Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

OCTAMETHYLCYCLOTETRASILOXANE,
DECAMETHYLCYCLOPENTASILOXANE

ECHA/RAC/RES-O-0000001412-86-97/D

ECHA/SEAC/RES-O-0000001412-86-109/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 10 March 2016) and SEAC's opinion (adopted 9 June 2016)

10 March 2016

ECHA/RAC/RES-O-0000001412-86-97/D

9 June 2016

ECHA/SEAC/RES-O-0000001412-86-109/F

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name:	**Octamethylcyclotetrasiloxane (D4)**
EC No.:	**209-136-7**
CAS No.:	**556-67-2**

Chemical name:	**Decamethylcyclopentasiloxane (D5)**
EC No.:	**208-764-9**
CAS No.:	**541-02-6**

This document presents the opinions adopted by RAC and SEAC. The Background Document (BD) provides support to both RAC and SEAC opinions, giving detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINIONS

United Kingdom has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report

conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at: http://echa.europa.eu/web/guest/restrictions-under-consideration on ***18 June 2015.*** Interested parties were invited to submit comments and contributions by ***18 December 2015.***

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: ***Michael NEUMANN***

Co-rapporteur, appointed by RAC: ***Marian RUCKI***

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment has been reached in accordance with Article 70 of the REACH Regulation on ***10 March 2016.***

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The RAC opinion was adopted ***by consensus.***

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: ***Thea Marcelia SLETTEN***

Co-rapporteur, appointed by SEAC: ***Tomas SMILGIUS***

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on ***11 March 2016.***

The draft opinion takes into account the comments of and contributions from the interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The draft opinion was published at http://echa.europa.eu/web/guest/restrictions-under-consideration on ***16 March 2016.*** Interested parties were invited to submit comments on the draft opinion by ***16 May 2016.***

The opinion of SEAC

The opinion of SEAC on the suggested restriction was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on ***9 June 2016***. The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation.

The opinion of SEAC was adopted ***by consensus***.

OPINION

The restriction proposed in the original dossier:

Designation of the substances, of the group of substances or of the mixture	Conditions of the restriction
a) Octamethylcyclotetrasiloxane EC Number: 209-136-7 CAS Number: 556-67-2 **b) Decamethylcyclopentasiloxane** EC Number: 208-764-9 CAS Number: 541-02-6	1. Shall not be placed on the market or used in concentrations equal to or greater than 0.1% by weight of each in personal care products that are washed off in normal use conditions. 2. Personal care products shall be taken to mean any substance or mixture intended to be placed in contact with the various external parts of the human body (epidermis, hair, 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 and/or correcting body odours and/or protecting them or keeping them in good condition. 3. Normal use may be determined by packaging instructions, indicating the purpose of the product and how it is to be used. 4. This restriction shall come into force on DD/MM/YY [at least 2 years after publication in the Official Journal]. 5. By DD/MM/YY [ten years after entry into force] the Commission shall carry out a review of the other sources of these substances to investigate whether any further emission reduction measures are necessary. On the basis of this review, the Commission shall, if appropriate, present a legislative proposal to extend the restrictions in paragraph 1.

The Dossier Submitter's proposal is intended to cover personal care products (PCPs) that are washed off the hair or body within several minutes of application in accordance with normal use instructions, with the rinsate discharged to wastewater. The restriction is not intended to cover PCPs that are removed from skin without water (e.g. with wipes or tissues) or that perform their function by being left on the hair or body for several hours and which are only subsequently removed as a result of normal washing routines (e.g. moisturisers, leave-on hair conditioners). The proposed restriction is not intended to cover therapeutic shampoos since they are normally left on overnight.

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on ***octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5)*** is the most appropriate EU wide measure to address the identified risks in terms of the effectiveness in reducing the risks provided that the conditions are modified.

The conditions of the restriction proposed by RAC are:

Designation of the substances, of the group of substances or of the mixture	Conditions of the restriction
a) **Octamethylcyclotetrasiloxane** EC Number: 209-136-7 CAS Number: 556-67-2 **b)** **Decamethylcyclopentasiloxane** EC Number: 208-764-9 CAS Number: 541-02-6	1. Shall not be placed on the market in cosmetic products used or disposed with water intended for consumer or professional use in concentrations equal to or greater than 0.1% by weight of each of the substances. 2. Cosmetic products are defined as being within the scope of Regulation (EC) 1223/2009 3. This restriction shall come into force on DD/MM/YY [18 months after publication in the Official Journal].

The term 'personal care product (PCP)' is used throughout the Background Document and opinion and is intended to have the same meaning as 'cosmetic product' in this context. The wording "used or disposed with water" refers to the intended conditions of use as described on a product's use instructions or packaging.

THE OPINION OF SEAC

SEAC has formulated its opinion on the restriction proposed by the Dossier Submitter based on information related to socio-economic benefits and costs documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC formulated its opinion based on the scope of the restriction described by the Dossier Submitter in the Background document. SEAC considers that the proposed restriction, with a two year compliance period, on ***octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5)*** is the most appropriate EU wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD AND RISK

Justification for the opinion of RAC

Description of and justification for targeting of the information on hazard and exposure (scope)

Both *octamethylcyclotetrasiloxane* (D4) and *decamethylcyclopentasiloxane* (D5) are high tonnage substances in Europe. D4 is registered under REACH in the 100 000 to 1 000 000 tonne per year band and D5 is registered under REACH in the 10 000 to 100 000 tonne per year band. They are mainly used as monomers in the manufacture of silicone polymers, but also have direct uses in personal care products (PCPs), cleaning products and a range of other uses. Their presence as intentional constituents or impurities in a very wide variety of consumer products means that they have significant potential for environmental release.

Cyclic siloxanes perform three main functions in PCPs (1) hair-conditioning agents, (2) skin-conditioning agents (emollient) and (3) solvents. They have unique functions as antistatic, emollient, humectant, solvent, viscosity controlling and hair conditioning agent. Their low surface tension allows them to spread rapidly on skin and hair (CTPA, 2008). The Scientific Committee on Consumer Safety (SCCS, 2015) states that the main uses of D5 in PCPs are in skin care products, deodorants/antiperspirants, hair care products and make up products. A survey by Cosmetics Europe (CoE, 2014) identified over 15 different types of categories and over 75 types of products with D5 concentrations from close to 0% to nearly 100%.

The restriction proposal is justified by the PBT and vPvB properties of D4 and the vPvB properties of D5. Experience with PBT/vPvB substances has shown that they give rise to broad concerns based on their potential to accumulate in the environment and cause effects that are unpredictable in the long-term and are difficult to reverse (even when emissions cease). Therefore, the risk from PBT/vPvB substances cannot be adequately addressed in a quantitative way (e.g. by derivation of risk characterisation ratios) and a qualitative risk assessment should be carried out (see Annex I/6.5 of the REACH Regulation). The aim for any regulatory action on D4 and D5 therefore has to be to minimise any releases to the environment as far as technically and practically possible.

Registration dossiers do not identify D4 and D5 as fulfilling the REACH Annex XIII criteria for PBT and/or vPvB substances. The Dossier Submitter considers that, despite recent updates during the preparation of this opinion, the operating conditions and risk management measures in REACH Registration CSRs are inadequate to minimise emissions into the environment. During public consultation, Candidate Listing as a regulatory action was proposed and the Dossier Submitter states that this might be the only way to oblige Registrants to take full account of the implications of the PBT/vPvB properties of D4 and D5 (see comments of Public Consultation #1411, 1444 and 1446).

The Dossier Submitter considers that whilst releases of D4 and D5 to air from the wide range of different uses can be significant and result in long-range transport to remote regions, they are unlikely to lead to significant exposure in surface media or accumulation in biota. Therefore, based on the results of the Dossier Submitter's risk assessment, the restriction proposal is targeted on uses that result in emissions to the aquatic environment and specifically on the use of D4 and D5 in wash-off personal care products (PCPs) e.g. shower gels, shaving foams and shampoos. The Dossier Submitter considers these uses to be the major source of D5 to the aquatic environment in the EU. Releases of D4 from wash-off PCPs are relatively much smaller, but D4 was included in this restriction as a contribution to its emission reduction and to prevent substitution of D5 with D4.

RAC notes that wash-off PCPs are cosmetics defined under Regulation (EC) 1223/2009 (Cosmetics Regulation). However, the Cosmetics Regulation considers that environmental risks posed by substances used in cosmetics, including PBT and vPvB properties, should be considered under the REACH regulation (EC 1223/2009 – recital 5). In this specific case the decision to target the restriction on wash-off PCPs was based on a thorough analysis of the environmental fate and behaviour characteristics of D4 and D5 by the Dossier Submitter (see B.4 in the Background Document), a review of registered uses in CSRs and the conclusions of a quantitative emissions assessment.

RAC notes that the Dossier Submitter intended that the proposed restriction addressed three potential sources of D4 and D5 to the aquatic environment:

1. Formulation of wash-off PCPs;

2. Use of wash-off PCPs by consumers or professionals that intentionally contain D4 or D5 as a substance (referred to by the Dossier Submitter as direct uses); and,

3. Use of wash-off PCPs by consumers or professionals that unintentionally contain D4 or D5 as impurities, most likely in silicone polymers (referred to by the Dossier Submitter as indirect uses).

Equally, RAC notes that the Dossier Submitter does not intend to restrict D4 or D5 in the formulation and use by consumers or professionals of leave-on PCPs, or PCPs that are not used, removed or disposed of using water. The rationale behind this targeting was that the Dossier Submitter considered that these uses do not result in significant emissions to water as D4 and D5 evaporate rapidly after use and before they can be removed by washing. Similarly, the Dossier Submitter does not intend to restrict the use of D4 or D5 in therapeutic shampoos (such as those used for the treatment of headlice) or products like sunscreens. RAC notes that therapeutic shampoos for the treatment of headlice that contain D5 are medicinal products for human use and would therefore not be considered as PCPs or cosmetics within the scope of this proposed restriction.

RAC has undertaken an evaluation of the Dossier Submitter's decision to target wash-off PCPs. RAC outlines the conclusions of this evaluation in subsequent sections of this opinion.

Assessment of environmental risks

Information on hazards(s)

RAC notes that the Member State Committee at its 41st Meeting in 2015 adopted an opinion on the persistence (P/vP) and bioaccumulation (B/vB) of D4 and D5 at the request of the Executive Director of ECHA under Art. 77(3)c of REACH. MSC was of the opinion that both D4 and D5 fulfil the REACH Annex XIII criteria for vP and vB (see MSC Opinion on persistence and bioaccumulation of D4 and D5 Adopted on 22 April 2015). RAC has not re-assessed the P/vP and B/vB properties of D4 or D5 as part of this opinion. However, as described below, RAC has examined the T properties of both D4 and D5.

D4 has a long-term NOEC of around 4 – 6 µg/L for rainbow trout (*Oncorhynchus mykiss*), although RAC notes that there is some uncertainty in this value, and a long-term NOEC of 7.9 µg/L for *Daphnia magna* survival. D4 meets the criteria for classification according to the CLP Regulation as Aquatic Chronic 1 (H410) based on the lowest reliable aquatic chronic NOEC of around 4.4 µg/L. The M-factor would be 10. Significant toxicity to invertebrates is also apparent in sediment organism studies. In addition, where human health is concerned, D4 has a harmonised classification as toxic to reproduction in category 2. The classification was based on evidence that inhalation exposure of female rats to D4 around the time of mating causes, in the absence of marked maternal toxicity, a dose-related reduction in the number of *corpora lutea*, implantation sites and litter size. Inhibition of the LH surge and subsequent ovulation is the mode of action, which is relevant to humans.

***Conclusion 1*: D4 meets the REACH Annex XIII criteria for both a PBT and vPvB substance. RAC agrees with the Dossier Submitter that D4 meets the REACH Annex XIII criteria for toxicity based on both aquatic and mammalian end points.**

The available aquatic toxicity data for fish, invertebrates and algae indicate that D5 does not cause severe toxic effects in either short- or long-term studies at concentrations up to (or close to) its water solubility limit. Therefore the available toxicity data for pelagic organisms seem not to fulfil the REACH Annex XIII criteria for toxicity.

D5 is toxic to sediment and soil organisms with the calculated pore water concentration in sediment tests corresponding to the lowest NOEC of around 0.014 mg/L (close to the water solubility limit of the substance). However, the available sediment toxicity data does not fulfil the REACH Annex XIII criteria for toxicity. In addition, the available data on soil toxicity do not allow a comparison with the REACH Annex XIII criteria for toxicity.

D5 does not meet the REACH Annex XIII criteria for toxicity, although RAC notes that a full dataset for human health hazards classification is not available. No adverse effects have been observed in an avian reproduction test. Other toxic effects (e.g. liver enlargement, increased incidence of uterine endometrial adenomas and adenocarcinomas) may be relevant for wildlife, but are not considered sufficiently adverse to trigger the REACH Annex XIII criteria for toxicity.

***Conclusion 2:* D5 meets the REACH Annex XIII criteria for a vPvB substance. RAC agrees with the Dossier Submitter that D5 does not meet the REACH Annex XIII criteria for toxicity on the basis of the available evidence.**

Information on emissions and exposures

Fate and behaviour in the environment

The proposed restriction is based on a thorough analysis of the environmental fate and behaviour characteristics of D4 and D5 (see section B.4 of the Background Document) by the Dossier Submitter. Behaviour in water and air is fundamental to the Dossier Submitter's justification for the targeting of the proposed restriction on wash-off PCPs. Only a brief summary of the key information is given here.

Water

In the freshwater compartment under relevant environmental conditions (including 12°C and the presence of organic matter in suspended solids and sediment) D4 and D5 are both assessed to be very persistent (MSC-41). D4 and D5 have a high tendency to adsorb to sediments and particles which hinders hydrolysis. The significance of hydrolysis was proven in clean water test systems but not under environmentally relevant conditions.

Sediment

In the freshwater sediment compartment D4 and D5 have degradation half-lives of between 242 - 365 and 800 - 3 100 days at 24 °C, respectively. Under environmentally relevant conditions (e.g. 12°C) negligible biodegradation of D4 and D5 should be assumed.

Soil

In the soil compartment the available data do not allow the derivation of reliable degradation half-lives for D4 and D5 (MSC-41). However, under environmentally relevant conditions (e.g. 12°C) the REACH Annex XIII criteria for very persistent (vP) is clearly fulfilled (MSC-41).

WWTP

Based on the values for vapour pressure and mean $K_{OC,}$ and noting that the substances are not readily biodegradable, the overall removal in a 'typical' WWTP predicted using SimpleTreat modelling within EUSES 2.0.3 is around 96% (i.e. about 48% to air and 48% to sludge) for D4 and around 95 per cent (i.e. about 22% to air and 73% to sludge) for D5. It must be noted that this removal from the water phase is not degradation but dissipation to the air compartment (volatilisation) and sludge.

Air

Both substances are volatile (with a Henry's Law constant of 1.21 × 106 Pa*m^3/mol at 21.7 °C for D4 and 3.34 × 106 Pa.m3/mol at 24.6 °C for D5, respectively). The volatilisation half-life from water is reported by the Dossier Submitter to be 2 hours for D5 in a model river (assuming a river depth of 1 m, a current velocity of 1 m/s, and a wind velocity of 5 m/s) and 183 hours in a shallow lake (assuming that the lake has a depth of 1 m, a current velocity of 0.05 m/s, and a wind velocity of 0.5 m/s), using the USEPA EPI estimation program. Volatilisation half-lives for D5 in soils are estimated to be one day for agricultural soil and half a day for grassland soil using the methods outlined in the REACH Guidance. The corresponding half-lives for D4 are slightly shorter.

Long-Range Transport

D4 and D5 have the potential to undergo long-range transport to remote regions via the atmosphere. Their atmospheric half-lives (D4 ca. 14 days; D5 ca. 10.4 days) are extremely long. Several modelling studies and air monitoring data are reflected in the Background Document, demonstrating that the travel distance is long (several thousand kilometres).

The Background Document outlines that atmospheric emissions of D4 and D5 are unlikely to result in significant deposition to surface media (see Section B.4 of the Background Document). However, a recent study submitted by industry in the public consultation (Sanchís, et al. 2015a,b), may indicate the opposite. This article presents new monitoring data for Antarctica and concludes that cyclic volatile methylsiloxanes (including D4 and D5) are "hoppers"[1] rather than "flyers"[14]. In this study, D4 and D5 were found in soil (median concentration 13.9/19.0 ng/g dw), vegetation (median concentration in moss, lichen and grass of 5.38/10.0 ng/g dw), phytoplankton (median 0.70/0.80 ng/g dw) and krill (median 41.1/33.9 ng/g dw, max. 117/63.1 ng/g dw). Sanchís, et al. (2015a,b) consider that D4 and D5 can undergo atmospheric deposition by snow scavenging during the Antarctic winter and accumulate in the Antarctic biota and soil after the summer snow melt.

Some comments received during public consultation (comments # 1450 and 1454) questioned the reliability of the Sanchís et al (2015a,b) study. Although the findings of this study are currently considered controversial, RAC considers that they cannot simply be overlooked. The analytical procedures may be reliable even if background levels of D5 in the analysed samples are high but consistent through all samples.

In contrast to modelling studies indicating a low potential for subsequent deposition to surface media (see section B.4.2.3 of the Background Document) the findings of Sanchís et al (2015a,b) raise concerns that the contamination of remote areas by D4 and D5 is possible. Despite of the fact that D4 and D5 may ultimately degrade in the atmosphere during Antarctic summer the concentration of OH radicals during the Antarctic winter is lower, resulting in slower degradation of D4 and D5 in the atmosphere. Consequently, deposition of D4 and D5 seems to be possible during extremely low temperatures. The Dossier Submitter states that the available information does not permit a detailed consideration of deposition in the Arctic because the data available are limited and

[1] After long-range transport "hoppers" can deposit in remote areas to surface media while "flyers" do not deposit and stay in the atmosphere till degraded.

uncertainties have been noted in some of these studies. The Dosser Submitter considers that the findings of the Sanchís et al study need confirmation before they can be considered reliable. RAC supports the Dossier Submitter's conclusions (see justification that the suggested restriction is the most appropriate EU wide measure).

The risks to non-human, air breathing organisms, including mammals, from exposure to D4 and D5 via air are not considered in detail by the Dossier Submitter as the focus of the restriction proposal is on aquatic emissions. However, they consider that these risks are likely to be low. As the scope of the restriction proposal was limited to emissions to the aquatic environment, RAC did not consider the risks of D4 and D5 via air exposure in this opinion.

***Conclusion 3*: RAC agrees with the Dossier Submitter that emissions of D4 and D5 to surface water from municipal WWTPs are assumed to be around 5% of the influent concentration. Removal from the WWTP will result in dissipation into the air compartment via volatilisation and dissipation into the sludge via adsorption. RAC notes that accumulation in the sediment compartment is expected to form a sink for D4 and D5 in the environment which can in turn lead to bioaccumulation in aquatic biota.**

***Conclusion 4*: RAC agrees with the Dossier Submitter that emissions of D4 and D5 to air can result in long-range transport to remote regions via the atmosphere due to their extremely long atmospheric half-lives. While it is clear that the major fraction of emitted D4 and D5 will reside in the atmosphere until degraded, it is unknown how much could be deposited to surface media. RAC notes that due to the high volume of total emissions into air from various different uses (not only in PCPs) of these substances, even if deposition rates were low, this exposure route would be a potential source of risk to remote areas.**

PCPs as a source of D4 and D5 into the aquatic environment

Summary of the emission scenarios developed by the Dossier Submitter

Cyclic siloxanes (such as D4 and D5) perform three main functions in PCPs (1) hair-conditioning agents, (2) skin-conditioning agents (emollient) and (3) solvents. Their low surface tension allows them to spread rapidly on skin and hair (CTPA, 2008). The Scientific Committee on Consumer Safety (SCCS, 2015) states that the main uses of D5 in PCPs are in skin care products, deodorants/antiperspirants, hair care products and make up products. A survey by Cosmetics Europe (CoE, 2014) identified over 15 different types of categories and over 75 types of products with D5 concentrations from close to 0% to nearly 100%.

The proposed restriction is targeted by the Dossier Submitter at reducing emissions of D4 and D5 to the aquatic environment from wash-off personal care products (PCPs). The Dossier Submitter selected relevant uses of D4 and D5 for the restriction based on information on their potential for aquatic emissions as described in registration dossiers and on the basis of a risk assessment. The Background Document identifies the uses considered during the development of the restriction (see Table 9 in the Background Document). D4 and D5 are widely used in both "leave-on" and "wash-off" PCPs either directly as components of PCP formulations (mixtures) or unintentionally as an impurity in other substances or silicone polymers (termed as indirect uses by the Dossier Submitter).

Environmental emissions of D4 and D5 from leave-on PCPs were not considered sufficiently significant by the Dossier Submitter to include them within the scope of the proposed restriction. The Dossier Submitter considered that D4 and D5 would evaporate before they could be removed through normal washing routines.

Information on releases of D4 and D5 from different types of PCPs to wastewater during use are limited. Available data are restricted to a small number of specific product types i.e.

deodorant and antiperspirant products, skin care products and rinse-off hair conditioner as described by Gouin et al. (2015) and Montemayor et al. (2013). Releases of D4 are read-across from data for D5. In each study only relatively few samples are investigated. The Dossier Submitter considers that the Gouin et al. (2015) and Montemayor et al. (2013) studies are reliable but acknowledge that they have some methodological limitations, which are described further in the Background Document (see section B.9.3.2 and Appendix B.2).

The Dossier Submitter's risk assessment, which established the scope of the proposed restriction, was initially based on two release factors. One factor for PCPs which are washed-off after application within a few minutes ("wash-off" PCPs) and a second release factor for PCPs which are left on the body under normal use ("leave-on" PCPs).

In their initial approach the Dossier Submitter selected a worst-case release factor of 100% w/w to wastewater for all types of wash-off PCPs. This was based on the findings of Montemayor et al. (2013) and HTR (2011) that the average release from wash-off PCPs was around 73% (range: 48% to 160% with 95% confidence interval of 54 – 93%).

For all types of leave-on PCPs the Dossier Submitter selected a release factor of 0.1% w/w to wastewater based on the findings of Gouin et al. (2013) that considerably less than 0.1% w/w of the D5 contained in leave-on PCPs such as antiperspirants and deodorants is likely to be available for washing-off 24 hours after application and Montemayor et al. (2013) that the fraction washed-off 8 hours after application is below 0.1% w/w.

Applying these release factors to the tonnages used by the Dossier Submitter in their initial approach resulted in a release to wastewater of <1 000 tonnes/year for D5 and < 15 tonnes/year for D4 in wash-off PCPs, and ca. <24 tonnes/year for D5 and <0.36 tonne/year for D4 in leave-on PCPs.

Initial discussions in RAC focussed on the uncertainties on the release factors selected by the Dossier Submitter for wash-off and leave-on PCPs. In response to these discussions the Dossier Submitter established a series of six emission scenarios, each based on different combinations of release factors for wash-off and leave-on PCPs (see Background Document Appendix section B.7). The Dossier Submitter considers that scenarios 1 and 3 represent the boundaries of the likely actual emissions and that scenarios 4, 5 and 6 are unrealistic because the overall level of emission is not consistent with the available wastewater influent monitoring data.

The Dossier Submitter states in Section B.9.3.2 of the Background Document that it seems likely that some of the D4 and D5 in wash-off PCPs may be retained on the hair or body, and there is some evidence to suggest that there may be losses due to volatilisation for some PCPs that are intended to be left on for a few minutes before wash-off (as indicated by Montemayor et al., 2013). Following the discussion in RAC the Dossier Submitter selected in emissions scenarios two and three an alternative release factor of 73% w/w to wastewater for all types of wash-of PCPs based on the measured mean value of Montemayor et al. (2013).

Following the discussion in RAC the Dossier Submitter uses in scenarios three and five separate release factors for different (sub)categories of leave-on PCPs: 0.21% w/w for leave-on skin care products, 0.02% w/w for leave-on hair care products and 1% w/w for all other leave-on PCP sub-categories (including deodorants) based on the findings of the Montemayor et al. (2013) study. The Dossier Submitter assumes, based on the available data, that on average people will have a full body wash once per day and that this will occur at the end of the day, which would make it likely that at least 10 hours will have elapsed before any applied PCPs would be washed off.

RAC evaluation of the emission scenarios

RAC notes that only very few studies have examined and measured the potential for D5 to

be released to wastewater following application of PCPs to the human body (see section B.9.3.2 of the Background Document). The reliability of these studies is burdened by experimental shortcomings and unexplained findings. Equally, RAC is unable to evaluate how representative the available information is for the wide range of different PCP categories and product formulations available on the market. No information is available about how some of the various products are applied to the body/hair. What can be concluded is that the various direct uses of D5 (and D4) in PCPs will cause emissions into the aquatic environment in different amounts depending on the type of PCP, the amount of D5 (and D4) contained in the formulation, the use condition, the behaviour by the consumer and the tonnage of the specific type of PCP on the EU market.

RAC therefore supports the approach by the Dossier Submitter to use different release factors in separate emissions scenarios for wash-off and leave-on PCPs.

Modelling indicates that as a pure substance D5 may evaporate rapidly from the various external parts of the human body even though exact evaporation time and rate depend strongly on temperature and the amount applied per cm^2 of skin. During public consultation (comment # 1419), D4 and D5 removal from skin of 99.3% and 97.2%, respectively, was modelled after 24 hour dissipation period. Similarly, the draft of an SCCS opinion (2015) states that D5 as a volatile excipient in cosmetic products evaporates from skin or hair within 4 to 12 hours after application. This mechanism reduces emissions into the wastewater caused by leave-on PCPs but results in emissions to air and the atmosphere.

In contrast to the approach by the Dossier Submitter, RAC considers that because of the high uncertainty and limitations of the available information on releases it is not possible to select reliable and representative release factors for individual types of PCPs within the two groups of wash-off and leave-on PCPs e.g. to distinguish between leave-on skin care products and leave-on hair care products. RAC considers that in the evaluation of the restriction proposal the emission scenarios for wash-off and leave-on PCPs must represent the underlying uncertainty and the limitations of the available information in a consistent way. Equally, the conservatism of assumptions on emissions factors for leave-on and wash-off PCPs should be comparable.

In the view of RAC, the Dossier Submitter initially used different approaches when selecting representative release factors for wash-off and leave-on PCPs. For wash-off PCPs an absolute worst case assumption (100% release factor) was selected. In contrast, in the Dossier Submitter's initial approach for leave-on PCPs, a release factor of 0.1% for all types of leave-on PCPs was assumed, which was not consistent - concerning the level of conservatism and protectiveness - with an absolute worst case for wash-off PCPs. Also, in scenarios three and five of the Dossier Submitter's updated approach, use of separate release factors for different types of leave-on PCPs is not comparable to the approach for wash-off PCPs. In the view of RAC the selection of different release factors for different product types within one of the groups is not supported by the available data and information.

RAC discussed and evaluated the release factor selected by the Dossier Submitter for leave-on PCPs. Gouin *et al*. (2013) found that between 0.004 and 5.8% w/w of the amount of D5 initially applied in a deodorant product was washed off after 7 hours. The variability of this experiment is extremely large caused by several low measured release values and a single high measured release value. RAC notes that sampling and analysis of D5 seems not to be an easy task. This is supported by the fact that Gouin et. al. (2013) measured a release factor of only 5.5–17.7% w/w for a deodorant directly after application (time =0). This low recovery is not explained by the authors. Perhaps more significantly, the mean recovery rate of the whole experiment as measured in a spiked experiment was only 81.0%. Taken together, RAC considers that there is enough evidence to question the reliability of the low measured values in this experimental set up by Gouin et. al. (2013). RAC therefore assumes that experimental and analytical shortcomings could be responsible for the low measured values and that this is not reflected sufficiently by the Dossier Submitter when

they chose release factors for leave-on PCPs, neither in their original or revised approach.

In the view of RAC, the maximum measured release factor of 5.8% w/w for a leave-on PCP (Gouin et. al. 2013) indicates that the variability in reality could be extremely high and that greater release factors for leave-on PCPs than those measured in the available studies might occur. RAC sees the need to take this into account when selecting release factors for leave-on PCPs. RAC considers that the highest release factor measured by Gouin et al. (2013) must not disregarded as an outlier, as proposed by the Dossier Submitter, based on statistical considerations without incorporating the possible experimental short comings in a scientific justification.

In addition to release factors for wash-off and leave-on PCPs the Dossier Submitter describes further release factors for the formulation of PCPs and for "other uses" of D4 and D5 in section B.9.3 of the Background Document. RAC agrees with the derivation of these release factors.

RAC agrees with the Dossier Submitter that D4 and D5 present as impurities in silicone polymers or other substances used in wash-off PCPs (referred to by the Dossier Submitter as indirect uses) could contribute to overall releases of D4 and D5 to wastewater and ultimately surface waters. Equally, RAC notes that the Dossier Submitter considers that the information available to estimate the likely magnitude of these emissions is rather limited and based on assumptions of tonnage and a maximum concentration of 0.5% w/w in PCPs. As such, whilst RAC acknowledges that indirect uses could be a potentially significant source of emissions to wastewater, particularly for D4, the limited information available to the Dossier Submitter prevents a reliable assessment of the likely size of these emissions. As such, RAC considers that the quantitative estimates of emissions for indirect uses of D4 and D5 in wash-off and leave-on PCPs should be interpreted with care.

Release factors proposed by RAC

To take account of the uncertainties in the release factors, RAC has undertaken a further exposure assessment using a modified approach based on lower and upper bound release factor ranges. The RAC approach incorporates the high uncertainty and the limited representativeness of the available information in a consistent way. Different release factor ranges were selected for wash-off and leave-on PCPs. Release factors for specific types of PCPs within each of these groups were not derived. The release factors are equally applicable to D4 and D5 present as an intentional component (direct use) or as an unintentional impurity (indirect use).

Wash-off PCPs

For wash-off PCPs, RAC concludes to use the 95% confidence interval of the measured data from Montemayor et al. (2013) of 54% to 93% (mean: 73% and range: 48% to 160%) as lower and upper boundary of the release factors (Figure 1).

Leave-on PCPs

RAC proposes a lower boundary release factor of 0.1% for all leave-on PCPs. This value is in line with the original approach of the Dossier Submitter. As an upper boundary RAC proposes a release factor of 2.6%. This value is derived from the mean plus one standard derivation (at 7h) of measured releases from Gouin et al (2013). This upper bound release factor is greater than the values used by the Dossier Submitter in their various emission scenarios but is still well below the maximum measured release factor of 5.8% for a leave-on PCP (Gouin et. al. 2013). The lower bound release factor assumes a full body wash 24 hours after application whilst the upper bound assumes a full body wash occurs no later than 10 hours after application (Figure 2).

This release factor range takes into account the potential that the variability of releases in

reality might be extremely high and that greater release factors for specific categories of leave-on PCPs might occur. It also takes into account that around 28% of the population have washing frequencies of more than seven full body washes per week i.e. more than once per day (Pullinger *et al*. 2013).

RAC is aware that this upper bound is likely to be conservative but it was derived in response to the absence of reliable and representative measured data. If more reliable data would become available it may be reasonable to select different values for these release factors.

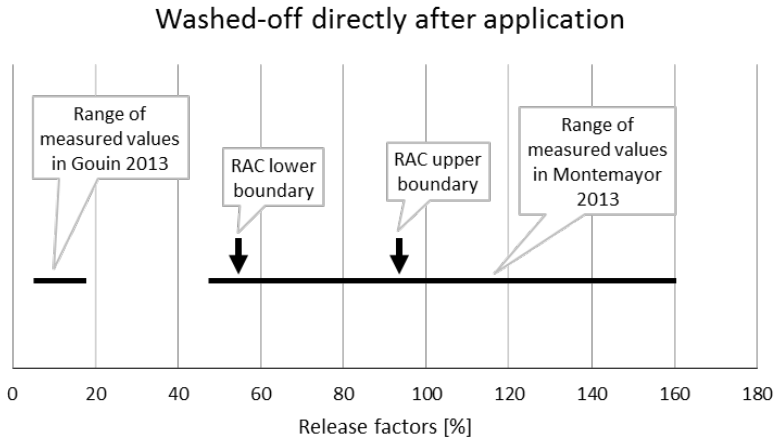

Figure 1. PCPs washed off directly after application (wash-off PCPs). Range of measured release factors from Gouin et. al. (2013) and Montemayor et al. (2013) and selected by RAC: lower and upper boundary

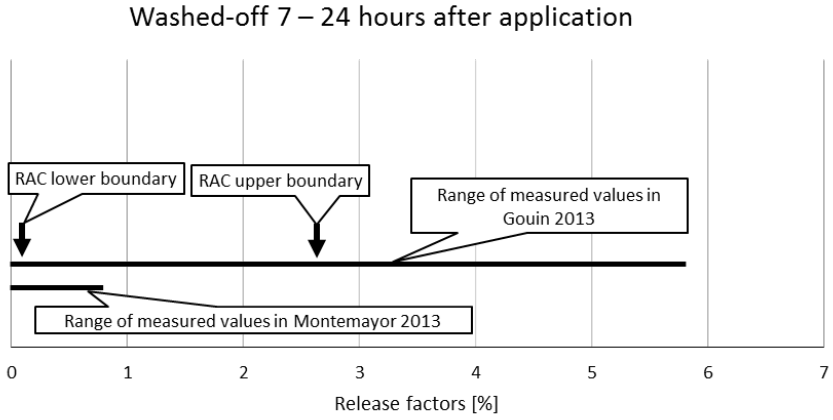

Figure 2. PCPs washed off 7 to 24 hours after application (leave-on PCPs). Range of measured release factors from Gouin et. al. (2013) and Montemayor et al. (2013) and selected by RAC: lower and upper boundary

Tonnages

The Background Document (Section B.9.3.1 of the Background Document) highlights the uncertainty in the available tonnage data. The minimum amount of D5 in wash-off and

leave-on PCPs was based on a survey of Cosmetics Europe members. This was then extrapolated by the Dossier Submitter (using a factor of 1.6) to a hypothetical 'maximum' EU tonnage by making an assumption about the market share represented by the survey respondents. This initially gave an amount of D5 in wash-off and leave-on PCPs of <1,000 and <24 000 tonnes/year, respectively. Although uncertain, this was the best information initially available to the Dossier Submitter.

Cosmetics Europe stated during the public consultation (comment #1431) that the amounts used in PCPs might be overestimated by using this approach, but had no information to verify or refute the assumption used in the dossier. Additional non-confidential information submitted by Cosmetics Europe later in the public consultation (comment #1452) gave quantities of D5 in wash-off and leave-on PCPs of 750 and 14 250 tonnes/year, respectively. These figures had been agreed between the REACH Registrants (i.e. the substance manufacturers and importers) and Cosmetics Europe, and so should represent a much higher proportion of the overall EU market than the Cosmetics Europe survey alone. It is possible that some users still exist that are not covered by these data (e.g. a company importing D5 from outside Europe below 100 tonnes/year does not need to register until 2018 and several PCP manufacturers are not members of Cosmetics Europe). It might therefore be appropriate to consider a higher tonnage figure. However, the Dossier Submitter has no way of assessing what further tonnage might be relevant outside of the public consultation process and consider that the amounts are likely to be relatively small in any case. In addition, the data provided is thought to include some tonnage that is subsequently exported and not used in PCPs in Europe.

The Dossier Submitter therefore considers that the new information is likely to be close to the amount of substance actually on the market. On this basis, the Dossier Submitter concludes a representative amount of D5 used in leave-on PCPs of 14 250 tonnes/year (and 750 tonnes/year for wash-off PCPs). In contrast, the relative total amount of D4 in wash-off and leave-on PCPs is estimated to be 11 and 214 tonnes/year, respectively, assuming the quantity of D4 is 0.015 times (1.5%) that of D5 (Section B.9.3.1).

Table 1. Emissions to wastewater estimated by RAC for direct uses of D5 in PCPs

D5	EU tonnages/a	RAC scenario "lower boundary"		RAC scenario "upper boundary"	
		Release factor	Emission tonnages/a	Release factor	Emission tonnages/a
Direct use in wash-off PCPs	750	54%	405	93%	697.5
Direct use in leave-on PCPs	14250	0.1%	14.3	2.6%	370.5

Table 2. Emission to wastewater estimated by RAC for direct uses of D4 in PCPs

D4	EU tonnages/a	RAC scenario "lower boundary"		RAC scenario "upper boundary"	
		Release factor	Emission tonnages/a	Release factor	Emission tonnages/a
Direct use in wash-off PCPs	11	54%	6.1	93%	10.5
Direct use in leave-on PCPs	214	0.1%	0.2	2.6%	5.6

***Conclusion 5*: RAC agrees with the Dossier Submitter that the available data and information allow the conclusion that wash-off PCPs with an estimated amount on EU market of 11 tonnes/year of D4 and 750 tonnes/year of D5 account for a significant amount of emissions to the aquatic environment in the EU. Based on the uncertainties in the underlying experimental data, RAC considers that upper and lower bound release factors of 93% and 54%, respectively, should be used to estimate emissions of D4 and D5 to the aquatic environment.**

***Conclusion 6*: The Dossier Submitter considers that leave-on PCPs with an estimated amount on EU market of 14,250 tonnes/year D5 and 214 tonnes/year D4 will lead to negligible emissions to the aquatic environment. However, RAC considers that emissions to wastewater may be significantly greater than this and that upper and lower bound release factors of 0.1 and 2.6%, respectively, should therefore be used to calculate emissions of D4 and D5 to the aquatic environment.**

Characterisation of environmental risk(s)

EU emissions to surface waters

Based on the lower and upper release factors agreed by RAC and the updated tonnage information provided by industry during the public consultation the use of wash-off PCPs will results in EU emissions to surface waters of between 97.8 and 168.3 tonnes/year for D5 (including ~0.5% from indirect uses) and between 1.9 and 3.2 tonnes/year for D4 (including ~20% from indirect uses), respectively (see Table 3 and Appendix I of the Background Document).

Corresponding emissions to surface waters from the use of leave-on PCPs are calculated to be between 5.5 and 91.5 tonnes/year for D5 (including ~2% from indirect uses) and between <0.3 and 2.0 tonnes/year for D4 (including ~33% from indirect uses), respectively (see Table 4 and Annex I of the Background Document).

Emissions to surface waters from "other" uses (i.e. anti-foam applications in the pulp and paper, detergents and the oil and gas industry) are estimated to be <1 tonne/year for D4 and < 1 tonne/year for D5, despite the use of a conservative emission factor to wastewater of 100%.

Emissions to surface waters from the formulation of wash-off PCPs are estimated to be 0.1 tonnes/year, whilst emissions to surface waters from the formulation of leave-on PCPs are estimated to be significantly greater at 2.0 tonnes/year. RAC notes that the Dossier Submitter's proposal intends to restrict the formulation of wash-off PCPs, but not the formulation of leave-on PCPs, despite the emissions from the formulation of leave-on PCPs being estimated to be a factor of 20 times greater. RAC notes that for both wash-off and leave-on PCPs emissions from the use phase seem to be greater than from the formulation stage.

Table 3. Emission calculations for uses of D4 and D5 in wash-off PCPs

Substance	Source	Annual tonnage	Release factor (%) [lower – upper]	Release to wastewater (tonnes/year) [lower – upper]	Release to surface water (tonnes/year)[a] [lower – upper]
D5	Formulation of wash-off PCPs	750	see note b	0.4	0.1
	Direct use in wash-off PCPs	750	54.0 - 93.0	405.0 – 697.5	97.2 – 167.4
	Indirect use in wash-off PCPs[c]	3.47	54.0 - 93.0	1.9 – 3.2	0.5 – 0.8
			Sum of emissions	**407.3 – 701.1**	**97.8 – 168.3**
D4	Formulation of wash-off PCPs	11.25	see note b	0.01	<0.01
	Direct use in wash-off PCPs	11.25	54.0 - 93.0	6.1 – 10.5	1.4 – 2.4
	Indirect use in wash-off PCPs[c]	3.47	54.0 - 93.0	1.9 – 3.2	0.4 – 0.7
			Sum of emissions	**8.0 – 13.7**	**1.9 – 3.2**

Table 4. Emission calculations for uses of D4 and D5 in leave-on PCPs

Substance	Source	Annual tonnage	Release factor (%) [lower – upper]	Release to wastewater (tonnes/year) [lower – upper]	Release to surface water (tonnes/year)[a] [lower – upper]
D5	Formulation of leave-on PCPs	14250	see note b	8.2	2.0
	Direct use in leave-on PCPs	14250	0.1 – 2.6	14.3 – 370.5	3.4 – 88.9
	Indirect use in leave-on PCPs[c]	92.5	0.1 – 2.6	0.1 – 2.4	<0.1 – 0.6
			Sum of emissions	**22.6 – 381.1**	**5.5 – 91.5**
D4	Formulation of leave-on PCPs	213.75	see note b	0.1	<0.1
	Direct use in leave-on PCPs	213.75	0.1 – 2.6	0.2 – 5.6	<0.1 – 1.3
	Indirect use in leave-on PCPs[c]	92.5	0.1 – 2.6	0.1 – 2.4	<0.1 – 0.6
			Sum of emissions	**0.4 – 8.1**	**<0.3 – 2.0**

Notes for Tables 3 and 4:

a. assuming 80% connection rate and removal in WWTW of 95% for D5 (i.e. factor applied is 0.24) and 96% for D4 (i.e. factor applied is 0.23); b. 40% of formulating sites are assumed to be well controlled (emission factor of 0.009%) and 60% of formulating sites are assumed to be less well controlled (0.09%), resulting in a release factor of 5.76 x 10^{-4}; c: derivation as described in section B.9.3.3/B.9.3.7 of the Background Document, acknowledged as a potentially significant source of emissions to the aquatic environment by RAC but excluded from cost-effectiveness calculations by SEAC as emission estimates were considered to be too uncertain.

'Reality check' on the assumptions about release factors and tonnages

The Dossier Submitter uses back-calculations from WWTP influent data as a 'reality check' on the assumptions about release factors and tonnages. The method is described in Appendix B.7 of the Background Document. The Dossier Submitter states that it is difficult to establish a representative influent concentration from the limited available information. 50 µg/L D5 is the maximum concentration observed worldwide, while 36 µg/L D5 is the maximum of the available European data (covering 19 sites with a total of just 22 samples). An influent concentration of 10 µg/L D5 is considered by the Dossier Submitter to represent both the arithmetic mean (9.91 µg/L) and median (9.8 µg/L) of observed EU influent concentrations. 15 µg/L is suggested by Rücker and Kümmerer (2015) as an upper measured concentration of D5 in European wastewater samples (i.e. 9 – 11 µg/L in the UK; <1 – <12 µg/L in the Nordic countries; 5 – 9 µg/L in Spain).

Table 5 presents the back-calculated tonnages released to EU wastewaters for D5. These are compared with the tonnage ranges of direct uses of D5 in wash-off and leave-on PCPs estimated by the Dossier Submitter and RAC.

Table 5. Back calculated tonnage/year of D5 released to EU wastewaters based on WWTP influent concentrations of 10, 15, 36 and 50 µg/L compared with the tonnage/year calculated by the Dossier Submitter and RAC for direct uses of D5 in wash-off and leave-on PCPs.

Influent concentration of D5 µg/L	D5 release to EU wastewater from direct uses in wash-off and leave-on PCPs (tonnes/year)		
	Back-calculated from influent	DS scenarios	RAC lower and upper boundary
50	920	562 – 893	420 – 1068
36	660		
15	275		
10	180		

Releases of D5 to EU wastewaters calculated by either release factors and tonnages or by back calculation from influent concentrations are considered comparable and overlap in the upper tonnage range. In general, the back-calculations of the Dossier Submitter corroborate the approach adopted by the Dossier Submitter and RAC to base the emission assessment on release factors and tonnages derived from the available empirical studies. Using the upper range influent values of 36 and 50 µg/L leads to EU wastewaters back calculated tonnages per year well inside the range estimated by RAC. Upper influent values also mimic the range of the Dossier Submitter scenarios much better than the lowest back calculated values.

The two lowest back calculated wastewater tonnages, based on the influent concentrations of 10 µg/L and 15 µg/L, are a factor of three lower than the lowest Dossier Submitter scenario. The lowest RAC scenario overestimates by factor of two.

The Dossier Submitter considers that these back calculations support the view that the influent concentrations observed can be explained predominantly by the use of D5 in wash-off PCPs.

RAC emphasise that the back-calculations are highly dependent on model inputs and assumptions (e.g. spERC). Equally, RAC considers that the representativeness of influent

monitoring data (22 samples from 19 sites for the EU) is potentially limited. In addition, the fate and behaviour of D5 in sewerage systems after release (but before WWTP) is also uncertain. Overall, these factors are considered to potentially affect the reliability of the back-calculation. As such, whilst acknowledging that overall these calculations broadly corroborate the emissions assessments of both the Dossier Submitter and RAC, RAC does not consider that these data provide conclusive evidence that emissions of D5 to wastewater and the environment can be explained solely by uses in wash-off PCPs and prefers to use the results from the empirical release studies and updated tonnage values for the emissions estimates.

The key concern for D4 and D5 is their PBT/vPvB properties, which are considered to lead to unpredictable long-term exposure and effects in the environment, including in remote regions and long-lived species. In general, the risks of PBT/vPvB substances to the environment or to humans via the environment cannot be adequately addressed in a quantitative way by deriving PNECs due to the high level of uncertainty (e.g. over the relevance of laboratory studies for such long-lived substances). Therefore, a qualitative risk assessment must be carried out.

Conclusion 7: **RAC agrees with the Dossier Submitter that since D4 and D5 are PBT/vPvB substances their risks cannot be quantified adequately and that therefore, their emissions to the environment can be considered as a proxy for risk.**

Assessment of human health risks

RAC notes that risks to human health from the use of substances in cosmetic products, as defined by Directive 76/768/EEC, are not within the scope of Title VIII of REACH (REACH Article 67(2)).

Therefore, RAC has not evaluated the hazards for human health of D4 or D5 including information from public consultation (comment # 1427) on possible endocrine modes of action. RAC however takes note of the draft opinion of the Scientific Committee on Consumer Safety (SCCS, 2015) on D5 in cosmetic products, which states that the use of D5 in cosmetic products is safe except for use in body lotion and hair styling formulations in product forms that can give rise to lung exposure of the consumer through inhalation, e.g. aerosols, pressurised sprays, powders, etc. SCCS recommended that the level of D4 as an impurity should be as low as possible and that the level of purity of D5 in the cosmetic products put on the market should be > 99%.

Human biomonitoring

Cyclosiloxanes seem to be ubiquitously distributed. RAC agrees with the Dossier Submitter that the exposure is mainly caused by direct exposure to consumer products. During the public consultation, information was submitted on the cooperation between the German Ministry of the Environment (BMUB) and the German Chemical Industry Association (VCI) launched in 2010 to develop analytical methods for D4, D5 and D6 in humans (see comment # 1425). RAC takes note that D4, D5 and D6 have the same metabolite in urine (Me2Si(OH)2) and that the limit of detection is too high to detect relevant quantities. Consequently, it is not possible to distinguish which of these substances causes exposure to humans. It can be concluded that it is currently not possible to determine the exposure to D4 and D5 in the general population with human biomonitoring (HBM) programmes.

ASSESSMENT OF ALTERNATIVES

Environmental and human health evaluation of alternatives for D4/D5

The Dossier Submitter has identified more than fifteen potential alternative substances (including linear volatile methylsiloxanes, D6, ethyl methicone, isodecyl neopentanoate, dicaprylyl carbonate , dicaprylyl ether, hydrogenated polydecene etc.), although other substances might also be suitable. Some are subject to Substance Evaluation under REACH, and others are subject to a PBT screening analysis. Definitive hazard property information is unavailable in some cases. No information on risk assessment is available in the Annex XV dossier or was submitted in the public consultation. In consequence, no definitive conclusion even on their hazard profile can be reached for the time being.

Based on the public consultation (comment # 1428), there is no universal and direct one-for-one substitute for D5 used in PCPs that could effectively duplicate all the specific product performance characteristics. For a number of product types, replacing D5 may require more than one alternative substance in order to achieve the desired performance characteristics of the finished product.

Comments (# 1412 and 1428) on possible alternatives were also received. The linear volatile methylsiloxanes (L2 – L5) are either considered too volatile to be used in both hair care and skin care applications (L2) or are potential alternatives at a higher cost and supplied in lower amounts (L3 - L5). D6 is used primarily in skin care. As a potential alternative to D4 and D5, D6 does not have the volatility to be used directly as a replacement.

Conclusion 8: **The analysis of alternative substances is hampered by lack of comparable hazard and risk data and/or ongoing evaluations that prevent definitive hazard conclusions from being drawn at this stage. RAC has concerns that some alternatives could pose similar hazards to D4/D5, the intrinsic properties of others appear to be of less environmental concern than D4 and D5.**

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

Justification for the opinion of RAC

D4 has PBT and vPvB properties and D5 has vPvB properties and both substances fulfil the criteria for Substances of Very High Concern (SVHC) (article 57 of REACH). Emissions into the aquatic environment result in long-term environmental exposure and accumulation and to exposure of humans via the environment.

Emissions into air result in long-range transport via the atmosphere to remote areas. Cyclic volatile methylsiloxanes (including D4 and D5) are widely dispersed in the environment in Europe and are found in remote regions. D4 and D5 have already been found in environmental monitoring in significant concentrations. RAC is of the opinion that in general for this type of hazardous substance any emissions into the environment must be minimised and regulatory action and risk management on an EU wide basis should apply well before contamination of the environment is demonstrated in environmental monitoring.

Thus, RAC considers that the primary reason to act on a Union-wide basis is to effectively reduce the environmental exposure to D4 and D5 in the EU. Because they are PBT/vPvB substances, in general any emissions to the environment have the potential to give rise to risks (including indirect risks to the general public because of potential long-term effects on the food chain). The aim for any regulatory action on D4 and D5 therefore is to minimise releases to the environment as far as technically and practically possible.

Action on a Union-wide basis would also limit the potential for trans-boundary exposure to

D4 and D5 from EU sources.

Conclusion 9: **RAC agrees that action to reduce the risks arising from D4 and D5 needs to be taken on an EU-wide basis.**

Justification for the opinion of SEAC

Summary of the proposal:

D4 is a PBT/vPvB substance and D5 is a vPvB substance. As such, minimisation of emissions is required under REACH. The objective of the restriction proposal is to effectively reduce emissions, and implicitly the risks, of D4 and D5 to the aquatic environment across all EU Member States. Whilst these substances are used in a wide variety of uses and products, the Dossier Submitter argues, based on the result of a risk assessment, that a targeted restriction of the use of D4 and D5 in a specific category of personal care products (wash/rinse-off products) will effectively eliminate emissions to the aquatic environment. To justify that action is required on an EU wide basis to reach this goal, the Dossier Submitter argues that Personal Care Products (PCP) are produced, used and transported across Member States. This implies that an EU wide restriction is necessary to minimise the risks. It is also highlighted that an EU wide restriction would remove any potential distorting effects that national restrictions might have on the free circulation of goods on the common market, thereby ensuring a level playing field for all the actors in the internal market.

SEAC view

SEAC agrees that action is required on an EU wide basis.

Key elements underpinning the SEAC view

SEAC recognises that action is required to reduce the risks from PBT and vPvB substances. The use of D4 (PBT and vPvB) and D5 (vPvB) in PCPs occurs across the EU. Specifically, D4 or D5 in PCPs produced in one MS can be transported and used in another MS. Equally, exposures in one Member State may be because of uses occurring in another Member State. This means that any action taken should also be EU wide. Securing the free movement of goods within the EU to ensure that the internal market functions properly also underpins the necessity of union wide action.

JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of SEAC

Summary of the proposal

Section E of the Background Document contains an analysis of other EU wide legislative measures that could have been utilised to control the risks of D4 and D5 to the aquatic environment as an alternative to the proposed, targeted, restriction. This analysis is summarised below.

Updates to existing REACH Registration dossiers

The Dossier Submitter notes that registrants should (in theory) update registrations to reflect the PBT/vPvB status of D4 and D5 and recommend risk management measures (RMMs) to minimise emissions, potentially choosing no longer to support certain uses (use advised against). The Dossier Submitter concludes that this risk management option has potential to significantly reduce environmental emissions, but that it is not guaranteed to do so because downstream users could still use the substance in PCPs even if such use is not

supported by the registrants (after notification to ECHA and preparation of a downstream user Chemical Safety Report). In addition, registrants are only legally obliged to consider the tonnage they supply individually, not collectively.

REACH Authorisation (including candidate listing)

The Dossier Submitter outlines several reasons why it considers that REACH authorisation and candidate listing (formal identification as a substance of very high concern) is not an appropriate risk management option for D4 and D5. Primarily, the Dossier Submitter considers that a listing on Annex XIV of REACH would not control the presence of D4 and D5 in silicon polymers or other siloxane homologues (such as D6) as impurities[2], which can lead to the presence of D4 and D5 in wash-off PCPs. The Dossier Submitter also considers that candidate listing could have a "black-listing" effect and promote unnecessary substitution in uses with low environmental risks, potentially with substances with less well understood hazard properties. In addition, as modelling suggests that concentrations of D4 and D5 in water and sediment can effectively be reduced by only targeting emissions to the aquatic compartment, the Dossier Submitter considers that Authorisation, which would affect uses with emissions to all compartments, would be a disproportionate regulatory response for these specific substances, as it would cover uses that do not pose a risk to the aquatic environment.

Regulation No 850/2004 on persistent organic pollutants (POP)

Regarding the POPs Regulation, the Background Document notes that identification of D4 and D5 as POPs may not be straightforward as the potential for harm posed by these substances, in the context of remote environments, is lower than substances that are currently considered to be POPs (e.g. some halogenated pesticides, dioxins and polychlorobiphenyls) and highlights that negotiations with countries outside the EU may take several years to complete, would require extensive socio-economic information (beyond that collated for this restriction) and is not guaranteed to reach consensus. The Dossier Submitter does not consider that identification of either D4 or D5 as a POP is necessary to ensure a proportionate level of environmental protection in the EU.

Regulation under the Water Framework Directive

The Dossier Submitter notes that neither of the two substances are currently considered as priority substances under the Water Framework Directive, although they are currently under consideration. The Dossier Submitter acknowledges that should either D4 or D5 be prioritised this would result in the setting of an EU wide environmental quality standard (EQS), but considers that this would be unlikely to effectively reduce aquatic emissions, as it could not directly prevent the use of D4 and D5 in PCPs. Rather, Member States would have to carry out measures (i.e. usually improved wastewater treatment) to achieve the EQS in the aquatic environment (when it is technically feasible and not disproportionately costly to do so). As it is uncertain if D4 or D5 will be prioritised, what the EQS would be, and if measures to reduce emissions would be implemented, the Dossier Submitter considers that supply controls such as the proposed restriction would be much more effective (and most probably more cost-effective) in reducing aquatic exposure than programmes of measures under the WFD. However, they consider that any requirement for monitoring introduced under the WFD would be complimentary to the proposed restriction.

Voluntary agreements

In addition to legislative measures, the Background Document discusses the possibility of reducing risks using voluntary measures. A voluntary product stewardship arrangement has been set up by the industry, and the D4 and D5 REACH consortia have a range of activities under assessment. However, the Dossier Submitter notes that the results of such voluntary

[2] Presence as impurities and use as chemical intermediates are outside of the scope of REACH Authorisation.

measures are uncertain, both on the level and timing of emission reduction.

In conclusion, the proposed targeted restriction was considered by the Dossier Submitter to be the most appropriate EU wide measure due to its effectiveness, proportionality and practicality, compared to the other RMOs.

SEAC view

SEAC agrees that the proposed restriction is the most appropriate EU wide measure.

Key elements underpinning the SEAC view

SEAC agrees with the argumentation presented by the Dossier Submitter with respect to REACH Authorisation, POPs, WFD and voluntary agreements being less effective or more costly ways of reducing aquatic emissions of D4/D5, than the proposed restriction.

RAC has developed supplementary emission scenarios for wash-off and leave-on PCPs based on upper bound and lower bound release factors. In the upper bound scenario the leave-on products contribute relatively more to total emissions than in the lower bound scenarios. Under the upper bound scenario a broader restriction, including leave-on PCPs, may be more effective in reducing the overall risks from D4 and D5, but there is currently not enough information to reach a robust conclusion on this.

However, irrespective of the relative contribution to total emissions from leave-on products it remains clear that PCPs that are washed off within a few minutes of application result in significant emissions of D4 and D5 to the aquatic environment. SEAC therefore concludes that the proposed restriction is an appropriate EU wide measure to reduce the risks from D4/D5. SEAC notes the uncertainties in the emission estimates highlighted by RAC and considers that additional RMOs for leave-on uses of D4 and D5 in PCPs may be needed should concentrations of D4 or D5 in the environment fail to decline in response to this proposed restriction.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Aquatic emissions

By applying lower and upper boundary release factors for direct uses in wash-off and leave-on PCPs RAC is able to evaluate the range of the effectiveness (emission reduction potential) of the restriction. If the lower bound for wash-off PCPs is assumed, the proposed restriction may reduce emissions in the range of **between 51.4% and 93.9%**. If the upper bound for wash-off PCPs is assumed then the proposed restriction may reduce emissions in the range of **between 64.6% and 96.3%**.

This means that if the upper bound scenario for leave-on PCPs is assumed the proposed restriction may reduce emissions only in the range of **between 51.4% and 64.6%**.

Table 6. Effectiveness (emission reduction potential) of the restriction in reducing emissions into surface waters in Europe

D5	Inside scope[a]	
Outside scope[b]	Lower boundary **97.8 t/y**	Upper boundary **168.3 t/y**
Lower boundary **6.4 tonnes/year**	93.9%	96.3%
Upper boundary **92.4 tonnes/year**	51.4%	64.6%

Notes: a. **inside scope** refers to the emissions that are considered to be within the scope of the proposed restriction i.e. formulation and direct and indirect uses in wash-off PCPs; b. outside scope refers to emissions that occur that are outside of the scope of the proposed restriction i.e. formulation and direct and indirect uses in leave-on PCPs as well as "other" uses as an anti-foam agent in the pulp and paper, detergent and oil and gas sectors.

If emissions from leave-on PCPs would be as high as assumed in the upper boundary scenario it could be questioned if the proposed restriction, which only targets wash-off PCPs, would be the most appropriate EU wide measure for addressing aquatic emissions of D4 and D5. If this scenario would realistically represent actual emissions a broader restriction, including leave-on PCPs, would be more effective in reducing the risks.

Nevertheless, RAC concludes that PCPs containing D4 or D5 that are intentionally washed-off or are disposed of via water within a few minutes of application will result in significant emissions of D4 and D5 to the aquatic environment. The suggested restriction is the most appropriate EU wide measure for addressing the emissions from wash-off PCPs, particularly noting the potential significance of D4 and D5 as impurities in other substances (silicone polymers or other silicone substances) that would not be efficiently controlled by other RMOs, such as inclusion on Annex XIV.

Review of the effectiveness of this proposed restriction

RAC considers that the relative contribution to total emissions from leave-on PCPs remains uncertain and could be significant (particular for categories of leave-on PCPs that have potential for direct release to water, such as sun protection products). Equally, RAC considers that the relative importance of emissions from the formulation of wash-off PCPs (should this continue after the entry into force of the restriction for export) as well as anti-foam uses in pulp and paper, detergents and the oil and gas industry may continue to contribute to emissions of D4 and D5 to the aquatic environmental after the entry into force of this restriction. In addition, whilst not specifically assessed by the Dossier Submitter, inappropriate disposal of wipe-based PCPs containing D4/D5 by flushing is considered to be reasonably foreseeable and could lead to emissions to the environment. However, information on recent trends from industry[3] suggests that D4 or D5 are no longer in common use in wipe-based PCPs in the EU.

RAC agrees with the Dossier Submitter that the significance of all of these potential sources to the aquatic environment might usefully be investigated as part of a review of the effectiveness of this proposed restriction by the Commission. RAC recommends, given the level of remaining uncertainty surrounding the emissions assessment, that this review should take place no later than five years after the entry into force of this restriction. The monitoring programme described by industry in their public consultation comments may provide information for such a review.

Conclusion 10: **RAC evaluates the proposed restriction as a targeted and**

[3] Mintel Global New Products Database (www.gnpd.com) – heath & hygiene category: 0/365 wipe-based products in EU labelled as containing D5; beauty & personal care category/face & neck care subcategory: 9/199 wipe-based products in EU labelled as containing D5.

appropriate EU wide measure to minimise any emissions caused by wash-off PCPs. The proposed restriction targets less than 0.2% D4 and less than 1% D5 of the total volume manufactured and used in the EU. However, if direct use of D4 and D5 in other types of PCPs or other uses of D4 and D5 in the EU also cause emissions to the aquatic environment in significant amounts, further regulatory action and risk management measures to reduce those emissions may be necessary.

Further minimisation of emission of D5

The Commission decision of 9 December 2014 established criteria for the award of the EU Ecolabel for rinse-off cosmetic products (2014/893/EU) and currently includes a maximum limit value for D4 but not D5. To be able to use the Ecolabel, D4 shall not be included in cosmetic products, either as part of the formulation or as part of any mixture, in concentration equal or exceeding 0.01% by weight of the final formulation. RAC considers that this decision could contribute to the minimisation of emissions of D4 into the environment. Equally, in addition to the proposed restriction, RAC considers that including D5 with the same limit as D4 (0.01% by weight of the final formulation) in the EU Ecolabel criteria for rinse-off cosmetic products would be appropriate to its status as a vPvB substance and may further minimise emissions of D5 (and D4 as impurity of D5) into the environment.

Opinion on proposed concentration limit of 0.1%

The proposed restriction focuses on the presence of D4 and D5 in the final PCP at a particular concentration limit, regardless of their source. A concentration limit of 0.1 per cent w/w is proposed by the Dossier Submitter to stop all intentional use of D5 and D4 in wash-off PCPs. During RAC consultation and public consultation (comment #1447) a lower concentration limit was requested to also stop all emissions into the environment caused by indirect and unintentional uses in wash-off PCPs.

RAC is of the opinion that in case of PBT/vPvB substances a concentration limit must fulfil both tasks: to stop all intentional uses and to minimise emissions to the environment. In general, RAC is of the opinion that PBT/vPvB substances should not become unintentional trace contaminants in products.

The ecological criteria for the award of the EU Ecolabel for cosmetic products already established a limit value of 0.01% w/w for D4. The SCCS is of the opinion that the level of D4 as an impurity of D5 should be as low as possible and recommends that the level of purity of D5 in cosmetic products put on the market should be > 99% (SCCS, 2015). The limit of detection of D4 and D5 is typically approximately 0.1 ppm (Background Document) which indicates that a lower limit value is technologically achievable.

The Dossier Submitter's assumption is that indirect uses of D4 and D5 in wash-off PCPs are within the scope of the restriction (section B.9.3.3 in the Background Document). When evaluating the significance of indirect emission caused by impurities of D4 and D5 in the final wash-off PCP, the Dossier Submitter assumed that residual concentration of both D4 and D5 in PCPs containing silicone polymers was the same for both substances and available for release. The assessment by the Dossier Submitter was based on an assumed tonnage of 20,000 tonnes/year of silicone polymers used and a maximum concentration for both D4 and D5 as an impurity of 0.5% w/w. After allocating the overall tonnage of silicone polymers between wash-off and leave-on products (by assuming the same relative proportion as the use of D5) this results in a volume of 3.47 tonnes/year used in wash-off PCPs (92.5 tonnes/year in leave-on PCPs) of both D4 and D5.

Based on the RAC release factors for wash-off PCPs the emissions to surface water caused by impurities in wash-off PCPs and the contribution to the overall emissions are presented in Table 7.

Table 7. Contribution of impurities to emissions to surface water caused by wash-off PCPs

substance	Emissions to surface water caused by impurities[a]	Relative contribution to overall emissions to surface water caused by wash-off PCPs
D5	0.5 – 0.8 tonnes/year	0.5%
D4	0.4 – 0.7 tonnes/year	21%

Notes: a. for example, contained in silicone polymers in wash-off PCPs

The absolute tonnage of D4 and D5 released as a result of its presence as an impurity is comparable and is estimated at <1 tonne/year for each of the substances. However, as the tonnage of D5 used in wash-off PCPs is much greater than the tonnage of D4, the relative contribution of impurities to overall emissions is much greater for D4 than for D5. This suggests that a proposed restriction with a concentration limit of 0.1% could be less effective in terms of relative emission reduction for D4 than for D5. However, there are many assumptions and uncertainties inherent in this analysis, particularly in relation to the assumed tonnages of silicone polymers used in personal care products and the concentration of D4 and D5 present as an impurity in these formulations.

As the Dossier Submitter assumes a maximum concentration for both D4 and D5 as an impurity of 0.5% w/w in wash-off PCPs a proposed concentration limit of 0.1% w/w would prevent 80% of the assumed emissions from impurities. A lower concentration limit of 0.01% w/w would prevent 98% of the assumed emissions from impurities.

This highlights that whilst a concentration limit of 0.1% is likely to be effective to prevent emissions from intentional (direct) uses, emissions of D4 and D5 as a result of its presence as an impurity in silicone polymers (and other substances) used in wash-off PCPs could still occur up to 21% for D4 (see Table 7).

Conclusion 11: **RAC concludes that the proposed concentration limit of 0.1% w/w effectively stops all intentional uses and also sufficiently minimises emissions from indirect uses in wash-off PCPs. The significance of indirect emissions could be further explored as part of a review of the effectiveness of this restriction by the Commission in the future.**

Emissions to air

While it is proven that D4 and D5 undergoes long-range transport to remote regions via the atmosphere due to their long atmospheric half-lives, it remains unclear if D4 and D5 stay in the atmosphere until degraded ("flyers") or if they deposit back to surface media to a certain extent ("hoppers"). Due to the extremely high total emissions into air of D4 and D5 from all EU uses and dissipation from WWTP, even if deposition rates in remote areas might be relatively low, this exposure route would be a potential source of risk to remote areas.

RAC recommends, given the level of remaining uncertainty surrounding the potential significance of emissions of D4 and D5 to air, that a review by the Commission should take place no later than five years after the entry into force of any restriction. It is likely that the monitoring programme described by industry in their public consultation comments (# 1416) would provide valuable information to any review. The results of the review may indicate a need for further risk management.

Industry is also working on a voluntary emission reduction plan (VERP) restricting industrial releases of D4 and D5 from manufacturing, processing, and formulating sites (public consultation comment # 1416). The initiation of this plan is set up for 2016. As RAC we appreciate this effort but we are currently unable to assess its effectiveness.

During Public Consultation several comments (see comments # 1411, 1449, 1455, 1456) were received which recommended the identification as SVHC through the Article 59 process. RAC has not discussed Candidate Listing as a risk management option.

Conclusion 12: **RAC agrees with the Dossier Submitter that both substances fulfil the criteria for Substances of Very High Concern (SVHC) and that Candidate Listing might be the only way to oblige Registrants to take full account of the implications of the PBT/vPvB properties of D4 and D5 (see comments # 1411, 1444 and 1446).**

Opinion on proposal for a review after entry into force

The Dossier Submitter proposes that the Commission shall carry out a review of the other sources of D4 and D5 to investigate whether any further emission reduction measures are necessary. RAC strongly supports this approach. RAC is currently unable to exclude the possibility that leave-on PCPs could be a significant source of emissions to wastewater, even if the release factor from these uses might be low.

Also if there would be no significant decreasing trend in environmental concentrations following the introduction of the proposed restriction, this would clearly indicate the need for further regulatory action. Also if the deposition of emissions into air to surface media is shown to occur this would indicate the need for further regulatory action.

Conclusion 13: **RAC concludes that, because of the uncertainties in the exposure assessment, the restriction should be subject to a review 5 years after entry into force.**

Justification for the opinion of SEAC

Proportionality to the risks

1. Summary of the proposal

The Dossier Submitter has provided an extensive proportionality assessment, where several different assessment methods are used: cost-benefit analysis, cost-effectiveness analysis, break-even analysis, qualitative information and affordability. The methods are partially complimentary and are recommended to be assessed together. In terms of the compliance period, the Dossier Submitter undertook two analyses, based on either a two year or five year compliance period.

1.1 COST-BENEFIT ANALYSIS

1.1.1 Cost estimates

The costs of restricting the use of D4/D5 in wash-off PCPs consists of: raw material costs, costs of reformulation and possible additional welfare losses associated with reduced product performance. The different elements are described further below.

Depending on different assumptions, the total cost estimates vary from €7.6 million per year to €439 million per year, with a methodologically preferred interval between **€7.6 million and €106 million per year**.

I. Raw material costs

One of the costs incurred by manufacturers because of the proposed restriction would be

the additional costs from purchasing alternative raw materials to replace D4/D5 in wash-off PCPs. The analysis in the Background Document is based on a conservative unit price for the substitute that is 100% more expensive than D4/D5, and a use ratio of one (the substitute will be used in the same amount as D4/D5 in the products). The resulting total **raw material cost increase is €3.4 million per year.**

II. *Reformulation production costs*

The other main cost faced by the manufacturers is the one-time investment associated with reformulating products to replace D4/D5.

To estimate the total cost of reformulation for the PCP industry the Dossier Submitter estimated a gross reformulation cost (based on average cost per product and the total number of products facing reformulation), and subtracts "baseline reformulation costs" that are assumed to occur in the absence of the proposed restriction. The reason for subtracting these baseline costs is that manufacturers are routinely reformulating their products every few years in response to factors such as changing consumer needs, changing costs and changes in raw material availability. The Background Document argues that rather than viewing the restriction as creating reformulation responsibilities by forcing firms to reformulate their products, it merely forces them to reformulate them sooner than they otherwise would have. Accordingly, the one-time cost to industry is the present value of bringing forward the costs that would nonetheless occur later without the proposed restriction.

The baseline costs that are subtracted from the gross cost are comprised of two basic elements:

1) Present value of the costs of reformulations that would be incurred during the compliance period (two years or five years), in the absence of the restriction. It is assumed that 5% of the products undergo a major reformulation every year, and that 15% of the products undergo minor reformulations every year, implying that 20% of the products are reformulated each year. The costs of these reformulations, for a time period of two years and five years respectively, are excluded when total reformulation costs are estimated.

2) For the remaining reformulations, the present value of the deferred costs of baseline major reformulations brought forward because of the proposed restriction. The Dossier Submitter argues that with a restriction, all products would need to undergo a reformulation during the compliance period. For the share of products that were not planned for reformulation until after the compliance deadline, there will be costs connected to undertaking reformulation sooner in order to comply with the proposed restriction. The Dossier Submitter claims that these reformulation costs would also be incurred in the absence of a restriction, only with a different and deferred time profile. Thus, it is only the cost of bringing forward the reformulation that should be included when total reformulation costs are estimated. Under this assumption, the present value of the costs of routine reformulation after the compliance period in a baseline scenario is subtracted (from year 3 to year 20, and from year 6 to year 20, depending on the length of the compliance period).

Using this method the Dossier Submitter estimates the **cost of reformulation as €20 - €58 million per year (two year compliance period) and €4 - €38 million (five year compliance period).**

III. *Product performance reduction loss*

In addition to the costs incurred by manufacturers, there may be a reduction in consumer surplus arising from any reduction in performance and quality of the reformulated products. The Dossier Submitter estimates this loss based on the results from a willingness to pay

(WTP) study (for more info on this study, see section "benefits" below). In the study, respondents were asked a series of choice questions in order to ascertain the consumer loss of functionality provided by D4 and D5 in personal care products. According to this study the WTP for beneficial properties (e.g. quick dry, smooth feel, no smell, low skin irritation etc.) provided by D4/D5 was estimated at €5 per person per year.

The Dossier Submitter has no information about the actual product performance loss that will occur due to the use of alternatives. In the absence of such information they include a scenario where reformulation will be successful in replicating the qualities of D4/D5 in only 50% of the cases, resulting in a product performance loss in 50 % of the cases. Aggregated to the EU population (excluding children under 14) and calculating only the share related to wash-off PCPs, the total **annual cost associated to this loss is approximately €45 million.**

IV. *Total annualised costs*

The total costs include raw material costs, reformulation costs and product performance loss. The Dossier Submitter presents the resulting annual costs under a number of different assumptions (see Table 8 below), highlighting the net costs that are annualised over a period of 20 years.

Assuming that the reformulations are completely successful in replacing the wash-off PCPs containing D4/D5 (excluding product performance loss), the Dossier Submitter estimates the costs to be in the order of **€7.6 - €42 million** and **€23 - €61 million** per year under five year and two year compliance periods, respectively. In another scenario, where the reformulations are assumed to be only 50% successful (including product performance loss), the costs are estimated at **€53 - €87 million** and **€68 - €106 million** per year under a five year and two year compliance period, respectively.

Table 8: Summary of annualised cost estimates (Table F.1 from the Background Document)[4]

Measure of annualised reformulation costs used	Compliance Period	Economic Impact Component			Agg Annual Impact (excluding PPR loss) (€) (d)= (a)+(b)	Agg Annual Impact (including PPR loss) (€) (e)=(d)+(c)	Cost-effectiveness (excluding PPR loss) €/kg (f)=(d)/199600	Cost-effectiveness (including PPR loss) €/kg(g)=(e)/199600
		Raw material substitution costs (€) (a)	Reformulation Costs (€) (b)	Product performance reduction loss (€)(c)				
annualised net costs (20 yrs)	**2**	**3 420 000**	**19 664 952 - 58 044 340**	**45 000 000**	**23 084 953 – 61 464 340**	**68 084 953 – 106 464 340**	**115.66 – 307.94**	**341.11 – 533.39**
	5	**3 420 000**	**4 188 567 - 38 307 702**	**45 000 000**	**7 608 567 – 41 727 702**	**52 608 567 – 86 727 702**	**38.12 – 209.06**	**263.57 – 434.51**
annualised net costs (5 yrs)	2	3 420 000	60 032 299 - 177 195 193	45 000 000	63 452 299 – 180 615 193	108 452 299 – 225 615 193	317.90 – 904.89	543.35 – 1130.34
	5	3 420 000	12 786 673 - 116 944 059	45 000 000	16 206 673 – 120 364 059	61 206 673 – 165 364 059	81.20 – 603.03	306.65 – 828.48
annualised gross costs (20 yrs)	2	3 420 000	89 551 902 - 127 931 288	45 000 000	92 971 902 – 131 351 288	137 971 902 – 176 351 288	465.79 – 658.07	691.24 – 883.52
	5	3 420 000	79 611 315 - 113 730 450	45 000 000	83 031 315 – 117 150 450	128 031 315 – 162 150 450	415.99 – 586.93	641.44 – 812.38
annualised gross costs (5 yrs)	2	3 420 000	273 380 086 - 390 542 980	45 000 000	276 800 086 – 393 962 980	321 800 086 – 438 962 980	1386.77 – 1973.76	1612.22 – 2199.21
	5	3 420 000	243 033 901 - 347 191 287	45 000 000	246 453 901 – 350 611 287	291 453 901 – 395 611 287	1234.74 – 1756.57	1460.19 – 1982.02

[4] The rows with bold typeface are the estimates preferred by the Dossier Submitter. The other rows outlining the five year annualisation period and the gross costs are considered by the Dossier Submitter as sensitivity checks.

1.1.2 Cost savings

In addition, the proposed restriction results in benefits from indirect economic impacts that arise from the avoidance of damage from siloxanes to energy generation equipment at anaerobic digestion plants. These avoided costs are estimated by the Dossier Submitter to result in **savings in order of €17 million per year** (bound estimate €4 - €39 million per year).

1.1.3. Benefits

The environmental benefits arise from the reduction in potential risks associated with accumulation of D4/D5 in the aquatic environment. To quantify the benefits associated with the proposed restriction, the Dossier Submitter has conducted a specially commissioned stated preference valuation study.

The study used a choice experiment questionnaire to quantify individuals' willingness to pay (WTP) to avoid the potential risks of accumulation of D4 and D5 in the aquatic environment. This WTP was valued relative to the associated consumer loss in the case of a restriction, connected to the functionality provided by D4 and D5 in personal care products. Respondents were asked to make choices amongst different levels of three attributes:

- PCP quality (based on the functional properties provided by D4/D5);
- Reduction of environmental accumulation/potential risk associated with the reduced use of D4/D5 in personal care products;
- Price of personal care products.

The survey respondents consisted of an internet based representative sample of the UK population (size = 829) split in two samples, each sample being asked to consider D4 and D5 separately in order to assess the differences in PBT and vPvB status.

The results from the study estimates WTP per person per year to be €46 to reduce the risk associated with the PBT substance (D4), and €40 to reduce the risk associated with the vPvB substance (D5).

The WTP for reducing D4/D5 accumulation was then aggregated to the EU level resulting in an annual WTP of €16 billion, excluding children aged 0 – 14 years. However, this estimate is based on valuation scenarios concerning all PCPs that contain D4/D5 (not only wash-off PCPs that are included in the scope of the proposed restriction). To transform the estimate to only count for the wash-off PCPs in question, the Dossier Submitter used the ratio of the volume of wash-off PCPs to total PCPs containing D4/D5 (i.e. 4%).

Based on this study, the total environmental benefits attributable to reductions in the accumulation of wash-off PCPs containing D4/D5 in the EU is estimated at **around €0.65 billion per year.**

1.2 COST-EFFECTIVENESS ANALYSIS

1.2.1 Emissions

The Dossier Submitter's approach to calculating the surface water emissions of D4 and D5 from direct and indirect uses in PCPs was based on use tonnages and release factors, combined with estimates of removal during wastewater treatment. In the absence of more reliable information on tonnages, and using emission factors of 100% for wash-off PCPs and 0.1% for leave-on PCPs, the Dossier Submitter initially estimated total combined emissions

of D4 and D5 to surface water from wash-off PCPs of ~200 tonnes/year[5] (196 tonnes/year for D5 and 4 tonnes/year for D4). This estimate included contributions from both direct and indirect (unintentional presence as an impurity in silicone polymer) uses.

During opinion development, the Dossier Submitter provided six further emission scenarios that explored the consequences of selecting different emission factors for wash-off and leave-on PCPs on overall surface water emissions of D4 and D5. The results of these emission scenarios are reported in a confidential annex to section B.9.4 of the Background Document, but were not used to update the cost-effectiveness calculations.

The Dossier Submitter has calculated the cost-effectiveness as the sum of economic impacts (cost and cost savings as presented above) divided by the reduction in emissions of D4/D5 as a result of the proposed restriction. The estimate range between €38 and €533 per kg of D4/D5 emissions reduced. Using the same definition, the cost per kg in the decaBDE restriction proposal was estimated to be €464. For PFOA the estimated cost-effectiveness was < €1 649 per kg, whilst the cost-effectiveness per kg of PFOA-related substances was €125 - €4 000 emissions. Finally, for phenyl mercury the estimated cost effectiveness was €649 per kg.

1.3 BREAK-EVEN ANALYSIS

The Dossier Submitter also conducted a break-even analysis. The method summarises the net costs of the restriction in order to show what the environmental benefits would have to be equal to in order to outweigh the costs.

The Dossier Submitter estimated that the environmental benefits would have to be €35-€69 million per year for the restriction to break even, and that this corresponds to an increase in the retail sales price of 0.5%-1% for wash-off PCPs. The Dossier Submitter concludes that the WTP for the environmental benefits of the restriction would have to be €0.07 – €0.14 per person in the EU, to offset the costs of the restriction.

1.4 AFFORDABILITY

As a supplement to the analysis of proportionality, the Dossier Submitter also discusses the unit price increase in retail sale as a result of the proposed restriction. This was done to give an indication of the affordability of the restriction.

Looking at the percentage retail sales price increases, the effect is small, ranging from 0.11 – 0.62% and 0.34 – 0.91% for five and two year compliance periods, respectively. Even with worst-case estimates, where the "gross reformulation cost" is used, the upper bound of the price increase, for the shortest compliance period, is 5.81%.

1.5 QUALITATIVE INFORMATION

The Dossier Submitter has also provided information on the damage potential of D4 and D5 in the environment. D4 and D5 have been detected in biota in remote regions, including in the Arctic at low concentrations. However, the Dossier Submitter considers that the presence of D4 and D5 in biota is unlikely to be because of long-range transport and re-deposition, since D4 and D5 are expected to reside in the atmosphere until they are degraded thus limiting re-deposition to surface media. The Dossier Submitter also notes that exposure of air-breathing organisms and humans is limited because of efficient excretion in the lungs. However, some fish species are more susceptible to these substances and D5 can attain concentrations up to a few mg/kg on a wet weight basis in tissues.

[5] This emission tonnage was initially reported in section F.2.5 of the confidential annex to the Background Document as the use tonnages used by the Dossier Submitter were considered by industry to be confidential. This tonnage information was subsequently disseminated publicly by industry in the public consultation (Annex XV restriction report consultation comment #1452) and can therefore be reported in this non-confidential opinion.

It is estimated that the D4 and D5 stock in society, including residual impurities in polymer articles, is likely to be much lower than for other persistent substances. The complete consumption of PCPs containing D4 and D5 is likely to take place within a year (12 months) of purchase in most cases.

The vast majority of emissions from wash-off PCPs would be expected to take place within 12 months. However, emissions from the waste disposal stage may occur several years after first placing on the market, and emissions from polymer waste in landfills may occur decades from the assumed end of service life.

1.6 OVERALL CONCLUSION AND PROPORTIONALITY

The benefits of €0.65 billion per year outweigh the costs (including the cost savings) ranging from €7.6 - €439 million per year, with a more realistic interval of €7.6 - €106 million per year. The Dossier Submitter thus concludes that the proposed restriction is proportionate to the risks.

Comparing the cost-effectiveness of the proposed restriction to other restrictions under REACH, the Dossier Submitter argues that this approach supports the conclusion that the risk reduction achieved by the restriction appears to be proportionate to the costs.

The restriction is also deemed affordable in terms of price increase of the end product.

In summary, the results of all the analysis undertaken by the Dossier Submitter supports the overall conclusion that the restriction is a proportionate measure.

2. SEAC view

SEAC finds the proposed restriction to be a proportionate measure to reduce emissions of D4/D5 to the aquatic environment.

3. Key elements underpinning the SEAC view

The environmental benefits of the proposed restriction arise from the reduction in potential risks associated with emissions to and accumulation of D4/D5 in the aquatic environment. Experience with PBT/vPvB substances has shown that they give rise to broad concerns based on their potential to accumulate in the environment and cause effects that are unpredictable in the long term and are difficult to reverse (even when emissions cease). RAC considers that emissions of D4/D5 can be considered as a proxy for risk.

Based on the lower and upper release factors agreed by RAC and the updated tonnage information provided by industry during the public consultation[6], the proposed restriction will prevent emissions to EU surface waters of between 97.8 and 168.3 tonnes/year for D5 (including approximately 0.5% from indirect uses) and between 1.9 and 3.2 tonnes/year for D4 (including ~20% from indirect uses), respectively (see Annex I of the Background Document).

3.1 COST-BENEFIT ANALYSIS

3.1.1 Cost estimates

SEAC is in general agreement with the approach taken by the Dossier Submitter. The SEAC evaluations and corresponding conclusions on the different cost elements are presented below.

[6] Annex XV restriction report consultation comment #1452

I. Raw material costs

For the raw material costs, SEAC agrees with the assumptions, calculations and results as presented by the Dossier Submitter. SEAC recognises that a 100% price increase is high compared with the reported price difference for some alternatives. However, the information on alternatives is sparse so SEAC cannot conclude on what the most realistic price increase will be. Nevertheless, based on the information presented, SEAC accepts the Dossier Submitter's choice of using 100% as the price increase between alternatives and D4/D5.

To be consistent across all cost and benefits elements, SEAC has undertaken a complimentary analysis where the onset of the raw material costs are delayed until after the compliance period (which slightly reduces the cost estimates), and has computed an annuity based on a 20 year analytical period.

II. Cost of reformulations

SEAC agrees with most of the assumptions made by the Dossier Submitter. SEAC, in collaboration with the Dossier Submitter, has chosen to perform additional calculations to relax some of the more stringent assumptions used by the Dossier Submitter and to investigate how sensitive the estimates are to certain parameters. The full analysis is presented in Annex I in the Background Document, and is summarised below.

- SEAC recognises that some coordination of ongoing R&D efforts with the R&D necessary to remove D4/D5 from all formulas is likely to be possible, and comments in the public consultation[7] also indicate that coordination with ongoing R&D may lower the costs. For example, if a company has scheduled to create a new formula for a conditioner to meet the market demand of "shiny hair", they might be able to undertake the necessary R&D to substitute D4/D5 at the same time, and thus reduce the cost as compared to doing the reformulations separately. However, SEAC notes that baseline reformulations would not be performed for the purpose of removing D4/D5, but rather be motivated by e.g. innovations to meet market demand, cost reductions or other R&D needs (this is also described by the Dossier Submitter, and confirmed in the public consultation)[8]. Market demand and related R&D needs are not necessarily known more than 10 years into the future, so SEAC does not agree that it will be possible to coordinate all major reformulations over the next 20 years, as implicitly assumed by the Dossier Submitter[9].

  In the additional cost estimates this assumption is relaxed, and the coordination of R&D efforts to remove D4/D5 with other required reformulations are assumed to be possible for an initial 5-10 year period after the entry into force. After this period, the companies R&D efforts return to business as usual, i.e. they reformulate at the same rate as before the restriction to meet market demand etc.

  However, some coordination of R&D efforts may also be possible after the compliance period. In such a case, the new cost estimates may be too high. The original cost estimates in the Background Document are also evaluated, but these will be given less weight as they are considered an underestimation of the real costs. On the opposite side, the Background Document includes gross costs, based on an assumption of no coordination being possible. SEAC will also evaluate the no coordination scenario, but this will also be given less weight due to the likely overestimation.

- The Dossier Submitter assumes for the lower bound scenarios that there are no costs

[7] Annex XV restriction report consultation comments 1417 and 1431
[8] Annex XV restriction report consultation comments 1417 and 1431
[9] Note that the Dossier Submitter has only made this assumption for the 'major' reformulations. For the 'minor reformulations' it is assumed immediate return to the baseline reformulation rate. SEAC agrees with this assumption.

connected to removing D4/D5 from products, but that it can be done with no additional costs when coordinating the reformulation with an already scheduled reformulation. For the upper bound the Dossier Submitter assumes that the additional costs of removing D4/D5 will amount to €150 000 per formula when it is coordinated with another reformulation. SEAC considers the 'no additional cost' assumption to be an underestimation, but has little to no information about the actual 'additional' costs of removing D4/D5 from a product to allow calculations to be reliably refined. Due to the lack of information about the costs of coordinating several reformulation processes, SEAC chooses to follow the Dossier Submitter's initial approach, but will be mindful about the potential for underestimation due to the 'no cost' assumptions in the lower bound scenarios.

- For the minor reformulations, the Dossier Submitter assumes that these will not be performed (or they will be integrated into the major reformulation without additional costs) during the compliance period. Since the minor reformulations can be performed with no additional cost in the restriction scenario, the affected companies would have a cost reduction as compared to the baseline. SEAC question whether such a cost saving would actually take place, and concludes the 'no cost' assumption will more likely lead to an underestimation. For simplicity SEAC has thus chosen to disregard these assumed cost savings, and rather assume that the minor reformulations will be unaffected by this restriction, i.e. a zero cost assumption rather than cost savings.

  The Dossier Submitter assumes that all of the reformulation costs will be expended in the last year of the compliance period. SEAC could not find any argumentation for why all of the costs would occur in the last year of the reformulation period. By placing the costs at a later point in time, the estimates are reduced, and the cost will be underestimated. To try to counterbalance this bias and in the lack of any particular timing of these reformulation costs, SEAC chose to spread the costs equally across the compliance period. The Dossier Submitter annualises the reformulation costs using two different analytical periods, 20 years and 5 years respectively. The calculations of the reformulation costs are based on a 20 year analytical period, thus annualising these over 5 years will be inconsistent. SEAC will thus only consider the estimates annualised over the 20 year period.

The number of reformulations necessary is recognised by the Dossier Submitter as highly uncertain, and probably overestimated. The Dossier Submitter has followed the assumptions presented by one large industry actor, leading to a total number of necessary reformulation of 3761. However, as described in the Background Document there are several data sources supporting the likelihood of an overestimation:

1) The EU market would under these assumptions have 23 times more products containing D5 as compared to the Canadian market, which seems unlikely. Extrapolating from Canadian data would give 160 necessary reformulations connected to the proposed restriction.

2) A 1 year sample of newly launched PCPs (March 2012 – March 2013) showed that only 0.13% of all the new PCPs were wash-off products containing D5. Extrapolating from this source would give 400 necessary reformulations connected to the proposed restriction.

3) A small sample study which tested 231 wash-off PCPs found that only 7% of the products (all conditioners) contained D4 or D5. Extrapolating from this source would give 850 - 1050 necessary reformulations connected to the proposed restriction.

4) Industry provided information in the public consultation[10] on the number of product

[10] Annex XV restriction report consultation comment1417

reformulations would be necessary if both wash-off and leave-on products were to be restricted. Extrapolating from this source gives fewer than 1500 necessary reformulations connected to the proposed restriction.

As a whole, the other available sources show that fewer than 1500 reformulations would be necessary to comply with the proposed restriction. In other words, the Dossier Submitter might have overestimated the number of necessary reformulations by between two to 23 times.

Overall, SEAC agrees with the Dossier Submitter's interpretation of the available data, and finds it highly likely that the number of necessary product reformulations is overestimated. To better reflect this overestimation, SEAC has included an additional cost scenario where the number of necessary reformulations is reduced by 50% (1881 necessary reformulations), which is equivalent of giving the original data source used by the Dossier Submitter three times as much weight as each of the other sources. A lower bound scenario is also included, where an average of the other four data sources are used (681 necessary reformulation), i.e. an 80% reduction in the number of necessary reformulations.

Table 9 below gives an overview of the different estimates evaluated by SEAC. Due to the underlying uncertainties, the estimates should only be considered as indicative. To underline this lack of precision, all of the numbers (except the original Dossier Submitter estimates) are rounded to the nearest €10 million.

Table 9: Summary of reformulations cost estimates evaluated by SEAC in Million €

Reformulation costs sensitivity - Yearly costs in Million €							
Compliance Period	**Bound**	**DS original estimates**	**5 year coordination and 80% less products**	**5 year coordination and 50% less products (Low)**	**10 year coordination (Medium)**	**5 year coordination (High)**	**No coordination**
2 years	Lower	20	10	30	50	70	90
	Upper	58	20	50	90	100	120
5 years	Lower	4	10	30	40	60	80
	Upper	38	20	50	80	90	110

SEAC concludes that the reformulation costs are likely to lie in the interval €30 million - €100 million for the two year compliance period, and €30 million – €90 million for the five year compliance period.

III. *Product performance loss*

SEAC agrees with the general approach taken by the Dossier Submitter to estimate the product performance loss. SEAC agrees that the assumption of 50% performance loss is likely to be rather high, because there are a large number of similar products on the market today, which do not contain D4/D5. In line with the Dossier Submitter, SEAC finds it more likely that the real performance loss will lie between 0% and 50%.

SEAC has chosen not to directly use the benefits estimates from the WTP study provided by the Dossier Submitter (see sections 1.1.3 and 3.1.1 on benefits). Since the WTP for the product quality was estimated in the same regression analysis as the WTP for reducing environmental accumulation of D4/D5, the WTP for product quality will not be directly used either.

Based on information provided by the Dossier Submitter as well as information from the public consultation, SEAC concludes that there is likely to be some loss in product performance. However, SEAC notes that the industry concern for performance loss is

primarily mentioned in connection with leave-on PCPs, and that the difficulties of replacing D5 in wash-off products may be less significant[11]. The size of this potential loss is unknown, but SEAC notes that the exclusion of these indirect costs may lead to an underestimation of the total costs to society of the proposed restriction.

IV. Testing costs

The Dossier Submitter has provided additional information on potential testing costs (see section F.2.1. in the Background Document), based on UK data on enforcement campaign costs. However, the costs are calculated for a few specific UK campaigns, and aggregation to the EU-level is not possible. Some industry actors indicated in the public consultation that surveillance testing costs (to ensure that PCPs did not contain D4 or D5) could be substantial, but their scale are unknown and no further information to justify them was provided.

SEAC notes that under the Cosmetics Regulation, persons responsible for placing cosmetic products on the market (usually the manufacturer or the importer) must ensure that the product in question has undergone a safety assessment and that a cosmetic product safety report is prepared. In the public consultation on the SEAC draft opinion an industry actor stated that safety testing to adopt alternatives to D4 and D5 may cost in the range of €20 million[12]. SEAC notes that the costs of safety studies were already integrated into the total reformulation costs provided by industry[13].

The Dossier Submitter (and SEAC) uses the cost estimates provided by industry, so at least part of the potential testing costs should be included in the total cost estimates (e.g. costs for safety assessment). However, due to the lack of precise data, SEAC is not able to conclude on what proportion of the overall testing costs is included in the costs estimates. SEAC acknowledges that if not all of the testing costs (i.e. enforcement and surveillance testing) are included, the total cost of the restriction would be underestimated.

V. Cost savings

As recognised by the Dossier Submitter, the potential costs savings for the EU Anaerobic Digestion (AD) plants are uncertain. They might be overestimated, since all of the damage from siloxanes is attributed to D4/D5, while other siloxanes may be more or less responsible for the damage. On the other hand, the lower bound estimate is based on costs from a Canadian study, which is specifically studying costs to AD plants from D4/D5. Even though the latter is not cost estimates based on EU data and the cost level might be somewhat different than in the EU, SEAC still considers this Canadian study to be more representative since it is specifically estimating costs related to D4/D5 and are not including costs that might be caused by other siloxanes. SEAC has thus disregarded the upper bound estimates of the cost saving.

The actual calculations of the cost savings (performed by an external consultant) deviate somewhat from the description in the dossier, due to a slight difference in discount rate, different analytical period and the assumption of the onset of the cost savings. To make the estimates consistent with the other cost estimates, updated cost savings estimates has been provided (Annex I in the Background Document) using the 4% discount rate and a 20 year analytical period.

There were only minor changes compared to the estimates used by the Dossier Submitter, and SEAC concludes that the cost savings are likely to lie in the interval €4 million - € 39

[11] Annex XV restriction report consultation comment 1431
[12] SEAC draft opinion consultation comment number 52x
[13] Annex XV restriction report consultation comment numbers 1417 and 1418

million per year for a two year compliance period, and €3 million - €31 million for a five year period.

VI. *Total costs*

To estimate the total costs, all the different cost elements are combined in the following way:

Total costs = Raw material costs + reformulation costs + product performance loss + testing costs – cost savings

The testing costs and the product performance loss could not be quantified, so the total cost estimates will be underestimated in terms of these missing elements.

Export and import have not been evaluated, but SEAC has currently no evidence supporting any bias (e.g. export>import) due to this omission.

Table 10: Summary of the elements in the main cost scenario

Yearly costs in Million € - 20 year analytical period - 10 year coordination (Medium)							
		Cost components (annuities)					
Compliance Period	**Bound**	*Raw material substitution Costs*	*Reformulation Costs*	*Cost savings*	*Compliance testing costs*	*Product performance reduction loss (PPL)*	**Aggregate Annual Costs (excl. PPL)**
2 years	Lower	3	50	-40	N/A	N/A	**20**
	Upper	3	90	-4	N/A	N/A	**90**
5 years	Lower	2	40	-30	N/A	N/A	**20**
	Upper	2	80	-3	N/A	N/A	**80**

Table 11: Sensitivity of aggregate costs estimates for different reformulation cost assumptions, testing costs are excluded

Aggregate costs (excl. PPL) - Reformulation costs sensitivity - Yearly costs in Million €							
Compliance Period	**Bound**	**DS original reformulation costs**	**5 y coordination and 80% less products**	**5 year coordination and 50% less products (Low)**	**10 y coordination (Medium)**	**5 y coordination (High)**	**No coordination**
2 years	Lower	-20	-30	-3	20	30	50
	Upper	60	20	50	90	100	120
5 years	Lower	-24	-20	1	20	30	50
	Upper	40	20	40	80	90	110

As shown in the tables above, the cost estimates are highly sensitive to different assumptions for the reformulation costs. The scenarios considered most likely are denoted "Low", "Medium" and "High", and will be used in the proportionality assessment. SEAC concludes that the total costs (excluding testing and product performance loss) are likely to lie in the interval €3 million - €100 million per year for the two year compliance period, and between €1 million - €90 million for the five year compliance period. As a central estimate, SEAC will use the average[14] of **€50 million per year** for the two year compliance period, and **€45 million per year** for the five year period.

3.1.1 Benefits

The benefits estimates are solely based on the WTP study, which was carried out specifically

[14] SEAC uses the average of the three most likely scenarios (low, medium and high).

to support this restriction proposal in cooperation with the Dossier Submitter[15]. SEAC appreciates the efforts that went into producing this study and the valuable contribution to the benefits assessment. In general SEAC supports the approach of trying to calculate the WTP as a measure of the societal benefits from a restriction, but also recognises that there are major challenges involved due to the complexity of the effects to be valued.

To get reliable WTP estimates, that is, estimates that actually reflect the true benefits to society, it is necessary that the respondents understand the attributes they are going to value. One of the problems with PBT and vPvB substances is that the risks of future effects are unknown, and often even the potential effects are unknown (even to experts). This means that the respondents must value a "black box", which may result in a large variety of responses not necessarily connected to the problem at hand. For example, a respondent may picture one particular "prototype[16]" effect and base their entire valuation on that. Alternatively, a respondent may misunderstand the scope of the problem and provide a generic WTP for a larger group of problems (part-whole bias[17]). For example, environmental problems in general or problems connected to hazardous substances in general. It should be underlined that these issues are also connected to contingent valuation (CV) studies in general, and that choice experiments (as was used in this study) are usually better at handling such scope effects. In general there are many different challenges connected to WTP estimations, but the more complex the attribute is, the more difficult will it be to get a representative estimate. It can also be questioned whether it will always be possible to estimate WTP, in particular for highly complex issues.

These challenges will often result in WTP estimates that have low scope sensitivity or are completely scope insensitive. This means that if a similar study had been performed for a different scope, one would get approximately the same results. This raises several problems, but in the case of the benefits of a restriction proposal, this would mean that the WTP estimates imply that it would be more beneficial to divide the original proposal into many small measures, even though the exact same amounts of emissions are reduced.

One particular result from the study underpins some of the concerns mentioned above. If one looks at the results from D4 (PBT and vPvB) and D5 (vPvB) separately, one finds that the individual WTP to stop environmental accumulation, i.e. reduce/remove all emissions, is €46 and €40 respectively. D4 emissions are around 1.9% of the D5 emission (See emission section 3.2.1 below). Using the WTP as a proxy for the benefits to society of avoiding D4 and D5 emissions, this would imply that society gains 60[18] times more per unit of D4 emission avoided than per unit of D5 emission avoided. It is difficult to justify such a large difference in the gains to society for the two substances (which are described as being rather similar in the valuation study). The differing valuations are probably due to the fact that no information was provided to the respondents on the relative amounts of the two substances. If the risks, and thereby the benefits to society can be assumed to be connected to the amount of the substances emitted into the environment, at least one of the WTP estimates will not be representative for the true benefits to society.

Another interpretation, which may circumvent some of the issues described, is to connect the WTP to the hazard of the substances rather than to the potential impacts. The WTP estimates may then reflect a societal preference for precautionary actions to prevent potential, but unknown, effects related to D4/D5. With this interpretation, it is expected that the estimates should be scope insensitive, but it would still reflect the societal gain from

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15 The stated preference study and corresponding analysis was carried out by a master student at LSE, with guidance from a supervisor from LSE as well as a representative from the Dossier Submitter team.

16 Kahneman, D. 1986. Comments on the contingent valuation method. Pp. 185-194 in *Valuing environmental goods: a state of the arts assessment of the contingent valuation method,* eds. R. G. Cummings, D. S. Brookshire and W. D. Schulze. Totowa, NJ: Roweman and Allanheld.

17 Whitehead, John C., Timothy C. Haab, and Ju-Chin Huang, "Part-Whole Bias in Contingent Valuation: Will Scope Effects Be Detected with Inexpensive Survey Methods?" *Southern Economic Journal*, 65, 160-168, 1998.

18 The ratio was derived by using the following approximation: (WTP per kg D4)/(WTP per kg D5) = (€46/0.019x kg)/(€40/x kg) = (46*x)/(40*0.019x) =60.

removing substances of concern. However, it also implies that it would not matter in terms of benefits to society, if the emissions in question actually cause any impacts. This means that the benefits could be more connected to all emission (or even use) of the substances. Moreover, it would be difficult to distinguish whether the WTP would be specific for D4/D5, or if it was rather related to a general concern for all PBTs and vPvBs (or all substances of similar concern). In the latter case, the benefits attributable to D4/D5 would only be a small share of the WTP to remove all PBTs or vPvBs.

The Dossier Submitter notes that the study is likely to be scope insensitive. It is not necessarily the case that scope insensitivity will always invalidate WTP estimates, but it means that if the estimates should be used, it is necessary to be very careful about how they are interpreted and used.

SEAC has concluded that the benefits estimates derived based on the WTP study are too uncertain to be used as direct comparators to the costs. However, it is found that the study provides evidence for a potentially large WTP for avoiding accumulation of D4/D5 in the environment. Furthermore, SEAC notes that the WTP for the environmental improvement is clearly higher than the WTP for superior PCP quality.

SEAC also notes that several of the cost estimates are negative, meaning that the cost saving incurred by the anaerobic digestion plants, are under some assumptions, enough to justify the restriction.

3.2 COST-EFFECTIVENESS ANALYSIS

Emissions, or here, accumulating emission, can be viewed as a proxy for the benefits. Accumulating emission refers to the part of the emissions that is likely to contribute to the accumulation of D4/D5 in the environment. This means that emissions to air are excluded, and only the emissions that remain after waste water treatment will be included.

RAC considers that the quality and applicability of the experimental studies used by the Dossier Submitter to select the release factors for leave on and wash-off categories of PCPs in the original Annex XV restriction proposal are limited and potentially of high uncertainty. In response, the Dossier Submitter has included in the Background Document a series of six supplementary sensitivity analyses of potential emissions, based on the use of different release factors for leave on and wash-off products to wastewater during use. In addition, these assessments are compared in a "reality check" to the available monitoring data of D4 and D5 in wastewater influents. However, the results of these sensitivity analyses were not used in the socio-economic parts of the Background Document.

Notwithstanding these additional analyses, and based on the remaining uncertainty in the available experimental studies, RAC considers that a simplified approach to exposure assessment for D4 and D5 is appropriate to the quality of the available experimental studies. The simplified RAC approach is comprised of lower and upper bound emissions factors for wash-off and leave on products. SEAC notes that RAC does not consider that either the upper or lower bound scenarios represent realistic worst case emissions. Rather, actual emissions are considered to occur somewhere between the upper and lower bound estimates.

Based on this simplified approach, RAC considers the following emission factors to be appropriate to be used as lower and upper bounds for emission of D4/D5 to waste water:

Table 12: Emissions factors (from Annex I in the Background Document)

Product	Bound	Value (%)
Wash-off	Lower	54.0
	Upper	93.0
Leave-on	Lower	0.1
	Upper	2.6

The original tonnage estimates of D4 and D5 used in wash-off and leave-on PCPs were based on industry data that only covered parts of the market. The Dossier Submitter extrapolated industry numbers to the entire market, by assuming a one-to-one relationship between tonnage used and sales revenue. In the public consultation, new data covering the entire market was received, which the Dossier Submitter found to be more reliable than the extrapolated estimates. SEAC agrees with this, and concludes that the likely tonnages are:

Table 13: Tonnages (from Annex I in the Background Document)

Tonnage uses			
Source	**D4**	**D5**	**D4+D5**
wash off	11,3	750,0	**761,3**
leave-on	213,8	14250,0	**14463,8**
other	4,0	4,0	**8,0**
Total	229,0	15004,0	**15233,0**
% wash-off of total use	4,9 %	5,0 %	**5,0 %**

Based on the updated emission factors and tonnages, RAC has provided new emission estimates, which can be found in the table below[19].

Table 14: Emission estimates (from Annex I in the Background Document)

Emission D4+D5, in tonnes per year		
Source	**low**	**high**
wash-off	98,7	169,9
leave-on	7,4	94,0
Total	106,1	263,9
% wash-off of total emission	93 %	64 %

SEAC uses the new emission estimates to calculate the average emission per year for a 20 year analytical period, when taking into account the latency of the 2 and 5 year compliance period respectively. The resulting average yearly emissions used in the cost-effectiveness calculations are as follows:

[19] Assuming 80% connection rate and removal in waste water treatment plant of 95%; 40% of formulating sites are assumed to be well controlled (emission factor of 0.009%) and 60% of formulating sites are assumed to be less well controlled (0.09%).

Table 15: Average yearly emissions from wash-off PCPs

Emissions annuity- 20 year analytical period		
Compliance Period	**Bound**	**Emission in kg D4/D5 per year**
2 years	Low	**89 000**
	Average	**121 000**
	High	**153 000**
5 years	Low	**74 000**
	Average	**100 500**
	High	**127 000**

SEAC has calculated new cost-effectiveness estimates based on the three emission scenarios (table 8) and the three most likely cost scenarios (table 4) presented in the cost-benefit analysis above. The result is a matrix of cost -effectiveness estimates (shown in the table below), which can be used to evaluate the efficiency of the restriction proposal.

Table 16: Cost effectiveness

Cost effectiveness (excl. PPL) - €/kg				
Compliance Period	**Emissions Costs**	**Low**	**Average**	**High**
2 years	Low	<0	<0	<0
	Medium	540	**400**	310
	High	1 100	830	650
5 years	Lower	10	10	8
	Medium	590	**430**	340
	Upper	1 200	900	710

As shown in the table, the cost-effectiveness ranges from below zero to 1200 €/kg D4/D5 reduced. Using the average emission reduction and the average costs, the estimates are around 400 €/kg for a 2 year compliance period and 430 €/kg for the 5 year compliance period. Keeping in mind that the costs are likely to be underestimated due to the non-quantified elements, testing cost and product performance loss, SEAC concludes that the real cost-effectiveness is still likely to be well below 1000 €/kg.

SEAC has no established benchmarks to compare these cost-effectiveness estimates with. One set of indicators can be to look at previous restriction proposals for substances with similar properties. The Dossier Submitter cites cost effectiveness for decaBDE (€464/kg), PFOA (< €1 649/kg), PFOA-related substances (€125 - €4 000) and lastly phenyl mercury (€ 649/kg), which all were considered likely to be proportionate by SEAC. The cost-effectiveness estimates for the proposed restriction are in the same range as all the above mentioned estimates. Even though the other mentioned restriction proposals are not directly comparable in terms of impacts, **SEAC finds that the similarities are sufficient to conclude that the proposed restriction is likely to be proportionate from a cost-effectiveness point of view.**

3.3 BREAK-EVEN ANALYSIS

There are several ways of calculating the necessary WTP to break even with the net economic impact costs of the restriction. In general, a break-even analysis would be a back calculation of the costs in such a way that if you replace the WTP used in the benefits calculation with the necessary WTP estimated in the break even, the resulting benefits estimates should be the same. In the Background Document the Dossier Submitter discuss

whether it is most reasonable to assume that the WTP estimates from the WTP study are connected to removing the use of the substance (precautionary valuation) or to removing the emissions (impact valuation). For each of these assumptions one would get a different attributable fraction of the WTP, which leads to different benefits estimates. Even though the benefits estimates are no longer used quantitatively, SEAC has chosen to use the same two assumptions in the break-even analysis.

The approach used to calculate the necessary WTP can be described as follows:

$$WTP_{tot}\ (attributable\ fraction\ ) = WTP_{ind} * const\ (compliance\ period)$$

This means that the annualised total WTP (based on either emission or use as the attributable fraction) is proportional to the individual WTP, but the constant being dependent on the chosen compliance period. The constant is calculated based on the annualised total WTP and individual WTP when using the estimates from the WTP study. When back calculating one can then find the necessary individual WTP to pay that would yield annualised total benefits equal to the costs. To reduce the number of estimates, only the average emission reduction capacity is used. The results from these calculations are summarised in the table below:

Table 17: Break-even analysis

Break-Even - Neccessary WTP in € per person			
Compliance Period	**Costs**	**WTP connected to emission reduction**	**WTP connected to use**
2 years	Low	-0,01	-0,2
	Medium	0,2	2,7
	High	0,4	5,7
5 years	Low	0,0	0,1
	Medium	0,2	3,2
	High	0,5	6,5

The necessary WTP ranges between - €0.2 and €6.5 per person[20], if the WTP is assumed connected to the use. If the WTP is connected to emissions the range is reduced to - €0.01 – €0.5. In all cases, the necessary WTP is higher for the five year compliance period.

SEAC notes that the necessary individual WTP estimates are fairly low for all the realistic scenarios. Moreover, if the more typical impact based WTP assumption is used, the necessary WTP is less than €0.5 per person for all the cost scenarios. Keeping in mind that there is some underestimation of the costs and in some cases the costs are even negative. This by itself is not enough to conclude on the proportionality of the proposed restriction.

3.4 AFFORDABILITY

Affordability in this case can be defined[21] as an actor's ability to pay, e.g. in terms of income or profits, relative to the size of the enforced costs. As long as the actors are able to pay, that is the enforced cost is not larger than the income or profit, the measure can be seen as 'affordable'. However, it should be underlined that an affordable measure is not necessarily economically feasible, and affordability does not in itself imply a measure is (net) beneficial for society.

As presented by the Dossier Submitter the price increase arising from the cost of the restriction will be small. Using the new additional estimates outlined above (and in Appendix

[20] Only counting people over the age of 15, as was done by the Dossier Submitter.
[21] There is no general definition of affordability, as it is not an analytically defined concept.

I of the Background Document), SEAC has estimated the price increase by dividing the respective cost to industry (excluding cost saving, which is an externality for the affected companies) by the total sales revenue for wash-off PCPs containing D4 and D5. The Dossier Submitter only provided sales revenue numbers for the PCPs containing D5, but considering the low tonnages of D4 as compared to D5 (and then probably comparably low revenue numbers), SEAC finds this underestimation to be acceptable for the purpose of the affordability analysis.

Based on the additional cost estimates as well as the abovementioned sales revenues, SEAC concludes that the price increase is likely to be <1.5% for the high cost scenario and <1% for the low cost scenario. It is noted that the product performance loss should not be (and is not) included in the affordability assessment, as these costs are intangible costs, only experienced by the consumers if they experience that the product they use has lower quality. The potential industry testing costs, on the other hand, should have been included, so the costs will still be somewhat underestimated. Keeping this in mind, SEAC observes that PCPs tend to vary considerably more in price between similar products than by the price increase estimated by the Dossier Submitter as a result of the proposed restriction e.g. you may find one shampoo being twice the price of another shampoo. **SEAC thus agrees with the Dossier Submitter's conclusion that even the worst-case price increase will be affordable for the consumers.**

However, it is not certain that these costs would be transferred to consumers through a price increase, in particular if the products in question lose some of their superior quality due to substitution of D4 and D5. Assuming as a worst-case scenario that none of the costs can be transferred to the consumers through prices, the companies in question would have to face a loss in revenue. If the retail sector is bearing the costs, the percentage loss would be the same as for the consumer: <1.5% and <1% for the high and low cost scenarios, respectively. If instead the manufacturers will bear the costs, the loss would be <2.5% for the high cost scenario and <1% for the low cost scenario. Whether this is affordable or not will depend on the profit margins of the affected companies. The exact profit margin for the affected companies is not known, but SEAC found some weak evidence claiming that skin and haircare products typically have profit margins greater than 60%[22].

In the public consultation SEAC asked if the 60% profit margin was representative, and one industry representative confirmed that the profit margin is representative for "wash-off" cosmetic products[23]. Another actor suggested that EBIT would be a better measure for affordability, and gave references showing that the profit margin (based on EBIT) would be around 12%[24]. This is still considerably higher than the worst-case scenario cost increase of <2.5%, based on the highest costs estimates combined with no cost transfer to consumers. By applying the definition of affordability as stated above, **SEAC concludes that the costs are likely to be affordable for the affected industry.**

3.5 QUALITATIVE INFORMATION

SEAC recognises the qualitative information which further elaborates on the damage potential of D4/D5.

Of the evaluated elements presented in Annex F.3 in the BD, RAC has identified long-range transport as a potential area of concern. The Dossier Submitter found that long-range transport was less problematic in the case of D4/D5, due to the limited re-deposition potential. RAC, on the other hand states that even with low deposition rates, the high volume of emission to air (not just by wash-off PCPs) may be a source of risk to remote

[22] http://www.forbes.com/sites/ryancaldbeck/2014/02/06/why-you-should-think-about-investing-in-beauty-instead-of-bitcoin/
http://newhope360.com/product-development/5-reasons-great-investors-brands-focus-gross-margin

[23] SEAC draft opinion consultation comment number 302
[24] SEAC draft opinion consultation comment number 303

areas.

SEAC takes note of RAC's concern, and finds that this provides an additional argument in favour of the proposed restriction, in addition to the PBT/vPvB concern.

3.6 OVERALL CONCLUSIONS AND PROPORTIONALITY

As presented above, the restriction proposal has been evaluated using several different proportionality measures. SEAC notes that the CBA and the break-even analysis are inconclusive, since the benefit estimates were deemed too uncertain to be directly compared with the costs. However, it is highlighted that there is evidence of a WTP for avoiding D4/D5 accumulation in the environment, and this WTP is substantially larger than the WTP to preserve the superior product quality. SEAC also notes that several of the cost estimates are negative, meaning that the cost saving incurred by the anaerobic digestion plants, are under some assumptions, enough to justify the restriction.

The CEA and affordability measures indicate that the restriction is likely to be proportionate. Even though each measure by itself has uncertainties connected to it, the collective evidence is very strong. **By taking into account all the available evidence, SEAC concludes that the proposed restriction is likely to be proportionate.**

3.7 COMPLIANCE PERIOD

The socio economic analysis can give an indication of which of the two proposed compliance periods that would be most beneficial to society.

A quantified CBA could not be performed, due to the underlying uncertainties in the WTP study, and thereby, the benefit estimates. Hence, from a cost-benefit point of view there is no conclusive evidence pointing in the direction of any particular compliance period.

All of the cost-effectiveness estimates indicate that the two year compliance period would be most cost-effective. However, the estimates for the two year and the five year compliance periods are very similar under all scenarios. Taking into account the remaining uncertainties, in particular the omission of some cost elements, the evidence is not conclusive.

The break-even estimates leads to the same ambiguous conclusion as the cost-effectiveness estimates. All of the necessary WTP estimates are higher for the five year period, and thus favouring a two year compliance period. On the other hand, also here the estimates are so similar across the different compliance periods, that one cannot conclude that one of the compliance periods are considered more beneficial from a break-even point of view.

The potential increase in the consumer price of PCPs is considered affordable for the end user in all scenarios for both compliance periods. The price increase will be higher, the higher the costs are, which means that the five year compliance period is more affordable under all sets of assumptions. The same conclusion will be reached if affordability for industry was used as a measure, so in general the five year compliance period is preferable from an affordability point of view.

From the combined analytical evidence there is a slight favouring of the two year compliance period, but no clear conclusion can be drawn. However, it should be underlined that the analytical modelling does not take into account potential costs that may occur if it is not technically possible to reformulate and test the products during the chosen compliance period. At the same time, there might be negative long-term effects for the environment, which are not captured in the current analysis.

Industry has contributed with information, both before and during the public consultation on the length of time to market reformulated products, including detailed descriptions of each

of the steps in the substation process. The information provided from different respondents is claimed as confidential and varies significantly between respondents[25]. SEAC notes that it has been known by industry for several years that regulation of these substances was likely to come. It thus seems reasonable to assume that industry would have started parts of the processes already, at least the search for potential alternatives. Still, this does not undermine the fact that the suggested compliance periods may be too short to complete reformulations for all affected actors and all affected products.

Some industry actors[26] are also worried about the possible scenario of a market recall, as some of the products are claimed to have a shelf life of several years between production and purchase. A product recall is said to damage the reputation of the company at hand, as well as create unnecessary product waste. SEAC agrees that a product recall would be unfortunate, and considers that the main purpose of the compliance period is to prevent unavoidable product recall and destruction.

During the public consultation on the draft SEAC opinion, one industry actor specified that cosmetics have shelf-lives of up to five years[27]. However, no specific examples or justification was provided to support this statement. Therefore, it is not known whether this shelf-life applies to the product types covered by the proposed restriction. Furthermore, a long shelf-life alone does not mean that PCP producers or retailers keep products in stock for long periods of time, and no examples of PCP producers or retailers needing to keep stocks of wash-off PCPs (e.g. shampoos and conditioners) for more than two years were provided in the consultation. In other words, it may be the case that if production of products containing D4/D5 is stopped in ample time before the end of the compliance period, the costs associated with product recall and destruction can be avoided.

SEAC notes that the number of affected products is probably highly overestimated in the Medium and the High cost scenarios. Looking at the new products releases between March 2012 and March 2013, the share of wash-off products containing D5 was only 0.13%. If this is somewhat representative for the coming years as well, temporarily reducing the product portfolio by 0.13% is not necessarily a large burden for consumers. In response to a specific request by SEAC to respondents to the public consultation on the SEAC draft opinion, industry actors stated that (some) products containing D4/D5 have specific consumer benefits, which may be lost from the market place under a two year compliance period. However, neither the nature of these benefits, the share of the product portfolio having such properties nor any examples of such products were provided. This makes it difficult for SEAC to draw any firm conclusion based on the stated information.

From the information provided by industry and the Dossier Submitter throughout the restriction process, it seems unlikely that all companies will achieve full substitution for the products containing D4/D5 within a 2- or 5- year compliance period. Therefore, under both of the compliance periods considered, it is likely that there will be a temporary loss of products with specific properties that can currently only be achieved by using D4/D5. The most likely response from consumer is then to find similar (but possibly inferior) products to use as substitutes. Some consumer surplus loss may occur, but it may also be the case that all of the product performance loss will be captured in a price reduction and thus be included in the profit loss for industry.

In the time period before full substitution is achieved, the EU industry will have a loss corresponding to the difference in profits between the products containing D4/D5 and the profits made from selling similar (inferior) products. The size of this loss will depend on how large share of the products are produced with D4/D5 and the relative difference in profit margins compared to products without D4/D5. SEAC did not receive any specific information

[25] Annex XV restriction report consultation comments 1417 and 1428
[26] Annex XV restriction report consultation comment number 1428 and SEAC draft opinion consultation comment numbers 302 and 303
[27] consultation comment 303

on this in the public consultation, despite specifically requesting this from respondents, meaning that no conclusion on the likely size of this profit loss can be drawn.

An industry actor stated that it was unlikely that a company would have D4/D5 in all their products, but that a significant portion of the portfolio could be affected[28]. No examples were given, so it is difficult to reach a conclusion on potential shut downs, if substitution was not successful within a 2-year compliance period. It is, however, likely that the burden of the temporary profit reductions may be worse for SMEs than for larger actors.

In conclusion, based on the information available, SEAC does not consider that additional costs connected to product recall and destruction under a two year compliance period would be unavoidable. Furthermore, there is no substantiated evidence available indicating that any temporary reduction in profit margins and product performance loss resulting from a shorter compliance period, would outweigh the reduction of risk from avoiding three years of additional emissions of D4/D5 to the aquatic environment.

SEAC is therefore basing its recommendation on the weak conclusions from the proportionality assessment, favouring a compliance period of two years.

Practicality, incl. enforceability

Justification for the opinion of RAC

Implementability and manageability

During PC (see comment # 1455) it has been confirmed that an important portion of the market of wash-off PCPs has already phased out of D4 and D5. In addition, alternative substances and substitutes are available for all types of wash-off PCPs. The implementation of the proposed restriction (by switching to alternative substances and substitutes) is clear and understandable to all actors involved. Also the public consultation has shown that analytical methods are likely to be available.

RAC is of the opinion that the proposed restriction should come into force no later than 2 years after publication in the Official Journal, preferable after 18 months (in line with the RAC opinion on the restriction of decaBDE and PFOA). From the risk (reduction) perspective the minimisation of emissions into the environment from PBT and vPvB substance should be achieved as soon as possible. This is of particular importance in this specific case, because the registration dossiers do not identify D4 and D5 as fulfilling the REACH Annex XIII criteria for PBT and/or vPvB substances and consequently the operating conditions and risk management measures in REACH Registration CSRs are inadequate to minimise emissions into the environment. ***Conclusion 14:*** **RAC concludes that the proposed restriction is implementable and manageable and shall preferably enter into force after a transitional period of 18 months.**

Justification for the opinion of SEAC

Summary of the proposal

There is no one-for-one drop-in alternative for D4/D5 in wash-off PCPs. However, the Dossier Submitter notes in the Background Document that around 64 % of wash-off PCPs (by sales volume) do not contain any D4 or D5. Based on this, the Dossier Submitter considers that substitution is generally technically and economically feasible for this product type, and that the proposal is considered implementable and manageable.

Companies that produce products that currently contain D4/D5 need to reformulate their

[28] SEAC draft opinion consultation comment 303

products, or cease their production, before the entry into force of the restriction. They may also need to seek confirmation from their supplier about the concentration of D4/D5 in the polymers they purchase. The retailers may request declaration from their suppliers that none of their products contains D4 and D5 above the proposed concentration limit of 0.1 per cent w/w. The enforcement authorities could review such agreements, along with assessment of ingredients lists on the product label (which is required by the Cosmetics Regulation) to enable sampling products more likely to be non-compliant. Subsequent sampling and analysis would then show the level of compliance.

According to the Dossier Submitter, there are no standard analytical methods to measure the content of D4/D5 in PCPs, however, suitable analytical methods exist. The limit of detection of such methods is typically around 0.1 ppm, which means that the suggested concentration limit of 0.1% w/w is well above the detection limit. Furthermore, industry has indicated in the public consultation that considerable effort is being put into developing a standardised method to detect D4/D5 in PCPs at the proposed concentration limit if 0.1% w/w[29]. The restriction is therefore considered enforceable.

SEAC view

SEAC concludes that the proposal is implementable, enforceable and manageable.

Key elements underpinning the SEAC view

SEAC does not have enough information to firmly conclude that there exist alternatives for all identified uses within the scope of the restriction proposal. However, since there exist so many similar products on the market without D4/D5, SEAC finds it likely that D4/D5 is replaceable and that the alternatives are likely to be both technically and economically feasible. SEAC does not exclude the possibility that replacing D4/D5 in wash-off PCPs might result in some product performance loss. However, SEAC concludes that the restriction proposal is implementable.

The Forum states that it is not necessary to develop a standardised sampling method for this restriction, and that even though no specific analytical method exists for the analysis, there are various methods available in the literature. The Forum considers the restriction to be enforceable, and finds the enforcement of the restriction practicable. It was indicated in the public consultation that there are challenges with measuring D4/D5 at a 0.1% w/w concentration level in PCPs, due to inference from other PCP components, particularly silicone polymers[30]. SEAC takes notes of these challenges, but also of the significant efforts put into developing a standardised analytical method by industry that will address the formation of analytical artefacts. As such, SEAC therefore concludes that the restriction is enforceable.

The Dossier Submitter lays out the necessary steps for ensuring compliance for the different actors (producers, retailers, governments), and these are considered by SEAC to be understandable and manageable for all the involved actors.

Based on the available evidence (see discussion on compliance period above), SEAC cannot firmly conclude on the manageability of the proposed restriction, but notes that a shorter compliance period is likely to be more challenging for industry than a longer one.

[29] Annex XV restriction report consultation comment number 1419, SEAC draft opinion consultation comment number 52x
[30] Annex XV restriction report consultation comment number 1419, SEAC draft opinion consultation comment number 52x

Monitorability

Justification for the opinion of RAC

Monitoring of the proposed restriction will be conducted through regular enforcement activities for wash-off PCPs on the market. Ongoing environmental monitoring might also illustrate the effectiveness of the restriction.

During the public consultation an issue was raised regarding analytical artefacts that can be introduced during the analysis of D4/D5 during sample injection. RAC notes that industry (see comment # 1419) is currently working on the development of a suitable standardised method for the analysis of D4 and D5 in PCPs.

Justification for the opinion of SEAC

Summary of the proposal

The Background Document notes that existing mechanisms, such as labelling requirements of the Cosmetics Regulation, should help to identify relevant PCPs for targeted analysis, and that monitoring in general will be carried out through regular enforcement activities for PCPs.

Environmental monitoring of the receiving environment is suggested to provide further evidence about whether the restriction is effective reducing the identified risks.

SEAC view

SEAC agrees that the restriction is monitorable.

Key elements underpinning the SEAC view

In the public consultation SEAC received a comment outlining the challenges with developing a suitably robust and representative monitoring programme for D4 and D5 in the environment[31]. SEAC notes that developing such a programme will require both time and resources, but the restriction is still considered to be monitorable.

[31] SEAC draft opinion consultation comment 52x

BASIS FOR THE OPINION

The Background Document, provided as a supporting document, gives the detailed grounds for the opinions.

Basis for the opinion of RAC

The main changes introduced in the restriction as suggested in this opinion compared to the restriction proposed in the Annex XV restriction dossier submitted by UK are:

- At RAC-35 the use of the term "rinse-off" cosmetic product (defined as per the Cosmetics Regulation (EC) 1223/2009) was introduced to replace the Dossier Submitter's term "wash-off personal care product". This change was proposed by the Dossier Submitter to enhance enforceability and was endorsed by the Forum. At RAC-35 comments from industry highlighted that certain "rinse-off cosmetics" are not intended to be used with water and would therefore not result in wastewater emissions (e.g. certain make-up removing PCPs, including wipes). As the Dossier Submitter's intention was not to capture in the restriction PCPs that are not used or disposed with water a derogation[32] was proposed to ensure that rinse-off PCPs that are not intended to be used, removed or disposed of with water were not included within the scope of the restriction. The proposal derogation text was provided to the Forum and Industry Stakeholders (Cosmetics Europe) for their comments. Forum considered that the wording of this derogation could be difficult to enforce and that restrictions should be as simple as possible. Industry Stakeholders were concerned by use of the "rinse-off" terminology that they considered was not appropriate to a restriction proposal intended to address environmental risks. At RAC-36 the term "rinse-off" was replaced with a proposed wording to specify *"cosmetics used or disposed with water….."*. The term "*used*" refers to the intended use of the product as described on packaging instructions. This wording reflects the intended scope of the Dossier Submitter and avoids the uncertainty introduced by the use of "rinse-off" cosmetics that includes products that are intended to be used both with and without water.

- At RAC-35 the ECHA Secretariat elaborated the proposed wording to highlight the implications of including the term "use" in the restriction, particularly with respect to its applicability to substances that could contain D4 or D5 as impurities during the formulation of PCPs based on alternatives to D4 or D5. Comments from the Dossier Submitter highlighted that it was not the intention of the restriction to prevent the formulation of PCPs using alternatives to D4/D5. At RAC-36 the wording of the proposal was modified to refer to "placing on the market" only, rather than use, reflecting that risks arise through the use of PCPs containing D4 or D5 by consumers and professionals.

- RAC notes that the intention of the proposed restriction is described in the BD and the opinion and that it could be achieved in a variety of ways. RAC has not intended to modify the intended scope of the restriction by proposing revisions to the Dossier Submitter's proposal, but reflect advice received during opinion development. RAC notes that further versions of the wording could equally be effective in capturing the proposed scope of the restriction and that the Commission will decide on the final wording of the proposal.

- RAC considers that the relative contribution to total emissions from leave-on PCPs remains highly uncertain, and could be significant. Equally, RAC considers that emissions from the formulation of wash-off PCPs as well as from anti-foam uses in pulp, paper and

[32] By way of derogation, paragraph 1 shall not apply to rinse-off cosmetics that are not used, removed or disposed with water under normal use conditions where use instructions are product labelling advise how to use the product without water and to dispose of waste materials, including used pads, tissues or wipes, in solid waste.

detergents and direct emissions from oil and gas industry may continue to contribute to emissions of D4 and D5 to the aquatic environment after this restriction comes into force. RAC recommends, given the level of remaining uncertainty surrounding the emissions assessment, that a review should be carried out no later than five years after any restriction coming into force.

- In the consultation on the SEAC opinion, an industry representative (2nd consultation comment COM 303) commented on the wording proposed in the final RAC opinion and stated that they considered that the "wash-off" terminology initially proposed by the Dossier Submitter more accurately captured the scope of the products to be included in the restriction that the RAC wording of "cosmetics used with water". The same respondent also considered that the term "disposed [with water]" may inadvertently include leave-on cosmetic products (e.g. body lotions) that are eventually washed-off with water when the consumer takes a shower, which was not the Dossier Submitter's intention. The industry representative considered that the restriction text capture cover cosmetic products that are washed off from the hair and body within several minutes of application in accordance with normal use instructions where the rinsate is discharged to wastewater.

Basis for the opinion of SEAC

The main changes introduced in the restriction as suggested in this opinion compared to the restriction proposed in the Annex XV restriction dossier submitted by UK are:

- SEAC has included several additional cost calculations:

    1. SEAC delayed the onset of the raw material costs until after the compliance period and computed an annuity based on a 20 year analytical period.
    2. The assumption that ongoing R&D can be coordinated with the R&D necessary to substitute D4/D5 was relaxed (co-ordination was only considered possible for an initial 5-10 year period after the entry into force of the restriction).
    3. SEAC disregarded the cost-savings assumed by the Dossier Submitter for minor reformulations during the compliance period and assumed that the costs of these would be unaffected (i.e. zero cost assumption, rather than cost savings).
    4. SEAC considered that it was likely that the number of reformulations required had been overestimated, exaggerating the potential costs of the restriction. SEAC therefore included additional cost scenarios where fewer reformulations were required.
    5. SEAC has assumed that the cost of reformulation will be distributed evenly across the compliance period, and not all in the last year before entry into force.
    6. SEAC updated the cost savings estimates using a 4% discount rate and a 20 year analytical period to make them consistent with the other cost estimates.

- SEAC used these additional cost calculations, in combination with the updated emissions estimates from RAC, to calculate a range of new cost-effectiveness estimates.

- SEAC used these additional cost calculations to revise estimates of affordability for both consumers and cosmetics producers. In addition, SEAC updated the break-even analysis provided in the Background Document and decided to calculate the necessary willingness to pay (WTP) in two ways: 1), assuming that WTP was connected to emission volumes (impact-based valuation) or 2), that WTP is connected to use volumes (precautionary-based valuation).

- The Dossier Submitter provided a WTP study and used the results from this study to

quantify the benefits of reducing D4/D5 emissions, and to estimate potential consumer surplus loss from reduced product quality if perfect substitution was not achievable. SEAC did not consider that the results from the WTP study were robust enough to be used quantitatively. Benefits and consumer surplus loss is therefore only evaluated qualitatively in the SEAC opinion.