ANNEX to the ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME(S): intentionally added microplastics

IUPAC NAME(S): N/A

EC NUMBER(S): N/A

CAS NUMBER(S): N/A

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Annex A: Background

A.1. Examples of definitions for 'microplastics'

Table 1: Examples of the 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 for cleaning, depending on the form and structure of the particle;	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
		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
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.	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	• 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*

Example	**Definition**	**Scope**	**Reference/further information**	**Definition elements**
	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.’.		products or detergents containing microplastics.’	*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 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,	**§ 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. 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.	Communication from the Commission - TRIS/(2017) 01661 2017/284/S (Sweden) Draft Ordinance amending the Chemicals Products (Handling, Import and Export Prohibitions) Ordinance (1998:944)	• particle • solid • polymer • solubility (water) • 5 mm

Example	Definition	Scope	Reference/further information	Definition elements
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; (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;	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)
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		Communication from the Commission - TRIS/(2018) 01172 2018/205/UK (United Kingdom) The Environmental Protection (Microbeads)	as UK

Example	Definition	Scope	Reference/further information	Definition elements
	into various solid forms and that retains its final manufactured shape during use in its intended applications;		(Northern Ireland) Regulations 2018	
Scotland	“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) 00266 2018/48/UK (United Kingdom) The Environmental Protection (Microbeads) (Scotland) Regulations 2018	as UK
Wales	“microbead” (“microbelen”) means any waterinsoluble 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
illinois	"Plastic" means a synthetic material made from linking monomers through a chemical reaction to create an organic polymer chain that can be		2014 Public Act 098-0638 s	• particle • solid • "plastic"

Example	Definition	Scope	Reference/further information	Definition elements
	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.			- 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 exfoliate or cleanse in a product that is intended to be rinsed off.		2015 WISCONSIN ACT 43	as Illinois but with extra criteria for size • 5 mm at its largest dimension
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		Assessment of the sale of microbeads in	• particles • solid

Example	Definition	Scope	Reference/further information	Definition elements
	diameter that are water insoluble and non-degradable, with typical diameters of around 100–300 μm.		personal care and cosmetic products Assessment of the voluntary phase-out of microbeads - report	- "plastic" - solubility (water) - degradable - 5 mm
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). Reference: G/TBT/N/KOR/672	- 5 mm
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 MS 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 the 6th March 2017, a French decree was published, aiming at banning the use of solid plastic particles in rinse-off exfoliating and cleaning cosmetics from 1st January 2018. This decree also affects plastic cotton buds, which will be banned from the 1st 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 1/1/2019) ("*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 intend 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 06/06/2018 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 30/06/2017 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 28/07/2017: http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2017&num=353

Northern Ireland notified on 10/05/2018: http://ec.europa.eu/growth/tools-

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[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=2018&num=205

Scotland notified on 01/02/2018: http://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2018&num=48

Wales notified on 29/01/2018: 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.

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

Californian legislation[6], that will come 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.

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[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/

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 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 methacryate 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
Melamine-formaldehyde	**Epostar** 0.1 to 2 µm – Nippon Shokubai (JP) - https://www.shokubai.co.jp/en/products/functionality/epokara.html

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[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

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)), 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 (see definition below); and,

(b) The amount of polymer molecules presenting the same molecular weight must be less than 50 weight percent of the substance.

In the context of this definition 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.

B.1.1. Presence of a particle or 'polymer-containing particle'

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) and ISO 14644-6:2007 (ISO, 2007)), a particle is defined as a "*minute piece of matter with defined physical boundaries*". This can be further 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).

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[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).

[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".*

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. 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/semi-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. 'Polymer-containing particle' means a particle of any composition with a polymer content of ≥ 1% w/w.

B.1.1.1. 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 particle and the polymer coating. Based on the information received in the public 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 object 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.1.1.2. 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.1.1.3. 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 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.

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[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.

[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.

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.

B.1.1.4. Solubility considerations

Many definitions have also included water insolubility as an inclusion criterion. However, none has included test methods to determine polymer solubility or derived pass/fail cut-off solubility values for "water insoluble". 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 would be 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."

OECD test method 120 is used to determine the solution/extraction behaviour of polymers in water (OECD, 2000). However, this method only gives the method relating to the experimental conditions (sample preparation, temperature, time) but not the methods to quantify polymer solubility.

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/stabilization. These polymers perform a variety of functions in aqueous media, including use as dispersing and suspending agents, stabilizers, thickeners, gellants, flocculants and coagulants, film-formers, humectants, binders, and lubricants".

Polymer "solubility" therefore can be understood differently depending on the context the term is used. Based on the above considerations from existing guidance under REACH and technical and industry literature, "solubility" as an element in the definition of "microplastic" may not be useful as the term is context dependent. As highlighted for the element "solid", "particle" captures that a polymer has kept its shape in the medium into which it is placed and can move as a unit.

"Solubility" is therefore not proposed for inclusion as an element in the regulatory definition.

B.1.1.5. Particle size and morphology

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. A possible element to include is therefore a lower limit of 1 nm or alternatively no lower limit.

B.1.1.6. 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.1.1.7. 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.1.1.8. Summary of proposed regulatory definition for microplastic

Based on the considerations above, the following regulatory definitions are proposed

- **'microplastic'** means a material consisting of solid polymer-containing particles, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 1nm ≤ *x* ≤ 5mm, or (ii), for fibres, a length of 3nm ≤ *x* ≤ 15mm and length to diameter ratio of >3. Polymers that occur in nature that have not been chemically modified (other than by hydrolysis) are excluded, as are polymers that are (bio)degradable.
- **'microbead'** means a microplastic used in a mixture as an abrasive i.e. to exfoliate, polish or clean.
- **'polymer'** means a substance within the meaning of Article 3(5) of Regulation (EC) No 1907/2006 (REACH).
- **'particle'** is a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface.
- **'polymer-containing particle'** means either (i) a particle of any composition with a continuous polymer surface coating of any thickness or (ii) a particle of any composition with a polymer content of ≥ 1% w/w.
- **'solid'** means a substance or a mixture which does not meet the definitions of liquid or gas.

- **'gas'** means a substance which (i) at 50 ^{o}C has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20 ^{o}C at a standard pressure of 101.3 kPa.
- **'liquid'** means a substance or mixture which (i) at 50 ^{o}C has a vapour pressure of not more than 300 kPa (3 bar); (ii) is not completely gaseous at 20 ^{o}C and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of 20 ^{o}C or less at a standard pressure of 101.3 kPa.

One element of the definition of a "polymer-containing particle" uses a concentration limit of ≥ 1% (w/w) polymer content w/w. The application of this limit is exemplified below.

Example: Company A manufactures a substance that consists of an inorganic particle stabilised with a polymer. If it is found that, the amount of polymer is equal or greater than 1 % w/w in the particle, and assuming that the size criterion is also met, this means the whole substance fulfils the definition of microplastic, independently from the quantity of the substance.

It is reasonable to say that an in-depth knowledge of the manufacturing process would assist in establishing whether the concentration limits are fulfilled or not. If, based on documentation, it is clear that either the particle size distribution or the polymer-containing particle concentration limits have been fulfilled, there is no need for specific analysis to determine the microplastic concentration of the content of a polymer in the particles. Proper documentation demonstrating that the given substance or mixture fulfils, or not, the criteria of the proposed definition would in any case be beneficial.

Hartmann et al. (2019) recently published recommendations for a standardised definition and categorisation framework for plastic debris, including for microplastics. Whilst there are some differences between the regulatory definition of a microplastic developed for the purposes of this restriction and that presented by (Hartmann et al., 2019), specifically in relation to solubility criteria, the approaches are on balance comparable. This is particularly notable in relation to the diversity of synthetic polymer types that are recommended to be included, and the exclusion of naturally occurring polymers and polymer gels.

B.1.1.9. 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) and hydrogels where the particle swell as they retain water to form gels (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.1.1.9.1. 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 sun screen 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.1.1.9.2. 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.1.1.9.3. 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 have potential for release to the environment under reasonably foreseeable conditions of use.

B.1.1.9.4. 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.

B.1.1.10. Polymers that occur in nature

Polymers that occur 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).

Polymers that occur in nature that have been chemically modified in some respect (e.g. 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. This consideration should not apply to polymers that occur in nature that have only been chemically modified via hydrolysis, as there is already an exemption to the registration requirements for these substances.

The relevance chemically modified naturally occurring polymers to the scope of a 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).

B.1.2. (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 screening level (bio)degradability (ready or inherent biodegradability) or (bio)degradation rates in relevant environmental compartments.

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, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 - Analysis of the final compromise text with a view to agreement states that "*The Commission shall by … [five years after the date of entry into force of this Regulation] assess biodegradation criteria for polymers referred to in point 2 of CMC 10 and test methods to verify the compliance with those criteria and, where appropriate, adopt a delegated act in accordance with paragraph 1 which lays down those criteria. The criteria shall ensure that the polymer is capable of undergoing physical and biological decomposition in natural soil conditions and aquatic environments across the EU, such that it ultimately decomposes only into carbon dioxide (CO2), biomass and water. They shall ensure that the polymer has at least 90% of the organic carbon converted into CO2 in a maximum period of 48 months after the end of the claimed functionality period of the fertilising product indicated on the label, and as compared to an appropriate standard in the biodegradation test. Those criteria shall ensure that the use of polymers does not lead to accumulation of plastics in the environment*".

CMC 10: Other polymers than nutrient polymers further specifies that "As of [seven years after the date of entry into force] the polymers shall comply with the biodegradability criteria adopted by the Commission in accordance with Article 42. In the absence of such criteria, the polymers must not be contained in any EU fertilising product placed on the market after that date”.

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. Amendments adopted by the European Parliament on 24 October 2017 on the proposal for a regulation of the European Parliament and of the Council laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 (COM(2016)0157 – C8-0123/2016 – 2016/0084(COD)) (1) (Ordinary
- 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;	OECD TG 301 A-F OECD TG 302B and 302C OECD 307 OECD 308 OECD 309

Regulation	Biodegradability criteria	Standard / test method
	(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.	
Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 - Analysis of the final compromise text with a view to agreement	(55a) A CE marked fertilising product may contain other polymers than nutrient polymers, however this should be limited to the cases where the purpose of the polymer is that of controlling the release of nutrients or increasing the water retention capacity of the CE marked 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 other polymers than nutrient polymers, the criteria for their biodegradation 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 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of defining the criteria of the conversion of polymeric carbon to be converted into carbon dioxide (CO2) and a respective testing method for biodegradation. Polymers which do not comply with these criteria should be prohibited after a transitional period. Art 42 Amendment of Annexes 3a. The Commission shall by … [five years after the date of entry into force of this Regulation] assess biodegradation criteria for polymers referred to in point 2 of CMC 10 and test methods to verify the compliance with those criteria and, where appropriate, adopt a delegated act in accordance with paragraph 1 which lays down those criteria. The criteria shall ensure that the polymer is capable of undergoing physical and biological decomposition in natural soil conditions and aquatic environments across the EU, such that it ultimately decomposes only into carbon dioxide (CO2), biomass and water. They shall ensure that the polymer has at least 90% of the organic carbon converted into CO2 in a maximum period of 48 months after the end of the claimed functionality period of the fertilising product indicated on the label, and as compared to an appropriate standard in the biodegradation test. Those criteria shall ensure that the use of polymers does not lead to accumulation of plastics in the environment. Article 47b Biodegradability review By … [five years after the date of entry into force of this Regulation], the Commission shall carry out a review in order assess the possibility of determining biodegradability criteria of mulch films, and the possibility of incorporating them into CMC 10. CMC 10: Other polymers than nutrient polymers 2. As of [seven years after the date of entry into force] the polymers shall comply with the biodegradability criteria adopted by the Commission in accordance with Article 42. In the absence of such criteria, the polymers must not be contained in any EU fertilising product placed on the market after that date. 3. Neither the polymer, nor its degradation by-products, shall show any overall adverse effect on animal or plant health, or on the environment, under reasonably foreseeable conditions of use in the CE marked EU fertilising product. The polymer shall pass a plant growth acute toxicity test, an earthworm acute toxicity test and a nitrification inhibition test with soil micro-organisms as follows: ….	Methods to be developed
• Plant protection	Annex II	OECD TG

Regulation	Biodegradability criteria	Standard / test method
products • Regulation (EC) No 1107/2009	• 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.	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 packaging and labelled as "compostable"	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 (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.	Standards for Compostable and biodegradable packaging EN 13432 (2000)
Detergents 648/2004/EC	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	Multiple test methods for primary

Regulation	Biodegradability criteria	Standard / test method
Detergents containing surfactants	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). • 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.	degradation, inherent biodegradation and other additional methods

Regulation	Biodegradability criteria	Standard / test method
	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.1.2.1. 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 Françaïse 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 fresh water 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.1.2.2. 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 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.1.2.3. Standards for biodegradability of plastics

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 waste water 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%.

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 an d 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, my 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.

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 14851:1999 **(EN ISO 14851:2004)**	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
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

STANDARD	**TITLE**	**CONDITION**	**ENVIRONMENTAL COMPARTMENT**
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
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” Includes three criteria for ‘compostable’ material; Biodegradation, disintegration and safety. Material needs to pass criteria set for these parameters to be ‘compostable’.	Aerobic, Disintegration	Compost
ORGANIC CHEMICALS			

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

Annex C. Hazard, releases, exposure and risk

C.1. Summary of review articles

Table 5: 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 vis this mechanism is 'very likely'.* 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

Journal reference	Key components	Summary/Overview
		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 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-

Journal reference	Key components	Summary/Overview
		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 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

Journal reference	Key components	Summary/Overview
		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 review of the emerging threats, identification of knowledge gaps and prioritisation of research needs*	Microplastic, Plastic contamination, Freshwater systems, Riverine litter, Lake litter, Marine debris Comprehensive table on estimates of microplastic concentrations across a range of FW environments/geographies Table 3 offers an excellent summary of effects in FW and marine biota	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 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

Journal reference	Key components	Summary/Overview
		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 showed 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. 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.

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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 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 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,	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 5mm 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

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	Microplastic Includes summary of methods	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 STWs. 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. 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.

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		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*) they 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 the observed energy 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 have a limited relevance as vector for the transfer of hydrophobic pollutants to fish. From a risk perspective, the highest measured levels of microplastics in the environment, which 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 and the prospective of strongly 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-

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		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: Evaluating the current understanding to identify the knowledge gaps and future research priorities*	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 fields including nanotechnology, agriculture and waste management. Plastic pollution Nanoplastics Litter Rivers Soil Hazard	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 sewage treatment works to remove up to 99.9% microplastic particles 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

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		observed at concentrations above 12.5 μgmL^{-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 μgmL^{-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 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

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		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 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.

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Galloway (2015) *Micro- and nano-plastics and human health*	This review considers the kinds of plastics in widespread, 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.	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 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 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 comparison with other pathways of exposure, based on the reported abundance of microplastics.

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		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). 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

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		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 of a global assessment*	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). 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.

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		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 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

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		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. 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

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		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 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*

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		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 Microbeads Microfibers Review Good table 1 summarising effects literature	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 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.

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		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 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*	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	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

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potential solutions	Ingestion Marine environment Sediments Bio-uptake	(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 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

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		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). 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*	Microplastics Field samples Laboratory exposures Ingestion	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.

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in laboratory experiments?	Biological effects	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 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

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		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 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) *Statement on the*	Microplastic Nanoplastic	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 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

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presence of microplastics and nanoplastics in food, with particular focus on seafood	Food Seafood Occurrence Risk assessment	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) *Ecotoxicological effects of microplastics on biota: a review*	The present review focused on the ecological impact of microplastics on biota at different trophic levels, its uptake, accumulation, and excretion etc., and its plausible mechanistic toxicity with risk assessment approaches.	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 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

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	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.	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 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

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		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 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

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		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 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.

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		• 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? Microplastics; Species sensitivity distribution; Risk; Persistent organic pollutants	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 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

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		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 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;

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		• 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.
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.

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		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) *Interactions of microplastics with freshwater biota*	The aim of this chapter is to synthesize and critically revisit these aspects based on the state 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. 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. 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

Journal reference	Key components	Summary/Overview
		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 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 behavioral 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

Journal reference	Key components	Summary/Overview
		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 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 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

Journal reference	Key components	Summary/Overview
		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 6: 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 7: 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 8: 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 9: 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 10: 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	*Daphina 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 11: 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 12: 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 13: 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 14: 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 15: 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 16: 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 17: 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 18: 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 19: 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 20: 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 21: 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 22: 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 23: 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 24: 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 25: 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 26: 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 27: 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 28: 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 29: 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 30: 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 31 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 31: 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 **LDPE** **PS**	Without pre-photodegradation With pre-photodegradation With pre-photodegradation in soil with growing plants	0.2% carbon conversion per 10 years 5.7% carbon conversion per 10 years ~5% biodegradation over 6 months	Guillet et al. 1988 as cited in Andrady et al. 2011
Polystyrene (PS)	Fungal species	< 1% within 35 days	Kaplan et al. as cited in Eubeler et al. 2010 II

Plastic	Condition	Reported result	Reference
Polymethyl methacrylate (PMMA)	Mixed microbial communities	0% within one month	
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)** **Poly (propylene carbonate) (PPC)** **Poly (butylenes succinate-co- adipate) (PBSA)** **Poly (butylenes succinate) (PBS)** **Poly (lactic acid) (PLA)** **Polyethylene (PE)**	ISO 14852, Aquatic with inocula derived from soil	Biodegradation (%) 14 days at 30 °C 78 62 53 36 26 25 15 5 4 3 3 2 1 0	Guo et al. 2012
Poly(3-hydroxy butyrate)-co-(3-hydroxy valerate) (PHBV) polymer (< 32 µm) milled,	Modified OECD 301B	After 28 days the mineralisation of PHBV milled	McDonough et al. 2017

Plastic	Condition	Reported result	Reference
PHBV foam (125 µm, 250 µm and 500 µm) and sodium benzoate (positive control).		polymer; 88 % PHBV foam (125 µm, 250 µm and 500 µm); 74%, 71% and 66%. The test duration was extended for 80 days.	
Polybutylene sebacate (PBSe) **pellets** **milled and sieved (89, 179, 193, 825 and 1650 cm^{2}g^{-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) ISO/DIS 19679 Test method for determining aerobic biodegradation of plastic materials sunk at the sea water/sandy sediment interphase (Sublittorial)	Inherent biodegradation in 28 °C Eulittoral in 195 days Mater-Bi; 76-110% Filter Paper (positive control); 77% PHB (polyhydroxybutyrate); 163 % Sublittoral in 259 days Mater-Bi; 93% Filter Paper (positive control); 96% PHB (polyhydroxybutyrate); 163%	Verification report ET/2015 Aerobic degradation of Third generation Mater Bi under marine condition https://ec.europa.eu/environment/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

Plastic	Condition	Reported result	Reference
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. Impacts 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 microplastics (≥ 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 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 microplastics (≥ 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 microplastics 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 be not to prevent future uses of microplastics in mixtures or any minor non-significant uses, where the users had not informed the Dossier Submitter of their use as they could easily transition to alternatives. Therefore the risk reduction would be similar to the proposed restriction but could be lower. The costs would also be similar. Therefore, the proportionality of this option would probably be decreased.

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. 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 micron 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 'noodles'. The Dossier Submitter also notes this may exclude rubber granules from scope (see Annex XV report, 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 ($\geq$ 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 the recast of the fertilising products regulation (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 32: 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 32: 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 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

Option	Reasons for discarding this option
	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 waste water 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 waste water 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.
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

Option	Reasons for discarding this option
	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. 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.8 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

Option	Reasons for discarding this option
	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 '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 D.4 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

Option	Reasons for discarding this option
	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 product or adjuvant, but are neither active substances nor safeners or synergists, referred to as 'co-formulants Co-formulant shall not be accepted for inclusion in a plant protection product where it has been established that 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 are not classified as CMR category 1a or 1b, nor are they identified as PBTs or vPvBs nor have they been identified as substances of equivalent concern. 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 CMR categories 1 or 2 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, and as fertiliser additives such as anti-caking agents, prilling agents, etc. All of 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 emissions 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:

- 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.[17] 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 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 SRF technologies (Fertilizers

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[17] 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.

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 33 gives an overview.

Table 33: 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, poly(butadiene-b-methylstyearene)s, crosslinked hydrophilic PAA, prepolymer of phenol- or urea-formaldehyde	Akelah (2013)

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.[18] Using Eurostat (2018b) data for 2016, the consumption of mineral fertilisers

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[18] 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

(nitrogen and phosphorus) in the EU28 (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.[19] Table 34 summarises the different estimates of the annual use volume of polymeric material released through CRFs in the EU.

Table 34: 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) and Eurostat (2018a, Eurostat, 2018b), see text
--	1 700-8 000 by 2020	By 2020	Amec Foster Wheeler (2017) [a]
Total	Central estimate: 10 000 Range estimate: 1 000-17 000		

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

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).[20] 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.[21] 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

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unlikely to increase far beyond 1% by 2022 (Grand View Research, 2018a).

[19] 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.

[20] 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.

[21] 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.

stream, it may still enter the environment via landfilling and/or industrial composting.

The fertiliser regulation (EC) No 2003/2003 requires coating material to undergo thorough phytotoxicity and toxicity testing before placing on the market. The proposed regulation on EU fertilising products (FPR) includes an additional requirement of 90% degradation of organic carbon in the coating material into CO_2 within 24 months at 25°C in soil (see Annex II, CMC 10, COM(2016) 157). The proposed amendments require non-natural polymers in fertilising products to biodegrade over a period of 48 months after the end of their functionality period. However, this biodegradability requirement pertains to CE marked fertilising products only which account 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.

Next to membrane encapsulation, there are other uses of non-natural polymers in CRF systems (Akelah, 2013) which would fall under the new FPR. Table 35 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 34 have to be considered a lower bound.

Table 35: 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

CRF Category	Method	Materials
		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-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 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 proposed 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 36 and discussed below.

Table 36: 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: 4 000-20 000 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: 12 500** **Range estimate: 4 000-21 000**		

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), one company alone stated to use 1 800 tonnes of polyethylene polymers per year. This company further informed that the concentration of the polymers in the final fertiliser product would be ranging from 0.05-0.3% w/w. However, not all fertilisers might be using anti-caking agents. As a working estimate, and in absence of better information, it was assumed that 2/3 of the total annual fertiliser consumption of 12.5 million tonnes in the EU28 (plus Norway) would be enhanced with anti-caking agents.[22] This results in a range estimate of 4 000-20 000 tonnes with a central estimate of 12 000 tonnes of microplastics emitted annually in the EU by the use of polyolefin waxes (polyethylene) applied to 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 less than 1 000 tonnes of polymeric material release per year.

D.4.1.3. Capsule suspension plant protection products

CSPs are used in a similar way to CRFs. The tailor-made capsules are loaded with active substances for plant protection and optimised for prolonged 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, 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).

Common materials to achieve the functionalities of CSPs are reported in the literature and in response to the CfE, see the summary in Table 37. 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).

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[22] 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).

Table 37: 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 2 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.[23] 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 EU28 (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

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[23] 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.

that around 11 000 tonnes of PPPs sold were SRF/CRF products likely to contain polymeric material (this figure does not only include membrane encapsulated products but also alternative systems listed in Table 41).

The conversion of revenues into quantities requires some assumptions to be made on the pricing of SRF/CRF 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.[24] 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. 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 38 summarises the annual emissions of polymeric material from CSPs in the EU.

Table 38: 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

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[24] 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.

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.

To estimate the total current emission of microplastic polymers from the use of seed coating, ESA used 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 39.

Table 39: 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).

To convert this quantity into polymeric material, ESA conducted a survey among some of their members which together hold ~50% of the global market share. Whilst the exact application rates are confidential, ESA informed that type i) requires dose rates of less than 2g per kg of seeds treated and has a polymer concentration of 4% or less; type ii) uses 2-10g per kg of seeds and has a polymer concentration of 35% or less; and type iii) uses 5-50g 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 39, 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 40).

Table 40: 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 23 500 tonnes of microplastics per year are emitted by the A&H sector (see Figure 1).[25] It is difficult to predict how the total quantity emitted will evolve over the next decade. On 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. Thus, it is difficult to predict the effects these two antagonistic drivers will have on the total quantity of microplastics emitted.

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[25] 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-jelly like gel. This hydrogel is not solid and thus does not fall under the definition of a microplastic used in this restriction.

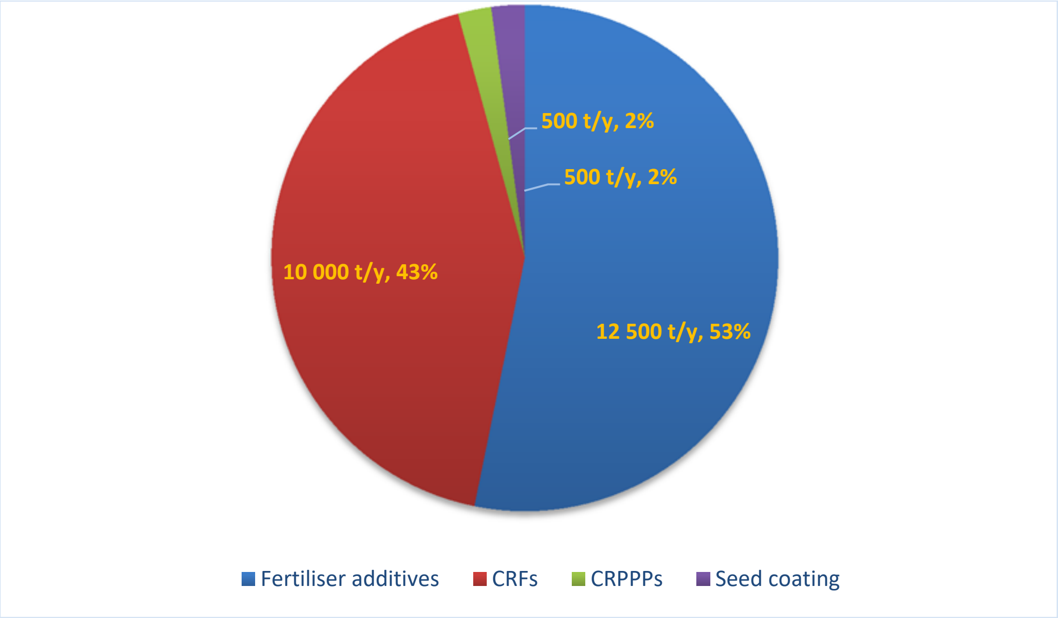

Figure 1: Estimated annual tonnage of polymeric material emitted by the different product groups within the EU A&H sector

D.4.2. Alternatives

D.4.2.1. Microencapsulation for controlled/target release

The challenge of finding a suitable alternative coating material 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 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 41. 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 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.

Table 41: 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 referred to ongoing substitution activities triggered by the FPR. The indicative timelines of 5-10 years for the transitioning to biodegradable polymers currently discussed in the context of the revision are 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.[26]

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 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 up to 300%, implying less fertiliser manured,

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

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 ongoing 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.[27] The proposal foresees a three-year transition period after entry into force for manufacturers to achieve biodegradability of their CRF products.[28] The timelines set in the FPR foresee a transition period of 7 years 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 with or without this proposal.

Although Regulation (EC) No 1107/2009 concerning the placing of PPPs on the EU market does not contain such a biodegradability criterion, it seems that the same principles could apply to CSPs. Moreover, it is foreseeable that innovation in terms of biodegradability achieved for encapsulated CRFs 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 at least the European Crop Protection Association (ECPA, 2018) has expressed concerns about. Information ECPA provided during the CfE suggests that a re-authorisation might be needed and would last up to that the average length of the authorisation process 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. They also estimate the cost per reformulation to be in the order of $1 million, corresponding to about €860 000 at the time of writing.

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 3 years of R&D activities were needed to find suitable alternatives that would not rely on non-degradable

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[27] 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.

[28] Annex 2, CMC 10, of COM(2016) 157 specifically suggests that “The […] polymer shall be capable of undergoing physical, biological decomposition, such that most of it ultimately decomposes into carbon dioxide (CO_2), biomass and water. It shall have at least 90% of the organic carbon converted into CO_2 in maximum 24 months […].” The European Council proposed extending the duration of decay from 24 to 48 months.

polymers.

Since at least one type of technically and economically feasible alternatives seems to be already available on the market, the costs of adopting these silica-based alternatives might be far lower than those indicated for the reformulation of CRFs. Indeed, if the supply of these alternative products on the market becomes large enough and their price and performance are not too different from current products, 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.

D.4.2.3. Seed coatings

In the CfE, no information was provided on alternative coating technologies. However, due to the inherent similarity of the function of the polymeric material in seed coatings and CRF products, it may be assumed that biodegradable coatings to be developed in the context of the FPR might be transferred to seeds. It could even be argued that compared to CRFs and CSPs, the technical demands on alternative seed coatings might be lower since the service life of the coating layer spans only over one growing season rather than over an 18-month period. As for the cost of developing an alternative coating standard that biodegrades after one growth season, it will thus be assumed that this would not impose costs larger than those estimated for finding a suitable alternative coating process in CRFs and CSPs (about €1 million per reformulation).

D.4.2.4. Synopsis of alternatives

Based on the above discussions, it can be concluded that there are several alternative materials and technologies currently researched for their suitability as coating material and/or additive in A&H applications. The difficulty in finding biodegradable polymers—it appears—relates to the delayed breakup that is required. Once this hurdle has been overcome, there appears not to be a genuine reason 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 already 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 the proposal of a biodegradability requirement in the FPR, which is presumed to enter into force by mid-2019. According to the draft positions of the European Parliament and the European Council this requirement is meant to be complied to within 7 years after entry into force of the FPR. However, as the biodegradability requirement will be binding only for CE marked fertilising products, the restriction proposal suggests expanding it to all fertilising products (incl. fertiliser additives and nutrient-treated seeds) placed on the EU market.

Further, the 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. Where seed coatings are loaded with nutrients, they would appear to fall under the scope of the FPR as reasoned above. However, in order to minimise the emission of non-degradable polymers in the EU it is proposed to extend the coverage of the biodegradability requirement to polymer-coated seeds even if the microencapsulation is not loaded with nutrients. The proposed restriction is expected to enter into force by mid-2021.

In order to account for the transitional period to be granted for complying with the biodegradability requirement in the revised fertilisers regulation, the restriction scenario will be assessed in line with the timeline given by Figure 2.

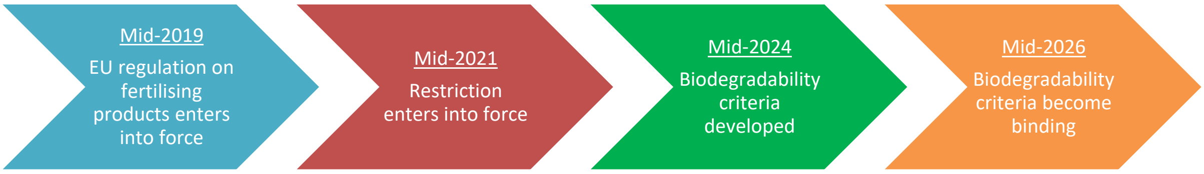

Figure 2: Indicative timeline for the proposed restriction

D.4.3.2. Restriction scenario

Under the restriction scenario, a 5-year transition period after EiF is assumed. 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 laid out in (COM) 2016/157, Annex II, CMC 10 in order to be placed on the EU market.

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. These 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 278 kilotonnes of microplastics over the first 20 years after EiF.

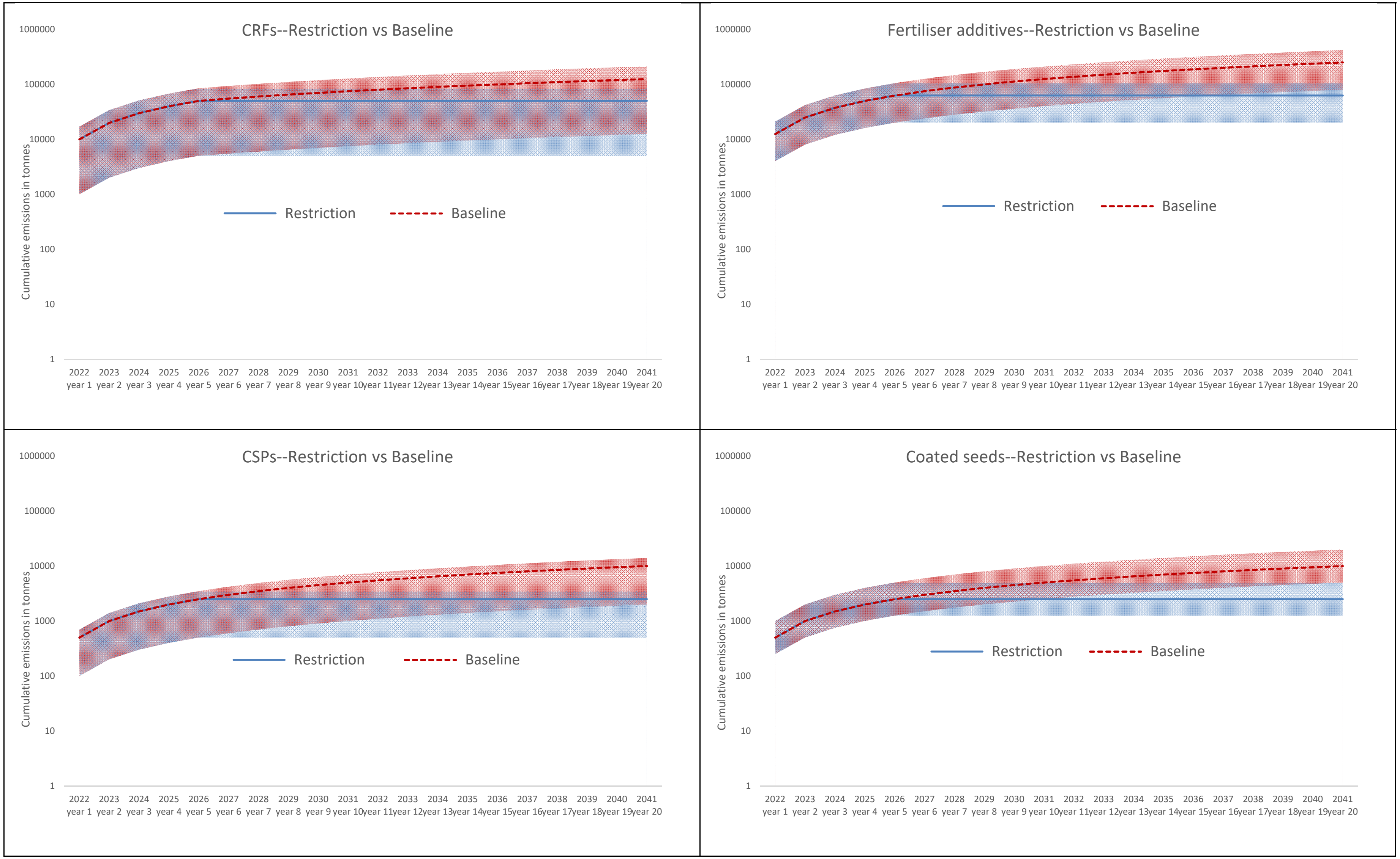

Figure 3: Cumulative emissions for the four use categories under the baseline and restriction scenario

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 uses of polymers in the A&H sector 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 are 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 biodegradable 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 here 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 the very persistent substances (ECHA, 2016a).[29] The key premise of this approach is therefore similar to the PBT/vPvB approach in that uses emissions 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 from which 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 the 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.

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[29] SEAC's agreed approach to evaluate PBT and vPvB substances is outlined here: https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf

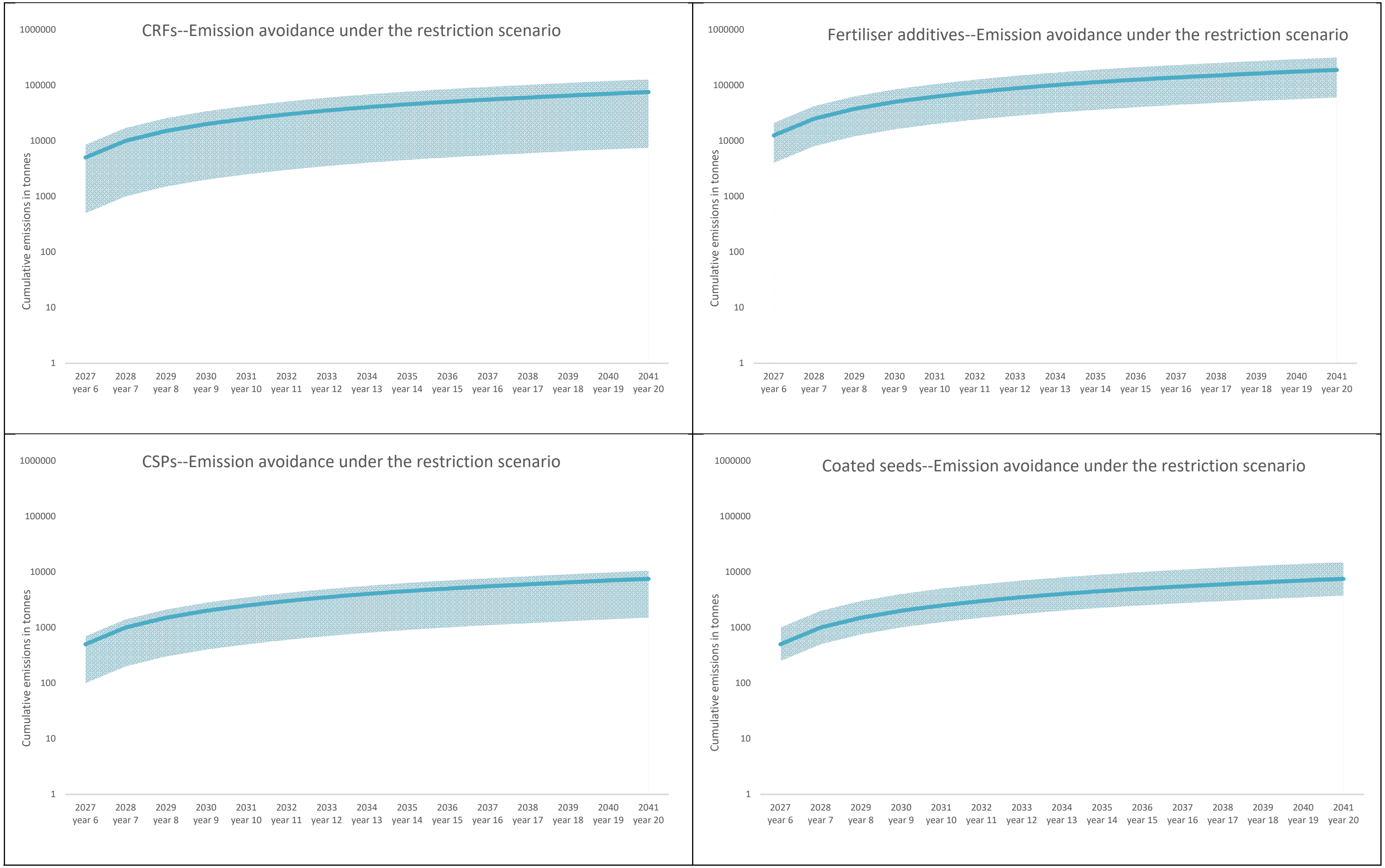

Figure 4: Emission avoidance under the restriction scenario

D.4.5. Economic impacts

D.4.5.1. Preliminary remarks

The following 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 are 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 or 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 what would be required for CE marked fertilising products to other A&H 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).

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.[30] 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, the 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. SMEs are considered to 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 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 (COM(2016) 157). Rounding up figures, one is left with central-cost estimates of €60 million/€300 million/€600 million attributable to the restriction, i.e. to the extension of the biodegradability requirement to non-CE marked fertilisers. This is considered an upper bound estimate because it ignores

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

that national fertiliser markets often trade speciality fertilisers which 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 €120 million/€600 million/€1.2 billion.

Lastly, it is unclear how long it will take to reformulate a particular 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 in reality 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, treated 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. According to information provided in the CfE, the functional requirements of CSPs are very similar to those of CRFs and the coatings in use are often identical;
    - Thus, any biodegradable alternative developed for CRFs may be adapted for use in CSPs and the cost of adapting is assumed to be similar to the adaptation costs assumed for CFRs, i.e. €0.15 million per reformulation;
    - Possibly, there are additional regulatory costs for requalifying modified PPPs. Hence, the cost per reformulation including their regulatory approval is assumed to be €0.25 million;
    - Similar to the CRFs it is unclear how many reformulations would be needed. It is considered that in total there are 50/100/200 CSPs on the market that would be affected by the restriction;
    - Thus, the central costs are estimated at €12.5 million/€25 million/€50 million. Following the argumentation above an additional effort factor of 3 is assumed to apply for a high-cost scenario of €37.5/€75 million/€150 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, but their existence demonstrate that for this use category there are non-polymeric materials which achieve the same 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 central-cost estimate of €50 million;
    - As before, half of these costs are to be attributed to the FPR so that the central costs attributable to the restriction proposal are assumed to be €10 million/€25 million/€50 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 1.25 is assumed for the high-cost scenario, resulting in replacement costs of €12.5 million/€31.3 million/€62.5 million.
- Modifications for seed coatings:
    - This use category is most difficult to assess because it is unclear from the information received what the existing share of treated seeds is that would fall under the definition of a fertilising product;
    - In the context of this restriction, the Dossier Submitter assumes that all treated seeds treated with fertilisers, i.e. seeds that are encapsulated by a polymeric shell together with "a substance, mixture, micro-organism or any other material, applied or intended to be applied, either on its own or mixed with another material, on plants or their rhizosphere for the purpose of providing plants with nutrient or improving their nutrition efficiency" (COM (2016) 157, Art. 2), are fertilising products;
    - The Dossier Submitter considers the coating of seeds to be less demanding than encapsulations that ensure controlled release since the former have to protect the seed during sowing and throughout the germination stage (i.e. several weeks), whilst the latter are designed to release PPPs over a period of several months;
    - On the other hand, R&D efforts to find biodegradable polymers for the purpose of seed coating seems to not have been initiated. Also, changes to the coating material may require re-approval under the regulation of PPPs or fertilising products if the seeds are loaded with active substances or nutrient, respectively;
    - Absent better information on costs, it is assumed that there are 10/20/50 primary reformulations needed and that each of them induces costs of €1 million. For each major reformulation there may be up to 10 additional adaptations needed, each costing €0.15 million. Thus, the total cost is €25 million/€50 million/€125 million;
    - If one assumes that 1/3 of these costs can be attributed to the FPR, then the costs attributable to the restriction proposal in the central scenario are €16.7 million/€33.3 million/€83.3 million;
    - Finally, an effort factor of 2 is applied to obtain a high-cost scenario with reformulation costs of €33.3 million/€66.7 million/€166.7 million.

Summing all together, the central-cost estimate ranges from €99 million to €783 million and the high-cost estimate ranges from €203 million to €1.58 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).[31] Table 42 presents an overview of cost-effectiveness estimates for both restriction scenarios and under the various assumptions made in the relevant Sections of this Annex.

Table 42: Cost-effectiveness of the restriction per A&H product category

	Cost-effectiveness estimates (€/kg emission avoided)		
Scenarios [emission abatement potential]	**Low**	**Central**	**High**
CRFs			
Central-cost scenario: - High effectiveness [128 kt/20 years] - Central effectiveness [75 kt/20 years] - Low effectiveness [7.5 kt/20 years]	0.5 0.8 8	2.4 4.0 40	4.7 8.0 80.0
High-cost scenario: - High effectiveness [128 kt/20 years] - Central effectiveness [75 kt/20 years] - Low effectiveness [7.5 kt/20 years]	0.9 1.6 16.0	4.7 8.0 80.0	9.4 16.0 160.0
CSPs			
Central-cost scenario: - High effectiveness [1.5 kt/20 years] - Central effectiveness [7.5 kt/20 years] - Low effectiveness [10.5 kt/20 years]	1.2 1.7 8.3	2.4 3.3 16.7	4.8 6.7 33.3
High-cost scenario: - High effectiveness [1.5 kt/20 years] - Central effectiveness [7.5 kt/20 years] - Low effectiveness [10.5 kt/20 years]	3.6 5.0 25.0	7.1 10.0 50.0	14.3 20.0 100.0
Fertiliser additives			
Central-cost scenario: - High effectiveness [315 kt/20 years] - Central effectiveness [187.5 kt/20 years] - Low effectiveness [60 kt/20 years]	<0.1 0.1 0.2	0.1 0.1 0.4	0.2 0.3 0.8
High-cost scenario: - High effectiveness [315 kt/20 years] - Central effectiveness [187.5 kt/20 years] - Low effectiveness [60 kt/20 years]	<0.1 0.1 0.2	0.1 0.2 0.5	0.2 0.3 1.0
Treated seeds			
Central-cost scenario: - High effectiveness [37.5 kt/20 years] - Central effectiveness [75 kt/20 years] - Low effectiveness [150 kt/20 years]	1.1 2.2 4.4	2.2 4.4 8.9	5.6 11.1 22.2
High-cost scenario: - High effectiveness [37.5 kt/20 years] - Central effectiveness [75 kt/20 years]	2.2 4.4	4.4 8.9	11.1 22.2

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

	Cost-effectiveness estimates (€/kg emission avoided)		
- Low effectiveness [150 kt/20 years]	8.9	17.8	44.4

Two observations are warranted on the estimates reported in Table 42.

- The cost per kg of microplastics not released into the environment is relatively low (equal to or less than €10/kg for the central estimates underlined in Table 42) compared to uses of microplastics in other sectors analysed in this restriction proposal (e.g. cosmetics);
- Even under the least favourable scenarios, the cost-effectiveness of restricting the uses found is equal to or less than €30/kg in the central case, which is far 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 that are 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 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 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 the restriction relatively is 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 after EiF of the restriction, it is assumed that there will not be major employment effects triggered by this restriction. Especially, it has to be considered that the implementation of polymeric coating 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 that 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. PPPs imported into the EU;
- On the export side, the restriction will not limit EU producers of CRFs, CSPs, fertiliser additives and treated seeds to place their products onto third country markets where these have no regulation of polymeric material in A&H products in place.

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, it 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[32], 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

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[32] 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.

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 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.12), 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 €6 per kg of microplastic release avoided (see Table 42). 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:

$$\kappa = \frac{C}{(1 - p)E} \Rightarrow €5\,000/\text{kg} = \frac{€600\text{m}/20\text{y}}{(1 - p)100\text{kt}/20\text{y}} \Leftrightarrow p = 1 - \frac{€600\text{m}/20\text{y}}{€5\,000/\text{kg} * 100\text{kt}/20\text{y}} = 99.9\%.$$

In other words, there would need to be an almost zero chance of finding a suitable substitute whilst investing €600 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 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 400 kilotonnes of microplastics. However, as Figure 5 shows, cumulative emissions could just as well be 1 000 kilotonnes. In relative terms this discrepancy would still appear relatively modest given that the forecasting horizon is so long.

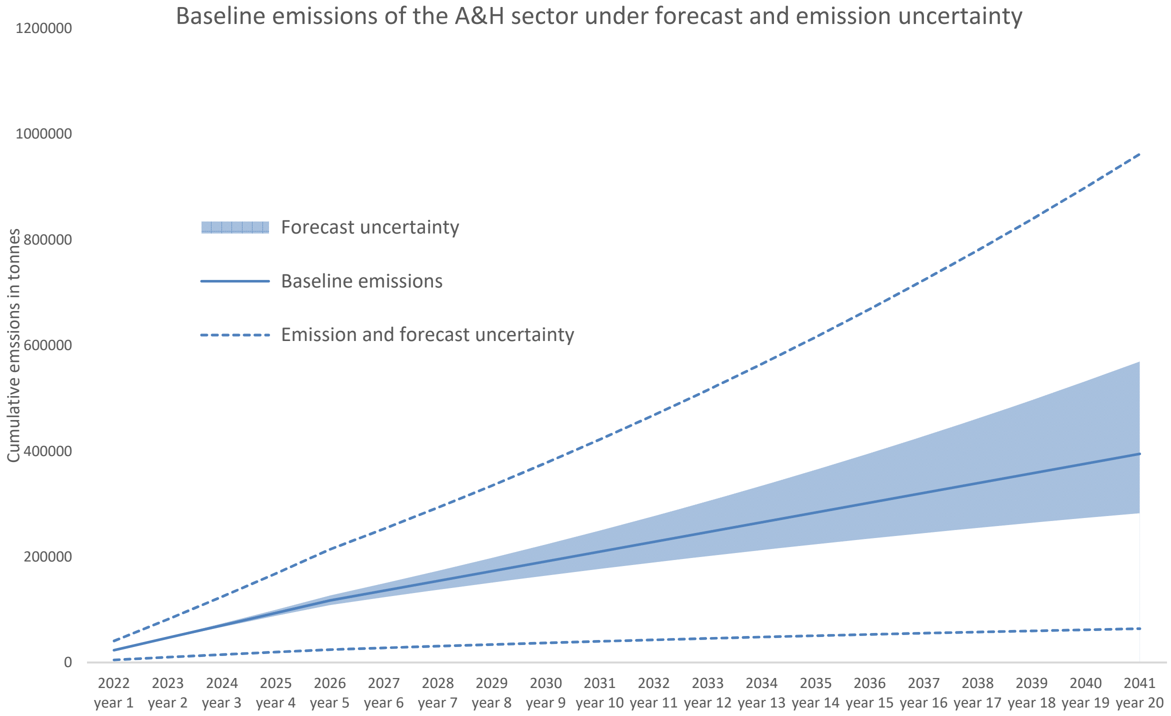

Figure 5: Uncertainty in cumulative baseline emissions

Moreover, 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 biodegradable polymers do not become available by the end of the transition period of 5 years, and hence specific fertilising products and PPPs could no longer be used in the EU, then 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 Annex XV report. 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 43 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 43: 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[33] and other mixtures containing microbeads; c) EiF + 4 years for 'rinse-off cosmetic products'[34] not already included in paragraph 6(a); g) EiF + 6 years for 'leave-on cosmetic products.'[35]

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 43 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

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[33] "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.

[34] "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

[35] "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

the definition of this restriction proposal for morphology, state, dimensions, non-biodegradability, intentional use (intentionally added and/or released).

Intentional use:

Microplastics are intentionally added to cosmetic products to impart specific functions (Table 44). 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, herein also referred to as "trash disposal" leave-on cosmetics). 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 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.[36] 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 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). 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). 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 (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

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[36] 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.

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 definition of microplastics 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,[37] 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 44) 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 include a list of 520 polymers used in the EEA (see Table 88:). An analysis of their molecular weight, chain length and degree of cross-linking was disproportionate and no such work has been done to date by other stakeholders, although the Dossier Submitter conducted a rough preliminary analysis. Therefore, the data on polymer use is interpreted as data on microplastics use (i.e., as defined to fall into the scope of the proposed restriction) in the extreme case, although an attempt was made for the scenario to be moderated.[38] 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 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 45) 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 Que Choisir and the Danish consumer council THINK. Therefore, the analysis presented in this dossier (in particular related to the High scenario for impact assessment) is primarily based on

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[37] "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).

[38] 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 about 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 cosmetics to the microplastic pollution. The approach rests on several assumptions and the public consultation on the proposed restriction will be used to further refine the assumptions employed if needed.

information in the CosmEthics database.

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,[39] cross-linking[40] of polymers or blending,[41] 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 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

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[39] Copolymerisiation is the polymerisation of different monomers in the same chain (either in random or alternating order or as blocks)[39] 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).

[40] 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).

[41] 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).

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

Microplastics by 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
Poly lactic acid	POLYLACTIC ACID	abrasive

Source: C4E 2018, CosIng 2018 (http://ec.europa.eu/growth/tools-databases/cosing/index.cfm), 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 45: 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	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 46 gives examples of functions of microplastics in cosmetics. More detailed information on the more typical functions for rinse-off or leave-on products is discussed in the sections below.

Table 46: Examples of microplastics and their functions

Function	Examples of synthetic polymers used in cosmetics
Adhesives	hydroxypropyl cellulose
Antifoam	simethicone and dimethicone silylate
Binders	aluminum 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)
Skin conditioning	alternating copolymer of ɑ-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	aluminum 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)

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,[42] Denmark[43]). 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)[44].

D.5.2. Baseline

Use of microplastics in cosmetics products is estimated in excess of 9 100 tonnes (Table 47). They are primarily used in rinse-off cosmetics (more than two-thirds of the use) but they also find wide application in leave-on products.

Table 47: 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	2 892	2 892	2 892	2 892	2 892	2 892
Leave-on	1 116	1 116	1 116	1 116	1 116	1 116
- down-the-drain*	635	635	635	635	635	635
- trash disposal**	481	481	481	481	481	481

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[42] *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)*

[43] *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/)*

[44] 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)
Grand Total	**4 115**	**4 061**	**4 034**	**4 008**	**4 008**	**4 008**
Central tonnage						
Exfoliant/cleansing	107	54	27	-	-	-
Other rinse-off	6 466	6 466	6 466	6 466	6 466	6 466
Leave-on	2 689	2 689	2 689	2 689	2 689	2 689
- down-the-drain*	1 246	1 246	1 246	1 246	1 246	1 246
- trash disposal**	1 443	1 443	1 443	1 443	1 443	1 443
Grand Total	**9 261**	**9 208**	**9 181**	**9 154**	**9 154**	**9 154**
High tonnage						
Exfoliant/cleansing	107	54	27	-	-	-
Other rinse-off	10 039	10 039	10 039	10 039	10 039	10 039
Leave-on	4 262	4 262	4 262	4 262	4 262	4 262
- down-the-drain*	1 857	1 857	1 857	1 857	1 857	1 857
- trash disposal**	2 405	2 405	2 405	2 405	2 405	2 405
Grand Total	**14 408**	**14 355**	**14 328**	**14 301**	**14 301**	**14 301**

*Notes: * Includes primarily cosmetics washed off with water and discharged into wastewater: skin care, sun/self-tanning products, deodorants/persperants, 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: nail polish, make-up & lip products.*

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). The Central scenario represents an average of the two.

The forecasted use of microplastics takes into account the Cosmetics Europe recommendation to phase out 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 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.

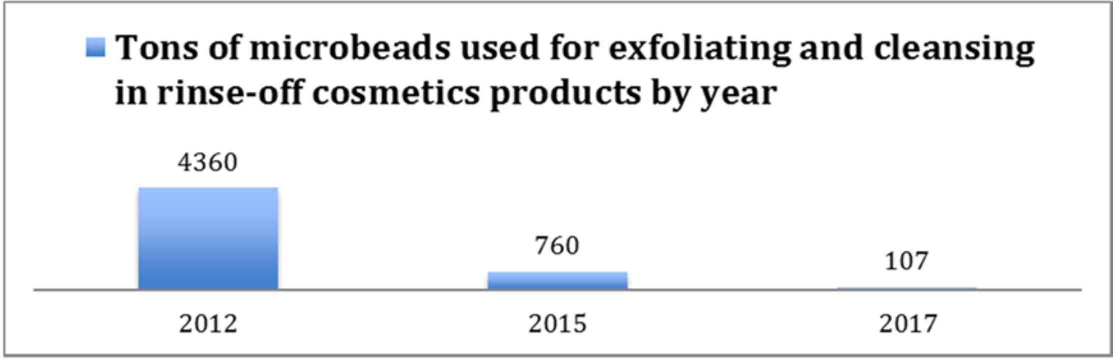
D.5.3. Rinse-off cosmetic products containing microbeads with exfoliating or cleansing functions

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 44 and Table 46) 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."[45] 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,[46] 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



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

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

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

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 48) 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,[47] with a base price £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 48: 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
- rice nuts or barks/shells
- pineapple/orange barks/shells
- peach or rosehip seeds
- apricot kernels
- argan pit shells
- wood dust
- hydrogenated castor oil
- jojoba beads or waxes
- hydrogenated vegetable oil
- beeswax
- rice bran wax
- castor oil
- mica
- 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

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[47] *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

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 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 46 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). Their functions can include binders or other sensorial (CfE, AI 2018).

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.[48] 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

As shown in Table 49 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. Alternatives (i.e., cosmetic products that do not contain microplastics according to the definition of the proposed restriction) have a share of

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[48] 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.

between 70% and 90% (respectively based on the 520-polymer and 19-polymer scenario) of the rinse-off cosmetics product market. Non-microplastic products represent a substantial share of cosmetics in each product category on the EEA market. The hair removal category has the lowest share of alternatives (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 a film forming function[49] 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 share 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 49 for further detail.)

Many of the alternatives to 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).[50] 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).

Table 49: Share of alternatives: other rinse-off cosmetics

Cosmetic product	**Proportion not containing MPs**	
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%

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[49] 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)

[50] Downloaded on 17/08/2018.

Cosmetic product	Proportion not containing MPs	
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).

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,[51] 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. 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 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

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[51] 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.

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);[52] 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 assessment of the impacts of the proposed restriction on EEA society. They are summarised in Table 50. 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 50: Restriction scenarios: Summary of assumptions used in impact assessment of rinse-off cosmetic products

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[52] https://www.cosmeticsinfo.org/product-reformulation

Impact category	Low scenario	Central	High scenario
Tonnes of microplastics used	2 900 tonnes (assuming 19 polymers in scope, see Table 47)	6 500 tonnes	10 000 tonnes (assuming 520 polymers in scope, see Table 88:)
Number of reformulation	300 (estimated based on Cosmetics Europe number of reformulations & availability of alternatives data, i.e., as share of alternatives is >70%, only 5% of reformulations will take place)[53]	8 800	17 400 (estimated based on total formulations on EEA market & availability of alternatives data, i.e., - share of alternatives is >70%, only 5% of reformulations will take place; - share of alternatives is >30% but < 70%, 50% of reformulations will take place)[54]
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 share of alternatives is high	Negligible	Negligible as share 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 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

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[53] 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).

[54] 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).

tonnages microplastics impacted by a restriction on solid and semi-solid particles of 19 polymers (Table 44). 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 (not well-represented in the Cosmetics Europe survey)[55] 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 Dossier Submitter has assumed that the share 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 share 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

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[55] 20 out of 56 respondents are SMEs. In comparison, 98% of the cosmetics sector are SMEs, majority of which are micro companies with less than 20 employees (CfE 2018, European Commission (2008)). Of the remaining companies surveyed by Cosmetics Europe, 15 companies are among the biggest 21 companies in the world (CfE 2018).

than 42% of the product category. (See Table 49.) This assumption is, however, used for leave-on products groups.

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 large share of reformulations undertaken by SMEs which tend to be focused on natural and organic cosmetics), 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.

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 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,[56] 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

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

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 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 (CfE 2018).

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)[57] for the duration of the study period. However, it should be highlighted that this is likely an overestimate, due to the already

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[57] Unpublished study

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 negligible 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 share of alternatives 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), 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.

D.5.4.4. 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 51 shows the estimated costs applying the assumptions described above.

Table 51: 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 share 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 negligible in comparison to other restriction costs.

D.5.4.5. Other impacts

Social impacts

Given the small share of total cosmetic products impacted (about 10% in the Low scenario, (CosmETHICS, 2018)) and the high share of alternatives (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, there’s information that larger companies tend to use more microplastics while smaller cosmetics companies tend to specialise in natural and organic cosmetics. These SMEs 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 share 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 microplastic-free and –containing cosmetics are dispersed throughout Europe and internationally. Given the small share of products impacted and the high share 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.5.4.6. Cost-effectiveness, affordability and proportionality to risk

Table 52 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 52: 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.

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

D.5.4.7. Impact of scope variations on proportionality to risk

Microplastics with no dimension greater than 1 mm

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.

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 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 likely if industry is not allowed sufficient time to reformulate or for 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.

D.5.4.8. Uncertainties and sensitivity analysis

Uncertainties are discussed in the relevant sections above. Their impact on the conclusions of the analysis is also summarised in Table 50. 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-on 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 microplastic-containing cosmetics have about 1.5 microplastic ingredients on average, although more than one-third can have between two and ten different polymer particles in the same formulation (CfE 2018, CosmETHICS 2018). 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-containing products have two polymer 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).

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/absobernts: These polymers have a large capacity to absorb oil, helping to reduce shine on the skin. Absobents 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[58] are registered with film forming function. (CfE 2018)

D.5.5.2. Alternatives

Table 53 shows that under the 19-polymer scenario of microplastics (Low scenario) the majority of cosmetic products on the EEA market do not contain microplastics, i.e., close to 80%, while in the High scenario (520-polymer): about 50% contain microplastics (CosmETHICS). The smallest share of alternatives are primarily for subcategories of leave-on products which are primarily disposed in the household trash (CfE AI, 2018) for

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

some nail polish, lipstick and powder make-up products, followed by sun/self-tanning and other skin care products (in High scenario). Often microplastics 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 53, microplastic-free products are available in all product categories. Many of the alternatives to microplastic ingredients are of natural (plant or mineral) origin, 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). These ingredients have been reported to have higher cost than microplastics.

Similar arguments related to rinse-off products could be made for the risks arising from the alternatives to micro-plastics 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.

Table 53: Share of alternatives: leave-on cosmetic products

Leave-on cosmetics		**Proportion containing MPs**	
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%

Leave-on cosmetics		Proportion containing MPs	
Subcategory	**Type**	**19 polymer (Low scenario)**	**520 polymer (High scenario)**
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%
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%

Leave-on cosmetics		Proportion containing MPs	
Subcategory	Type	19 polymer (Low scenario)	520 polymer (High scenario)
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%
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%

Leave-on cosmetics		Proportion containing MPs	
Subcategory	Type	19 polymer (Low scenario)	520 polymer (High scenario)
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).

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 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%) and where they represent between 30% and 70% of the market, EEA cosmetic companies currently using microplastics to reformulate about half of their products using alternatives. The remaining 50% of formulations containing microplastics are expected to be discontinued and their market share to be taken over by alternatives. 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 rinse-off products are expected to be compensated with gains from manufactures of microplastic-free products.

- For nine leave-on product categories,[59] where the microplastic 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 about 1.5 times the length of a typical reformulation process (4.5 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. Therefore, it is assumed that industry will be able to comply and complete the reformulations within six years.

- 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

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[59] 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.

of high reformulation costs may lead to relocation of manufacturing to non-EEA market), it is unlikely that their number would be large given the share of cosmetics impacted and the share of microplastic-free products on the market, as well as the proposed transitional period. This could lead to profit and employment losses. If these impacts materialise, they would likely only be associated with leave-on cosmetics categories where microplastic-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 determined by brand image (ECHA Workshop on microplastics, 2018).

- 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).

- 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 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

On the basis of the available information on the specificities of the market segment of leave-on cosmetics, the use of microplastics in these products and the anticipated reactions of stakeholders, three restriction scenarios are developed to assist with the assessment of the impacts of the proposed restriction on EEA society. They are summarised in Table 54.

Table 54: Restriction scenarios: Summary of assumptions used in impact assessment of leave-on cosmetic products

Impact category	**Low scenario**	**Central**	**High scenario**
Tonnes of microplastics used	1 100 tonnes (assuming 20 polymers in scope, see Table 47)	2 700 tonnes	4 300 tonnes (assuming 520 polymers in scope, see Table 88:)
Number of reformulation	11 000 (estimated based on Cosmetics Europe number of reformulations & availability of alternatives data, - as share of alternatives is >70%, only 5% of reformulations will take place) - share of alternatives is < 70%, 50% of reformulations will take place)	51 000	92 000 (estimated based on total formulations on EEA market & availability of alternatives data, i.e., - share of alternatives is >70%, only 5% of reformulations will take place; - share of alternatives is >30% but < 70%, 50% of reformulations will take place - share of alternatives is < 30%, 95% of reformulations will occur)
Price premium for materials	€650/tonne		
Costs per reformulation	€547 500 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)		
Baseline reformulations	Coordination with major (during transitional period + five years) & minor (during transitional period) reformulations		
Profit losses	Negligible net impacts	Negligible net impacts	Unlikely & only associated with 25% of reformulations where the share of alternatives is <30%
Employment losses	Negligible as share of alternatives is high	Negligible	Unlikely & only associated with SMEs assumed to have 25% of reformulations where the share of alternatives is <30%
Other impacts	Negligible	Negligible	Negligible
Uncertainties (impact on restriction costs)	- likely more polymers fall in scope (↑) - based on historical data (↑↓) - 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 & 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, 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 (↑)

The approach to estimating 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 share of microplastic-containing leave-on products, justifications are provided below.

Costs per reformulation

About two-thirds of Cosmetics Europe survey respondents indicated that an alternative does not exist for their applications. 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 microplastics, contain particles of more than one polymer. 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).

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 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, microplastic-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 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 share of alternatives (i.e., microplastic-free products represent less than 30%) and high number of microplastic 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).

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 value for the consumer loss connected to the functionality provided by D4 and D5 in cosmetics. This was estimated at €5/person/year.
- 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).[60]

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[60] *For example, 66% of respondents replied that they choose a product that is not polluting (Natrue, 2016).*

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.

D.5.5.4. Economic impacts

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 €19 million or about €12 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 55). Based on the described assumptions, they are estimated to range between €1.6 billion and €13.3 billion annually or approximately €7.4 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 microplastic uses in "trash-disposal" products are for the purpose of forming a film and therefore, out of scope of the proposed restriction.

Table 55: 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)	0.5
Total incremental to restriction (1)-(4)+(5)	7.4

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.

Profit losses

Given the share of alternatives 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 share of alternatives is low and the number of microplastic ingredients is high. Applying the assumptions presented in Table 54, 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 via household waste ("trash disposal") 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.

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 therefore, require reapplication. 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 share 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 share of alternatives is low and the number of microplastic ingredients is high. Applying the assumptions presented in Table 54 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 €25 million. About 80% of these losses are associated with product groups that tend to be disposed via household waste (trash disposal) 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 share of their products may put substantial pressure on their business. On the other hand, there's information that larger companies tend to use more microplastics while smaller cosmetics companies tend to specialise in natural and organic cosmetics. These SMEs could directly benefit from a restriction on microplastic-containing products as they already have on the market microplastic-free formulations. It is unclear whether on balance the impacts on EEA SMEs would be negative as a result of the proposed restriction on leave-on cosmetics.

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.

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 €14.4 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 €820. Therefore, the proposed action is as proportionate as previous REACH restrictions on environmental pollutants.

Table 56: Restriction costs – leave-on cosmetic products (NPV, 2017 values)

Restriction costs \ Scenarios	**Low**	**Central**	**High**
Economic costs (million €)			
• Material	5	12	19
• Reformulation	1 600	7 400	13 300
• Enforcement	0.4	0.4	0.4
• Profit losses	-	-	1 100
Other impacts (million €)			
• Employment losses	-	-	25
Total Restriction costs	**1 600**	**7 400**	**14 400**
Emissions (cumulative)	**4 200**	**9 100**	**13 900**
Cost effectiveness (€/kg)	**380**	**820**	**1 040**

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 17% and 20% of the estimated average profits per reformulation (€60 000/reformulation: see Profit loss assumptions above). Therefore, the proposed restriction on rinse-off products is deemed affordable.

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

D.5.5.7. Impact of scope variations on the proportionality to risk

Restriction on "down-the-drain" leave-on products only

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., "trash disposal" products, thus leading to substantially lower emissions to the environment (about 25% of all leave-on emissions in the Central scenario). These include: sun and self-tanning products, skin care, deodorants/anti-perspirants, hair care and other cosmetic products. 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: €430 per kilogram of reduced emissions. The results show that the a restriction on "down-the-drain" 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 57 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 57: Restriction costs – impact of scope variations: leave-on cosmetic products (NPV, 2017 values, Central scenario)

Restriction costs (million €)\ Scenarios	"Trash disposal" cosmetics*	Other Leave-on cosmetics**
Material	6.4	5.6
Reformulation	4 500	2 900
Enforcement	0.4	0.4
Total Restriction costs	**4 500**	**2 900**
Emissions (cumulative)	**2 330**	**6 750**
Cost effectiveness (€/kg)	**1 940**	**430**

Notes: * Includes leave-on cosmetic categories of nail polish/remover, make-up and lip products.
** Includes leave-on cosmetics categories of sun and self-tanning products, skin care, deodorants/persperants, hair care and other cosmetic products.

As shown in Table 57, the cost-effectiveness of an action solely on "trash disposal" cosmetics is significantly lower. This is primarily because high compliance costs are estimated to reduce emissions of 170 tonnes of microplastics annually. One potential alternative to a restriction on the use is the introduction of comprehensive labelling requirements which instruct users to dispose of cosmetics in household trash to minimise emissions to the environment. While this action would likely not eliminate emissions to the environment from these products, it would lead to decline in emissions sooner (from mid-2023 if similar to other labelling requirements 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).

Microplastics with film-forming functions are included in the scope

Film forming is one of the essential microplastic functions in many leave-on products and it is equally important for both trash disposal and down-the-drain products. The Dossier Submitter concludes that this use of microplastics does not result in an intentional release of microplastics, therefore, assumptions are made to exclude to the extent possible tonnages, material and reformulation costs associated with microplastics with film-forming functions from the Low scenario based on information from CfE 2018. No sufficient information was available to do the same in the High scenario. Therefore, in the event the scope of the proposed restriction is expanded to include microplastics with film-forming functions, the costs and tonnages impacted would likely be higher. Whether this would lead to erosion or an improvement in the overall cost-effectiveness in comparison to the presented in Table 56 would depend primarily on whether the substitution of this particular microplastic function is more costly than the substitution of microplastics with all other functions in leave-on products.

Microplastics with no dimension greater than 1 mm

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 (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.

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 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.

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 Table 50. 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.5.5.9. 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.

The proposed restriction has 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 for monitorability considerations of the proposed restriction.

D.6. Detergents and maintenance products

Polymers used in detergents and maintenance[61] 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:

- **Detergents containing microbeads**: 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.

- **Detergents containing polymeric fragrance encapsulates:** Polymeric fragrance encapsulates are used in detergents 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.

- **Other detergents:** This group includes all remaining detergents containing microplastics 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 and polishes**: 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.

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 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.

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[61] 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.

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 ECHA's call for evidence (CfE), industry submitted information both related to the definition of microplastics presented in the CfE and related to the definition 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 5mm or less in at least one external dimension[62]."
- A.I.S.E.'s definition of microplastic particles: "Water-insoluble solid plastic particles with a size less than 5mm that can be found as aquatic litter."

A.I.S.E. has collected information from its members on uses of microplastics as defined both in the CfE and by A.I.S.E. The information shows that there is a large difference in the estimations of polymers, tonnages, affected formulations and impacts depending on which definition of microplastics is used. While the CfE definition covers approximately 100-120 different polymers, the A.I.S.E. definition covers around 15-25 different polymers (A.I.S.E. CfE #666).

Since the CfE, ECHA has further developed the definition of microplastics in such a way that the scale of microplastics used according to the latest definition is expected to be between the scale covered by the CfE definition and that covered by the A.I.S.E. definition. Because of this, there has been a need to make a number of assumptions in the subsequent analysis. In the impact assessment, the Dossier Submitter has 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. Since the CfE, the Dossier Submitter has also received from some stakeholders additional information regarding how the scale of use and socio-economic impacts may change based on updates to certain elements of the definition of microplastics. These have also been incorporated into the analysis.

D.6.2.1. Scope of use according to the A.I.S.E. definition

According to the consultation performed by A.I.S.E. in response to the AMEC study (AMEC, 2017), the total amount of *microbeads* used in soaps, detergents and maintenance products was approximately 200 tonnes in the EU[63]. In an updated

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[62] 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.

[63] A.I.S.E. extrapolated the amount to the whole sector based on responses from companies that account for about 70-75% of the total EU market.

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.

In the 2018 survey, A.I.S.E. also collected information on the number and volumes of polymers other than microbeads, which fulfil the definition of microplastic under the A.I.S.E. definition. The industry respondents that provided quantitative data represent a market share of approximately 50%. Table 58 outlines the estimated tonnages and number of polymers reported by the respondents for different product categories.

Table 58: Volume of polymers reported by respondents based on the A.I.S.E. definition

Product category	**Total volume (tonnes) of polymer used by respondent in 2017**	**Estimated number of polymer used**
Solid laundry detergent	40	4
Liquid laundry detergent	340	5
Fabric conditioner	20	2
Glass/window, bathroom, kitchen cleaners	40	3
All-purpose hard surface cleaners	100	3
Toilet cleaners	<10	2
Automatic dishwasher detergent	20	3
Manual dishwasher detergent	10	2
Waxes and polishes	430	8
Air care products	<10	1
Professional building care	10	2
Bleaches	<10	3
Other	10	1
TOTAL	**1 010**	**21**

Notes:
1. The volumes have been rounded to the nearest 10 tonnes to avoid the impression of false accuracy
2. The category “Other” includes maintenance (pest control), oven cleaner and laundry stain remover.
3. Insufficient data have been provided for professional building care and bleaches.
4. The number of polymers used is an approximation based on the responses given, as in some cases a generic chemical group has been given.

Source: A.I.S.E. AI 2018, #013

According to A.I.S.E. (ECHA AI 2018, #013), the concentration of polymers in the formulation varies depending on the product category and on the specific substance used to deliver a specific function. Industry respondents reported polymer concentrations of 0.01% - 40% in these product groups, with the mean concentration being 4.8% and the median being 1.3%. Waxes and polishes were the group with the highest concentrations (0.7-40%). However, since only a portion of the polymers fall within the A.I.S.E. definition, the sample size was considered too low to be representative.

Information on the polymer groups used by respondents is outlined in Table 59. The information shows that the majority of polymers used are polyacrylates.

Table 59: Total volume of polymers used by respondents per polymer group (based on A.I.S.E. definition)

Polymer group	**Total volume (tonnes) of polymer used by respondents in 2017**	**Estimated number of polymers used**
Polyethers	<10	1
Polyacrylates	620	4
Polyvinyl	10	1
Polyesters	80	4
Polyolefins	170	3
Polyurethanes	60	2
Other	60	3
Unknown	10	3
TOTAL	**1 010**	**21**

Notes:
1. The volumes have been rounded to the nearest 10 tonnes to avoid the impression of false accuracy
2. The number of polymers used is an approximation based on the responses given, as in some cases a generic chemical group has been given.

Source: A.I.S.E. (ECHA AI 2018, #013)

Extrapolated to the whole EU, the total use of microplastic particles under the A.I.S.E. definition is approximately 2 000 tonnes per year. This tonnage will be taken forward as the Low tonnage scenario in the impact assessment, split up between detergents containing microplastics other than microbeads (1 140 tonnes) and waxes and polishes (860 tonnes[64]). For products containing microbeads, it will be assumed that the use continues to decrease and is phased out by 2020. Detergents containing fragrance encapsulates do not contain microplastics as defined by the A.I.S.E definition. Use of microplastics in these products will therefore only be included in the Central and High tonnage scenarios.

D.6.2.2. Scope of use according to the ECHA CfE definition

Under the CfE definition, a wider range of polymers (100-120 different polymers) are covered, as outlined in Table 60 and Table 61.

Table 60: Total number of polymers affected per product category based on the ECHA CfE definition

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[64] Industry respondents representing ~50% of the market reported a total use of 430 tonnes if waxes and polishes in the A.I.S.E. (2018) consultation

Product category	Estimated number of polymer used
Solid laundry detergent	21
Liquid laundry detergent	32
Fabric conditioner	16
Glass/window, bathroom, kitchen cleaners	16
All-purpose hard surface cleaners	36
Toilet cleaners	24
Automatic dishwasher detergent	26
Manual dishwasher detergent	5
Waxes and polishes	23
Air care products	11
Professional building care	2
Bleaches	12
Other	2
TOTAL	**117**

Notes:

1. The number of polymers used is an approximation based on the responses given, as in some cases a generic chemical group has been given.

Source: A.I.S.E. (ECHA AI 2018, #013)

Table 61: Total number of polymers affected per polymer group based on the ECHA CfE definition

Polymer group	Estimated number of polymers used
Polyethers	23
Polyacrylates	19
Siloxanes and Silicones	14
Polysaccharides	14
Polyvinyl	8
Polyesters	11
Polyolefins	3
Polyurethanes	2
Polyamides	2
Polyphosphates	1
Carboxylates	3

Polymer group	**Estimated number of polymers used**
Paraffins	2
Other	8
Unknown	7
Total	**117**

Source: A.I.S.E. (ECHA AI 2018, #013)

Again, the concentration of polymers in the formulation varies depending on the product category and on the specific substance used to deliver a specific function. Industry respondents reported polymer concentrations of <0.01% - 40% in the above product category, with the mean concentration being 3.1% and the median being 1%. Waxes and polishes were again the category with the highest concentrations (<0.01%-40%). The concentrations per product category are outlined in Table 62. While the overall data was considered representative, it was noted that at product category level, only those categories with a high sample size can be considered representative. (ECHA AI 2018, #013)

Table 62: Concentration of polymer used per product category (based on ECHA CfE definition)

Product category	**Concentration of polymers used based on A.I.S.E. definition**					
	Minimum	**Maximum**	**Mean**	**Median**	**Standard deviation**	**Sample size**
Solid laundry detergent	0.01%	14.67%	3.39%	1.30%	5.14%	22
Liquid laundry detergent	0.01%	15%	1.77%	0.4%	3.57%	45
Fabric conditioner	0.01%	19.16%	6.72%	0.40%	20.90%	23
Glass/window, bathroom, kitchen cleaners	0.02%	8.21%	2.25%	1.00%	2.75%	18
All-purpose hard surface cleaners	0.01%	15.00%	2.52%	1.00%	3.88%	50
Toilet cleaners	0.23%	5.00%	1.96%	1.00%	3.65%	31
Automatic dishwasher detergent	0.03%	43.25%	5.96%	1.65%	11.39%	44
Manual dishwasher detergent	0.05%	0.13%	0.08%	0.08%	0.04%	4
Waxes and polishes	<0.01%	40.00%	8.24%	1.8%	11.23%	29
Air care products	0.01%	2.70%	2.02%	0.97%	4.23%	18
Professional building care	1.00%	15.00%	8.20%	10.00%	8.13%	5
Bleaches	0.24%	2.17%	1.03%	0.91%	0.76%	14

Other	0.09%	11.40%	2.35%	0.23%	4.39%	14
All products	**<0.01%**	**43.25%**	**3.10%**	**1.00%**	**8.64%**	**317**

Notes:
1. The data is based on around 100-120 polymers provided by 14 respondents who account for around 50% of the market size. Therefore, the data overall can be considered representative. At product category level the data can only be considered representative where there is a high sample size.
2. The minimum, maximum and average values exclude the two lowest/highest values (i.e. possible outliers)
3. Respondents who noted values such as <1% and <5% were changed to 0.5% and 2.5% respectively.
4. The standard deviation is a measure of how widely values are dispersed from the average value (the mean).
5. The category "Other" includes maintenance (pest control), oven cleaner and laundry stain remover.

Source: A.I.S.E. (ECHA AI 2018, #013)

For the ECHA CfE definition, no tonnage was provided by industry. In the absence of any tonnage data, the Dossier Submitter has scaled up the A.I.S.E. tonnage based on the information available on the number of affected polymers and formulations under the two definitions. Based on this scaling up, it will be assumed that a total of 17 400 tonnes of microplastic particles are used in detergents and maintenance products under the ECHA CfE definition.[65]

For the purpose of the subsequent analysis, assumptions need to be made regarding what proportion of the above total tonnage can be attributed to waxes and polishes. In the CfE, stakeholders were not able to provide information on what share of waxes and polishes used in the EU contain microplastic particles. After the CfE, ECHA consulted A.I.S.E. on what the revised elements of ECHA's definition means for the use of microplastics in waxes and polishes. A.I.S.E. responded that if the absence of particles would preclude a material from being considered a microplastic, then the impact of a restriction on waxes and polishes would probably be rather limited. A.I.S.E.'s members have confirmed that the biggest use is for floor products and that products can be divided into two macro-categories: floor wax and floors maintainers. Both categories are normally manufactured as mixtures of polymers and a variable percentage of wax, higher for the purely wax products (i.e. floor waxes), and lower for the floor maintainers. A.I.S.E. estimates that the total market for these products in the EU would be between 3 000 and 4 000 tonnes of polymers per year. However, importantly, since it is not possible to distinguish between solid/semi-solid and liquid ingredients, what share of that tonnage would be covered by the current definition of microplastics is not known. Therefore, the actual tonnage of microplastics is likely to be lower. (A.I.S.E. #016)

The 3 000 - 4 000 tonnes upper value for waxes and polishes can be compared with a study undertaken by the Swedish Chemicals Agency, which through the Swedish product registry found that 78 tonnes of polymers are used in waxes per year in Sweden (KEMI, 2018). Extrapolating this to the EU level based on population[66] gives a total volume of 3 994 tonnes per year. The product registry does not give any information on the solid state of the polymers, which would be needed in order to determine whether these can be considered microplastics. Nevertheless, it is within the maximum tonnage range

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[65] Number of reformulations A.I.S.E./ECHA CfE definitions: 1575/31500=0.05 (low); 2575/51500=0.05 (high).

Number of polymers A.I.S.E./ECHA CfE definitions: 21/117=0.18.

ECHA CfE tonnage: 2000/(weighted average of 0.115) = 17,400

[66] Population in Sweden 2017: 9.995 million inhabitants. Population in the EU 2017: 511.8 million inhabitants

provided by A.I.S.E.

For the purpose of the impact assessment, the Dossier Submitter will therefore assume that up to 4 000 tonnes of microplastics are used in waxes and polishes in the EU in the High tonnage scenario. For detergents containing other microplastics than microbeads, a use of 13 400 tonnes will be assumed in the High tonnage scenario. This tonnage will be split up between detergents containing fragrance encapsulates (containing up to 300 tonnes of microplastics according to additional information provided by IFRA [ECHA AI 2018, #193]) and other detergents (the remaining 13 100 tonnes). For microbeads, it will be assumed that the use continues to decrease and is phased out by 2020.

D.6.2.3. Baseline

As previously explained, the Dossier Submitter has used the information related to the A.I.S.E. definition as the starting point for the Low Tonnage Scenario and the information related to the ECHA CfE as the starting point for the High Tonnage Scenario. Any additional information has also been incorporated into the estimates. The Central Tonnage Scenario represents the mid-point between the Low and the High scenarios.

The estimated tonnages and releases of microplastics in detergents and maintenance products are outlined in Table 63. 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 63: Microplastic use in detergents and maintenance products: Baseline scenarios (tonnes/year)

Scenarios	**2017**	**2018**	**2019**	**2020**	**2021**	**2022-2041 (average)**
Low tonnage						
Detergents containing microbeads	200	95	40	-	-	-
Detergents containing fragrance encapsulates	-	-	-	-	-	-
Other detergents	1 140	1 140	1 140	1 140	1 140	1 140
Waxes and maintenance products	860	860	860	860	860	860
- to water*	258	258	258	258	258	258
- to air*	129	129	129	129	129	129
Total use	2 095	2 048	2 024	2 000	2 000	2 000
Total releases	1 622	1 575	1 551	1 527	1 527	1 527
Central tonnage						
Detergents containing microbeads	200	95	40	-	-	-
Detergents containing fragrance encapsulates	150	150	150	150	150	150
Other detergents	7 120	7 120	7 120	7 120	7 120	7 120

Waxes and maintenance products	2 430	2 430	2 430	2 430	2 430	2 430
- to water*	729	729	729	729	729	729
- to air*	243	243	243	243	243	243
Total use	9 795	9 748	9 724	9 700	9 700	9 700
Total releases	8 337	8 290	8 266	8 242	8 242	8 242
High tonnage						
Detergents containing microbeads	200	95	40	-	-	-
Detergents containing fragrance encapsulates	300	300	300	300	300	300
Other detergents	13 100	13 100	13 100	13 100	13 100	13 100
Waxes and maintenance products	4 000	4 000	4 000	4 000	4 000	4 000
- to water*	1 200	1 200	1 200	1 200	1 200	1 200
- to air*	600	600	600	600	600	600
Total use	17 495	14 349	14 325	14 301	14 301	14 301
Total releases	15 295	15 248	15 224	15 200	15 200	15 200

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, household and maintenance product formulations can be grouped into six polymer categories, as outlined in Table 64. The properties of these polymers vary depending on the type and size of the polymer used.

Table 64: 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 alchohol)	• 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[67] 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.[68]

A range of alternatives are available for microbeads used as abrasives. Natural mineral components, such as silica 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 (2017b) 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.

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

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[67] 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.

[68] Population in the Netherlands (2017): 17.08 million. Population in the EU (2017): 508 million.

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, [ECHA AI 2018, #192 and #193]) estimates that the total volume of shells used for all fragrance encapsulation is up to 300 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 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 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).

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 and polishes**

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)

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)

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.

- Companies using 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[69]. 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.

- For companies producing detergents containing fragrance encapsulates, confidential information (ECHA AI 2018, #193, #303 and #304) has been received which affects the Dossier Submitter’s assumptions regarding the restriction response. As some of the relevant information is confidential, all assumptions cannot be outlined. Nevertheless, it can be noted that the assumptions relate to differences in the timing and R&D required to implement alternatives to microplastics. The information not claimed as confidential is outlined later in this section.

- While the socio-economic analysis report submitted by A.I.S.E. (ECHA AI 2018, #013) assumes that the majority of products could be reformulated within 5

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[69] 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)

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. While the assumption seems to be based on a limited number of industry responses and it is not clear on what basis the assumed percentages have been derived, the Dossier Submitter has decided to test what impact such unsuccessful reformulations could have as a sensitivity check. With a 5-year transitional period, 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 detergents containing fragrance encapsulates, other detergents and waxes and polishes. 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 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 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 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

Because of the large differences in the estimated tonnages, affected formulations and socio-economic impacts depending on which definition of microplastics is used, the Dossier Submitter has developed three scenarios. As previously explained, the information received related to the A.I.S.E. definition has been used as the starting point for the Low Scenario, while the information received regarding the CfE definition has been used as the starting point for the High Scenario. Where no other information has been available on actual use, the mid-point between the Low and the High Scenarios has been used for the Central Scenario. Since the CfE, ECHA has further developed the definition and received additional information from stakeholders. This additional information has also been taken into account in the estimates. The scenarios and the assumptions are summarised in Table 65. 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 65: Restriction scenarios: Summary of assumptions used in impact assessment of detergents and household products

Impact category	Low scenario	Central	High scenario
Tonnes of microplastics used per year			
Detergents containing fragrance encapsulates	0	150	300
Other detergents	1 140	7 120	13 100
Waxes and polishes	860	2 430	4 000
Tonnes of emissions reduced per year			
Detergents containing fragrance encapsulates	0	76	152
Other detergents	579	3 618	6 657
Waxes and polishes*	260	734.5	1 210
Number of formulations affected			
Detergents containing fragrance encapsulates	0	750	1 500
Other detergents	2 075 (1 575 - 2 575)	21 038 (15 788 - 26 288)	40 000 (30 000 – 50 000)
Waxes and polishes	1 565 (1 188 – 1 943)	7283 (5 528 - 9 037)	12 388 (9 403 - 15 373)
Raw material costs			
Detergents containing fragrance encapsulates	75% more perfume required (50 - 100%)/ alternatives to microplastics 50% more expensive (0 - 100%)		
Other detergents	50% (0 - 100%)		
Waxes and polishes	50% (0 - 100%)		
Costs per reformulation / R&D			
Detergents containing fragrance encapsulates	€40 000 (€30 000 - €50 000)		
Other detergents	€15 000 (€10 000 – €20 000)		
Waxes and polishes	€15 000 (€10 000 – €20 000)		
R&D premium	5%	12.5%	20%
Baseline reformulations	Coordination during transitional period		
Other impacts	Profit losses included as upper bound		

Impact category	Low scenario	Central	High scenario
Uncertainties (impact on restriction costs)	- likely that more polymers fall in scope (↑) - based on limited sources of information and some assumptions (e.g. number of reformulations for waxes and polishes)	Mid-point between Low & High scenario	- several products are likely to represent one reformulation case (↓) - based on limited sources of information and several assumptions (e.g. tonnage for waxes and polishes, as well as number of reformulations for both other detergents and waxes and polishes)

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 detergents containing 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 (2017b) 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 (2017b), 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. Reformulation/R&D costs

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.6.5.3. Number of reformulations

According to RPA (2018), there are an estimated 63 000 to 103 000 detergent products in total covering both consumer and industrial/institutional subsectors across the EU/EEA (31 500 to 51 500 consumer detergent products and 31 500 to 51 500 detergent products in the industrial/institutional subsector). This estimated range of detergent products does not include products that do not contain detergents (i.e. waxes and polishes).

The socio-economic analysis submitted by A.I.S.E. (ECHA AI 2018, #013) assumed that between 31 500 and 51 500 formulations (50% of the total number) might contain microplastics under the ECHA definition used in the call for evidence in April 2018. Based on the respondent data from its own consultation, A.I.S.E. assumed that 2.5% (1 575 – 2 575 formulations) of the total number of detergent product formulations on the market would contain microplastics according to the A.I.S.E definition. These values are taken forward as the total number of detergent formulations for the High tonnage (ECHA definition) and the Low tonnage (A.I.S.E. definition) scenarios. The Central tonnage scenario will be based on the mid-values between the High and Low tonnage scenarios (i.e. 16 538 – 27 038).

The above numbers of required reformulations cover both detergents containing polymeric fragrance encapsulates and other detergents. In accordance with information provided by IFRA (ECHA AI 2018, #193), no reformulations would be required for detergents containing polymeric fragrance encapsulates under the A.I.S.E. definition, while up to 1 500 reformulations would be required under the ECHA CfE definition. Therefore, the Low tonnage scenario will assume 0 reformulations, the Central tonnage scenario will assume 750 reformulations and the High tonnage scenario will assume 1 500 reformulations for detergents containing polymeric perfume encapsulates. These reformulations will be subtracted from the above total number of detergent reformulations in order to get the numbers for the category of 'other detergents'. As such, for other detergents the Central tonnage scenario will assume 15 788 – 26 288 reformulations, with the low tonnage scenario assuming 1 575 – 2 575 reformulations and the High tonnage scenario assuming 30 000 – 50 000 reformulations.

Industry was not able to provide any information on the number of reformulations required for waxes and polishes. In the absence of data, the Dossier Submitter has assumed that the proportion of reformulations in relation to tonnage is the same for waxes and polishes as for detergents. This gives 5 528 - 9 037 reformulations required under the Central tonnage scenario, 1 188 – 1 943 reformulations under the Low tonnage scenario and 9 403 – 15 373 reformulations required under the High tonnage scenario[70].

D.6.5.4. Costs per reformulation

The Dossier Submitter has received information suggesting that the reformulation costs would be the highest for detergents containing polymeric fragrance encapsulates. According to IFRA (ECHA AI 2018, #193), the reformulations for these products would

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[70] To illustrate, the number of wax and polish reformulations required under Central tonnage scenario was calculated like this: (16 538/(9 700 – 2 430))*2 430 = 5 528 (low) and (27 038/(9 700 – 2 430))* 2 430 = 9 037 (high).

cost €30 000 – €50 000 (central estimate €40 000).

For other detergents and for waxes and polishes, 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[71] 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 line with the socio-economic analysis submitted by A.I.S.E. (ECHA AI 2018, #013), the Dossier Submitter will also apply 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% will be assumed for the Central tonnage scenario. This R&D premium will be applied to all product categories.

D.6.5.5. 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:

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[71] 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.

- 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[72]. 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 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).

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[72] 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.

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.6.5.6. Profit losses

As previously explained, the socio-economic analysis submitted by A.I.S.E. (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. While this assumption seems to be based on a limited number of industry responses, the Dossier Submitter has decided to test what impact this could have as a sensitivity check.

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 (i.e. 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.

To test the upper boundary of the impacts, the Dossier Submitter will assess the profit losses related to 10% of the reformulations required in the Low tonnage scenario and 25% of the reformulations required under the High tonnage scenario. For the Central tonnage scenario, the profit losses will be assessed for 17.5% of the reformulations.

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.6.5.7. 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.6.5.8. Economic costs

In relation to the substitution of microbeads 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. Raw material costs

For detergents containing fragrance encapsulates, the raw material cost is expected to increase by €57.9 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 €362.4 million.

For other detergents, the raw material cost is expected to increase by €29.4 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 €108.2 million.

For waxes and polishes, the raw material cost is expected to increase by €10 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 €33 million.

Table 66: Raw material costs (NPV, 2017)

		Low tonnage scenario	**Central tonnage scenario**	**High tonnage scenario**
Detergents containing fragrance encapsulates	Lower	-	€0	€0
	Central	-	€57.9M	€115.7M
	Upper	-	€181.2M	€362.4M
Other detergents	Lower	€0	€0	€0
	Central	€4.75M	€29.4M	€54.1M
	Upper	€9.4M	€58.8M	€108.2M
Waxes and polishes	Lower	€0	€0	€0
	Central	€3.64M	€10M	€16.5M
	Upper	€7.1M	€20M	€33M

D.6.5.10. Reformulation/R&D costs

For detergents containing fragrance encapsulates, 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 €56.4 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 €0 to €177.9 million.

For other detergents, the incremental reformulation/R&D costs are expected to be €235.9 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 €9.8 million to €890.9 million.

For waxes and polishes, the incremental reformulation/R&D costs are expected to be €81.7 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 €7.4 million to €273.9 million.

Table 67: Incremental reformulation/R&D costs (NPV, 2017)

		Low tonnage scenario	**Central tonnage scenario**	**High tonnage scenario**
Detergents containing fragrance encapsulates	Lower	€0	€24.2M	€48.3M
	Central	€0	€56.4M	€112.9M
	Upper	€0	€79.6M	€177.9M
Other detergents	Lower	€9.8M	€118M	€267.3M
	Central	€19.4M	€235.9M	€534.5M
	Upper	€32.1M	€393M	€890.9M
Waxes and polishes	Lower	€7.4M	€41.3M	€83.8M
	Central	€14.6M	€81.7M	€165.6M
	Upper	€24.2M	€135.1M	€273.9M

D.6.5.11. Profit losses

Profit losses have been estimated to test the upper bounds of costs and have not been included in the central calculations. For detergents containing fragrance encapsulates the profit losses could be up to €26.1 million, for other detergents the profit losses could be up to €869.8 million and for waxes and polishes the profit losses could be up to €267.4 million.

Table 68: Profit losses (NPV, 2017)

		Low tonnage scenario	Central tonnage scenario	High tonnage scenario
Detergents containing fragrance encapsulates	Lower			
	Mid			
	Upper	€0	€9.1M	€26.1M
Other detergents	Lower			
	Mid			
	Upper	€17.9M	€320.1M	€869.8M
Waxes and polishes	Lower			
	Mid			
	Upper	€13.5M	€101.1M	€267.4M

D.6.5.12. 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. 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 five years is proposed and the existing labelling requirements under the Detergents Regulation and CLP, 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 detergents and maintenance products containing microplastics 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 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. Cost-effectiveness, affordability and proportionality to risk

Table 69 presents the total costs of the proposed restriction on 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 detergents containing fragrance encapsulates, the total restriction costs are expected to be €114.7 million in the Central tonnage scenario. When considering the lower and upper bounds of all three tonnage scenarios the total costs range from €0 to €566.8 million.

For other detergents, the total restriction costs are expected to be €265.7 million in the Central tonnage scenario. When considering the lower and upper bounds of all three tonnage scenarios the total costs range from €10.2 million to €1 869.4 million.

For waxes and polishes, the total restriction costs are expected to be €92.1 million in the Central tonnage scenario. When considering the lower and upper bounds of all three tonnage scenarios the increase in costs range from €7.8million to €574.8 million.

Table 69: Restriction costs for detergents and maintenance products (NPV, 2017 values)

		Low tonnage scenario	**Central tonnage scenario**	**High tonnage scenario**
Detergents containing fragrance encapsulates	Lower	-	€24.6M	€48.7M
	Central	-	€114.7M	€229M
	Upper	-	€270.3M	€566.8M
Other detergents	Lower	€10.2M	€118.46M	€267.7M
	Central	€24.5M	€265.7M	€589.1M
	Upper	€59.8M	€772.4M	€1 869.4M
Waxes and polishes	Lower	€7.8M	€41.7M	€84.2M
	Central	€18.6M	€92.1M	€182.5M
	Upper	€45.2M	€265.6M	€574.8M

		Low tonnage scenario	Central tonnage scenario	High tonnage scenario

The cost-effectiveness can be calculated based on the above costs and the emissions reduced reported in Table 65 in the section on restriction scenarios and key assumptions.

For detergents containing fragrance encapsulates, the cost-effectiveness is expected to be €101 in the Central tonnage scenario. When considering the lower and upper bounds of all three tonnage scenarios the cost-effectiveness ranges from €0 to €249.

For other detergents, the cost-effectiveness is expected to be €5 in the Central tonnage scenario. When considering the lower and upper bounds of all three tonnage scenarios the cost-effectiveness ranges from €1 to €19.

For waxes and polishes, the cost-effectiveness is expected to be €8 in the Central tonnage scenario. When considering the lower and upper bounds of all three tonnage scenarios the cost-effectiveness ranges from €2 to €32.

The cost-effectiveness for detergents containing 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 70: Cost-effectiveness of the proposed restriction (€/kg)

		Low tonnage scenario	Central tonnage scenario	High tonnage scenario
Detergents containing fragrance encapsulates	Lower	-	€22	€21
	Central	-	€101	€100
	Upper	-	€237	€249
Other detergents	Lower	€1	€2	€3
	Central	€3	€5	€6
	Upper	€7	€14	€19
Waxes and polishes	Lower	€2	€4	€5
	Central	€5	€8	€10
	Upper	€12	€24	€32

Another way of looking at the proportionality of the restriction is to assess the restriction cost per kilogram of microplastics used. For detergents containing fragrance encapsulates, this is estimated to be €0 – €94/kg, with €38/kg as the central estimate. For other detergents the estimated cost is €0.4 - €7/kg used with €2/kg as the central estimate. For waxes and polishes the estimated cost is €0.5 - €7/kg used with €2/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.6.8. 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.

In relation to the cost estimations, the key uncertainties concern the tonnages of microplastics currently used and the number of formulations that would be affected by the restriction. Because of these uncertainties, three tonnage scenarios were developed, which all tested lower and upper boundaries of the various cost elements. While the effects of some uncertainties lead to overestimation or underestimation of the overall costs of the proposed restriction, on balance the ranges can be seen as realistic lower and upper bounds of the impacts. 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.

D.6.9. 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 functions 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 hgher 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.

D.7. Medical devices (MD) and *in vitro* diagnostic medical devices (IVD MD)

D.7.1. Uses and functions

Medical Devices (MD) and *in vitro* medical devices (IVD MD) containing microplastic particles 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. Microplastics (polymeric microbeads) are indeed widely used in medical and biological applications 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.

D.7.1.1. Medical devices (MD)

According to MedTech Europe (CfE #726, and ECHA AI 2018 #31-311), microplastics are used 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.

MedTech Europe also noted in their call for evidence response that, according to the ECHA working definition of a microplastic, certain very small articles used in medical devices (e.g. O-rings, ferrules) could be considered to be microplastics.

D.7.1.2. In vitro diagnostic medical devices (IVD MD)

The uses of microplastics in IVD MD consists essentially in two main applications: (i) IVD reagents and assays, and (ii) analytical and purification chemistry for IVD applications.

According to MedTech Europe (CfE #726, and ECHA AI 2018 #31-311) and several companies placing IVD MDs on the market (CfE #652, #677 #746), various microplastic materials are used in *in vitro* diagnostic medical devices. The identity and properties of some microplastics materials used in IVD MD, as well as their technical function, are summarised in the Table 71 below.

Table 71: Example of microplastics used in IVD MD 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 component 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 heath areas (toxoplasmosis and rubella infection, HIV, hepatitis, oncology, thyroid, fertility, cardiac, hormones, inflammation, brain damage, pregnancy, immunosuppressant drug monitoring, anaemia and bone).

Type of microplastic	Function	Example of application
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 the 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
Ion Exchange Resins (Size 1-300 µm) - solid, water insoluble, and non-degradable polymeric microbeads (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 MD	Solid phase extraction (SPE): a methodology widely used in bioanalytical sample preparation e.g. biopharma, toxicology, drugs' abuse screening, environmental pesticides and toxins testing. Anti-body purification using liquid chromatography. Purification of oligonucleotide intermediate in R&D (no resin in final product).
Sodium polyacrylate, polyacrylamide	Purification chemistry for IVD MD (absorption of 'waste' substance)	Waste bags in blood gas monitoring

Source: MedTech Europe (CfE #726, and ECHA AI 2018 #31-311), companies placing IVD MDs on the market (CfE #652, #677 #746)

Although focussed on the IVD MD uses by professionals, the uses indicated in Table 71 can be considered to be generic. There are numerous applications of MD 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), insuline manufacturing, etc.)
- Adsorbent for blood treatment
- Demineralisation of water (industrial and consumer uses)
- Metals removal
- Food industry: e.g. removal of the bitterness in orange juice manufacturing

D.7.2. Baseline – tonnage used and releases

According to the information received from MedTech Europe (CfE #726, and ECHA AI 2018 #31-311) and several companies placing MDs and IVD MDs on the market (CfE #652, #677 #746), the professional uses of microplastics in these fields is limited in term of quantity.

With regards to the MD applications, 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 aquatic environment. At the 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.

As far as the Ion Exchange Resins is concerned (Analytical and purification chemistry for IVD MD), the resin is 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 MD, during their use, microplastics are in general contained in equipment or cartridge without direct release to the aquatic environment. Nevertheless, releases of microplastics to the environment from the IVD MD applications can occur but seem to be limited to few applications where the microplastics are disposed down the drain as part of the liquid waste. MedTech Europe indicated indeed 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): 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 waste water and then directed to a municipal WWTP: e.g. rinsing water after calibration or use, or in case of antifoaming function for reagent preparation.

Once in the wastewater, treatments 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 ground waters. 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, can be made. This is summarised in Table 72.

Table 72: Estimated amounts and releases of microplastics particles from MD and IVD MD uses (professional uses)

Use	**Amount of microplastics used [EU tonnes/year]**	**Release assumption**	**Estimated release of microplastics to environment [EU tonnes/year]**
Medical devices (MD)	Ca. 10 tonnes	Used in closed systems. Treated as clinical waste	Negligeable

Use	**Amount of microplastics used [EU tonnes/year]**	**Release assumption**	**Estimated release of microplastics to environment [EU tonnes/year]**
		or disposed of via B2B[73] scheme	
In vitro diagnostic medical devices (Analytical and purification chemistry for IVD MD)	Ca. 100 tonnes This includes: - Analytical and purification chemistry for IVD MD (contained during their all life-cycle) - Reagent and assays, calibration and anti-foaming	Essentially treated as biohazardous waste. Estimated 0.5 tonnes would be discarded as liquid waste. Estimated 0.7 tonnes would be discarded as solid waste and incinerated (in the worst case scenario, it is assumed that the solid waste is sent to municipal solid waste instead of incineration)	0.25 -0.29 tonnes (0.27 tonnes as a median value)

Sources: MedTech Europe (ECHA AI 2018 #31-311)

According to the information provided by the sector, professional uses of microplastics in MD and IVD MD would therefore appear to result in negligible releases to the environment. Those releases would occur essentially if the microplastics are not disposed properly, and/or discarded down the drain.

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 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). 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.

D.7.3. Alternatives

For medical devices (polymeric filter, adsorber and absorber granulates, and ultrasound devices) and in-vitro diagnostic medical devices (IVD reagents and assays, analytical and purification chemistry for IVD), MedTech (CfE#726) and several MD, IVD MD suppliers (CfE #652, #677 #746) have indicated that there is currently no alternative available.

Replacing polymers particles for these applications would take most probably years of research to identify potential candidates and then years to manufacture them before the

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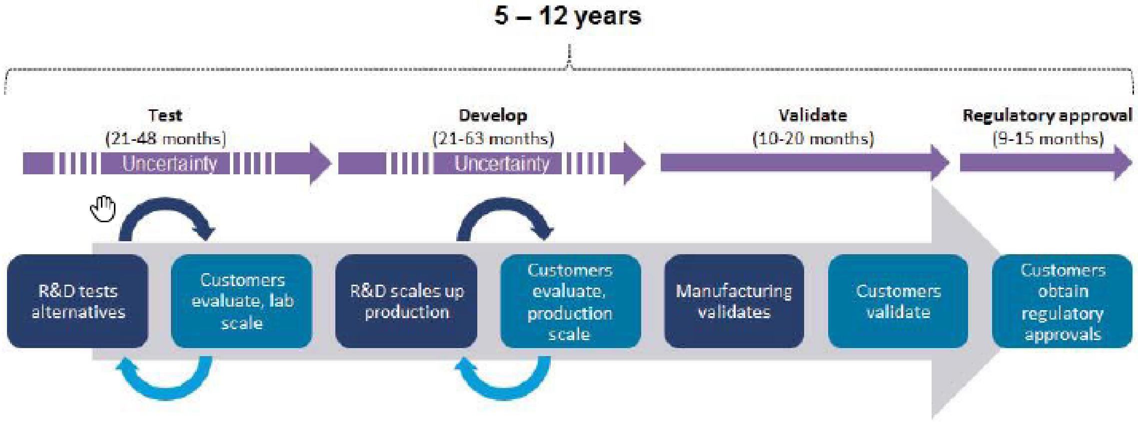
[73] B2B: business to business

validation in MD, and IVD applications, could even begin. Alternatives would have also to be reassessed by competent agencies in Europe and worldwide before the MD or IVD MD is placed on the market. MedTech estimates that it might take between 5 and 12 years per application to substitute microplastics on the market in MD and IVD MD as shown on Figure 7. For example, the replacement of polystyrene microspheres in IVD assays (that are custom molecules) is estimated by MedTech to cost $5 million per product. Some companies have up to 250 products using polystyrene microspheres.

Figure 7: Timeline for Medical Device and IVD MD development



Source: MedTech

It should be noted as well that even though alternatives would be available and approved by the competent regulatory bodies, as microplastics are the basis for the good and expected functioning of the *in vitro* diagnostic instruments. Any change to the microplastic could require redesigning the structure of the IVD and instrument combination, resulting in substantial costs for redevelopment and recertification by regulatory agencies. Also, many standard procedures such as OECD, ICH, etc. would have to be revised or finally replaced by new standards.

D.7.4. Other existing regulatory provisions

Medical devices and *in vitro* diagnostic medical devices are regulated by the EU Regulations (EU) 2017/745 on Medical Devices (aka MDR), and (EU) 2017/746 on *in vitro* diagnostic medical devices (aka IVDR). Both EU regulations repeal the existing directives on MD and IVD MD and 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 (label, and instruction 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 and IVD MD manufacturers will also be required in many cases: e.g. Periodic Safety Update Reports (PSUR)[74], and reporting to a central database named EUDAMED.

The MDR and IVDR do not explicitly require environmental concerns to be assessed.

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[74] 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.

Nevertheless according to the legislator (source: DG GROW), 'the definition of risk in 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.7.5. Proposed action

Because microplastics are extremely persistent in the environment, their emissions should be minimised. Medical devices and in-vitro diagnostic medical devices contribute to a fraction, even though minor, of the release of microplastics into the environment. These releases mainly come from the improper disposal of waste that are directly discarded down the drain. As these releases could potentially be further minimised through targeted measures, there is a need for an EU wide action.

The Dossier Submitter concluded that the best course of action is to derogate the uses in medical devices and in-vitro diagnosis medical devices where microplastics would be contained throughout their use, and properly disposed at their end-of life. The Dossier Submitter also accompany the derogation with the obligation to indicate in 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).

This measure implies therefore 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. Nevertheless, the Dossier Submitter is also proposing a transition period (2 years), so technical/procedural means could be put in place by the actors in the supply chain (e.g. suppliers, end-users) so microplastics in these uses are also appropriately contained during their life-cycle and, specifically, that waste containing microplastics is not discarded to municipal wastewater.

In term of risk management option, a full ban of microplastics in MD and IVD MD applications was also considered but finally dismissed, as considered to be disproportionate with regard to the amount of releases vs the reformulation time and cost needed to search for alternatives.

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. Medical devices and in-vitro diagnostic medical devices contribute to a minor fraction of the release of microplastics into the environment: releases to the environment happens in case of improper use or disposal of their waste. 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.
- Restriction cost: if the use of microplastics in MD and IVD MD would be fully banned, the reformulation costs are expected to be large and the cost effectiveness of the restriction expected to be extremely low with regard to the level of emissions. Rather, the restriction should seek to push for the development and implementation of technical means where microplastics would be contained throughout their use and incinerated at the end of their life-cycle. This will induce development cost to find these technical or procedural means, as well as costs for modifying the instructions and labels of the concerned MD and IVD. To allow sufficient time to implement the technical/proposal means and update the IFU and labels, it is propose to grant a transitional period of 18 months for the change of labels/IFU and 2 years for the implementation of the technical means. This transition time is expected to allow the label/IFU requirement to be implemented as part of the regular label/IFU updates for the majority of MD and IVD MD as well as to minimise any costs related to label/IFU-stocks and the replacement of old

labels/IFU for products already on the market. In addition, additional cost for the incineration / hazardous substance disposal of the microplastics at the end of their life cycle would have to be supported by the end-user. These costs are assumed to be affordable considering the amount of releases and the existing current practices in this sector with regard to biological/hazard wastes.
- Other socio-economic impact: MD and IVD MD containing microplastic particles are used by healthcare professionals in hospitals, and laboratories in order to treat patients and provide reliable diagnostic test results. Progress made in medical devices (MD and IVD) during the last 50 years has had very positive impacts on society. A ban on the use of microplastics in MD and IVD uses could affect the availability of key MD/IVD for diagnosis, particularly as it is not clear if there are alternatives available for the uses concerned. Polymers, some of which fall under the definition of microplastics, have an important function in these products. These functionalities are not intended to be negatively affected by this restriction proposal. Rather, the restriction seeks to push for the development of and implementation of technical/procedural means where microplastics would be contained throughout their use and incinerated at the end of their life-cycle.
- Practicality and monitorability: there are sector-specific EU regulations that already govern the placing on the market and the market-safety surveillance of MD and IVD MD. 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 supply chains. The proposed restriction should therefore seeks to reinforcing the provisions from the newly adopted MDR and IVDR which bring significant changes in term of Vigilance, Post-market Surveillance and communication on safe use. Monitorability of the proposed measure should also be feasible via the instruments put in place in the RMD and RIVD regulations.

In conclusion, the proposed restriction could be seen as a way of reinforcing the sector-specific regulations MDR and IVDR that will enter into force in 2020 and 2022 (e.g. in term of environment risk management and communication on safe use), and is considered as an effective, practical and monitorable measure to address the main source of emissions from medical devices, and in-vitro diagnosis medical devices.

Finally, as some releases of microplastics to the environment might arise from industrial use (cf. section on releases: manufacturing of polymers used in MD/IVD MD, and analytical and purification chemistry using IVD technologies in industrial setting), the Dossier Submitter is proposing to monitor the polymer uses and releases in these applications and is therefore proposing a reporting requirement for the industrial uses.

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 MD and IVD 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: Microplastics with film-forming functions are included in the scope

Not applicable for the MDs and IVD MDs.

Scope variation 3: 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 0.02 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 of MD/IVD MD affected by the restriction proposal. Based on the information provided by MedTech Europe, and several suppliers of MDs and IVD MDs, 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 end-users of MDs and IVD MDs.

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.

Also the enforceability of the proposed reduction especially at end-user sites (e.g. hospitals, laboratory) remains uncertain.

D.8. Medicinal products for human and veterinary use

D.8.1. 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 ‘controlled-release’ (CR) medicines. In contrast to immediate release (IR), 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
- 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
- Improve the compliance and observance of the treatment by the patient.

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. Table 73 below gives an overview of the CR mechanisms and required polymer properties for medicinal product applications.

Table 73: 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)

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 particles excreted and released to the environment fall also under the scope of the microplastics 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 particle (cf. section B.1.1).

D.8.1.1. Diffusion controlled release:

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 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.

The polymers listed in Table 74 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 criteria, and intentional use/release. 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. Therefore the information in this table might be reviewed after the public consultation.

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 ‘polymer-containing particle’. 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 74: 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

Chemical name	Function(s)	Concentration range	Comment
			mm
Polymethacrylates	Binders for CR in wet granulation[75] 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	
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	
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	Film coating for CR		

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[75] 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
(phtalate)	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 75: Example of therapeutic area

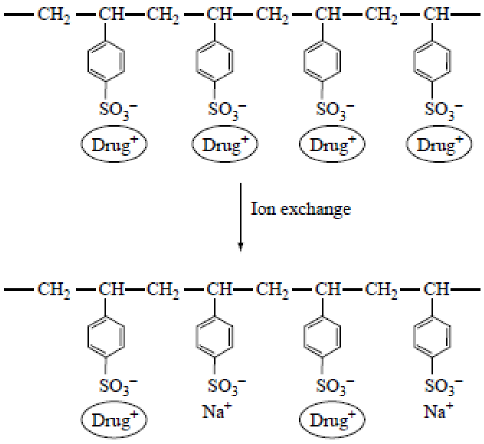
Disease	Coating functionality
Gastro-intestinal diseases (e.g chronic pancreatitis, stomach ulcers, duodenal ulcers)	Gastro resistance, drug protection. The microplastics prevents the drug to be degraded or inactivated in the stomach.
Colon related diseases (e.g. Crohn, ulcerative colitis)	Colon targeting. 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. 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.8.1.2. Ion exchange based controlled-release:

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[76].

The table below provides examples of IER available in Europe.

Table 76: 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 diarhea, clostridum difficult - 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	Posology: up to 24 g/day/patient (e.g. Questran®) Concentration: ca. 70% w/w in the formulation (powder)

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[76] 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
		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 Ph. Eur., and incorporated into nicotine gums for smoking cessation (e.g. Nicorette gums®)	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 is described in the European Pharmacopea either as an excipient[77], or an active pharmaceutical ingredient (API).

D.8.1.3. Osmotic systems:

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

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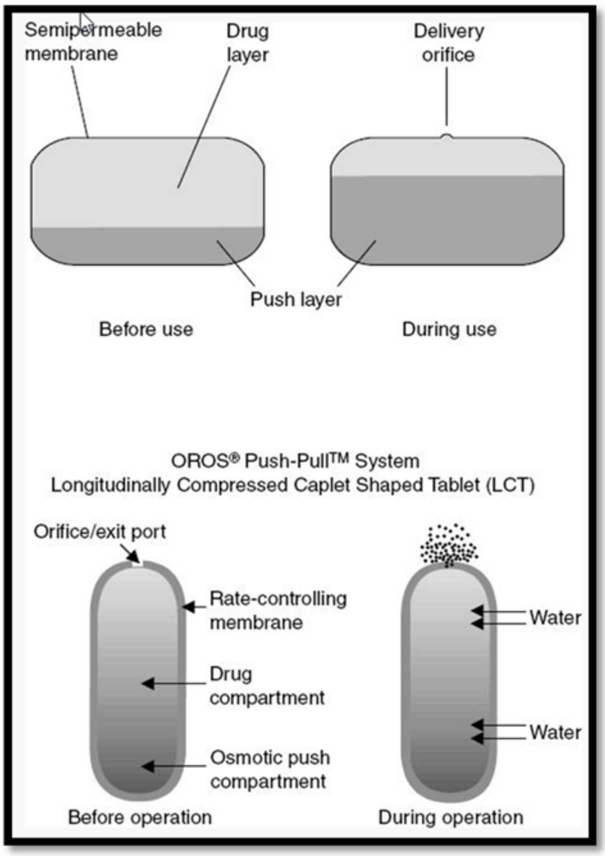
[77] Pharmaceutical excipients can be defined as non-active ingredients that are mixed with therapeutically active compounds to form medicines.

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[78] (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



Source: (Bass et al., 2002)

D.8.2. Baseline – tonnage used and releases

With regard to pharmaceutical/medicinal applications, AMEC Foster Wheeler study (AMEC, 2017a) 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

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[78] 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.

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 77, 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 Dossier submitters has made the following assumptions for estimating the used tonnages:

<u>Diffusion controlled system:</u>

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 this Annex XV restriction proposal, 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 at point of use by consumer and release only if the core/granule/tablet all dimensions are ≤ 5 mm (aka ‘mini-tablets’ or pellets)
    - Not a microplastic at point of use by consumer and release 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):
    - Microplastic at formulation stage (industrial use – out of scope of the current proposal)
    - Microplastic at point of use and release by consumer

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 an 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 <u>one specific</u> 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.

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 77: 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)
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:

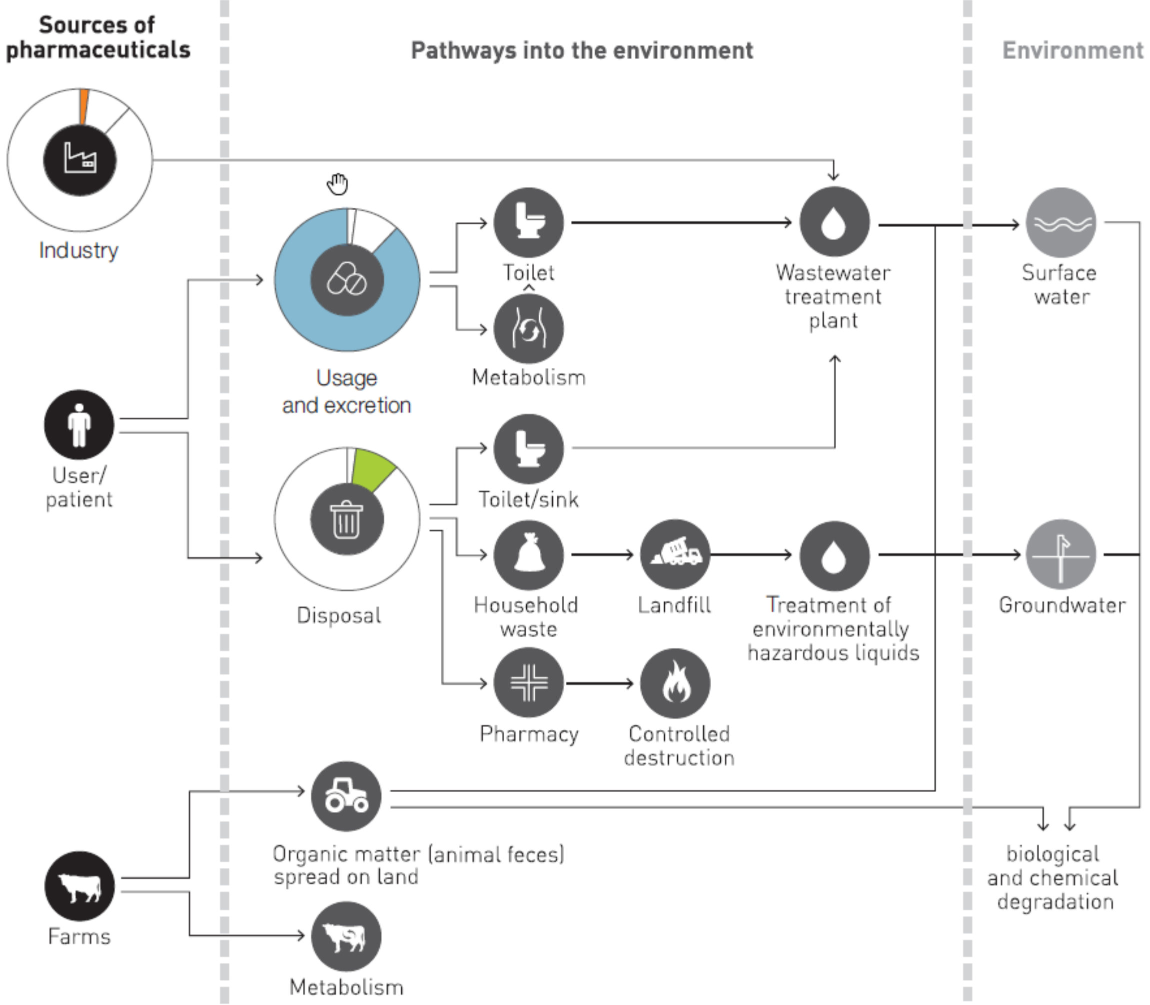
The key steps (from an environmental perspective) in the life cycle of a medicinal product are manufacturing, consumption by patients/use by professional and waste management. In our case, the consumption phase is considered to be the largest contributor to the emissions of medicinal products into the 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 feaces: 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 77.

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.

Figure 10: Sources and pathways into the environment of microplastics used in the formulation of medicinal products



Source: EFPIA (EFPIA, 2017)

D.8.3. Alternatives

With regard to the use of microplastics as excipient or active substance in medicinal products, alternatives might be available with biodegradable polymers[79] even so there is no study made on their releases to the environment, and there is 'no solution fits all'. 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 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 development of controlled-release formulations 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 78 lists some examples of alternatives, and their limitations.

Table 78: Example of potential alternatives

Alternative	Use/function	Comment
Maize starch	Disintegrant	Less effective than a synthetic polymer. Formulation would be also more sensitive to humidity.
Shellac	CR coating	Naturally produced polymer from insect. Quality is variable – does not meet the current pharmaceutical standards
Lipid based excipients	Diffusion CR (matrix)	API release rate might
Cellulose based material (if not microplastics)	Taste masking,	Limited taste masking functionnality as these substances are soluble in saliva.

Source: EFPIA (ECHA AI 2018 #10-101),

Last but not least, similarly to the medical devices, and in-vitro diagnosis medical devices, even if an alternative to microplastic would be readily 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[80] 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

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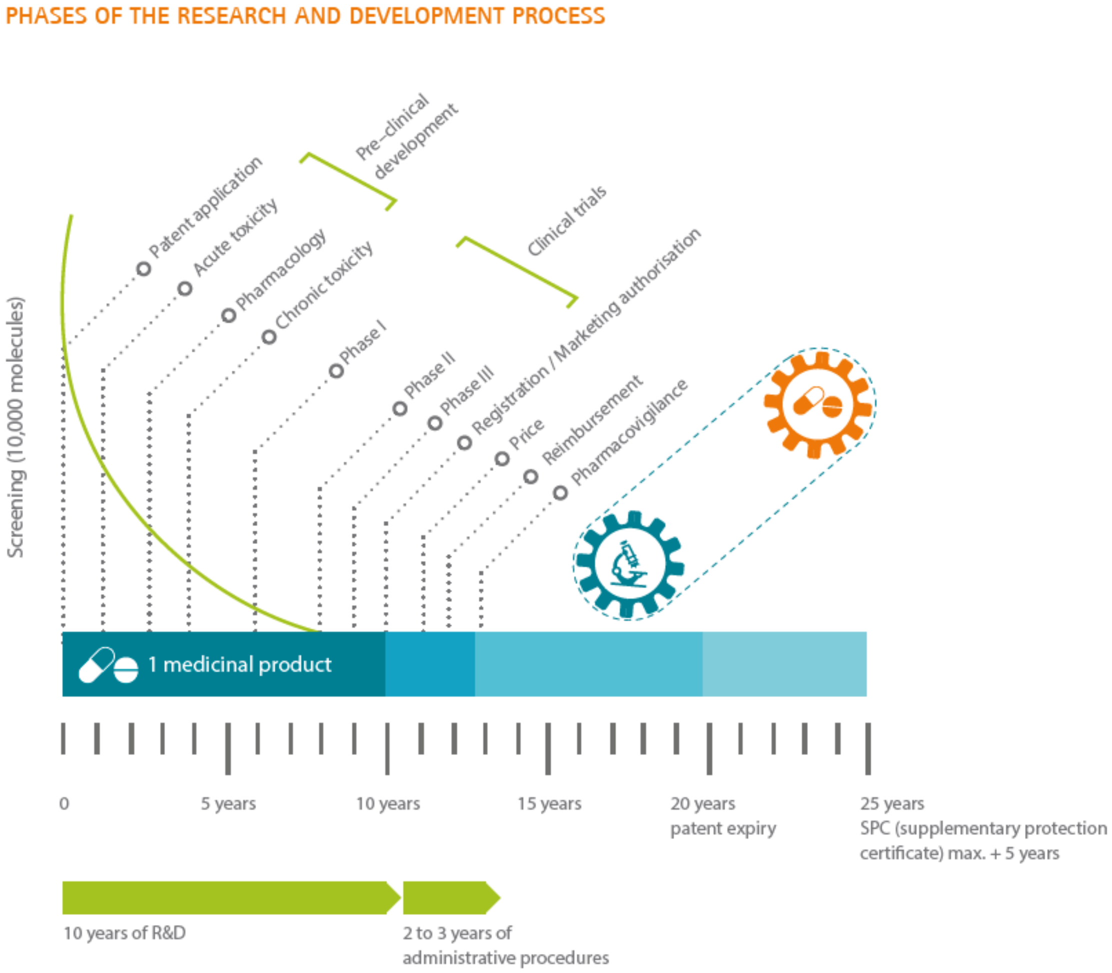
[79] Biodegradable polymers are designed to degrade because of hydrolysis of the polymer chains into biologically acceptable and progressively smaller compounds. For some degradable polymers, most notably the polyanhydrides and polyorthoesters, the degradation occurs only at the surface of the polymer, resulting in a release rate that is proportional to the surface area of the drug delivery system.

[80] 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.

product which might leave some patients without treatments.

Figure 11: Development phases of a medicine



Source: EFPIA (EFPIA, 2017)

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 Immediate Release formulation exists in the same therapeutic areas, and could substitute easily the controlled release formulation; 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.8.4. Other existing regulatory provisions

D.8.4.1. Sector-specific regulations

Medicinal products for veterinary and human health use are regulated by the EU Directive 2001/82/EC 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
- 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.

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.'

D.8.4.2. 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 Commission has therefore developed a strategic roadmap to tackle this issue: the 'Strategic approach to pharmaceuticals in the environment' (REF) has been initiated in 2017.

This roadmap currently focuses on:

- Active ingredients found in aquatic environment, and that can affect the wildlife, but also the human via drinking water
- Antibiotics

D.8.5. Proposed action

Microplastics are intentionally added in the formulation of medicinal products for human and veterinary uses, essentially as controlled-release agent and taste-masking agent. 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 improper disposal of unused medicines. 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 finally 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 it is not clear if there are alternatives medicines available for the pathologies where microplastic is used either as an excipient or an active substance.

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.

Even though medicinal products seem to contribute substantially 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:

i. 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.
ii. Labelling requirement with a 2 years 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 reinforce 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. For example: ”This medicine contains microplastics. 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 improper disposal of the unconsumed medicines. There is currently no information about the presence of microplastics on the medicines packages or leaflet, therefore a labelling 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 negligible 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 new 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.
- 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 need to be gathered.
- 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 reinforcing existing sector-specific regulations.

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 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.8.4.1).

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 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: 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 3: 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.8.7. 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 diffusion controlled release formulations.

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.9. Food supplements and medical food

Uses and function:

Uses of substances in food or feedingstuffs can also be restricted under REACH.

In the course of the Annex XV dossier preparation, companies supplying microplastics to the pharmaceutical industry for controlled-release (CR) application indicated that they were supplying the same type of microplastics to medical food and food supplement industry. No additional information has been received.

According to suppliers of microplastics, similarly to the medicinal products sector, microplastics in medical food and food supplement are essentially used as controlled-release and taste-masking agent associated to a film forming function. As per the definition in the Annex XV restriction proposal, this means that only the core/tablet/granules/pellet/encapsulated medicine coated and with all dimensions ≤ 5 mm would be considered as a microplastic.

Microplastics in food supplements allow to deliver for example slowly vitamins over an extended period of time. They are authorised as food additives under the EU Regulation (1333/2008) for use in food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable. Examples are listed in Table 79.

Table 79: Example of microplastics authorised in food supplements

E number	Additive name	Specifications according to Annex II to EU Regulation (1333/2008)	Authorised since
E1205	Basic methacrylate copolymer	Maximum limit: 100 000 mg/kg	?
E1206	Neutral Methacrylate Copolymer	Maximum limit: 200 000 mg/kg	2013
E1207	Anionic Methacrylate Copolymer	Maximum limit: 100 000 mg/kg	2013
E1208	Polyvinylpyrrolidone-vinyl acetate copolymer	Maximum limit: 100 000 mg/kg	2014

Source: EU food additive database available at https://webgate.ec.europa.eu/foods_system/main/?event=substances.search&substances.pagination=1

Availability of alternative:

Instant release food supplements, that do not contain microplastics, are available on the market.

D.10. Oil & gas

D.10.1. 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,[81] reduce energy use (regulated),[82] 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[83]), 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

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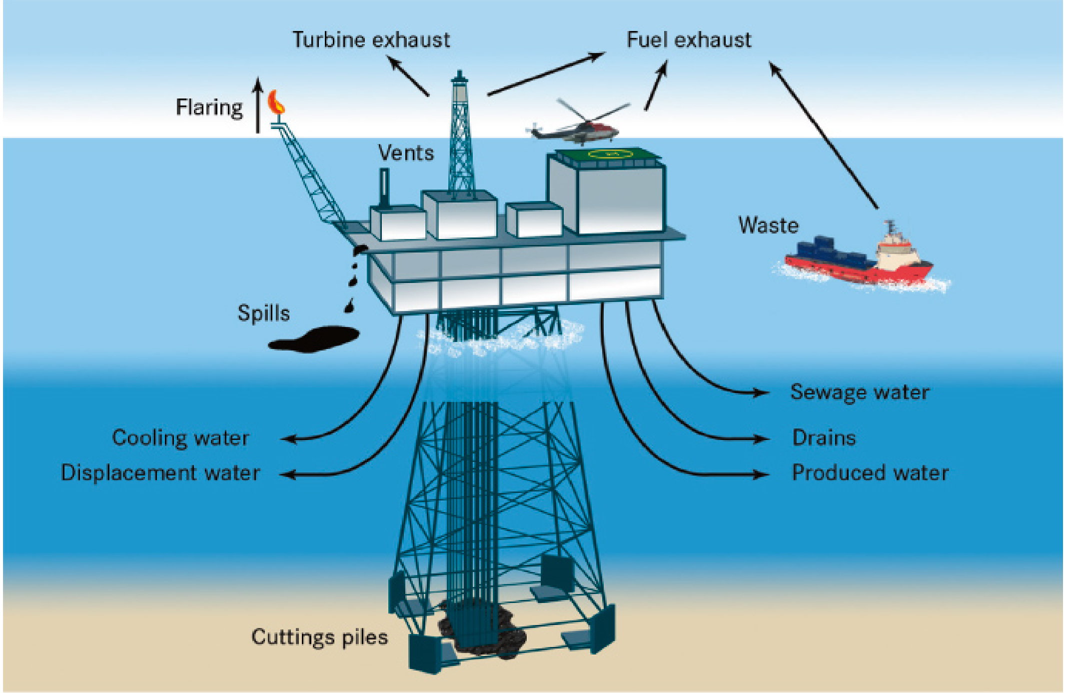
[81] According to OSPAR Recommendation 2001/1 for the management of produced water in offshore applications "no individual offshore installation should exceed a performance standard for dispersed oil of 30 mg/l for produced water discharged into sea" as a monthly average of at least 16 samples per month. 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).

[82] 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

[83] *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)*

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.

Figure 12: Discharge of hazardous substances in the offshore oil and gas industry



Source: OSPAR[84]

D.10.1.1. 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),[85] 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 80 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 80, 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

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[84] https://www.ospar.org/work-areas/oic/chemicals

[85] 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).

point or use or release, as they may not be particles, may be dissolved in organic solvent 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 80: 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

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[86], imidazoline and amide based products[87], 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[88], Piot (2009), Schlumberger (2019)

The information in Table 80 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[89]). 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 chemically intensive than offshore. Gas operations in general tend to be less chemically intensive than oil operations (pers. comm.).

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[86] 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).

[87] CRODA, https://www.crodaoilandgas.com/en-gb/discovery-zone/functions/viscosifiers

[88] 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

[89] http://europa.eu/rapid/press-release_IP-11-1260_en.htm

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.10.1.2. 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.10.2. Alternatives

In principle, there are non-microplastic containing oil & gas products for every function shown in Table 80. 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 80; 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.[90] 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).

D.10.3. 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.

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[90] 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).

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.10.4. 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),[91] the Helsinki Convention,[92] the Barcelona Convention (UNEP-MAP),[93] and the Bucharest Convention.[94] The EU Marine Directive[95] requires that, in developing

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[91] *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/.*

[92] *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*

[93] *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.*

[94] *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.*

[95] *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*

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.10.4.1. 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 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.[96] 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

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within the geographical boundaries of the existing Regional Sea Conventions.

[96] Article 2.5 of OC states that the Contracting Parties are not prevented from taking more stringent measures more stringent requirements.

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 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),[97] 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,

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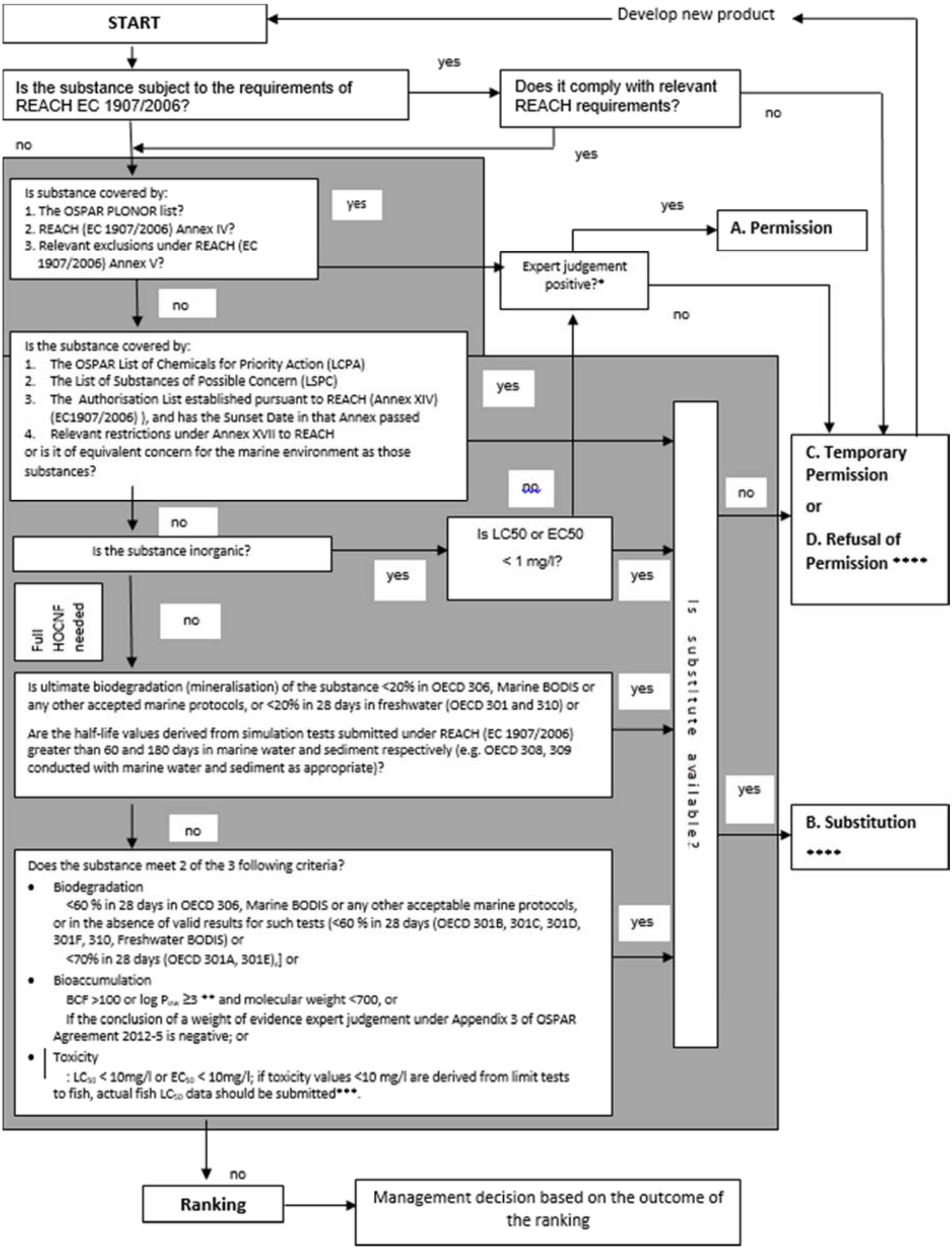
[97] The OSPAR List of Chemicals for Priority Action (LCPA) was established in 2002 (https://www.ospar.org/work-areas/hasec/chemicals/priority-action). OSPAR 2005A/02 recommends to authorities not to issue new authorisations for the discharge of these chemicals unless those offshore chemicals have already 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).

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 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.

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



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.

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.[98]

D.10.4.2. 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).

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[98] *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.*

D.10.4.3. Conclusion

OSPAR has an established chemical substitution process (HMCS) which creates a driver 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[99] 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.10.5. 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.10.5.1. 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 consequences in the long run. Therefore, microplastic emissions to the environment

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[99] 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.

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.10.5.2. 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.10.5.3. 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 of for all critical applications needs to be gathered in order to be able to 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.10.6. Conclusion on proposed action for microplastic use in oil & gas

Taking into considerations the possible actions under existing provisions (e.g., OSPAR) and 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 81: 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.11. 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 82, 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 82: 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.11.1. 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.11.1.1. 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)

D.11.1.2. 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, 2017b). 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.

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.11.1.3. 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 83:).

Table 83: 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, delustering agent.	Paints and coatings (inkl. leather)	Spherical?	Copobeads PBMA	Coating Products OHZ e.K.	https://www.coating-products.com/additives.htm#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 coatings, ship decking, swimming pools, heavy duty industrial flooring	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

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-stick/multiple release coatings for kitchen ware.	Granules, powder, spherical in aquose or isopropyl dispersions	Ultraflon, Marzon	Laurel Products	http://laurelproducts.com/additives-for-coatings/
Acetic acid ethenyl ester.	5-40 (unexpanded),	Soft-touch, matting effects, anti-slip, sound-dampening, chip-resistance, low weight,	Underbody coatings, artificial leather and	Expandable thermoplastic spheres as	Expancel®	Akzo Nobel	https://expancel.nouryon.com/

Dichlorethene & 2-propenenitrile	~10-100 (expanded)	higher water vapour permeability, improve applicability.	wallpaper,	powder, slurries			
? (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
Benzoguanamine/melamine - formaldehyde 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.11.2. 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, 2017b). 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 84).

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 84: 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, 2017b), 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 EU28 + 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%. Eunomia (2018) further assumes that the sector is split between interior/exterior paint and consumer/professional paints as presented in Table 85.

Table 85: 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
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. about0.97% 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 86: Emissions from decorative paints

Market	Paint tonnage	Polymer content	Release factor	Releases to water
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[100] produced for the Swedish market amounts to 40 000 – 50 000 tonnes (Table 87). 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 87). 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 87: 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, 2017b, 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 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.[101]

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[100] 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.

[101] 4 213 520 tonnes / 6 796 000 tonnes = 62%

D.11.3. 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 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.11.4. 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.

A labelling 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 labelling shall be clearly visible and easily understandable. The labelling 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 labelling may involve pictograms, if these are able to convey how to correctly dispose of the paint and clean the equipment. Where necessary because of the size of the package, the labelling shall be included on the instructions for use.

In proposing such a labelling 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 labelling 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 a labelling 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, a labelling 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 labelling 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 labelling 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 label 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 label 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.
- Cost-effectiveness and benefit-cost comparison: Numerous studies have been undertaken on the effectiveness of labels, 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, 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 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 labels, thereby reducing emissions from the disposal of waste and cleaning of equipment. Considering that the costs are expected to be relatively low, the labelling requirement is considered cost-effective for consumer products. While the emissions from professional paints are likely to be lower than from consumer paints, the labelling 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 labelling 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 labelling requirement should be practical and monitorable. The proposed reporting requirement is a practical approach to gather information for possible further action.

In conclusion, a labelling 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 labelling 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.12. Option value theory

D.12.1. Introduction

This section provides an economic underpinning for why regulatory action in face of an uncertain harm may be justified because of 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 a number of 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 some 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, which leads them to be 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 by-standing and free-riding);
- 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 within the next decade;
- because of the lack of understanding, no economic metric such the social cost of carbon exists to quantify the damages associated with emissions of (micro-) plastics to the environment.

To summarise, the emissions of (micro-) plastics into the environment causes irreversible effects. Irreversibility poses a challenge to conventional policy analysis—especially if the consequences are poorly understood and cannot be priced with some degree of certainty (Traeger, 2014). In such situations, restricting an activity can be the optimal strategy 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).[102] 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.12.2. Model

This section presents an abstract model that helps in finding the optimal regulatory

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[102] 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.

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 he expects that this uncertainty is (at least partially) resolved before the beginning of the second period.[103]

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 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.[104]

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

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[103] 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.

[104] This type of optimization problem is typically solved recursively.

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:

$$OV \equiv \max\{V^L(0),V^L(e_1)\}-\max\{V^N(0),V^N(e_1)\}. \tag{2}$$

Adapted to the context of this restriction proposal, the option value corresponds to the maximum value obtained from 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.[105]

D.12.3. 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.12.2, this suggests that whenever learning about a possible harm is expected to happen, regulatory action may be justified 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.

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[105] 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.

Appendix D.1

Table 88: List of polymers used in High scenario (520-polymer scenario)[106]

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][107]	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 %
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 %

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[106] Not all uses of these polymers may meet the proposed microplastics definition in Table 3 of the report. The INCI (International Nomenclature of Cosmetic Ingredients) name is sometime insufficient, as the phase of the material with the same INCI name may be different. Therefore, at this stage, liquid polymers, water soluble, film forming or other polymers outside the scope of the proposed restriction have not been excluded. Please see Section D.5. Cosmetics for assumptions and approach, including section on "State" in D.5.1. Use and functions.

[107] 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 [%][107]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
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.
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%

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][107]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
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 %
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 %

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][107]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
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.
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 %

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][107]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
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 %
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 %

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][107]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
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 %
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 %

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][107]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
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.
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.
ACRYLATES/LAURYL ACRYLATE/STEARYL ACRYLATE/ETHYLAMINE OXIDE METHACRYLATE COPOLYMER	< 0.05 %	N.A.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][107]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
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.
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.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][107]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
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.
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.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][107]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
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.
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.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][107]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
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.
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.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][107]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
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.
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.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][107]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
'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.
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.
POLYPENTAERYTHRITYL TEREPHTHALATE	N.A.	N.A.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][107]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
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.
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.

INCI name	Estimated occurrence of the INCI in the leave-on cosmetics containing one of the 520 polymers [%][107]	Estimated occurrence of the INCI in the rinse-off cosmetics containing one of the 520 polymers [%]
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.
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 E. Stakeholder consultation

E.1. Introduction

The Dossier Submitter has undertaken an extensive stakeholder consultation to ensure that all sectors that used microplastics could be identified.

E.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.

E.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.

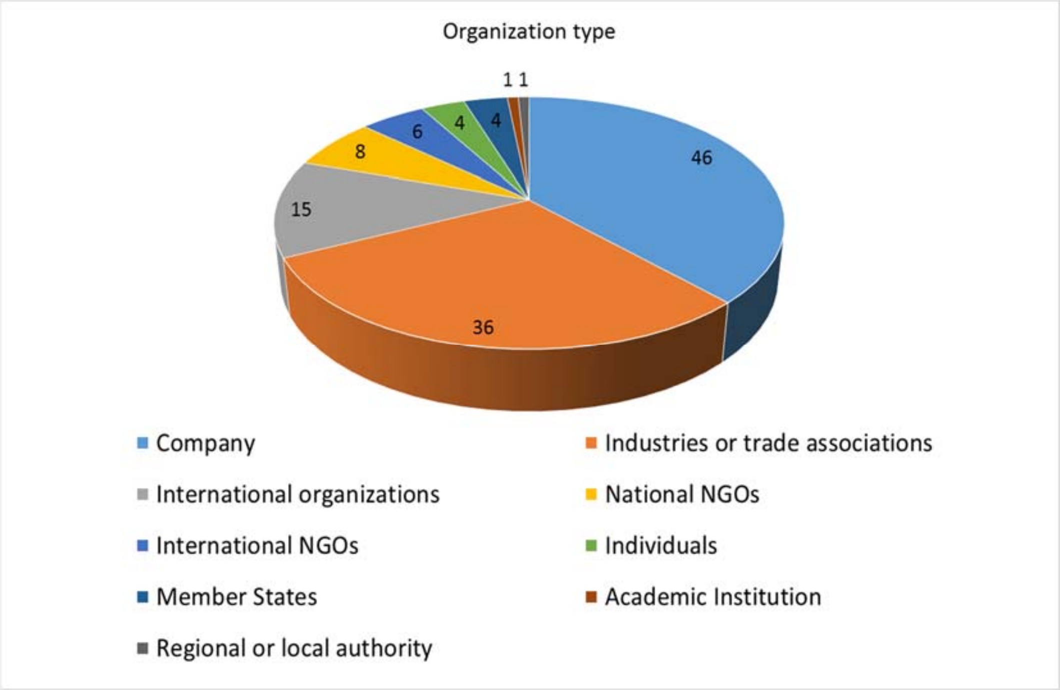
In the Background Document was a working definition of microplastic particles:

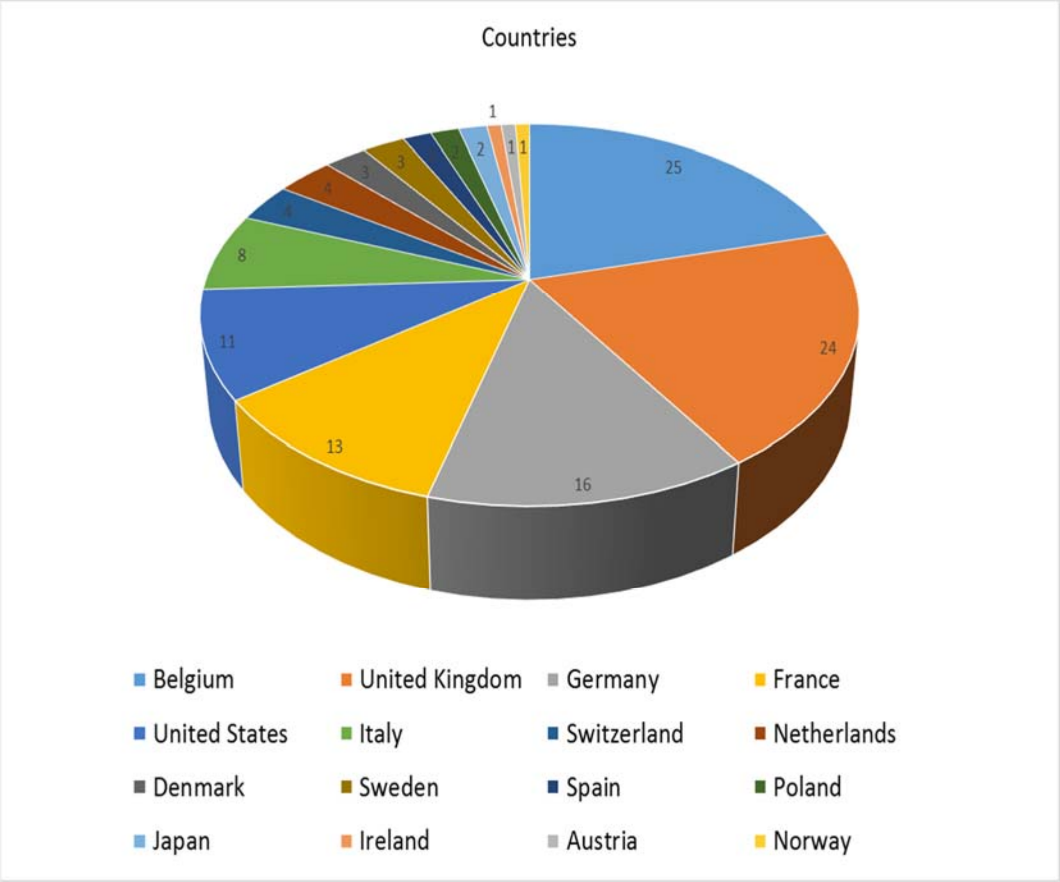
"Any polymer-containing solid or semi-solid particle having a size of 5mm or less in at least one external dimension."

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.





E.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.

E.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_potential_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).

E.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.

E.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.

E.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.

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