18	N.A.	N.A.
POLYACRYLATE-19	N.A.	N.A.
POLYACRYLATE-21	N.A.	N.A.
POLYACRYLATE-24	N.A.	N.A.
POLYACRYLATE-25	N.A.	N.A.
POLYACRYLATE-26	N.A.	N.A.
POLYACRYLATE-27	N.A.	N.A.
POLYACRYLATE-28	N.A.	N.A.
POLYACRYLATE-29	N.A.	N.A.
POLYACRYLATE-31	N.A.	N.A.
POLYACRYLATE-5	N.A.	N.A.
POLYACRYLATE-6	N.A.	N.A.
POLYACRYLATE-7	N.A.	N.A.
POLYACRYLATE-8	N.A.	N.A.
POLYACRYLATE-9	N.A.	N.A.
POLYBUTYL ACRYLATE	N.A.	N.A.
POLYCHLOROTRIFLUOROETHYLENE	N.A.	N.A.
POLYETHYLENE/ISOPROPYL MALEATE/MA COPOLYOL	N.A.	N.A.
POLYETHYLENE/POLYETHYLENE TEREPHTHALATE LAMINATED POWDER	N.A.	N.A.
POLYETHYLENE/POLYETHYLENE TEREPHTHALATE LAMINATED POWDER (JPN)	N.A.	N.A.
POLYETHYLENE/POLYPENTAERYTHRITYL TEREPHTHALATE LAMINATED POWDER (JPN)	N.A.	N.A.
POLYETHYLHEXYL ACRYLATE	N.A.	N.A.
POLYETHYLHEXYL METHACRYLATE	N.A.	N.A.
POLYMETHYL METHACRYLATE/POLYPENTAERYTHRITYL TEREPHTHALATE/STEARATE/PALMITATE LAMINATED POWDER (JPN)	N.A.	N.A.
POLYMETHYLSILSESQUIOXANE/TRIMETHYLSILOXYSILICATE	N.A.	N.A.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
POLYPENTAERYTHRITYL TEREPHTHALATE	N.A.	N.A.
POLY-P-PHENYLENE TEREPHTHALAMIDE	N.A.	N.A.
POLYSTEARYL METHACRYLATE	N.A.	N.A.
POLYTETRAFLUOROETHYLENE	N.A.	N.A.
POLYTETRAFLUOROETHYLENE ACETOXYPROPYL BETAINE	N.A.	N.A.
POLYURETHANE-12	N.A.	N.A.
POLYURETHANE-13	N.A.	N.A.
POLYURETHANE-16	N.A.	N.A.
POLYURETHANE-21	N.A.	N.A.
POLYURETHANE-23	N.A.	N.A.
POLYURETHANE-24	N.A.	N.A.
POLYURETHANE-24/METHYL METHACRYLATE CROSSPOLYMER	N.A.	N.A.
POLYURETHANE-26	N.A.	N.A.
POLYURETHANE-27	N.A.	N.A.
POLYURETHANE-28	N.A.	N.A.
POLYURETHANE-29	N.A.	N.A.
POLYURETHANE-32	N.A.	N.A.
POLYURETHANE-36	N.A.	N.A.
POLYURETHANE-4	N.A.	N.A.
POLYURETHANE-40	N.A.	N.A.
POLYURETHANE-41	N.A.	N.A.
POLYURETHANE-42	N.A.	N.A.
POLYURETHANE-43	N.A.	N.A.
POLYURETHANE-44	N.A.	N.A.
POLYURETHANE-45	N.A.	N.A.
POLYURETHANE-46	N.A.	N.A.
POLYURETHANE-47	N.A.	N.A.
POLYURETHANE-5	N.A.	N.A.
POLYURETHANE-51	N.A.	N.A.
POLYURETHANE-52	N.A.	N.A.
POLYURETHANE-53	N.A.	N.A.
POLYURETHANE-8	N.A.	N.A.
POLYURETHANE-9	N.A.	N.A.
POLYVINYL IMIDAZOLINIUM ACETATE	N.A.	N.A.
POLYVINYL ISOBUTYL ETHER	N.A.	N.A.
POLYVINYL METHYL ETHER	N.A.	N.A.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
POLYVINYLACETAL DIETHYLAMINOACETATE	N.A.	N.A.
POLYVINYLACETAMIDE	N.A.	N.A.
POLYVINYLACETATE	N.A.	N.A.
POLYVINYLCHLORIDE	N.A.	N.A.
POLYVINYLFORMAMIDE	N.A.	N.A.
POLYVINYLIDENE DIFLUORIDE	N.A.	N.A.
POTASSIUM ACRYLATES/ACRYLAMIDE COPOLYMER	N.A.	N.A.
POTASSIUM ALUMINUM POLYACRYLATE	N.A.	N.A.
POTASSIUM POLYACRYLATE	N.A.	N.A.
PROPYL TRIMETHICONE METHACRYLATE CROSSPOLYMER	N.A.	N.A.
SODIUM ACRYLATE/HYDROXYETHYL ACRYLAMIDE COPOLYMER	N.A.	N.A.
SODIUM ACRYLATE/VINYLACETAMIDE COPOLYMER	N.A.	N.A.
SODIUM ACRYLATES/ETHYLHEXYL ACRYLATE COPOLYMER	N.A.	N.A.
SODIUM ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER	N.A.	N.A.
SODIUM ACRYLOYL DIMETHYL TAURATE/PEG-8 DIACRYLATE CROSSPOLYMER	N.A.	N.A.
SODIUM DVB/ACRYLATES COPOLYMER	N.A.	N.A.
SODIUM MA/VINYL ALCOHOL COPOLYMER	N.A.	N.A.
SODIUM METHACRYLATE/STYRENE COPOLYMER	N.A.	N.A.
SODIUM STYRENE/ACRYLATES/DIVINYLBENZENE COPOLYMER	N.A.	N.A.
SODIUM STYRENE/ACRYLATES/ETHYLHEXYL ACRYLATE/LAURYL ACRYLATE COPOLYMER	N.A.	N.A.
SODIUM STYRENE/ACRYLATES/PEG-10 DIMALEATE COPOLYMER	N.A.	N.A.
SODIUM TAURIDE ACRYLATES/ACRYLIC ACID/ACRYLONITROGENS COPOLYMER	N.A.	N.A.
STEARYL METHACRYLATE/PERFLUOROOCTYLETHYL METHACRYLATE COPOLYMER	N.A.	N.A.
STEARYLVINYL ETHER/MA COPOLYMER	N.A.	N.A.
STYRENE/ACRYLATES/ACRYLONITRILE COPOLYMER	N.A.	N.A.
STYRENE/ACRYLATES/ETHYLHEXYL ACRYLATE/LAURYL ACRYLATE COPOLYMER	N.A.	N.A.
STYRENE/MA COPOLYMER	N.A.	N.A.
STYRENE/METHACRYLAMIDE/ACRYLATES COPOLYMER	N.A.	N.A.
SUCROSE BENZOATE/SUCROSE ACETATE ISOBUTYRATE/BUTYL BENZYL PHTHALATE/METHYL METHACRYLATE COPOLYMER	N.A.	N.A.
TIPA-ACRYLATES/ETHYLHEXYL ACRYLATE COPOLYMER	N.A.	N.A.
TROMETHAMINE ACRYLATES/ACRYLONITROGENS COPOLYMER	N.A.	N.A.
VA/CROTONATES/VINYL PROPIONATE COPOLYMER	N.A.	N.A.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][189]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
VA/ISOBUTYL MALEATE/VINYL NEODECANOATE COPOLYMER	N.A.	N.A.
VINYL CHLORIDE/VINYL LAURATE COPOLYMER	N.A.	N.A.
VINYL DIMETHICONE/LAURYL/BEHENYL DIMETHICONE CROSSPOLYMER	N.A.	N.A.
VINYL DIMETHYL/TRIMETHYLSILOXYSILICATE STEARYL DIMETHICONE CROSSPOLYMER	N.A.	N.A.
VINYLAMINE/VINYL ALCOHOL COPOLYMER	N.A.	N.A.

Source: ECHA market survey based on CosmEthics and Que Choisir data

Note on the table: N.A. means that the presence of INCI was not identified in the products

Annex F. Appendix D.2

The information below is extracted from the ECHA Guidance R.12 on Use description (ECHA, 2015).

The REACH legal text differentiates between industrial and professional use [activity] in definitions 13, 25 and 35, as well as section 6 of Annex VI. In Annex XVII also the terms 'industrial installation' and activity of a 'professional outside industrial installations' are used. However, no detail is given on the difference between the two and clarification is needed to support companies in this decision.

The terminology 'industrial' and 'professional' is used in two different contexts:

- To differentiate between life cycle stages
- To define the level of occupational health and safety management systems applied in companies

It is recommended to understand the concept 'professional' as a characteristic to distinguish between use: i) at industrial sites and ii) uses outside industrial sites (but not consumers or general public). This will lead to different life cycle stages in terms of use description.

The following table provides a non-exhaustive list of characteristics associated with industrial sites and professional activities outside industrial sites, and can be used in a weight of evidence approach to determine whether a use is considered: as 'use at industrial site' or as a 'widespread use by professional workers'.

Table 114: Characteristics helping in differentiating between industrial sites and professional activities outside industrial sites and relation with the life cycle stages

	Use at industrial site	**Widespread use by professional workers**
REACH Legal text	Industrial use (activity)	Professional use (activity)
Number of places where substance is used (at EU level)	Low to high	High
Number of persons potentially in contact (at EU level)	Low to high	High
Type of enterprises, type of business, examples	Production sites Large construction sites Large maintenance/repair and service sites	Services (mobile or stationary micro sites), administration, education, small building and construction works
Number of users/enterprises proportional to size of municipality by inhabitants	No	Yes
Activity requiring a permit according to the Industrial Emissions Directive (IED)	Often yes	Usually not
Availability of capital intensive equipment for automation and engineering controls	Often yes	Usually not, but can be

	Use at industrial site	Widespread use by professional workers
Amount of processed chemicals per single enterprise/actor	Low to high	Low
Connection to public sewer	Often yes, sometimes not	Yes
Tonnage reference for local environmental standard assessment	Tonnage for one representative industrial site per use (industrial point source)	Tonnage per use proportional to 10,000 inhabitants (municipal point source)

Examples:

The following list includes typical examples for business involving chemicals which would be considered as 'widespread use by professional workers':

- Building and construction business with broad variety of activities (mostly micro companies)
- Maintenance services for office/household equipment
- Indoor cleaning services for all kind of buildings
- Facade cleaning services
- Car wash and other car care services
- Hairdressing and other beauty services
- Health care services

Typical examples for business involving chemicals which would be considered as 'uses at industrial site' are:

- Production of cars and other vehicles
- Production of paper
- Textile dyeing and finishing
- Production of semiconductors

There are also cases which are considered 'borderline' i.e. it is more difficult to conclude on their Life cycle stage. Some examples have been listed below including some possible approaches:

- **Industrial cleaning services carried out by small or large, well-trained or less trained service providers**. This can include tank-cleaning, boiler cleaning, cleaning of machinery, etc. at industrial sites. This case should be regarded as a 'use at industrial site' regardless if the actual work is carried out by employees of the site or by external service providers. The resulting releases will be from the site where the cleaning operation takes place;
- **Workshops for car repair and finishing**. The sites may be small but could be also large. The predominant characteristic of the business is the huge number of small enterprises and the correlation to the municipal infrastructure (population density) so they should be reported as 'widespread use by professional workers'. In some cases, the workers' protection standards under which these businesses operate are similar to those of the car industry. This can be reflected when performing the human health exposure assessment by e.g. selecting the conditions of uses corresponding to 'industrial' settings;

- **Consumer textile cleaning with solvents and other heavy duty or specialised chemicals in micro-workshops**. The predominant characteristic of the business are the small size of the enterprises and the correlation to the municipal infrastructure so they should be considered as 'widespread use by professional workers', even though a high level of engineering control may be applied;
- **Large sites for water based washing/cleaning of textiles used in industry (cleaning wipes and work wear)**. These should be considered as 'uses at industrial sites'. The number does not correspond to the size of the municipality as few large sites normally serve a bigger region. Extensive and site-specific treatment infrastructure for wastewater and waste are normally present;
- **Large sites for maintenance and repair related to public transport infrastructure (trains, airports/harbours)**. These cases should be considered as 'uses at industrial sites'. The structure of the service for trains, ships and planes does not correlate with the municipal infrastructure. Sites for maintenance of buses and trams are more closely related to the municipal infrastructure. Nevertheless usually their size is sufficiently big to treat them as an industrial site.

With regard to the use of the terms 'industrial' and 'professional' in the context of human health exposure assessment, they flag the occupational conditions under which the workers use a substance or product. In general, it is assumed that 'industrial' conditions are associated with training of workers, proper work instructions and supervision. The use of exposure assessment models can result in different exposure estimates depending on the type of conditions selected (industrial or professional) e.g industrial conditions may assume a higher level of effectiveness for RMM.

Actually, a use can take place 'at industrial site', but for workers exposure assessment a lower effectiveness of RMM may be assumed ('professional setting'), as for example when workers from a contractor cleaning machinery between shifts in an industrial site. There may also be uses where the opposite is the case, well trained, instructed and equipped mobile services with chemicals (e.g. biocides).

The Table 115 illustrates the two aspects and how they relate to each other in different examples.

Table 115: Illustration of life cycle versus operational health and safety management systems

Life cycle stage	Occupational health and safety management system	Example
Use at industrial site	Advanced ('industrial conditions' or similar)	Use of substance as intermediate in manufacturing process
	Basic ('professional conditions')	Contractors working in an industrial site on cleaning tasks
Widespread use by professional workers	Advanced ('industrial conditions' or similar)	Application of biocidal products by specialised companies

	Basic (‘professional conditions’)	Self-employed painter painting in private households

Annex G. Stakeholder consultation

G.1. Introduction

The Dossier Submitter has undertaken an extensive stakeholder consultation to ensure that all sectors that used microplastics could be identified.

G.2. Registry of Intentions

The RoI entry was made on 17/01/2018. On 9/04/2018, 13242 letters were sent to registrants, and classification and labelling notifiers of substances potentially used in intentionally added microplastics. They were identified as having previously submitted a registration dossier or notification to the classification and labelling inventory to ECHA for one or several substances for which the use description contains the term "monomer" or "polymer". As some polymers are known to be used as materials in intentionally added microplastics, the Dossier Submitter has used these terms as the basis for identifying substances from our database that can potentially be in the scope of the restriction. The letters also informed the recipients about the ongoing call-for-evidence.

G.3. Call for Evidence

A call for evidence was open from 03/2018 - 05/2018 and an online information session was held on 12/3/2018 to provide a Question and Answer session to allow stakeholders to ask questions. 217 participants took part in the Q&A.

The call was intended to gather information on all possible intentional uses of microplastic particles in products, including both 'rinse-off and 'leave-on' cosmetics and personal care products (such as make-up and moisturisers) as well as in household / professional cleaning products and detergents. The call also investigated intentional uses in paints, agriculture and any further applications where microplastic particles could be intentionally used. The Background Document made it clear it was especially important for stakeholders to make the Dossier Submitter aware of any intentional uses of microplastic particles in products beyond those identified above.

In the Background Document was a working definition of microplastic particles:

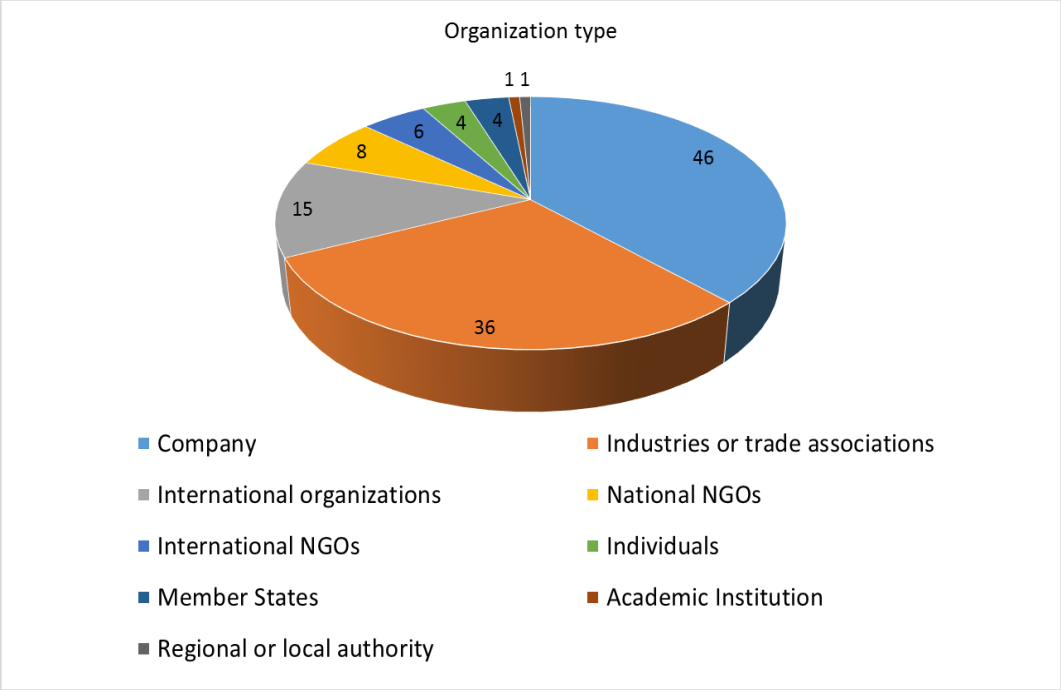
"Any polymer-containing solid or semi-solid particle having a size of 5mm or less in at least one external dimension."

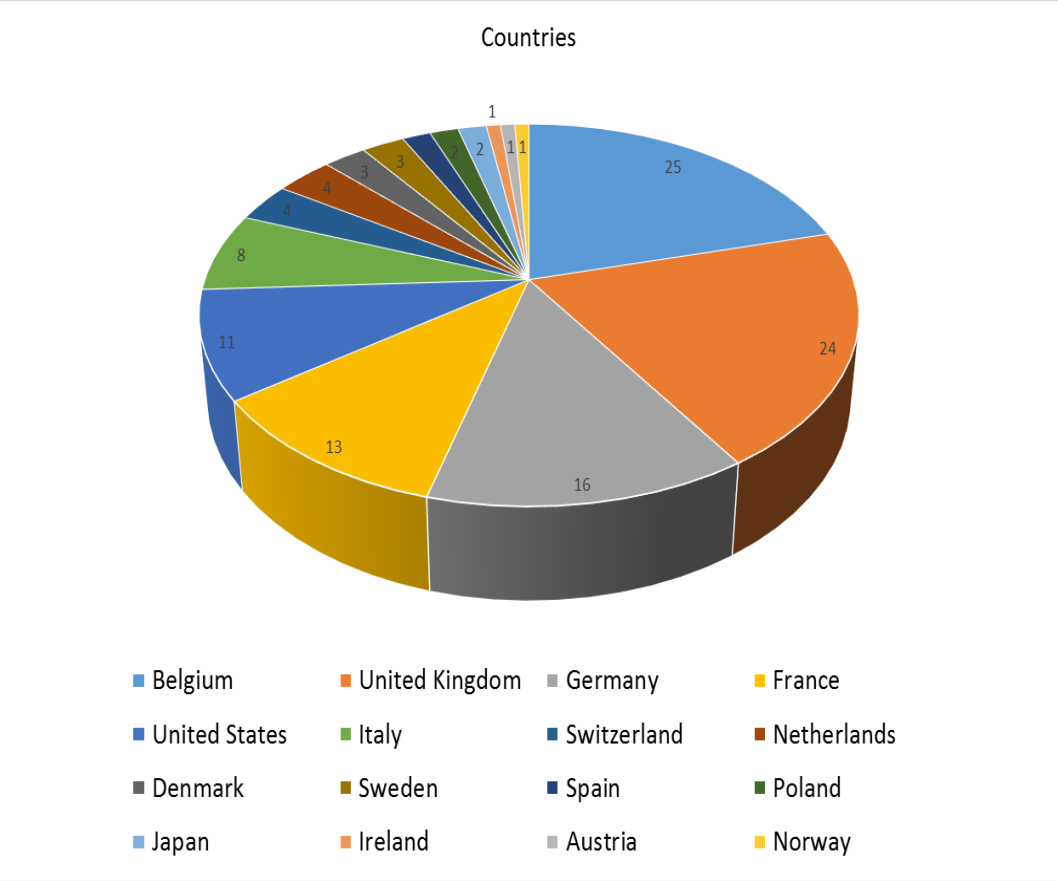
The objective of this call was to gather information or comments on:

- Our working definition.
- The specific uses of intentionally added microplastics in products, specifically the types of products they are intentionally added to.
- The technical function provided by the microplastic particles in products.
- Potential alternatives to the use of microplastic particles in products
- Information on other socio-economic impacts on society in response to a possible restriction in terms of costs and benefits to any affected actors.
- Available analytical methods for detecting and characterising microplastic particles in products.

In total there were 122 responses to the call for evidence. Of these 122, 46 came from companies, 4 from individuals, 36 from industries or trade associations, 8 from National

NGOs, 4 for Member States, 15 from International organisations, 6 International NGOs, one from an academic institution and one from a Regional or local authority. 16 answers came from Germany, 24 from the United Kingdom, 2 from Spain, one from Ireland, 25 from Belgium, 11 from United States, 8 from Italy, 13 from France, one from Austria, 3 from Denmark, 3 from Sweden, 4 from Switzerland, one from Norway, 4 from the Netherlands, 2 from Poland and 2 from Japan. 56/122 of the submissions were claimed confidential. These results are presented also in chart 1 and 2.





G.4. Workshop

From 30 to 31 May 2018, the Dossier Submitter held a workshop on microplastic particles to supplement the information obtained from the recent call for evidence by facilitating dialogue between stakeholders on the key issues relevant to a potential restriction on the intentional uses of microplastic particles under REACH. Further information is found here: https://echa.europa.eu/-/stakeholder-workshop-on-microplastic-particles. 59 invited participants from industry, stakeholder organisations, research institutions, the European Commission, Member State Competent Authorities and ECHA attended the conference in person. In addition, approximately 200 remote participants followed the plenary session of the workshop through web-streaming.

G.5. Note on substance identification and the potential scope of a restriction on uses of 'microplastics'

As an outcome of the stakeholder workshop on the intentional uses of microplastic particles held at ECHA on 30-31 May 20181, ECHA announced that it would publish a note outlining in broad terms what it has learnt about the identification of 'microplastics' (which is often referred to as the microplastics definition) and what steps the Agency will take to refine its understanding on key unresolved issues as it concludes its investigation by January 2019. The note would also elaborate on the relationship between substance identification and the potential scope of any proposed restriction. The note was published on 11 July 2018 and updated on 16/10/2018 (https://echa.europa.eu/documents/10162/13641/note_on_substance_identification_pot

ential_scope_en.pdf/6f26697e-70b5-9ebe-6b59-2e11085de791). This was accompanied by a Q&A on substance identification and the potential scope of a restriction on intentional uses of 'microplastics' (https://echa.europa.eu/documents/10162/22286145/rest_microplastics_qa_table_en.pdf/61a410c8-ddb7-a0d1-7a0c-67a3d0991ddf).

G.6. Targeted stakeholder consultation

Following the above consultations, the Dossier Submitter undertook a number of targeted consultations with companies or Trade Associations. 33 additional submissions were received and are referenced in the report.

G.7. Micro2018

The Dossier Submitter also attended the Micro2018 conference (https://micro2018.sciencesconf.org/) attended by many of the most prominent academic researchers. ECHA organised an invitation only side event at the conference to present the outline risk assessment to key academic experts. A number of comments were received that were incorporated into the report.

G.8. Biodegradation criteria consultation

The Dossier Submitter undertook a targeted consultation of their draft criteria on biodegradation with ECHA's PBT expert group consisting of Member States and Stakeholders (The European Chemicals Industry Council (CEFIC); The oil companies' European organisation for environment, health and safety in refining and distribution (CONCAWE); European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC); and the European Environmental Bureau (EEB)). Three comments were received and these were taken into account in the report.

Annex H. Q&A on intentionally added microplastics

QUESTIONS AND ANSWERS ON

THE RESTRICTION PROPOSAL ON

INTENTIONALLY ADDED MICROPLASTICS

(Dossier Submitter Proposal)

VERSION NUMBER: 3.0

DATE: 10 November 2020

PURPOSE:

The purpose of this document is to clarify aspects of the Dossier Submitter proposed restriction on intentionally added microplastics. It is presented in the form of 'questions and answers', and is presented as an Annex to the Background Document.

This document is based on questions received from stakeholders before, during and after the opinion making phase. It replaces the Q&A document published to support the call for evidence held during the preparation of the proposal, and the Q&A document (version 1) published to support the Annex XV consultation (from March 2019 to September 2019). It aims at clarifying solely the Dossier Submitter's proposal (as revised in response to the comments received in the Annex XV consultation) that is described in the Background Document. The document should be read in conjunction with the opinions of RAC and SEAC on the proposal.

Readers are reminded that the text of the REACH and CLP Regulation is the only authentic legal reference and that the information in this Q&A document does not constitute legal advice.

The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document. Use of the information in this document remains the sole responsibility of the reader.

CHANGE HISTORY

Revision n.	Change history	Date	Prepared by
1.0	Initial publication as a stand alone document based on the content of the Annex XV restriction proposal version 1.1 (20 March 2019). The Q&A was intended to support respondents to the Annex XV consultation which was open from 20 March 2019 until 20 September 2019.	10.07.2019	Dossier submitter
2.0	Revised version of the Q&A to take into account the updates in the Background Document (formerly the Annex XV restriction proposal) during the opinion making phase. The Q&A is intended to clarify solely the Dossier Submitter proposal presented in the Background Document (version 25.05.2020). New questions have been added: - Question 2.18b - Questions 2.26b, 2.26c, 2.26d - Question 5.6 - Question 6.8 - Question 8.17b - Question 8.26 The following questions have been removed: - Questions 1.1 to 1.15 - Question 2.22 - Question4.1 - Question 7.3 - Question 8.1 - Question 8.7 The following questions or elements have been updated or clarified: - Section 2.1 of the Q&A (decision trees) - Section 3 of the Q&A on the Obligations in the supply chain - Questions 2.3, 2.6, 2.11, 2.12, 2.17, 2.19 to 2.21, 2.23, 2.24, 2.26 to 2.28, 2.31, 2.34, 2.38, 2.39, 4.4 to	20.05.2020	Dossier submitter

	4.7, 4.10, 4.11, 5.1, 5.5, 6.2 to 6.5, 8.3, 8.5, 8.8 and 8.14 Additional updates have also been made, to adapt the wording, and Background Document references to the latest version of the Dossier Submitter proposal.		
3.0	Q&A added on lignin (2.11b), on bioresorbable implants (8.17c), and small articles (8.27). Title of section 8.7 changed from 'Pharmaceuticals and substance based medical device' to 'Pharmaceuticals and medical device'. Clarification added in figure 'Box2' in section 3. Clarification for question 2.6	10.11.2020	Dossier submitter

TABLE OF CONTENTS

1. REACH Restriction proposal

The questions from this section are removed as not relevant anymore.

2. Microplastic definition

2.1. Decision tree (definition)

The decision tree on the microplastics definition (***Figure 23***) presents the key questions, arranged across three tiers, which need to be answered to identify if a substance or a mixture placed on the market contains microplastics and would therefore be subject to the proposed restriction. It is possible to leave the assessment at each of the tiers as it will be possible to conclude that a substance or mixture is not a microplastic in many cases without additional assessment.

There is no hierarchy in the various elements of the microplastic definition set in the restriction proposal. Nevertheless, it is advised to start with simple checks, such as for the presence of solid particles or polymers in the substance or mixture placed on the market. The absence of either of these, or the presence below the proposed concentration limit of 0.01% w/w, will lead to a conclusion that the substance or mixture will not be affected by the proposed restriction.

Importantly, the decision trees below present one way to interpret the microplastic definition in a stepwise way. However, it is likely to be equally valid to approach the definition from different starting points and this may be more appropriate for particular substances to mixtures depending on the prior knowledge available.

More details on Tiers 1a, 1b, 2 and 3 are presented in:

- **Microplastic decision tree – Tier 1a – relevant solid particles** – are relevant solid particles present?
- **Microplastic decision tree – Tier 1b – relevant polymers**– are relevant polymers present?
- **Microplastic decision tree – Tier 2 – polymer-containing particle** – are particles containing solid polymer present?
- **Microplastic decision tree – Tier 3 – concentration considerations** – is the concentration limit exceeded?

Note that both of the elements in Tier 1 (i.e. 1a and 1b) have to be fulfilled to progress to tier 2, and can be assessed independently. In some cases, e.g. when information is available on a label or via the supply chain or other prior knowledge, it will be easier to start with criteria 1b rather than 1a.

At any step in the decision tree, if the answers to the criteria questions lead you to the conclusion that there is "no microplastics in the substance/mixture placed on the market" (as indicted in the green shapes), then no further assessment is needed, and the restriction does not apply to the substance or mixture placed on the market. For example, if criterion 1a is not met there is no need to assess criteria 1b, and visa-versa.

Additional decision trees are included in Section 3. They can assist in concluding whether the use is derogated or if placing on the market can continue after fulfilling the proposed 'reporting' and 'instructions for use and disposal' requirements.

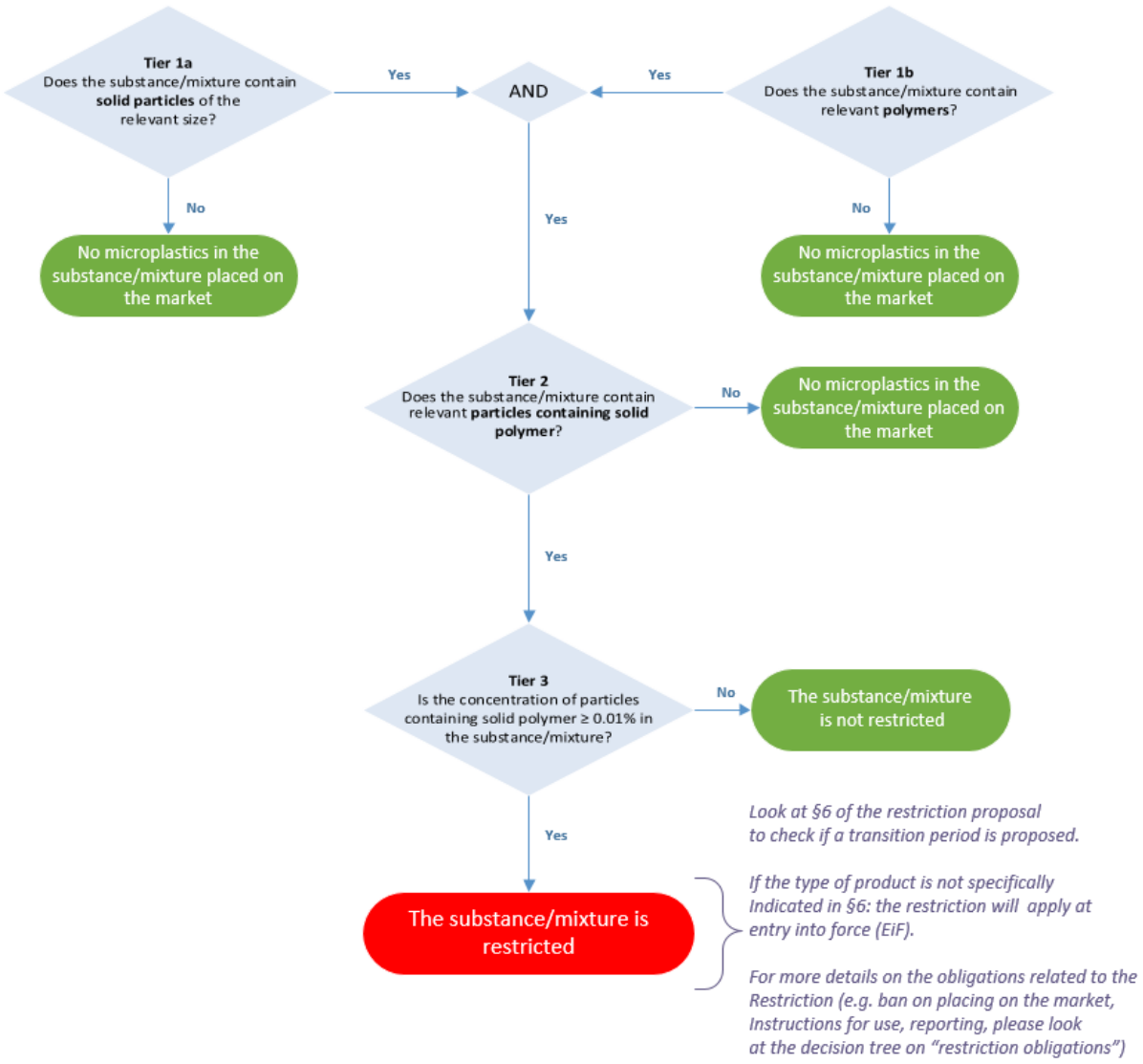


Figure 23 Microplastics definition decision tree overview

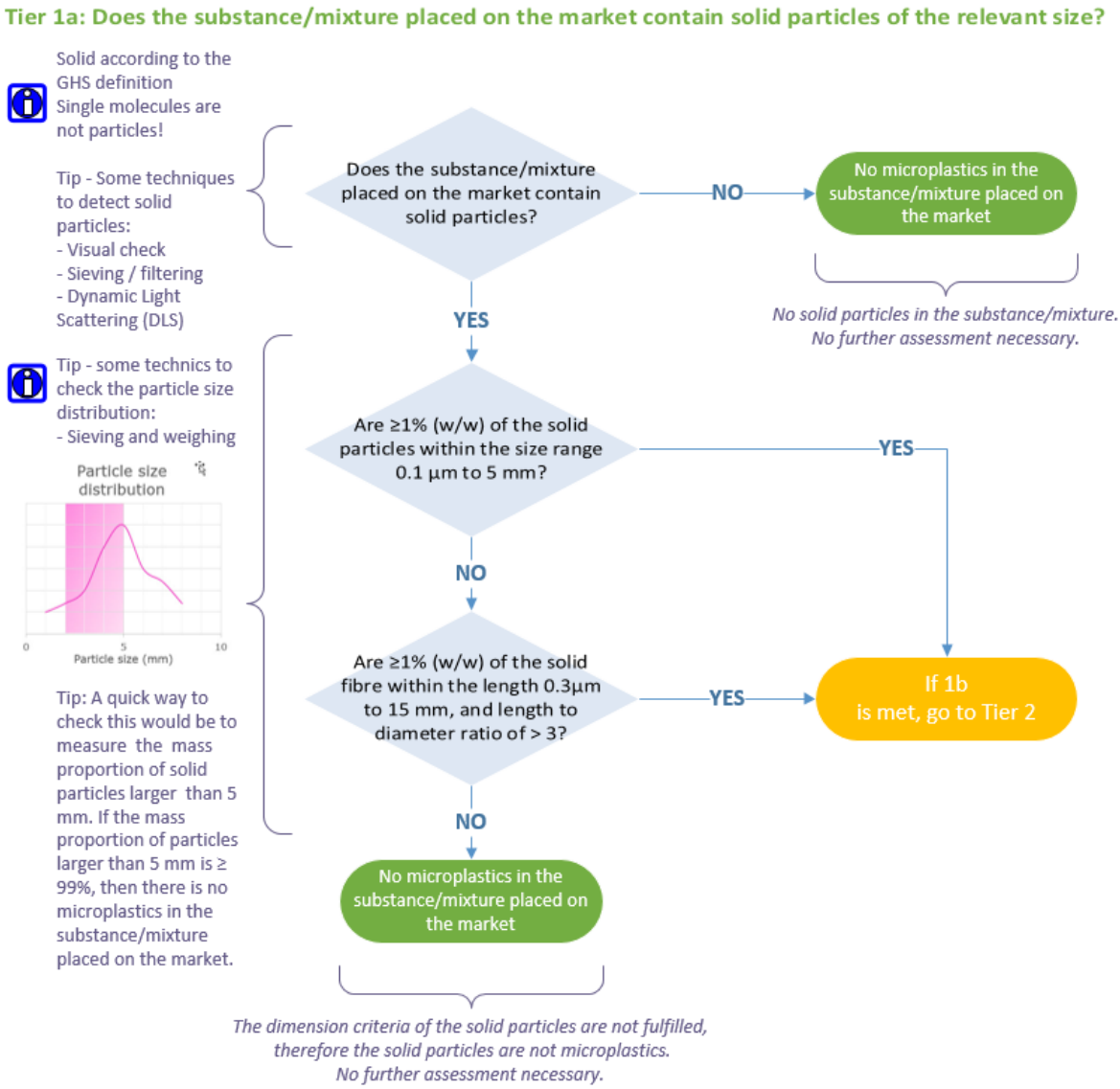


Figure 24 Microplastic decision tree – Tier 1a – relevant solid particles [190]

[190] Note that the size range indicated in the Figure 2 refers to the Dossier Submitter proposal. The size range proposed by RAC and SEAC in their opinion, might differ. Please refer to the RAC and SEAC opinion for detailed information

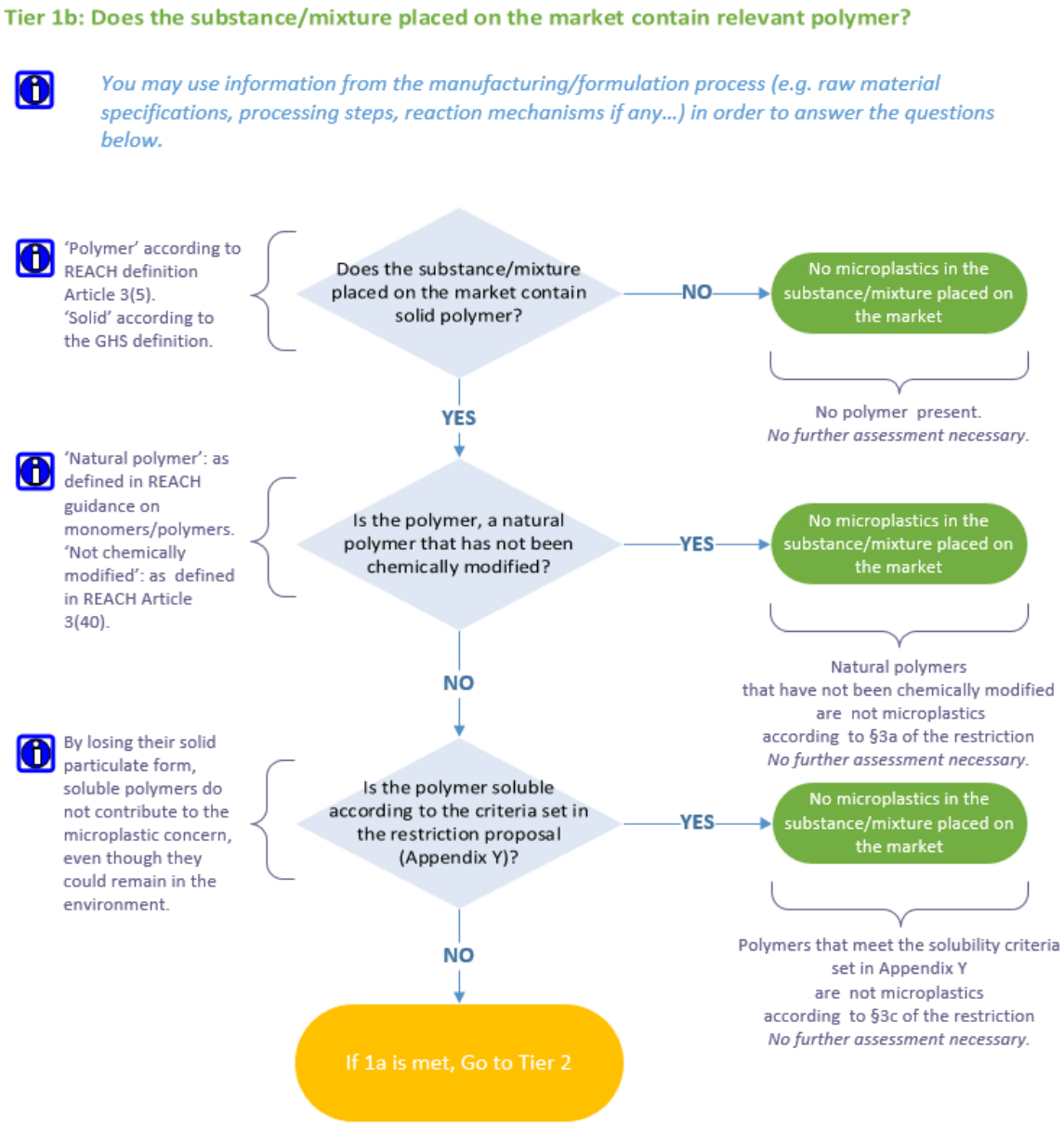


Figure 25 Microplastic decision tree – Tier 1b – relevant polymers

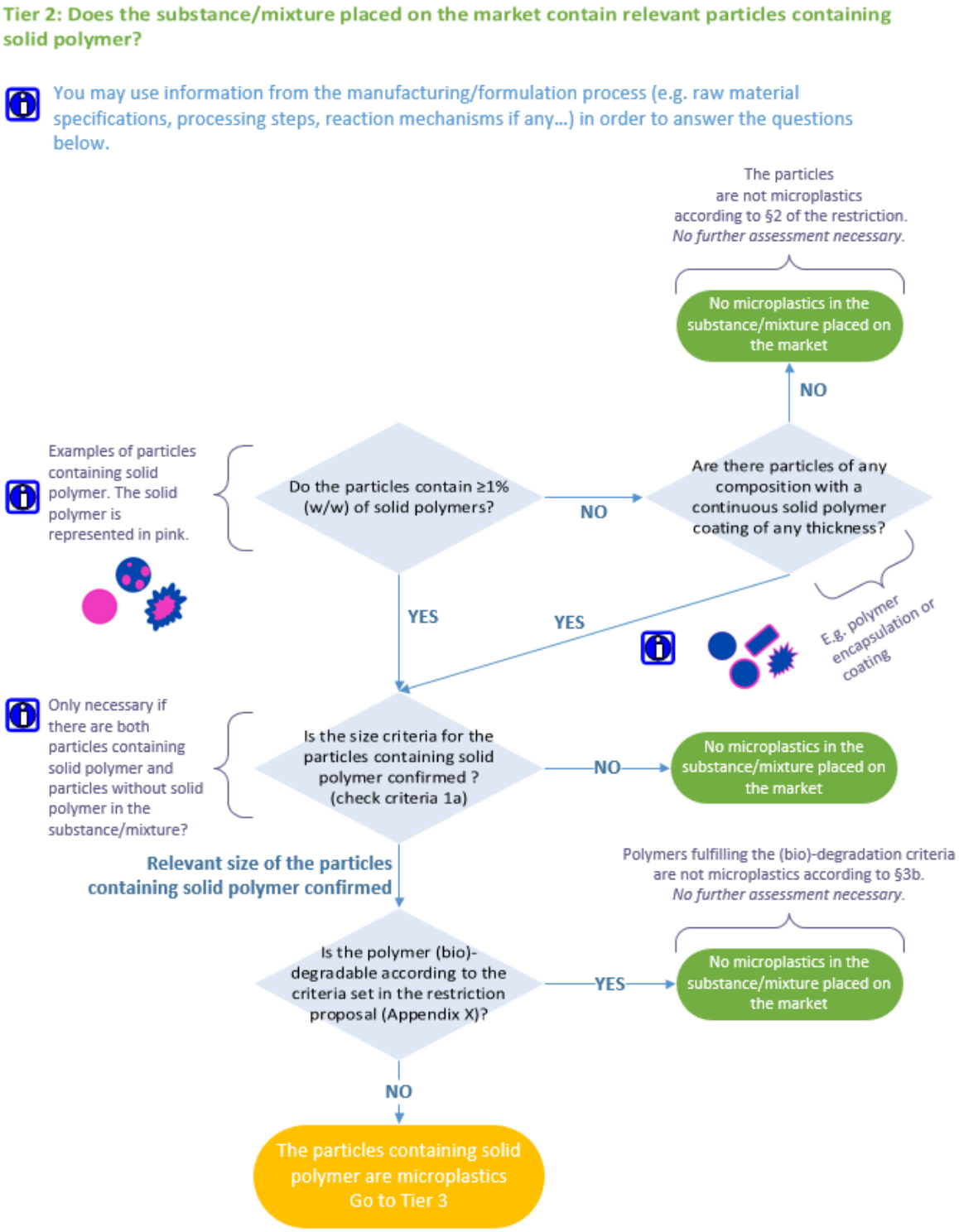


Figure 26 Microplastic decision tree – Tier 2 – polymer-containing particle

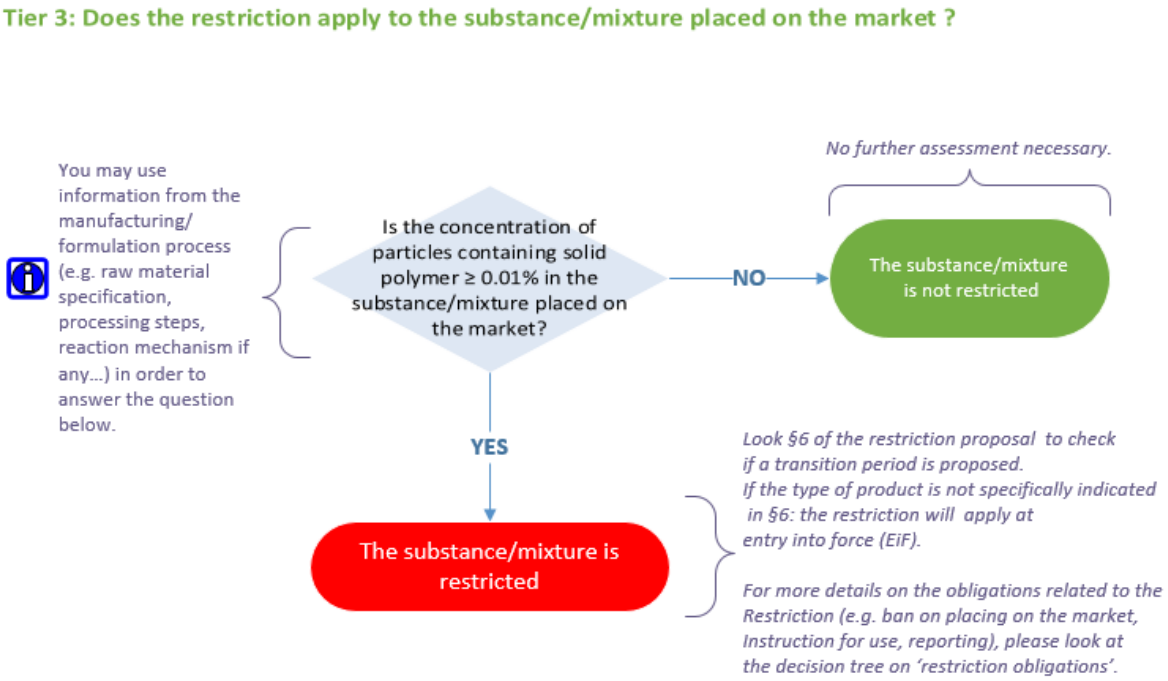


Figure 27 Microplastic decision tree – Tier 3 – concentration considerations

2.2.General questions

#	Question	Answer
2.1	Is the definition of microplastic harmonised across all of the EU/EEA?	No. There is currently no harmonised definition of a microplastic in the EU or internationally. The proposed restriction will harmonise the definition of microplastic under the REACH regulation. Other organisations may develop other definitions that would be appropriate for their specific purposes.
2.2	Microbeads, as understood in common language, have uses different from the defined term, e.g. in order to improve flow. Does that mean some uses of microbeads will have different transitional periods before the proposed restriction would enter into effect?	In a similar way as the term 'microplastic', there is no harmonised definition of the term 'microbead' neither in EU/EEA countries or elsewhere in the world. This is why the Background Document proposes to define 'microbeads' as microplastics used in a mixture as an abrasive i.e. to exfoliate, polish or clean. Other uses of microplastics, e.g. to improve flow, are referred to in the Background Document simply as uses of 'microplastics'. According to information provided by stakeholders, industry is on course to fully phase out the use microbeads (as defined in the Background Document) in cosmetics and household products before the entry into force or the restriction. Therefore, no transitional period is proposed for this use and microbeads must not be placed on the market once the restriction enters into force, unless for a derogated use e.g. use for abrasive blasting at industrial sites (see paragraph 4a). Other uses of microplastics, including some uses of what could commonly be referred to as microbeads, will have different transitional periods. These are outlined in paragraph 6 of the proposed conditions of the restriction.
2.3	What is the hierarchy of applying the criteria of the definition of a microplastic?	There is no hierarchy for the criteria. All criteria of the definition must be met to be considered as a microplastic: polymer, solid particle/fibre, dimensions, concentration limit, not (bio)-degradable (according to criteria in Appendix X), and solubility <2g/L (according the criteria in Appendix Y).

2.3. Polymers

#	Question	Answer
2.4	I thought polymers were not included in REACH. How can they be restricted?	Polymers are exempted from the registration and evaluation elements of the REACH Regulation (Article 2(9) of REACH), but as they are substances, they are covered by other REACH provisions, such as in relation to information in the supply chain (Title IV), authorisation (Title VII), restrictions (Title VIII). • A polymer is a substance consisting of molecules characterised by the sequence of one or more types of monomer units (Article 3(5) of REACH). • Monomers need to be registered; their lifecycle needs to be covered in the Chemical Safety Report (CSR) (Articles 6(2) and (3) of REACH).
2.5	How do I assess whether my substance is or is not a polymer under REACH?	You need to know the chemical composition of the polymer together with information on the relevant manufacturing process (polymer-forming reaction) in detail in order to identify all polymeric and non-polymeric molecules that are present in the substance composition. In addition, you also need to know the molecular weight distribution of the above molecules in the substance composition. A polymer is a substance consisting of molecules characterised by the sequence of one or more types of monomer unit. Such molecules must be distributed over a range of molecular weights. Differences in the molecular weight are primarily attributable to differences in the number of monomer units. In accordance with REACH (Article 3(5)), a polymer is defined as a substance meeting the following criteria: (a) Over 50 percent of the weight for that substance consists of polymer molecules; and,

#	Question	Answer
		(b) The amount of polymer molecules presenting the same molecular weight must be less than 50 weight percent of the substance. A 'polymer molecule' is a molecule that contains a sequence of at least 3 monomer units, which are covalently bound to at least one other monomer unit or other reactant. It should be noted that, for example, a well-defined mono-constituent substance cannot be a polymer since the substance needs to consists of polymer molecules with certain molecular weight distribution. See more detail in the "'Guidance for monomers and polymers"' available from the ECHA website.
2.6	Are all polymers microplastics?	No. Only polymers whose properties in a substance/mixture fulfil **all** of the criteria described in paragraph 2a of the proposal are 'microplastics' i.e. synthetic, solid, in the form of particles within appropriate dimensions. Equally, natural polymers that have not been chemically modified, or that meet the criteria for (bio)degradability or for solubility included in the restriction proposal (cf Table 3 in the Background Document) are not microplastics.
2.7	If a substance is already registered under REACH, and is by definition not a polymer, can I consider it as being out of the scope of the proposed restriction?	Yes. It is true that a registered substance should not fulfil the REACH polymer definition. However, please note that the fact that a substance has been registered does not automatically mean that it is not a polymer. Some registered substances have been found to be polymers after review and their registrations annulled. Please also note that it is the responsibility of the Registrant to assess whether their substance fulfils the polymer definition or not.
2.8	Are acrylic emulsions microplastics?	No, on the basis that the term 'emulsion' refers to a liquid-liquid mixture. If the acrylic polymer is not present as a solid particle then it is not a

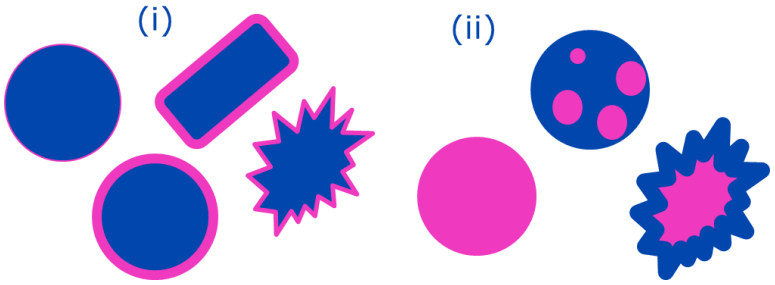
#	Question	Answer
		microplastic. Where particles contain solid polymer they could be microplastics, depending on whether the other elements of the definition are also met. Please refer to the decision trees in this document.
2.9	Are the polymers listed in Table 46 of the Annex to the Background Document already regarded as microplastics?	No. The polymers listed in Table 46 in the Annex are known to be commonly used in cosmetics but, based on the information available to the Dossier Submitter, it was not fully clear which would be considered as microplastics. These and other polymers listed in Table 88 were used as an appropriate basis for estimating the 'high scenario' of the socio-economic impacts arising from the proposed restriction on cosmetic products, which is likely to have overestimated impacts, as not all polymer uses would fall within the scope of the proposed restriction.
2.10	Polysilicone-15 is a liquid. Why is it mentioned in Table 46 of the Annex to the Background Document?	The polymers listed in Table 46 in the Annex are known to be commonly used in cosmetics but, based on the information available to the Dossier Submitter, it was not fully clear which would be considered as microplastics, as defined in the proposal. This would depend on the physical state of the polymer, its morphology and size. These and other polymers listed in Table 88 were used as an appropriate basis for estimating the 'high scenario' of the socio-economic impacts arising from the proposed restriction on cosmetic products, which is likely to have overestimated impacts, as not all polymer uses would fall within the scope of the proposed restriction. Polysilicone-15 is an INCI name used in cosmetics. It does not refer to a specific polymer. If the substance referred to as 'polysilicone-15' is not present in a form of a solid particle, then this would not fulfil the definition of a microplastic and would not be covered by the proposed restriction. However, any synthetic polymer, including polysilicone, which would fulfil the definition, will be included in the proposed scope.
2.11	Are natural cellulose fibres, polyethylene glycols	Natural polymers that have not been chemically modified are derogated

#	Question	Answer
	and polyamines microplastics?	according to paragraph 3(a). For synthetic polymers, such as polyethylene glycols and polyamines, other criteria should be considered, e.g. it should be considered if the substance meets the other relevant criteria for a microplastic. Please refer to the decision trees in Section 2 of this Q&A document.
2.11b	Are lignin (including Kraft, isolated) considered to be natural polymers which are not chemically modified?	Lignin as such is considered to be natural polymer which has not been chemically modified and therefore Paragraph 3a of the restriction proposal is applicable. If 'kraft lignin' or 'isolated lignin' refers to lignin which has been extracted using different processes but once isolated it is not further chemically modified it would also be considered as natural polymer according to paragraph 3a. The company manufacturing/extracting lignin has the responsibility to ensure that the exemption is applied correctly.
2.12	If a synthetic polymer also occurs in nature, is it derogated?	No. Natural polymers that have not been chemically modified are derogated according to paragraph 3(a). A polymer, which has been synthesised in an industrial facility is not considered as a 'natural polymer' even if the chemical structure would mimic a polymer which can be extracted from nature.
2.13	If polymer 'A' is chemically modified to obtain polymer 'B' (which occurs in nature), would polymer 'B' be a microplastic?	Yes, but only if all of the other relevant criteria for the polymer are met. Please refer to the decision trees in Section 2 of this Q&A document.
2.14	Would polymers obtained from polylactic acid be considered as a microplastic?	Particles containing solid polymers should be evaluated as to whether or not all the criteria described in the proposal for a microplastic are met, e.g. is the polymer present in a solid particle within the specific dimensions. Please refer to the decision trees in Section 2 of this Q&A document.
2.15	If a polymer is dissolved in oil, is it a microplastic?	The restriction proposal focuses on presence of particles containing solid polymers in the product(s) placed on market. If the polymer is not in the form of a solid particle it would not fall within the proposed definition of a microplastic. The type of solvent is not an element of the definition.

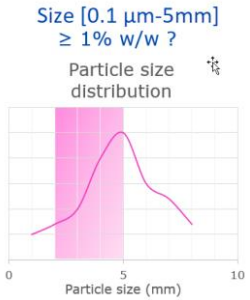
#	Question	Answer
2.16	Does a polymer fall within the scope if it is not added as a microplastic but during the use of the substance/mixture becomes a "microplastic"?	No. Spontaneous formation of microplastics at the 'point of use/disposal' is not included in the scope of the proposal.
2.17	Will amorphous polymers with a glass transition temperature below 20 degrees Celsius be included in the microplastic definition? Are they solid or liquid?	Glass transition temperature is not proposed as one of the criteria for a microplastic. Specifically, you should consider whether or not the particles containing fully amorphous polymer(s) meets the definition of solid as defined in the GHS (which is used for the proposed restriction). For a substance or a mixture which does not exhibit specific melting point the status can be determined either via ASTM D 4359-90 test or via Fluidity test (penetrometer test) described in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).
2.18	Will there be a list available with CAS-numbers of the polymers that are potentially microplastics?	No. It is not possible, for various reasons, to provide an exhaustive list of the identifiers for the polymers that would fulfil the microplastic definition proposed in the Background Document. For example, a single polymer may exist in several forms, some of which would be considered as microplastic whilst others would not. Nevertheless, non-exhaustive lists of polymers that typically meet the definition of a microplastic could be provided by ECHA, or other stakeholders, in the future once there was greater practical experience of the definition. These lists could be used to aid the workability and enforceability of the proposal.
2.18b	My polymer is produced using industrial fermentation, can it be considered as a natural polymer?	No. The derogation outlined in paragraph 3a of the proposed restriction on intentionally added microplastics is for 'natural polymers'. The REACH Guidance defines natural polymers as "*polymers which are the result of a polymerisation process that has taken place in nature, independently of the extraction process with which they have been extracted. This means that natural polymers are not necessarily 'substances which occur in nature' when assessed according to the criteria set out in Article 3(39) of the REACH*

#	Question	Answer
		Regulation." More information is available in the "Guidance for monomers and polymers" at https://echa.europa.eu/guidance-documents/guidance-on-reach. If an industrial process is used to manufacture a polymer, the resulting polymer is not considered to be covered by the definition of a natural polymer. This is valid even if the synthesised polymer is chemically the same as its natural analogues.

2.4. Particles and particles containing solid polymer (including particle size)

#	Question	Answer
2.19	What is meant by the term 'polymer containing particle'?	Please note that the term 'polymer-containing particle' has been changed to 'particles containing solid polymer' during the opinion making phase. 'Particles containing solid polymer' means either (i) a particle of any composition with a continuous solid polymer surface coating of any thickness or (ii) a particle of any composition with a solid polymer content of ≥ 1% w/w.  Note: the pink colour represents the polymer element of a 'particle containing solid polymer' The reason to distinguish particle type (i) from particle type (ii) stems from

#	Question	Answer
		the fact that the amount of polymer used in encapsulation applications may be <1% w/w, relative to the overall mass of the particle whilst these uses are a key focus of the restriction. A threshold of 1% for particle type (ii) was chosen on the basis that this is the established standard for reporting the constituents of a well-defined substance under REACH.
2.20	Are particles coated or encapsulated with polymers considered to be microplastics?	Yes, according to the illustration in the response to question 2.19, these would be type (i) particles containing solid polymer and would be considered as microplastics as long as the other elements of the definition are met.
2.21	How should the fact that synthetic polymers in a solution might behave differently with respect to their particulate form at different stages during life cycle be considered, i.e. formulation of cosmetic products, in the cosmetic product placed on the market and during the use of the product?	The microplastic criteria should always be considered at the point of placing a substance or mixture on the market e.g. after formulation or after import. If a derogation from the ban on placing on the market is applicable (e.g. for use at industrial sites), various obligations may exist for providing 'instructions for use and disposal' and/or for 'reporting' depending on the actor involved and the type of product. Please refer to the decision trees in this document for further information. In addition, the state of the microplastic at the point of end use by a consumer or professional is relevant for determining if the restriction on placing on the market can be derogated according to the conditions described in paragraphs 5(a), 5(b) or 5(c) e.g. if a microplastic is contained by technical means during end use, if microplastics are 'consumed' during end use or if microplastics as contained in a solid matrix at end use. Please refer to Section 3 of the Q&A for further details of the obligations that will arise under the proposed restriction at different levels of the supply chain of microplastics.
2.22	Question removed - not relevant anymore	
2.23	How should particle size be measured?	A particle is defined as a 'minute piece of matter with defined physical boundaries'. This can be further specified as: 'a particle has a physical boundary that can also be described as an interface and that a particle can move as a unit'.

#	Question	Answer
		Particle size can be measured according to various ISO standards e.g. CEN ISO/TS 27687:2008 (ISO, 2008) and ISO 14644-6:2007 (ISO, 2007). In addition, techniques used for the characterisation of nanomaterials could be useful for very small particles, e.g. dynamic light scattering (DLS) or field flow fractionation (FFF). In relation to the particle size criteria a particle size distribution needs to be considered. In any given test sample, the particle size measured will have a distribution and there may be particles present with sizes both above and below the size cut-off for a microplastic. Note that it is the weight distribution rather than the number distribution that is the key parameter to be measured. To assess the distribution we suggest to use a mean value obtained from several batches over time. 
2.24	Establishing 0.1 µm as a lower limit of the microplastic definition could already include a single polymer molecule. Does that mean that single molecules fall under the microplastic definition?	Single molecules are not considered to be particles and, by definition, cannot be microplastics. The size of polymer itself is not under question as long as the substance itself considering all polymeric molecules that are present in fulfil the polymer definition as defined in Article 3(5) of REACH. When considering if the substance is a microplastic or not the total substance composition needs to be taken into account. The question further relates to whether or not the potential particles comprises of polymers as defined under REACH and whether or not these

#	Question	Answer
		particles are in solid form as defined in the GHS Regulation and whether or not other parameters such as percentage of polymer molecules in the particles with the appropriate dimensions are met.
2.25	What about larger particles, for example 20 mm size, with a small amount of abraded dust in the µm or nm range? Determining a number or size distribution in this kind of situation if challenging.	The current proposal refers to weight average particle size distribution, not to a number size distribution. In general, it should be more straightforward to determine the weight size average distribution for such substances rather than the number size distribution.
2.26	Are 'swellable' polymer particles included in the scope of the proposed restriction e.g. gels, microgels or absorbing gels?	If a swellable particle containing solid polymer retains its solid form during use (and remains <5mm in size), then these particles are microplastics. Should a swellable polymer **permanently** lose its microplastic form (either by losing solid form, particulate form or by exceeding the relevant size dimensions) during end use then it would cease to be a microplastic and could continue to be placed on the market (as per the derogation described in paragraph 5(b). However, as the swelling properties of polymers are known be reversible depending on e.g. environmental conditions (such as temperature) a pragmatic approach to determine whether a swellable polymer is in or out of the scope of the proposed restriction would be to base any assessment on the physical properties of the polymer before swelling. In practice this would mean that if the polymer used as superabsorbent, hydrogel, gel, microgel, absorbing gel etc. is solid before swelling it is considered as microplastic. On the contrary, if the polymer has a liquid state (if such exists) before swelling, it would not be considered as a microplastic. That means the original physical state of the polymer as placed on the market would define if the swellable polymer in question is in or out of the scope of the restriction.
2.26b	Regarding the particle definition for 'swellable polymers', how much do they need to swell	See answer to question 2.26

#	Question	Answer
	before they are no longer particles (with a defined interface)?	
2.26c	Thermosetting plastic is one which, after formation, cannot be molten again. The polymer chains of the plastic have been crosslinked to form a three-dimensional network. The polymer chains thus form a single molecule. Its size depends on the form in which the thermoset has been formed no molecular weight distribution which means no polymer according to REACH. Is that correct?	No. Most polymers, including thermoset plastics, have a distribution of constituents according to different molecular weight. That means that after analysing the polymer by a suitable analytical method (e.g. chromatography) the composition of the substance consists of a range of constituents with different molecular weight species and not one and only one single molecule with an exact molecular weight and with one sharp peak in the chromatogram. Polydispersity index is a value to assess how far away the distribution of the substance is from a uniform distribution. Therefore based on the obtained analytical data it needs to be assessed whether the substance fulfils the polymer definition according to Article 3(5) of the REACH Regulation. In case the substance contains only one single polymeric molecule with the same molecular weight (i.e. it is not a polymer according to Article 3(5) of REACH Regulation), this substance would need to be registered as any other manufactured substance.
2.26d	How should the products belonging to the group of aqueous wax emulsions/dispersions be treated under the microplastic definition?	It depends on the properties of individual aqueous waxes emulsions/dispersions that would need to be assessed against the definition on a case-by-case basis. Waxes that are solid as defined by the regulatory definition are within the scope of the restriction proposal. In addition, it should be noted that for instance a polymer dispersed in a liquid might be considered as a microplastic should particles containing solid polymers be present.

2.5. Particle state (solid, semi-solid and liquid)

#	Question	Answer
2.27	Are semi-solid particles included in the scope of the proposed restriction?	The term 'semi-solid' was considered during the development of the restriction proposal (e.g. call for evidence stage), but was ultimately not used in the microplastic definition in the submitted proposal. Therefore, the term 'semi-solid' is not a relevant parameter. The restriction proposal considers solid particles containing solid polymers as microplastics (assuming they are within the relevant size range). Solid is defined as per the GHS definition of solid. On this basis, any material which is not considered to be a liquid or a gas is considered to be a solid. Certain polymer materials that could be considered to be 'semi-solid' would be considered to be solid according to the GHS regulation definition.
2.28	According to Background Document, the definition for semi-solids refers to the glass transition temperature (Tg). However, Tg is a range and the value depends largely on the measurement conditions, so making Tg part of a definition does not seem to be robust.	The term 'semi-solid' was considered during the development of the restriction proposal (e.g. call for evidence stage), but was ultimately not used in the microplastic definition. Therefore, the term 'semi-solid' is not a relevant parameter. The state of a polymer consistent with a microplastic in the proposal is based solely on the definition of solid in the GHS. Therefore, Tg is not considered when determining if a polymer meets the definition of a microplastic.
2.29	Are polymers synthesised by emulsion polymerisation and dispersed in an aqueous solution microplastics?	Possibly. The process of polymerisation is not a determining factor in the proposed definition of a microplastic. The definition refers to a presence of solid particles with the relevant physical parameters (dimension, polymer concentrations etc.).
2.30	Are 'antifoam' particles considered to be microplastics? i.e. ions of silica nanoparticles and polydimethylsiloxane? These droplets are ~4 microns in size and since these emulsions are not stable upon mechanical shear they are not considered as solid particles.	Where there are no solid particles present in a substance or mixture then any polymers present would not be considered as a microplastic as defined in the restriction proposal. In addition, where a substances ceases to be a particle containing solid polymer at the point of use (e.g. on the basis of mechanical sheer) it would cease to be a microplastic and would be derogated from the restriction on the basis of paragraph 5b.

2.6. Solubility

#	Question	Answer
2.31	Why is solubility not included as a parameter in the microplastic definition? Are water-soluble polymers exempted from restriction?	The term solubility has been used in several of the internationally available definitions of microplastic defined for regulatory and non-regulatory purposes and was initially not considered as an element of the microplastic definition in the Annex XV restriction proposal. The relevance of a 'solubility' consideration to the microplastics concern is however acknowledged. Soluble materials would not contribute to the microplastics concern as they would not be present as solid particles (single molecules are not considered to be particles). Therefore, the solubility element has been reconsidered after the submission of the Annex XV report and proposed to be used as a criteria for derogation from the scope of the proposed restriction, see paragraph 3(c) of the restriction proposal.

2.7. (Bio)degradability

#	Question	Answer
2.32	The proposed legal text does not say at which point in the life cycle the (bio)degradability criteria must be considered.	The criteria for biodegradability apply throughout the life-cycle and is considered as intrinsic property of the particles containing solid polymers. The purpose of the criteria is to provide a means to demonstrate that microplastic would not accumulate in the environment. This can be demonstrated either by screening methods or higher tier methods.
2.33	Are biodegradable polymers 'excluded' from the microplastics definition or 'derogated'. Which of the two is it: excluded or derogated?	Particles containing solid polymers that fulfil the criteria for (bio)degradability set out in Appendix X are not considered to be microplastics and are derogated from the proposed restriction with no obligations for providing 'instructions for use and disposal' or 'reporting'.

#	Question	Answer
2.34	Can data from GLP-certified labs be used to assess biodegradability (instead of ISO 17025 certified labs)? How will ECHA check that biodegradability data used have well been obtained in quality certified labs?	Data on the (bio)degradability of polymers used to satisfy the derogation proposed in paragraph 3b must be obtained from reliable, quality assured, studies. The enforcement of REACH restrictions is performed by competent national enforcement authorities, not ECHA. They will check if the scope and criteria set in the restrictions are fulfilled by the companies placing substances and mixtures on the market. This is the key reason why the test methods and pass/fail criteria are prescriptive and require appropriate quality assurance. Equally, this is the reason that 'weight of evidence' approaches to compliance with this element of the restriction were ruled out by the Dossier Submitter. The required competence to assess weight of evidence approaches cannot be assumed to be available within Member States, and may be interpreted different in different Member States. During the opinion making phase, the Dossier Submitter clarified that data from either laboratories with ISO 17025 accreditation or with GLP certification would be acceptable to demonstrate that (bio)degradation criteria have been achieved. Please see section 2.2.1.6 and table 22 of the Background Document for additional information.
2.35	Does a biodegradation screening test have to be specifically listed in order to be accepted as a valid test? For example, certain test methods accepted under OSPAR are not included in the list of potential test protocols.	The acceptable standard test methods with the corresponding pass/fail criteria are detailed in the Background Document (cf. table 22 in section 2.2.1.6) and are proposed to be listed in an Appendix to the REACH Annex XVII entry in order that they can be readily updated in response to technical progress. The Background Document refers to this Appendix as 'Appendix X'.
2.36	How will inorganic polymers be regarded with respect to (bio)degradability? Acc. to REACH this is not an applicable information requirement for inorganics.	Polymers that contain carbon in the side-chains or backbone can be assessed using the biodegradability tests listing in Appendix X. Polymers that do not contain carbon cannot be assessed using the biodegradability tests listed in Appendix X, but these polymers should be assessed against the other criteria used to identify a microplastic to determine if the proposed restriction will affect their use.
2.37	Is it possible to use different methodologies or approaches (i.e. weight of evidence) when	No. The proposed methods and pass/fail criteria in Appendix X are prescriptive and cannot be modified. This is on the basis that enforcement is

#	Question	Answer
	assessing if the derogation in paragraph 3b on (bio)degradability is satisfied?	undertaken by Member State Competent Authorities.
2.38	Is it possible that other (bio)degradable test methods will be added to Appendix X?	The proposed test methods are listed in 'Appendix X' in the Background Document (cf. table 22), it is proposed to be listed in an Appendix to the REACH Annex XVII entry in order that they can be readily updated in response to technical progress.
2.39	Does the evaluation of biodegradation take into account the marine environment?	Yes. The criteria set for biodegradability also cover the marine environment. For example, several of test methods included in groups 4 and 5 are directly relevant to the marine environment. Similar to other aspects of REACH (e.g. PBT/vPvB assessment), the screening methods included in Appendix use 'ready biodegradation' tests, 'enhanced/modified ready biodegradation' tests or 'inherent biodegradation' tests, that are independent of specific environmental compartments but which have very stringent pass/fail criteria. It is considered that where a screening test is passed then (bio)degradation will occur in the environment in the event that a material is released. These criteria are no less stringent than for chemicals in general.

3. Obligations arising from the restriction at different levels of the supply chain

The boxes below outline the obligations for suppliers (manufacturers, importers, distributors and downstream users according to REACH definition), and downstream users at industrial sites, that will arise from the proposed restriction when placing on the market a substance or mixture containing a microplastic, or when using it (obligations for the downstream users at industrial site)

Each box is relevant to a particular actor/role in the supply chain, and includes the questions that the actor/role should ask themselves to identify its obligations:

- Box 1 represents the obligations of an **EU manufacturer of substances**, or an **importer of substance or mixture.**
- Box 2 represents the obligations of **downstream users**[191] [192]**(industrial activities) benefiting from the derogation 4a (use at industrial site)**
- Box 3 and 4 identify the different types of products, and the associated obligations of the importer or downstream user when placing on the market, **for consumer or professional**, substance or mixture containing microplastics. It identifies in particular the obligations of suppliers 'placing for the first time'[193] microplastics on the market for an end use allowed on the basis of paragraphs 4(b), 4(d), 4(e), or 5.

The obligations (in terms of reporting, 'instructions for use and disposal', placing on the market…) of each actor in the supply chain are identified in orange, magenta or salmon-pink coloured shapes.

A company in the supply chain might have also different roles under REACH: for example, a REACH manufacturer can also be a formulator, or a downstream user of the microplastics they are manufacturing (for example: plastic compounding for the production of plastic nurdles or pellets). In this case, the company will have to fulfil all obligations associated to the different roles.

It should be kept in mind that the definition of 'use' is defined in REACH Article 3(24) as 'any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation'.

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[191] More information on downstream users and end-users is available here: https://echa.europa.eu/regulations/reach/downstream-users/about-downstream-users/who-is-a-downstream-user, or in ECHA Guidance R12.

[192] End users are downstream users, they use substances or mixtures but do not supply them further downstream. Examples include users of adhesives, coatings and inks, lubricants, cleaning agents, solvents and chemical reagents like bleaching products. Ex. Producers of articles are end-user at industrial site. Professional painters or Consumer using a paint are also end-user.

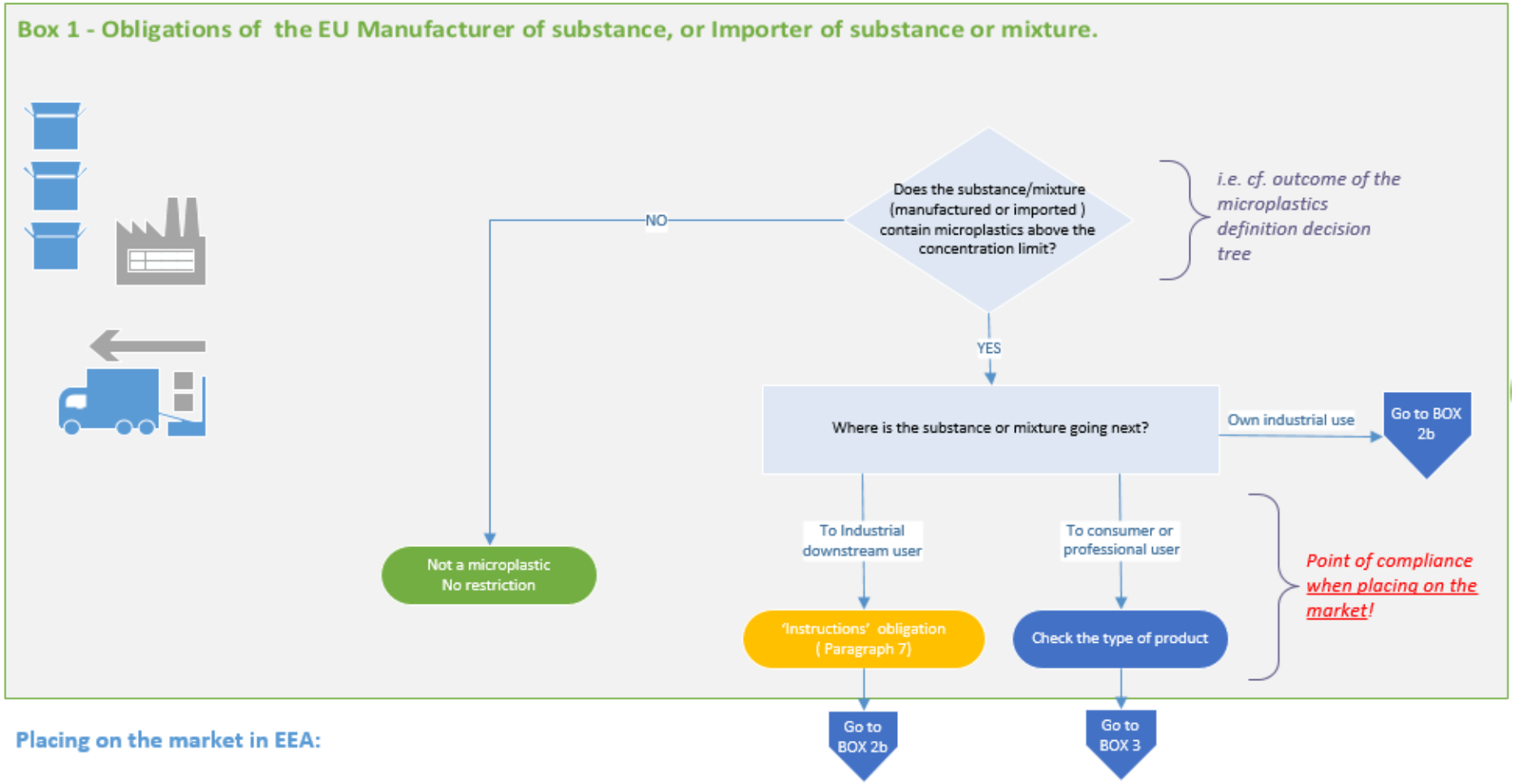
[193] 'Placing on the market for the first time' means the first natural or legal person who supplies or makes available substances, mixtures or articles on the market in the EU. The first placing on the market in the EU will either be by the manufacturer or the importer of the substance, mixture or article concerned.

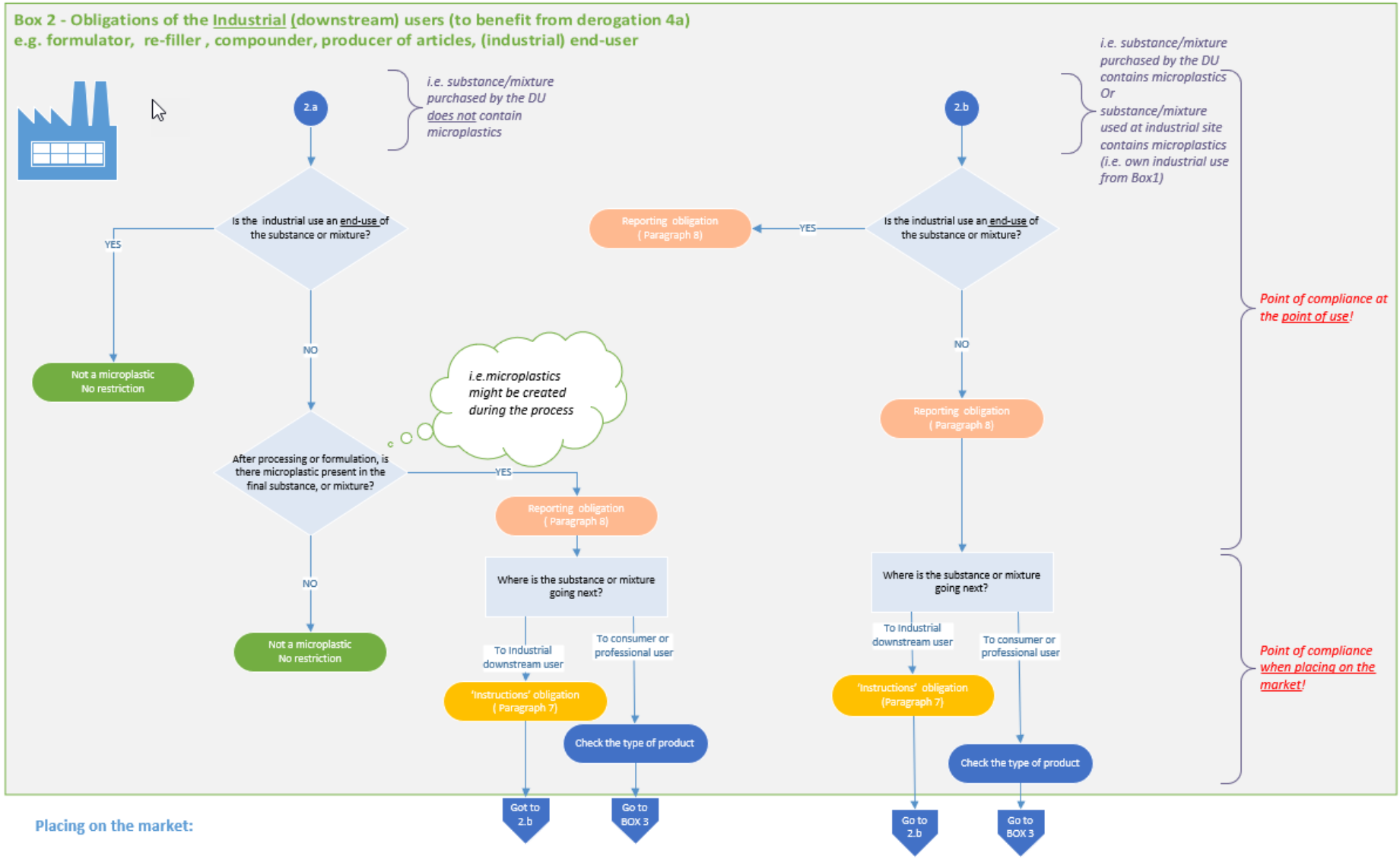
Distributors[194] are not considered as downstream users, they would have to comply with the 'instructions for use and disposal' obligations and pass down the supply chain relevant information necessary to enable appropriate use and disposal of the substance or mixture containing microplastic.

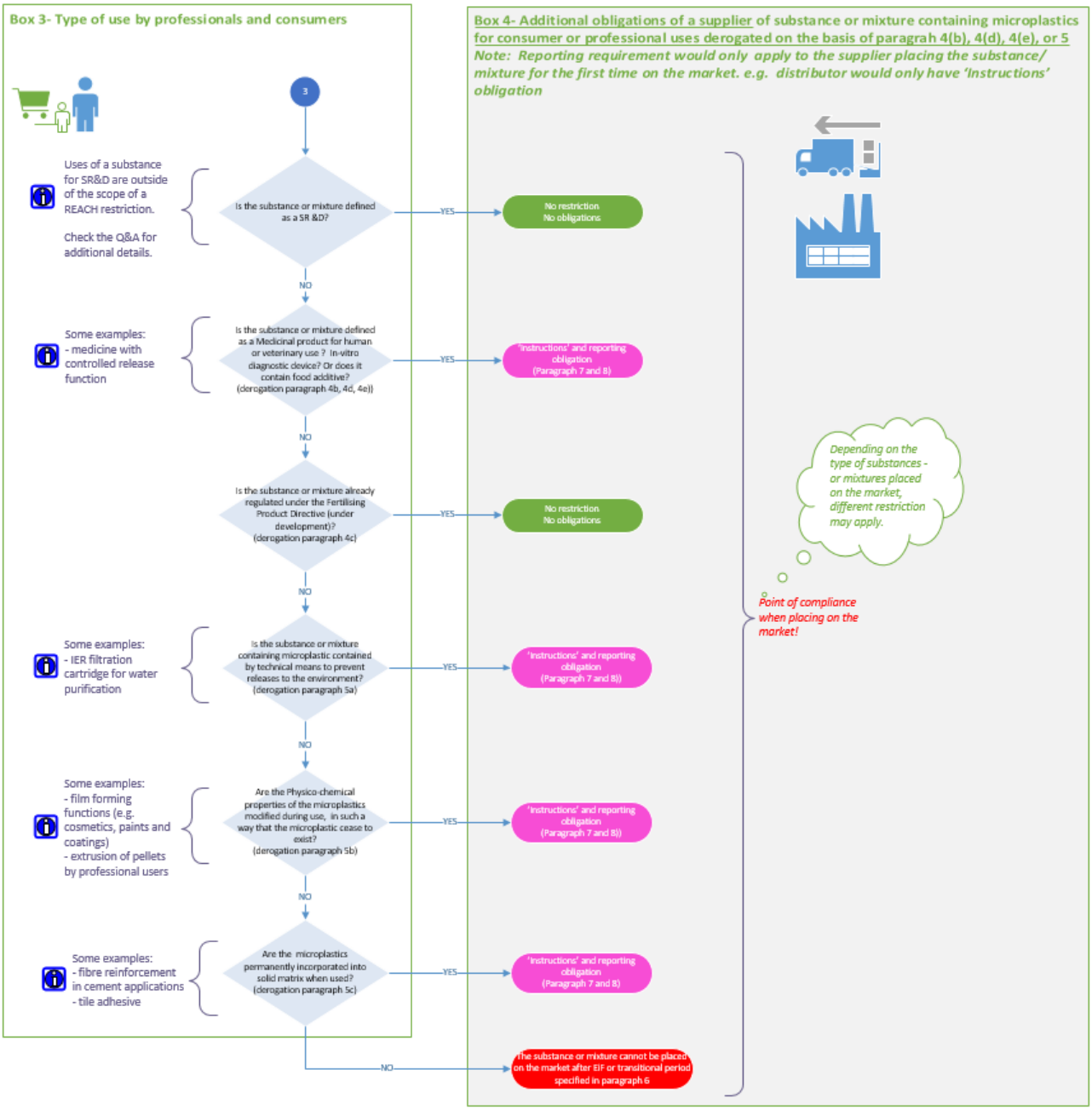
The green shapes indicate that there is no microplastic concern, or that no restriction applies ('full' derogation).

The red shape indicates that the substance or mixture cannot be placed on the market after the Restriction's entry into force (EiF) or the transitional period specified in paragraph 6 of the restriction proposal.

[194] Distributor: Actor who only stores and places on the market substances, on their own or in a mixture. This is not a downstream user according to REACH definition in Article 3(13 and 14).


Box 1 - Obligations of the EU Manufacturer of substance, or Importer of substance or mixture.
Does the substance/mixture (manufactured or imported) contain microplastics above the concentration limit?
NO
YES
i.e. cf. outcome of the microplastics definition decision tree
Where is the substance or mixture going next?
Own industrial use
Go to BOX 2b
To Industrial downstream user
To consumer or professional user
Not a microplastic
No restriction
'Instructions' obligation (Paragraph 7)
Check the type of product
Point of compliance when placing on the market!
Go to BOX 2b
Go to BOX 3
Placing on the market in EEA:


Box 2 - Obligations of the Industrial (downstream) users (to benefit from derogation 4a)
e.g. formulator, re-filler , compounder, producer of articles, (industrial) end-user
2.a
i.e. substance/mixture purchased by the DU does not contain microplastics
Is the industrial use an end-use of the substance or mixture?
YES
Not a microplastic No restriction
NO
After processing or formulation, is there microplastic present in the final substance, or mixture?
i.e.microplastics might be created during the process
YES
Reporting obligation (Paragraph 8)
Where is the substance or mixture going next?
To Industrial downstream user
To consumer or professional user
'Instructions' obligation (Paragraph 7)
Check the type of product
Got to 2.b
Go to BOX 3
NO
Not a microplastic No restriction
2.b
i.e. substance/mixture purchased by the DU contains microplastics Or substance/mixture used at industrial site contains microplastics (i.e. own industrial use from Box1)
Is the industrial use an end-use of the substance or mixture?
YES
Reporting obligation (Paragraph 8)
NO
Reporting obligation (Paragraph 8)
Where is the substance or mixture going next?
To Industrial downstream user
To consumer or professional user
'Instructions' obligation (Paragraph 7)
Check the type of product
Go to 2.b
Go to BOX 3
Point of compliance at the point of use!
Point of compliance when placing on the market!
Placing on the market:


Box 3- Type of use by professionals and consumers
Box 4- Additional obligations of a supplier of substance or mixture containing microplastics for consumer or professional uses derogated on the basis of paragrah 4(b), 4(d), 4(e), or 5
Note: Reporting requirement would only apply to the supplier placing the substance/ mixture for the first time on the market. e.g. distributor would only have 'Instructions' obligation
3
Uses of a substance for SR&D are outside of the scope of a REACH restriction.
Check the Q&A for additional details.
Is the substance or mixture defined as a SR &D?
YES
No restriction
No obligations
NO
Some examples:
- medicine with controlled release function
Is the substance or mixture defined as a Medicinal product for human or veterinary use ? In-vitro diagnostic device? Or does it contain food additive?
(derogation paragraph 4b, 4d, 4e))
YES
'Instructions' and reporting obligation
(Paragraph 7 and 8)
NO
Is the substance or mixture already regulated under the Fertilising Product Directive (under development)?
(derogation paragraph 4c)
YES
No restriction
No obligations
NO
Some examples:
- IER filtration cartridge for water purification
Is the substance or mixture containing microplastic contained by technical means to prevent releases to the environment?
(derogation paragraph 5a)
YES
'Instructions' and reporting obligation
(Paragraph 7 and 8))
NO
Some examples:
- film forming functions (e.g. cosmetics, paints and coatings)
- extrusion of pellets by professional users
Are the Physico-chemical properties of the microplastics modified during use, in such a way that the microplastic cease to exist?
(derogation paragraph 5b)
YES
'Instructions' and reporting obligation
(Paragraph 7 and 8))
NO
Some examples:
- fibre reinforcement in cement applications
- tile adhesive
Are the microplastics permanently incorporated into solid matrix when used?
(derogation paragraph 5c)
YES
'Instructions' and reporting obligation
(Paragraph 7 and 8)
NO
The substance or mixture cannot be placed on the market after EIF or transitional period specified in paragraph 6
Depending on the type of substances - or mixtures placed on the market, different restriction may apply.
Point of compliance when placing on the market!

4. Derogations

4.1. General questions

#	Question	Answer
4.1	Question removed - not relevant anymore	

4.2. Derogation for use at industrial sites (paragraph 4a)

#	Question	Answer
4.2	What is the definition of 'industrial sites' under the REACH regulation?	The REACH legal text refers to industrial and professional use [activity] in the definitions in Articles 3(13), 3(25) and 3(35), as well as section 6 of Annex VI. In Annex XVII the terms 'industrial installation' and activity of a 'professional outside industrial installations' are used. Guidance R.12 on Use description (ECHA, 2015) provides a non-exhaustive list of characteristics associated with industrial sites. Cf. Background Document Annex F for additional information.
4.3	ECHA R.12 Guidance does not fully clarify what an 'industrial site' is. Would onshore and sub-sea wells (offshore oil and gas) be considered as industrial sites?	ECHA R.12 Guidance covers various REACH-related considerations. The intention of the Dossier Submitter (in this case ECHA) was that the term 'for use at industrial sites' included in Paragraph 4a of the proposal would apply to **all industrial uses** of microplastics, including onshore and offshore oil and gas sites.
4.4	Would a recycling plant be considered to be an industrial site? Hence, do recyclers have to report to ECHA according to Paragraph 4a?	ECHA R.12 Guidance covers various REACH-related considerations. The intention of the Dossier Submitter was that the term 'for use at industrial sites' included in Paragraph 4a of the proposal would apply to **all industrial uses** of microplastics, including recycling facilities. The interface between waste legislation and REACH can be complex. Nevertheless, the Dossier Submitter considers that where a recycling plant manufactures microplastics (e.g. manufacture pellets of recycled plastic) and

#	Question	Answer
		places these on the market (for further use by a downstream user), then the requirements outlined in paragraph 7 to provide information on appropriate conditions of use to minimise releases to the environment would apply. In addition, the definition of 'use' in REACH is broad, it includes for example 'any processing, storage, keeping, filling into containers, transfer from one container to another'. Therefore, the recycling plant in order to benefit from the derogation 4a (use at industrial site) would also have to fulfil the reporting requirements outlined in paragraph 8. (cf section 3 Box1 –branch 2b and then Box 2 – branch 2b <Is the DU an end-user?><NO>). On the other hand, where a recycling plant produces the microplastics (e.g. pellets of recycled plastic) and uses them to produce articles at the same location (aka an 'integrated recycler'), then the reporting requirements outlined in paragraph 8 would apply to the recycling plant, but not those outlined in paragraph 7 (cf section 3 Box1 –branch 2b and then Box 2 – branch 2b <Is the DU an end-user?><YES>).
4.5	Our understanding is that only mixtures containing microplastics that have their end use at industrial sites would be subject to reporting and labelling criteria set out in paragraphs 7 and 8, and not raw materials used at industrial sites higher up the supply chain. Can you confirm this?	Your understanding is not correct. The purpose of paragraph 7 is to ensure that relevant information on conditions of use to minimise releases of microplastics to the environment is available throughout the supply chain: this includes all industrial uses derogated from the restriction on the basis of paragraph 4(a). The 'instructions for use and disposal' requirement is also intended to enhance information availability in industrial supply chains in relation to the presence of microplastics in substances and mixtures with the aim to facilitate compliance with the proposed restriction, in particular the reporting requirement (paragraph 8). This is why the information to be identified either on the label and/or SDS and/or 'instructions for use' (IFU) and/or 'package leaflet' is extended in case of industrial use of the microplastics. The purpose of the reporting requirement outlined in paragraph 8 is to understand where residual releases of (derogated uses) of microplastics may occur, in order that the effectiveness of restriction can be assessed over time. It would therefore apply to industrial end use (e.g. use of coatings containing

#	Question	Answer
		microplastics at industrial site, or use of pellets to produce articles), but also where a substance or mixture containing microplastics is further processed at an industrial site (e.g. formulation) before being supplied further down in the supply chain either to another industrial site or a consumer. Section 3 of this documents sets out the obligations arising from the proposed restrict for different actors Additional details on the paragraph 7 and 8 requirements are also available in section 2.2.1.4 and 2.2.1.5 in the Background Document.

4.3. Derogation for containment by technical means (paragraph 5a)

#	Question	Answer
4.7	What is the definition of 'contained by technical means'? (in paragraph 5a)	Please note that the wording of the paragraph 5a has been changed to 'Substances or mixtures containing microplastic where the microplastic is contained by technical means to prevent releases to the environment during end use' during the opinion making phase. Paragraph 5a aims at derogating from the restriction uses of microplastics where a specific technical design is implemented to prevent, by technical means, the release of microplastics to the environment during their use. 'Contained by technical means' could be, for example, when microplastics are contained during their use in a cartridge or column with no potential for release. An analogy could be the concept of 'rigorous containment' introduced in REACH when considering the registration of substances used as intermediates under 'strictly controlled conditions'.
4.6	Are ion exchange resins used for water treatment microplastics within the scope of the proposed restriction?	According to the information provided during the call for evidence and the Annex XV restriction consultation, Ion exchange resins (IER) used for water treatment would fall under the definition of microplastics.

#	Question	Answer
		If used at an industrial site, IER for water treatment would be derogated according to paragraph 4a. In other cases (professional and consumer uses), IER for water treatment could be derogated according to paragraph 5a as long as IER is contained by technical means to prevent releases of microplastic to the environment during end-use. In all the above situations, the requirement (paragraph 7) to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) and reporting would apply as well.
4.8	Are microplastics contained in an article out of the scope of the restriction?	Microplastics contained within an article throughout their whole lifecycle to prevent releases to the environment would benefit (i) either from the derogation under paragraph 5a if the microplastic are contained by technical means such as a cartridge or closed container, or (ii) from the derogation under paragraph 5c if the microplastic are permanently 'contained' at the point of use and permanently incorporated into a solid matrix when used. The derogation is intended to work together with the requirement (paragraph 7) to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) and reporting elements of the proposal (paragraph 8).

4.4. Derogation for loss of microplastic form at point of use (paragraph 5b)

#	Question	Answer
4.9	Paragraph 5b of the proposed restriction provides a derogation for 'substances and mixtures where the physical properties are permanently modified when the substance is used'. The Background Document section 2.2.1.2. indicates that this applies when 'the particle ceases to exist'. Can this concept be	This derogation is indeed intended to address the issue where microplastics are present in a substance or mixture placed on the market, but these are 'consumed' or otherwise cease to exist in the form of microplastics at the point of use. This mainly corresponds to the loss of the particulate nature of the microplastic through various physico-chemical processes or chemical reactions. e.g.

#	Question	Answer
	further clarified.	• Coalescence of film-forming particles (e.g. polymer binders in paints and coatings) when applied to a surface. • Water 'soluble' polymers, including the disassociation of polymers from the surfaces of inorganic particles • Use of pre-production pellets or powders to manufacture articles though an extrusion or similar process (**if not at an industrial site**). Section 2.2.1.2 of the dossier simply recognises that the presence of a 'particle' is one of the key diagnostic properties of a microplastic. Any of the properties, e.g. state, could be substituted for particle. The derogation is intended to work together with the requirements (paragraph 7) to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) and reporting elements (paragraph 8).
4.10	Are super absorber polymers (SAP) an example for when derogation 5b would apply? How about a polymer-based thickener for cosmetic use where the polymers swell in the cosmetic formulation?	The Dossier Submitter has taken a pragmatic approach to determine whether a swellable polymer is in or out of the scope of microplastic restriction based on the 'original' physical state of the polymer particle prior to swelling taking place. The determining factor is whether or not the SAP or polymer-based thickener is in a solid particulate form in the product before swelling. Having said that, if the swelling process of the SAP or the polymer-based thickener is irreversible (i.e. after swelling the liquid is strongly retained and it is not released mechanically any more), then these polymers might be derogated based on paragraph 5(b) as a permanent modification happened at point of use resulting in loss of microplastic form (e.g. the size of particle >5mm). This is valid provided that all other criteria of the regulatory definition has also been carefully assessed and not met. Section B.1.3.9 of the Background Document annex contains further details.
4.11	Regarding 'film forming', does it only refer to	The derogation proposed in paragraph 5b is not limited by the type of

#	Question	Answer
	leave-on cosmetic products or to rinse-off products, e.g. all conditioning polymers form a film on the hair.	product and could apply to a rinse-off cosmetic product. Paragraph 5a requires a **permanent** loss of particle form at the point of end use.
4.12	Are all waxes and polishes covered? If a wax contains solid glittering polymers, is it still covered by the derogation scope?	The intention is that the film-forming elements of a formulation would be derogated, but that other components, if they would remain microplastics, would not unless they are **permanently** incorporated into a solid matrix – i.e. derogation 5(c).
4.13	Why are microplastics that form films excluded? Don't they break down into microplastics over time and are released into the environment.	The proposed restriction relates to intentionally added microplastics. Any secondary microplastics that are formed during the service life of a film are not covered by the current restriction proposal as they are not intentionally added to the product.
4.14	How could a manufacturer or downstream user placing a microplastic on the market demonstrate that microplastics are permanently modified when used (exemption 5b)	Enforcement is the responsibility of Member States. Downstream users should consider collating relevant evidence that supports their conclusion that the derogation would apply for their product, that could include the results of experimental studies e.g. on the presence of solid particles and make this available to enforcement on request.

5. Supply chain information / communicating 'instructions for use and disposal' (paragraph 7)

#	Question	Answer
5.1	How do you suggest 'microplastic content' information is passed down the supply chain to the end user placing on the market?	The requirement specified in paragraph 7 of the proposed restriction is intended to inform downstream users and consumers about appropriate conditions of use to minimise releases of microplastics to the environment. It does <u>not</u> require that products are labelled as 'contains microplastics'. Although this requirement was initially referred to, for brevity, in the Annex XV report as the 'labelling' requirement, it has been renamed in the Background Document as 'instructions for use and disposal'. It should be

#	Question	Answer
		understood as a requirement for actors placing microplastics on the market (for derogated uses) to provide instructions on how to use or dispose of the product in the most appropriate way. This information could be included e.g. on a label, in a product leaflet or as part of the SDS. If the information is included as part of the SDS, sections 2, 6, 7, 8, 13, 14, 15, 16 and/or the appended exposure scenarios may be relevant, depending on the specific circumstances. Section 15 of the SDS for 'Regulatory Information' is likely to be the appropriate place to identify that a substance/mixture is subject to the conditions of use prescribed in the proposed restriction and provide sufficient information on the composition of the substance/mixture to allow industrial downstream users to comply with the paragraph 8 reporting requirements. Additional details on the 'instructions for use and disposal' requirement is available in the Background Document section 2.2.1.4.
5.2	Why do we need labelling/reporting for derogated substances like pharmaceuticals?	The purpose of the paragraph 7 requirement is to influence how the products are used and disposed of in a way that minimises the negative impacts on the environment. For pharmaceuticals, this could for example instruct users not to dispose of the unused products down the drain. The paragraph 8 reporting requirement will help to monitor residual release of microplastics and to assess whether there is a need for further regulatory action on the derogated uses in the future.
5.3	Does a biodegradable microplastic need labelling?	Polymers that are biodegradable (as set out in the criteria in Appendix X in the restriction dossier) are not considered microplastics. Therefore, paragraph 7 requirement does not apply to them.
5.4	What will be the requirements of 'instructions for use and disposal', because most polymers are not classified as hazardous, and as such their identity does not need to be detailed on the SDS.	According to Article 32 of REACH, suppliers who do not need to supply an SDS still need to provide relevant information about the substance to enable appropriate risk management measures to be identified and applied e.g. an SDS can be supplied on a voluntary basis. As such, the requirements under paragraph 7 would not be different for substances/mixtures that are not

#	Question	Answer
		required to have SDS. In these cases, actors placing substances/mixtures on the market should identify that a substance/mixture is subject to the conditions of use prescribed in the proposed restriction and provide sufficient information on the composition of the substance/mixture to allow downstream users to comply with the paragraph 8 reporting requirements.
5.5	Will a product SDS have to disclose the chemical identity of the microplastic? How can proprietary information be maintain?	If the substance/mixture is classified or if the substance is persistent, bioaccumulating and toxic (PBT) or if it is, based on other hazards, included in the Candidate list of substances of very high concern under REACH, then the substance must be identified in accordance with the rules outlined in sections 1 and 3.1 (or 3.2 for a mixture) of the SDS. If the mixture is not classified and the substance does not fulfil the conditions of REACH Article 31(3) then there is no requirement for an SDS. In this case an SDS can be provided on a voluntary basis. In these cases, to facilitate the communication in the supply chain, and the reporting requirement, actors placing substances/mixtures on the market for industrial use should identify that a substance/mixture is subject to the conditions of use prescribed in the proposed restriction and provide sufficient information on the quantity (or concentration) of microplastics present as well as sufficient information on polymer identity to allow DUs to comply with paragraph 8 reporting requirements. As paragraph 8 reporting requirements only require generic information on substance identify proprietary information will not be needed.
5.6	If products, for example detergents, containing microplastics are ban only after a transition period, will these products be subject to reporting and labelling requirements before the transition period has expired?	The requirements for providing 'instructions for use and disposal' (paragraph 7) and reporting (paragraph 8) only apply when a derogation from paragraph 1 is required to continue placing a substance / mixture containing a microplastic on the market. Thus paragraph 7 and 8 requirements only apply after the transitional periods outlined in paragraph 6 have expired. However, if not specifically identified in paragraph 6 then it will be necessary to provide 'instructions for use and disposal' and/or reporting from EIF + 24

#	Question	Answer
		months and EIF + 36 months, respectively when derogated from paragraph 1. For example: 1. Paragraph 7 requirements apply (EIF + 24 months) when placing on the market ingredients containing microplastics that are used to formulate a detergent (as defined in regulation (EC) No 648/2004) derogated from paragraph 1 under para 4(a) [i.e. a use at an industrial site]. 2. Paragraph 8 requirements apply (EIF + 36 months) for a DU undertaking formulation with microplastics taking place under para 4(a) [use at industrial sites] irrespective of the type of product. 3. Paragraph 7 and 8 apply to consumer paints containing microplastics derogated from paragraph 1 on the basis of para 5(b), and well as relevant preceding life-cycle steps e.g. formulation.

6. Reporting requirement (paragraph 8)

#	Question	Answer
6.1	If a polymer particle or particle containing solid polymer meets the microplastic definition and falls under some of the derogations, a reporting and labelling obligation arises. If in the further course it is or contains no more microplastics, when will this reporting and labelling obligation be expired? Or in other words, once it is a microplastic, will it remain a reportable microplastic for all time?	The reporting requirement (paragraph 8) and the requirement (paragraph 7) to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) expire when the use no longer requires the derogation to continue.
6.2	There are examples of materials which if they enter the environment they effectively cease to be microplastics (e.g. they swell). As such they cannot contribute to microplastic loadings in the	Please refer to the question 2.27 and 4.10.

#	Question	Answer
	environment and cannot contribute to any risk. How is the need to label or report justified here?	
6.3	Can you explain the reporting responsibilities for industrial users again please? does, and as such their identity does not need to be detailed on the SDS. The polymer identity may be CBI, and disclosing this to industrial Downstream Users would be an issue.	The reporting obligations for industrial users are detailed in Section 3 of this Q&A document, and in section 2.2.1.5 of the Background Document. The reporting requirement will help to monitor residual release of microplastics and to assess whether there is a need for further regulatory action on the derogated uses in the future. To aid the interpretation of the reporting requirement the Dossier Submitter has separated and clarified the obligations for industrial (downstream) users to report their own uses (derogation for industrial use set in paragraph 4a) from the obligation of suppliers to report information about the end uses (predominantly of professionals and consumers) derogated from paragraph 1 by means of paragraph 5. The information on the polymer identity to be communicated in the supply chain (paragraph 7) to allow a proper reporting has been deliberately worded to allow flexibility in its application: 'sufficient information on the polymer(s) contained in the substance or mixture' should be communicated via the supply chain. In addition, the information gathered via the reporting will be collated and published (in an anonymised form if necessary).
6.4	Confidentiality of polymers in case of reporting: What if my upper suppliers refuse to disclose information (the identify of polymers) to us even under NDA (Non Disclosure Agreement)? Would there be any flexible ways of reporting?	The information on the polymer identity to be communicated in the supply chain (paragraph 7) to allow a proper reporting has been deliberately worded to allow flexibility in its application: 'sufficient information on the polymer(s) contained in the substance or mixture' should be communicated via the supply chain.
6.5	The quantities of microplastics in mixtures of chemicals are often commercial sensitive information. There are cases that end-users have	During the opinion making phase, the Dossier Submitter has proposed to extend the 'instructions for use and disposal' requirement to oblige actors placing substances or mixtures on the market for downstream use at

#	Question	Answer
	no access to detailed percentage or full disclosure of mixtures, only content ranges are available. How can paragraph 8 obligations be met in these cases?	industrial sites (paragraph 4(a)) to clearly identify that the substance/mixture is subject to the conditions of the proposed restriction and to include on, where relevant, (i.e. either on the label or package leaflet or SDS or instructions for use) the quantity (or concentration) of microplastics present and sufficient information on polymer identify for downstream users or suppliers to comply with the proposed reporting requirements.
6.6	How can one quantify the release of microplastics to the environment either estimated or measured?	The standard methodologies for exposure assessment of chemicals, e.g. those outlined in relevant REACH Guidance, are expected to be sufficient to satisfy the reporting requirements outlined in the proposed restriction, including the use of default values i.e. those established for ERCs or in OECD emission scenario documents In addition, refined default-based approaches for specific uses/sectors, such as those used to derive spERCs, are envisaged to be usefully applied to meet the reporting obligation. Please refer to the ECHA website for more information https://echa.europa.eu/csr-es-roadmap/use-maps/concept
6.7	Related to reporting requirement, paragraph 8, it says any downstream user using a microplastic, Does it include upstream polymer producers using polymer as their pre production? i.e. do upstream producers also have reporting requirement?	The purpose of the reporting requirement outlined in paragraph 8 is to understand where residual releases of (derogated uses) of microplastics may occur, in order that the effectiveness of restriction can be assessed over time. It would therefore apply to industrial end use (e.g. use of coatings containing microplastics at industrial site, or use of pellets to produce articles), but also where a substance or mixture containing microplastics is processed at an industrial site (e.g. formulation) before being supplied further down in the supply chain either to another industrial site or a consumer. Section 3 of this documents sets out the obligations arising from the proposed restrict for different actors.
6.8	In paragraph 8, what is the meaning of placing a microplastic on the market for the first time?	Article 3(12) of REACH defines 'placing on the market' as supplying or making available, whether in return for payment or free of charge, to a third party. Import is deemed to be placing on the market.

#	Question	Answer
		'Placing on the market for the first time' limits the scope of the restriction to the first natural or legal person who supplies or makes available substances, mixtures or articles on the market in the EU. The first placing on the market in the EU will either be by the manufacturer or the importer of the substance, mixture or article concerned.

7. Socio-economic aspects of the restriction proposal

#	Question	Answer
7.1	'Capsule Suspension' formulation can reduce the amount of active substance required in a plant protection product. Can the environmental benefits of uses of microplastics be compared to the potential risks of microplastic emissions?	The Dossier Submitter acknowledges that microencapsulation can provide environmental benefits, especially in agricultural uses (reduction of pesticides and fertilisers used, reduced run-off, etc.). Therefore, the proposal suggests that the transition to biodegradable polymers is closely monitored after the implementation of the proposal and, where socioeconomically valuable applications appear likely to be lost to society despite efforts to substitute, a review of the implementation timetable of the restriction may be needed. The restriction is intended to lead to an overall reduction in risk. The environmental benefits of microencapsulation, as well as availability of alternatives, have been evaluated by RAC and SEAC during the opinion making phase.
7.2	How is proportionality assessed in the restriction?	Proportionality of the proposed restriction is assessed on a per-sector basis (and where information permits even on a product group level). Thereby the costs incurred per sector are compared to their microplastic emission potential. A detailed description of the approach taken can be found in Chapter 2.3 of the Background Document.
7.3	Question removed – not relevant anymore	

8. Sector specific questions

8.1. Agrochemicals

#	Question	Answer
8.1	Question removed – not relevant anymore	
8.2	In the assessment of agrochemicals in the Background Document, reference is made to biodegradation criteria that may be set under Article 42(6) of the new fertilising products regulation (EU 2019/1009). As these criteria have not yet been set (and may not be set until at least 2024) how can they be used for assessing the biodegradability of microplastics?	The new fertilising products regulation sets an obligation for the Commission to assess biodegradation criteria for polymers used in coating agents and to increase the water retention capacity or wettability of the EU fertilising products by 16 July 2024. Where appropriate, based on this assessment, biodegradation criteria shall be set provided that they comply with the requirements listed in Article 42(6) of this Regulation. In the absence of these criteria, the criteria outlined in Table 22 of the Background Document (Appendix X) *for 'demonstrating (bio)degradability if microplastics are deliberately applied to soil or foliage'* can be used to assess the (bio)degradability of microplastics in agrochemicals.
8.3	Will the restriction also apply to the application of biosolids (e.g. treated sewage sludge) to agriculture land?	Paragraph 4 of the restriction proposal propose a complete derogation of sludge and compost from the scope of the restriction. Microplastics are indeed not intentionally added into sludge and composts. However, they might be present in industrial sludge and compost supplied or sold to professionals (e.g. farmers) or consumers as a result of water treatment or composting process. These microplastics will be present unintentionally and it is not the intention of this restriction to prevent the placing on the market of these products

8.2. Infill material for synthetic turf

#	Question	Answer
8.4	Will you elaborate the term 'in fill material'? What is it?	Infill material are the granules of synthetic polymeric material that are used in many types of artificial sports turf. The infill material supports individual blades of synthetic grass so that they remain upright. Infill material also gives artificial turf its cushioned feel, or bounce. Infill material may be produced from end-of-life tyres (ELT) or other synthetic elastomeric materials. They are likely to be an intentionally added microplastic.
8.5	Is artificial turf infill exempted from the restriction if it is demonstrated that its dispersion into the environment is prevented by the use of appropriate 'technical means'?	No. The Dossier Submitter has proposed two restriction options to address releases of microplastics from synthetic turf sports pitches : Option A – use of risk management measures after a transition period of three years; Option B – complete ban on placing on the market after a transition period of 6 years. The derogation proposed under 5a of the restriction proposal for containment by technical means is not considered to be applicable to the use of infill material for synthetic turf.

8.3.Cosmetic products

#	Question	Answer
8.6	Should the restriction be adopted, who would be responsible for ensuring that a microplastic placed on the market falls within the scope of a derogation? Would it be the raw materials manufacturers or the finished cosmetic product manufacturer?	In general, it is the responsibility of the actor who is putting a product on the EU market to ensure that it complies with EU regulation. The requirements detailed in paragraph 7 of the proposal for actors placing microplastics on the market to include appropriate 'instructions for use and disposal' on a label and/or SDS should help downstream users to comply with their obligations under the proposed restriction.
8.7	Question removed – not relevant anymore	
8.8	Microbeads contained in rinse-off products are not covered by transitional agreements. Will the	Yes. It is proposed that the restriction on the placing on the market of 'microbeads' (as defined in the proposal) in cosmetic products or other

#	Question	Answer
	restriction consequently enter into force directly after adoption? Or, in other words, is the date of adoption the date of entry into force?	mixtures (e.g. substance-based medical devices) would apply from the entry into force date of the restriction. No transitional period is proposed for the use of microbeads.
8.9	Does the CosmEthics database provide information on alternative ingredients or only alternative products?	CosmEthics, Que Choisir and the Danish Forbrugerrådet Tænk are all sources of information on the ingredients used in cosmetic products placed on the EU market. These data were used by ECHA to analyse the availability of cosmetic products on the EU market that were not likely to contain microplastics in different product categories. Alternative ingredients, per se, were not identified. The information collated by CosmEthics, Que Choisir and the Danish Forbrugerrådet Tænk were collected independently. The analysis of data from different sources lead to comparable results.

8.4. Inks and printing

#	Question	Answer
8.10	What are the grounds for considering printing inks as derogated i.e. labelling and reporting requirement, no ban on use).	Microplastics in printing inks form a film when used and are therefore derogated in accordance with paragraph 5(b) of the restriction proposal. The releases from printing inks are mainly expected to come during the maintenance of the machines. Since these releases are not inevitable, the requirement to provide information about conditions of use is expected to minimise releases to the environment. This information can be included on a label, as a package insert, or an SDS or similar.
8.11	Are printing inks in the scope of microplastics? Toners seem to be in the scope, but what about inkjet printing liquid inks?	Yes. Any substance or mixture placed on the market that contains microplastics is within the scope of the proposed restriction, unless derogated. Therefore, printing inks containing microplastics (including inkjet printing

#	Question	Answer
		liquid inks) would be included the scope of the restriction. If these microplastics form films during use then paragraph 7 ('instructions for use and disposal') and 8 (reporting) requirements would apply to them, but not the ban on the placing on the market (described in paragraph 1).

8.5. Packaging

#	Question	Answer
8.12	Are food-contact materials included within the proposed restriction?	If by 'food-contact materials', it is meant the packaging of food within the meaning of Regulation (EC) No 1935/2004. Then this is outside the scope of the proposed restriction as packaging would not fall within the relevant size limits of the microplastic definition.
8.13	Is the primary packaging used for medicines for human or veterinary use within the scope of the proposed restriction?	No. The primary packaging of medicines for human and veterinary products (e.g. blister, pill box, etc.) would not fall within the relevant size limits of the microplastic definition. Nevertheless, the paragraph 7 and 8 requirements would apply to the master-batches/pellets used to produce the primary packaging. It should be noted that the paragraph 7 requirement to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) and the reporting requirements (paragraph 8) apply to microplastics used in human and veterinary medicines.

8.6. Paints and coatings

#	Question	Answer
8.14	If I make a raw material for paints that contains microplastics as per the definition and send to company B for formulation into a final paint, who is responsible for labelling/reporting?	The requirement to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) applies to both you and company B as it concerns 'any supplier responsible for the placing on the market'. The purpose of the reporting requirement outlined in paragraph 8 is to understand where residual releases of (derogated uses) of microplastics may occur, in order that the effectiveness of restriction can be assessed over time. It would therefore apply to Company B if Company B is an industrial formulation site. Company B would have to report its own use. In case Company B is a retailer or a distributor (even if Company B undertake further formulation – e.g. mixing of custom paint colours on retailer premises), then the reporting requirement would have to be made by the industrial formulator (in this case you) placing the product on the market for consumer or professional end use for the first time. Note that the definition of use is broad in REACH, therefore in case you, in your company, do some pre-formulation, or storage, keeping, filling/transfer into containers, would also have to report your own use. To aid the interpretation of the reporting requirement the Dossier Submitter has separated and clarified the obligations for downstream users to report their own uses from the obligation of suppliers to report information about the end uses (predominantly of professionals and consumers) derogated from paragraph 1 by means of paragraph 5. Section 3 of this documents sets out the obligations arising from the proposed restrict for different actors. You can also refer to section 2.2.1.4 and 2.2.1.5 in the Background Document.
8.15	Would microplastics in artist's paint that are film-forming be derogated from the proposed restriction?	Paints, including artist paints, are derogated from the ban on the placing on the market (derogation 5b). However, the requirement (paragraph 7) to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) and the

#	Question	Answer
		reporting requirements apply to them.
8.16	Would the derogation for paints be applicable to the use of those paints by consumers?	Yes. The proposed restriction is on the placing on the market of microplastics, rather than their use. The proposed derogation for placing microplastics on the market that are film-forming (derogation 5b) applies to paints and coatings for professional and consumer uses. However, microplastics may be placed on the market only where the conditions specified in paragraph 7 to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) and in paragraph 8 on reporting are satisfied. Therefore, while the restriction does not introduce any legal obligations for consumers, the label requirements will ensure that consumers are provided with relevant 'instructions for use and disposal', for example in relation to the correct disposal of wastes arising from brushes/rollers.

8.7. Pharmaceuticals and medical device

#	Question	Answer
8.17	Is our understanding correct that Pharmaceutical applications (e.g. polymer coatings to allow lower Active Pharmaceutical Ingredient concentrations in medicine, pills, etc.) are out of scope of this restriction?	Partially. The proposed restriction is that microplastics in human and veterinary medicines (as defined in EU Directives 2001/83/EC and 2001/82/EC, and in EU Regulation (EC) No 726/2004) are derogated from the ban on the placing on the market but that the paragraph 7 ('instructions for use and disposal') and paragraph 8 (reporting) requirements apply.
8.17b	Will substance based medical devices be derogated from the restriction proposal?	No. According to the Dossier Submitter restriction proposal, Substance based medical devices (i.e. medical devices in the form of substance or mixture) containing intentionally added microplastics are proposed to be banned from the market after a transition period of 6 years as proposed in paragraph 6b.

#	Question	Answer
		Nevertheless, if the microplastic in the substance based medical devices has an abrasive function (e.g. some microplastics in dental toothpaste classified as medical device), then the ban would apply without any transition period.
8.17c	Is our understanding correct that 'Bioresorbable implants' (Medical Device - class III, EU-Regulation 2017/745) are out of scope of this restriction? Bioresorbable implants are regarded as Articles under the REACH Regulation. Most of the final implants have a size which is much larger than the one set in the paragraph 2a, but some implants for very specialised applications like very small screws, which are used in ligament ruptures, could have a dimension as small as the one defined in the paragraph 2a of the proposed restriction.	The scope of the restriction refers to the placing on the market of substances on its own or in a mixture as a microplastic. Your understanding is therefore correct: the placing on the market of the bioresorbable implant for use by professional (e.g. surgeon) would therefore not fulfil the microplastic definition. Articles, whatever their dimensions, used in medical device applications would not be affected by the restriction proposal. Nevertheless, Paragraph 7 and 8 requirements would apply to the preceding life-cycle steps e.g. formulation at industrial site unless the polymers particles could benefit from one of the derogations set in paragraph 3 of the proposed restriction.

8.8. Feed and food

#	Question	Answer
8.18	What is the rule regarding the inclusion of substances that are authorised under sectorial legislation, such as food additives and food and feed applications?	A REACH Restriction can apply, irrespective of the existence of other sectoral legislation, especially if a different risk is being managed - i.e. in this specific case the environmental risk is not addressed under the food regulation.
8.19	Are feed and food applications within the scope of the proposal even though these are regulated under other sectoral legislation? If so, are wax-like materials (polymers) used for coating feed/food that are digested within the scope?	Yes. Uses of microplastic in feed and food are in within the scope of the proposed restriction if all elements of the microplastic definition are met e.g. dimensions, solid particles etc. The digestion of polymers after ingestion could be analogous to the derogation outlined in paragraph 5b of the proposal. The derogation for (bio)degradable or natural polymers may also be applicable.

#	Question	Answer
8.20	If food fortified with ingredients using microplastics is manufactured and distributed from Europe for consumption in Africa, does the restriction apply?	The direct export outside of the EU/EEA of food supplements containing microplastics manufactured in Europe would still be possible under the proposed restriction, but only where not placed on the EU/EEA market first.

8.9. Pre-production plastic pellets (nurdles) and plastic compounding

#	Question	Answer
8.21	Are pre-production pellets and masterbatches outside of the scope of the proposed restriction?	Partially. Placing microplastics on the market for use at industrial sites is derogated from the restriction, but paragraph 7 ('instructions for use and disposal') and paragraph 8 (reporting) requirements would apply. Paragraph 8 would apply, because the definition of 'use' in REACH is broad, it includes for example 'any processing, formulation, storage, keeping, filling into containers, transfer from one container to another, etc'. Therefore the pre-production of pellets and masterbatch in order to benefit from the derogation 4a (use at industrial site) would have to fulfil the reporting requirements outlined in paragraph 8. (cf section 3 Box1 –branch 2b and then Box 2 – branch 2b <Is the DU an end-user?><NO>). Note that the derogation described in paragraph 5b for permanent modification would also apply if placing on the market for use outside of an industrial site. In this case the paragraph 7 ('instructions for use and disposal') and paragraph 8 (reporting) requirements would also apply. It should be noted that in this situation, only the supplier placing the product on the market for the first time has to comply with the reporting requirement, not retailers. Products containing microplastics which are directly exported, thus not placed on market, are not subject to the reporting requirement.
8.22	Company A ships microplastic particles to Company B within the EU. Company B produces	From the question, we understand that:

#	Question	Answer
	an article whereby the microplastic particles are 'consumed' in accordance with derogation 5.b. What are the obligations of Company A and Company B?	- both company A and B are industrial sites - company A is producing (and using) microplastic particles and placing them on the market - company B is using a microplastic to produce articles during which the microplastic particles are permanently modified 'consumed'. The articles are then placed on the EU/EEA market. Both paragraph 7 and 8 would apply to company A. It should be kept in mind that the definition of 'use' defined in REACH Article 3(24) is broad and includes for example 'any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation'. Company A would therefore be considered as both a manufacturer and industrial user of the microplastics (cf section 3 Box1 –branch 2b, and Box2 –branch 2b <Is the DU an end-user?><NO>). The reporting requirement only applies to company B, as a downstream end-user of the microplastic (cf. section 3 Box2 - branch 2b <Is the DU an end-user?><YES>). Please refer to Section 3 of this document for further information on the obligations that arise at different levels of the supply chain from the proposed restriction.
8.23	Does an electrical cable (with polymer insulation material) fall within the scope of this restriction?	No. An electrical cable would be very unlikely to fulfil the definition of microplastic as it would typically exceed the maximum size criterion of either 5mm (for non-fibres) or 15mm (for fibres).
8.24	What about pellet losses during transportation by exporters outside of the EU/EEA? Are exporters from the EU/EEA required to report losses?	Not as currently proposed. Transportation is not a 'use' under the REACH Regulation. However, if the transportation includes at least one of the following activities: such as any storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, then this would be considered as a 'use' under the REACH Regulation, and the restriction would apply. Uses at industrial site could benefit from a derogation, but reporting requirement would apply.

8.10. Other sectors

#	Question	Answer
8.25	Are biocidal products excluded from the proposed restriction?	No. Biocidal products are within in the scope of the proposed restriction, as are plant protection products. In this specific case, the risk posed by the presence of microplastics in Biocidal products is not addressed by the existing Biocidal Products Regulation and it would be covered by the REACH restriction.
8.26	Is glitter in clothes (printed/coated) under the scope of the restriction?	Glitter would be in scope if the use would not meet the 5 c derogation for permanent containment in a solid matrix.
8.27	Are lego® blocks, or other type of small articles (REACH definition of article) under the scope of the restriction?	The scope of the restriction refers to the placing on the market of substances on its own or in a mixture as a microplastic. Therefore, the placing on the market of Articles, whatever their dimensions, would not be affected by the restriction proposal. Nevertheless, if the article contains substance or mixture, the restriction would apply if not derogated (cf. question 8.26 as an example). In any case, Paragraph 7 and 8 requirements would also apply to the preceding life-cycle steps e.g. formulation at industrial site unless the polymers particles could benefit from one of the derogations set in paragraph 3 of the proposed restriction.

9. Miscellaneous questions

#	Question	Answer
9.1	Will there be a guidance developed by ECHA to support the interpretation of the provisions in the restriction?	If the restriction is adopted, the Commission may consider whether additional guidelines are appropriate.

#	Question	Answer
9.2	Will there be R&D and/or low-volume exemptions for microplastics similar to other REACH requirements (e.g. registration, authorisation)?	Derogations from the restriction that are currently foreseen are listed in the Background Document in section 2.2.1.2. The SR&D exemption applies.
9.3	For microplastics incorporated in a final use (film/coating of an article) is there any disposition regarding microplastics related with the end of life of the article (Waste treatment/management)?	Where microplastics are permanently incorporated into a film or coating during the manufacture of an article i.e. under derogation 5c the proposed restriction by the Dossier Submitter does not foresee any specific conditions for the end of life of the article. Nevertheless, RAC (draft) opinion notes that reporting requirement could be extended to end of life for the 5c derogation.
9.4	Some wet wipes contain plastic fibres that will be regulated by the Single Use Plastics Directive (subject to marking requirements & paying extending producer responsibility schemes). Would the proposed restriction on intentionally added microplastics mean that they would be doubly regulated?	No. The Dossier Submitter understands that the individual polymer fibres in non-woven textiles would exceed the Dossier Submitter proposed upper size limit for a microplastic fibre of 15mm or would be chemical bonded to each other such that they would exceed the upper size limit for a non-fibrous particle of 5mm.
9.5	How would carbon black be considered under the proposed microplastic definition?	Carbon black would not fulfil the polymer definition within the meaning of Article 3(5) of the REACH Regulation. Therefore, it is out of the scope of the restriction proposal.

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