Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5) and

Dodecamethylcyclohexasiloxane (D6)

ECHA/RAC/RES-O-0000006700-80-01/F

ECHA/SEAC/RES-O-0000006742-72-01/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 28 November 2019) and SEAC's opinion (adopted 12 March 2020)

28 November 2019

RES-O-0000006700-80-01/F

12 March 2020

RES-O-0000006742-72-01/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 (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	**Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5) and Dodecamethylcyclohexasiloxane (D6)**
EC No.:	**209-136-7; 208-764-9; 208-762-8**
CAS No.:	**556-67-2; 541-02-6; 540-97-6**

This document presents the opinions adopted by RAC and SEAC and the Committee's justification for their opinions. The Background Document, as a supporting document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitter's proposal amended in response to further information obtained during the consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

ECHA 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 **20 March 2019**. Interested parties were invited to submit comments and contributions by **20 September 2019**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

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

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

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **28 November 2019**.

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

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

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: ***Martien JANSSEN***

Co-rapporteur, appointed by SEAC: ***Jean-Marc BRIGNON***

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **5 December 2019.**

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

The draft opinion was published at http://echa.europa.eu/web/guest/restrictions-under-consideration on **18 December 2019.** Interested parties were invited to submit comments on the draft opinion by **18 February 2020.**

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **12 March 2020.**

The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and][5] 71(1) of the REACH Regulation.

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

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OPINION OF RAC AND SEAC

The proposed wording of the restriction set out below aims to express the intention of the Dossier Submitter. Should a restriction be adopted then the final wording of the Annex XVII entry will be decided by the European Commission. Any final wording should take into account entry 70 of Annex XVII, which already restricts the placing on the market of D4 and D5 in wash-off cosmetic products.

The restriction proposed by the Dossier Submitter is:

Brief title: Restriction of D4, D5 and D6 in consumer and professional products

Designation of the substances, of the group of substances or of the mixture	Conditions of restriction
a) Octamethylcyclotetrasiloxane EC Number: 209-136-7 CAS Number: 556-67-2 INCI name: Cyclotetrasiloxane or Cyclomethicone *Also known as D4.* **b) Decamethylcyclopentasiloxane** EC Number: 208-764-9 CAS Number: 541-02-6 INCI name: Cyclopentasiloxane or Cyclomethicone *Also known as D5.* **c) Dodecamethylcyclohexasiloxane** EC number: 208-762-8 CAS number: 540-97-6 INCI name: Cyclohexasiloxane or Cyclomethicone *Also known as D6.*	1. Shall not be placed on the market: a) As substances. b) As constituents of other substances (except polymers as defined under the REACH Regulation (EC) No 1907/2006), in a concentration equal to or greater than 0.1% w/w. c) As constituents in mixtures in a concentration equal to or greater than 0.1% w/w. 2. Shall not be used: a) As a solvent for the dry cleaning of textiles, leather and fur. 3. This restriction shall come into force: a) On DD/MM/YY [at least 5 years after publication in the Official Journal] for (i) leave-on cosmetic products (as defined in the Regulation (EC) No 1223/2009 – Preamble to Annexes II to VI), and (ii) medical devices as defined in the Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to the Regulation (EU) 2017/745. b) On DD/MM/YY [at least 7 years after publication in the Official Journal] for (i) medicinal products for human health as defined in EU Directive 2001/83/EC, and (ii) veterinary medicinal products as defined in EU Directive 2001/82/EC or in Regulation (EU) 2019/6. c) On DD/MM/YY [at least 10 years after publication in the Official Journal] for D5 as a cleaning solvent in the dry cleaning of textiles, leather and fur. d) On DD/MM/YY [at least 2 years after publication in the Official Journal] for all other uses. 4. By way of derogation, paragraph 1 shall not apply to: a) Placing on the market of D4, D5 and D6 for the following uses: - Industrial use as a monomer in the production of silicone polymer - Industrial use as an intermediate in the production of other organosilicon substances - Industrial use as a monomer in emulsion polymerisation

Designation of the substances, of the group of substances or of the mixture	Conditions of restriction
	- Industrial use in formulation and/or (re-)packing of mixtures - Industrial production of articles - Industrial use in non-metal surface treatment - Industrial use as laboratory reagent in Research & Development activities b) Placing on the market of D5 and D6 for use as medical devices, as defined in Directive 93/42/EEC or in the Regulation (EU) 2017/745, for the (i) treatment/care of scars and wounds, (ii) prevention of wounds, and (iii) care of stoma. c) Placing on the market of D5 for professional use in the cleaning or restoration of art and antiques. 5. In addition, by way of derogation, paragraph 1 shall not apply to the placing on the market of mixtures that contain silicone polymers with residues of: a) D4 or D5 or D6 in a concentration equal to or less than 1% w/w, for use in adhesion, sealing, glueing and casting b) D5 in a concentration equal to or less than 0.3% w/w or D6 in a concentration equal to or less than 1% w/w, for use as medical devices (as defined in Directive 93/42/EEC or in the Regulation (EU) 2017/745) for dental impression. c) D4 in a concentration equal to or less than 0.5% w/w, or D5 or D6 in a concentration equal to or less than 0.3 % w/w for use as protective coatings (including marine coatings). d) D5 in a concentration equal to or less than 1% w/w or D6 in a concentration equal to or less than 3% w/w, for (i) rapid prototyping and mould making, and (ii) high performance uses stabilised by quartz filler. e) D4 or D5 or D6 in a concentration equal to or less than 0.2% w/w, for use as medical devices as defined in Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to the Regulation (EU) 2017/745. f) D4 in a concentration equal to or less than 0.2% w/w, or D5 or D6 in a concentration equal to or less than 1 % w/w for use as silicone insoles for horses, or as horseshoes. g) D4 or D5 or D6 in a concentration equal to or less than 0.5 % w/w, for use as adhesion promoters. h) D6 in a concentration equal to or less than 1 % w/w, for professional use in the cleaning or restoration of art and antiques. i) D5 or D6 in a concentration equal to or less than 1 % w/w, for use in pad printing, or manufacturing of printing pads. j) D4, or D5, or D6 in a concentration equal to or less than 1 % w/w, for use in 3D-printing 6. By way of derogation, paragraphs 1 and 2 shall not apply to:

Designation of the substances, of the group of substances or of the mixture	Conditions of restriction
	a) Use of D5 in strictly controlled closed dry cleaning systems for textile, leather and fur where the cleaning solvent is recycled or incinerated.

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of 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 restriction proposed by the Dossier Submitter on **octamethylcyclotetrasiloxane (D4); decamethylcyclopentasiloxane (D5); dodecamethylcyclohexasiloxane (D6)**, **CAS 556-67-2; 541-02-6; 540-97-6**, **EC 209-136-7; 208-764-9; 208-762-8** is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion.

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the restriction proposed by the Dossier Submitter on **Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5); Dodecamethylcyclohexasiloxane (D6) , CAS 556-67-2; 541-02-6; 540-97-6, EC 209-136-7; 208-764-9 ; 208-762-8** is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs as demonstrated in the justification supporting this opinion.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

Description of and justification for targeting (scope)

Summary of proposal:

Octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6) are volatile, cyclic substances with four, five and six dimethyl siloxane groups, respectively. They have been grouped for the purposes of this restriction proposal as they have a similar chemical structure and hazard profile (all are identified as vPvB substances[1]); a substance-by-substance approach to restriction could result in 'regrettable substitution'. The substances are mainly used as monomers for the production of silicone polymers but are also used as substances on their own or in mixtures that are used by consumers and professionals.

In 2015, the UK proposed a REACH restriction on the use of D4 and D5 in wash-off cosmetic products. In their opinion on the proposal (ECHA, 2016), ECHA's scientific committees for risk (RAC) and socio-economic analysis (SEAC) concluded that the proposed restriction on the placing on the market of D4 and D5 in wash-off cosmetics was targeted and appropriate, but were unable to exclude the potential that the risks from the use of D4 and D5 in leave-on cosmetic products were not adequately controlled[2]. The Commission published a decision amending Annex XVII of REACH, adopting the proposed restriction on wash-off cosmetic products, in January 2018. The restriction will enter into effect from 31 January 2020.

In December 2016, the European Commission requested ECHA (hereafter referred to as the Dossier Submitter) to prepare a further Annex XV restriction proposal on uses of D4 and D5 in leave-on cosmetic products and in other consumer or professional products that were not covered by the UK's proposal. In February 2018, the European Commission additionally requested ECHA to include uses of D6, including in wash-off cosmetic products, in the scope of the proposal. In order to target only consumer and professional uses of D4, D5 and D6, the conditions of the proposed restriction explicitly exclude registered industrial uses of D4, D5 and D6 from the scope by means of the derogation described in paragraph 4(a) of the conditions of the restriction.

Uses of silicone polymers are not specifically targeted by the proposal but may be inadvertently impacted if they contain D4, D5 or D6 as impurities above the proposed specific concentration limit of 0.1% w/w. The Dossier Submitter assessed the impact of the proposed restriction on uses of silicone polymers and has proposed specific derogations to avoid unintended impacts, where these are justified as necessary. This is in line with the request to the Dossier Submitter from the European Commission.

[1] D4 is also identified as a PBT substance

[2] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18050cc56

RAC conclusions:

RAC concludes that the rationale and justification for grouping D4, D5 and D6 (similar chemical structure, physical/chemical substance properties, hazard profile, potential for regrettable substitution) for the purpose of the proposed restriction is clear.

RAC concludes that the rationale and justification for targeting the proposed restriction at consumer and professional uses is clear (as set out in the request to the Dossier Submitter from the European Commission[3]). It specifically targets substances or mixtures intended for end use by consumers or professionals. The restriction should also not apply when substances or mixtures are transported between industrial sites or where a substance or mixture is imported into the EU for downstream (or intermediate) use at an industrial site. Consequently, the Dossier Submitter proposes a derogation for placing on the market for specified industrial uses (i.e. those industrial uses identified in the respective registration dossiers).

RAC concludes that the reasons to exclude the silicone polymers from the scope of the restriction are clear (as set out in the request to the Dossier Submitter from the European Commission[4]).

RAC therefore supports the proposed scope of this restriction.

Key elements underpinning the RAC conclusions:

The proposed restriction is complementary to and provides a logical extension to the existing restriction on the placing on the market of D4 and D5 in wash-off cosmetic products. The uses are in principle based on the volatility of D4, D5 and D6. These compounds have similar chemical structure and similar physical/chemical substance properties. D4, D5 and D6 could substitute each other which could lead to regrettable substitution.

D4, D5 and D6 are mainly used as monomers for producing a large variety of silicone polymers, which are further used as substances as such, in mixtures and/or as substances in articles. Silicone polymers are extensively used across many different industry sectors, including the construction (sealants, paints and coatings), automotive (parts and lubricants), electronics, pulp and paper, oil and gas, medical and aerospace/defence sectors. Silicone polymers are often present in consumer and professional products, including medicinal products, cosmetic products and in household products.

Several uses of D4 and D5 have recently been removed by registrants from their respective registration dossiers, on the basis that these are now understood not to be uses of the substances as such, but rather uses of silicone polymers that contain residual levels of D4 and D5 as impurities. Instead, a generic use/exposure scenario describing the use of silicone polymers containing residual amounts of monomer has been introduced in most registrations of D4 and D5, including the joint-CSR submitted by the lead registrant on behalf of the other registrants.

The Commission's request for a restriction proposal excludes industrial uses of D4, D5 and D6 (such as formulation of mixtures, production of silicone polymers or production of articles) as well as the use of silicone polymers. These are therefore not in the scope of the proposed restriction or of this opinion. RAC nevertheless notes that raw materials (e.g. silicone

[3] https://echa.europa.eu/completed-activities-on-restriction
[4] https://echa.europa.eu/completed-activities-on-restriction

polymers) could contain D4, D5 and D6 at significant concentrations and that the direct export of these substances is outside of the EU/EEA is not within the scope of the proposal. RAC notes that the long-range transport potential of D4, D5 and D6 are still the subject of scientific debate. Whether emissions of these substances used outside the EU cause exposure within the EU remains to be seen.

Description of the risks addressed by the proposed restriction

Information on hazards

Summary of proposal:

PBT and vPvB substances:

On 27 June 2018, D4, D5 and D6 were identified by ECHA's Member State Committee as SVHC substances with vPvB properties. D4 was also identified as having PBT properties. Further details are available in the corresponding decisions of the ECHA MSC and related support documents [D4: https://echa.europa.eu/documents/10162/680ea46d-b626-1606-814e-62f843fe2750; D5: https://echa.europa.eu/documents/10162/1b116de3-d5f9-40a2-d681-2e00d3953a7b; D6: https://echa.europa.eu/documents/10162/81c323a0-f0ce-8375-5091-b08d44f35553].

RAC conclusions:

RAC takes note of ECHA's Member State Committee decision that D4, D5 and D6 meet the REACH Annex XIII criteria for very persistent and very bioaccumulative substances (vPvB) and that D4 also meets the criteria for a persistent, bioaccumulative and toxic substance (PBT). D5 and D6 are also considered to be PBT substances where the concentration of D4 (as a constituent) exceeds a concentration limit of 0.1 % w/w.

RAC takes note that the identification of a PBT/vPvB substance as a substance of very high concern (SVHC) under REACH is independent of the environmental compartment. ECHA Guidance R.11 specifies that if a 'P' or 'vP' conclusion is reached for one environmental compartment, no further testing or assessment of persistence of other environmental compartments is normally necessary, acknowledging in this way the fact that a conclusion for one compartment has broader environmental implications.

Key elements underpinning the RAC conclusions:

The RAC opinion on the hazards of these substances is based on Section 1.1 of the Background Document, Annex B.8 and the information submitted in the consultation.

Some stakeholders challenged the hazard and intrinsic substance properties of D4, D5 and D6 in the consultation. Comments #2141, #2170, #2177, #2196, #2469, #2638, #2705, #2716, and #2724 disagreed that D4, D5 and D6 have PBT/vPvB properties and with the fact that they have been identified as SVHC by the ECHA MSC. Some comments questioned the toxicity potential of D5 and D6 and questioned if the impact is hazardous as they are "only" vPvB substances. In response to these comments, it should be noted that the identification of D4, D5 and D6 as substances of very high concern due to their PBT/vPvB properties was previously evaluated and decided by ECHA's Member State Committee (MSC) and is not therefore considered by RAC in this opinion.

Information on emissions and exposures

Summary of the proposal:

D4, D5 and, to a lesser extent, D6 are high tonnage substances. They are used as monomers for the production of silicone polymers, but also used as substances on their own or in the formulation of various mixtures that are subsequently used in by consumers and professionals in wide-dispersive applications (e.g. cosmetic products).

The Dossier Submitter has estimated emissions to the environment using the latest information available in the REACH registration dossiers and, where relevant, the min/max release factors adopted by RAC as part of its evaluation of the restriction proposal on D4 and D5 in wash-off cosmetic products (ECHA, 2016). Detailed information on the assumptions used to estimate releases for each use is available in Annex D of the Background Document.

The total releases to the environment have been estimated to be approximately 18 000 tonnes per annum (tpa) (Table 1). Based on the fate of D4, D5 and D6 in the environment the Dossier Submitter also estimated a steady-state stock of D4, D5 and D6 in the EU environment of approximately 500 tonnes associated with these annual releases (and a stock of ca 470 tonnes in the EU environment arising from the releases from cosmetic products only). The steady-state stock estimates the quantity (mass) of D4, D5 and D6 remaining in the environment under steady-state conditions assuming the baseline releases reported in Table 1 and typical fate and degradation processes (estimated using the SimpleBox model).

Table 1: Release estimates per use

Use	Use tonnage [tpa]	Low release scenario (water only) [tpa]	High release scenario (all environmental compartments) [tpa]
Uses within the scope of the proposed restriction			
Leave-on cosmetic products (D5 and D6)	17 000	7 - 50	16 399 – 16 641
Pharmaceutical products and medical devices (D5 and D6)	350	6 - 11	273 - 305
Wash-off cosmetic products (D6)	200	12 - 20	55 - 114
Detergents, household care and vehicle maintenance products (D5 and D6)	90	3 - 6	50 - 66
Dry cleaning (D5)	50	0 - 0	46 - 46
Cleaning of art and antiques (D4 and D5)	0.3	ca. 0	ca. 0.3
Uses outside the scope of the proposed restriction			
Formulation of mixtures[1]	-	0 - 1	5 - 8
Impurity in silicone polymers[2]	1 613	26 - 50	597 - 707
Impurity in silicone polymers used in cosmetic products	638	6 - 12	567 - 595
Grand Total	**19 940**	**63 - 153**	**17 994 – 18485**

Notes:
[1]: Industrial life-cycle stage, included for comparative purposes
[2]: Silicone polymers excluding the uses in cosmetics products

The wide-dispersive use of D4, D5 and D6 in cosmetic products remains the main source of releases. Other uses contribute to the overall releases, but are relatively much less significant.

The Dossier Submitter performed a detailed analysis of the releases across various cosmetic product categories and, where appropriate, sub-categories of cosmetic products. This analysis allows a better appreciation of the contribution and significance of each of them to releases (Table 2).

Table 2: Release estimates per cosmetic product category and subcategory

Cosmetic product category	Use tonnage [tpa]	Low release scenario (water only) [tpa]	High release scenario (all environmental compartments) [tpa] *(% grand total release)*
Leave-on and rinse-off (excluding wash-off) products (D5 and D6)			
Deodorants and antiperspirants	7 316	0 – 20	7201 – 7310 *(42%)*
Hair styling and hair care products ("LEAVE-ON")	4 831	0 – 13	4754 – 4827 *(28%)*
Skin care products[A]	1 932	0 – 4	1906 – 1931 *(11%)*
Make up and make up removing products[A]	1 794	0 – 1	1784 – 1793 *(10%)*
Disposed cosmetics' packaging (leave-on)	850	5 – 9	479 – 502 *(3%)*
Other personal care products	265	0 - 0	261 – 264 *(2%)*
Nail varnish/remover products	3	0 - 0	2 - 2
Products for tanning without sun	3	0 - 0	2 - 2
Products intended for application to the lips[A]	3	0 - 0	2 - 2
Sun protection products	3	0 - 0	2 - 2
Wash-off products (D6)			
Wash-off cosmetics	200	12 – 20	55 – 114 *(0%)*
Presence of impurities (D6)			
Presence of impurities in cosmetics (leave-on and wash-off)	638	6 – 12	567 – 595 *(3%)*
Grand Total	**17 838**	**26 - 83**	**17 022 – 17 350**

Note A: in the SEA these cosmetic product categories have been grouped under the label 'Make-up and lipsticks + Skin care'

RAC conclusions:

RAC notes that the manufacture (import) and use of D4, D5 and D6 are clearly identified, described and listed in the Background Document and that they provide a good basis for the exposure/emissions assessment.

RAC is of the opinion that the exposure estimates derived for each of the identified uses are reasonable. The relevant exposure estimates are well explained and the models used to calculate them are described sufficiently. For each substance, the relevant emissions have been quantified and they are plausible.

RAC notes that the Background Document for the restriction proposed by the UK on D4 and D5 in wash-off cosmetic products estimated Predicted Environmental Concentrations (PECs) and compared them with monitoring data to check that the emission estimates were broadly reliable. The Dossier Submitter for this restriction does not specifically indicate why this has not been done for the current proposal.

Nevertheless, RAC notes that a voluntary industry monitoring programme has provided data on concentrations of D4, D5 and D6 in WWTP influent measured at six EU sites. Industry has updated their registration CSRs based on these measurement campaigns. The release estimates and release factors included in the most recent registration CSRs are only modestly different from the release factors adopted by RAC (ECHA, 2016) in their opinion on the use of D4 and D5 in 'wash-off' cosmetic products. Therefore, RAC concludes that it is reasonable to derive release factors based on theoretical considerations and without measurement data. Consequently, RAC supports the assumptions made by the Dossier Submitter to calculate the emissions of D4, D5 and D6 to both the aquatic and the atmospheric environment in this way.

RAC also concludes that for PBT/vPvB substances, environmental monitoring may be used to check estimates on emissions and on release factors, but may not be used to derive a safe environmental concentration. For PBT/vPvB substances it is not scientifically justifiable to set an appropriate threshold and all releases and every environmental concentration is associated with a risk.

Key elements underpinning the RAC conclusions:

The RAC opinion on emissions and exposures is mainly based on the Background Document section 1.5.3, the annex section B.9 and the information submitted in the consultation.

The exposure assessment performed by the Dossier Submitter follows an approach consistent with that previously described by RAC in their opinion on the proposed restriction on D4 and D5 in wash-off cosmetic products (ECHA, 2016). The Dossier Submitter took into account the releases of D4, D5 and D6 as impurities from silicone polymers when assessing the overall effectiveness of the proposed restriction.

Section B.4.1 on environmental fate modelling gives details of the key assumptions and input parameters used in the multi-media modelling of the fate and environmental distribution *('environmental stock pollution modelling'*) of D4, D5 and D6. The Dossier Submitter used the SimpleBox multi-media fate model, which is widely used in the EU for regulatory risk assessments of chemicals, and is incorporated into the ECHA CHESAR tool and the EUSES model that is routinely used for chemical safety assessment under REACH.

During the consultation, comments were received on the tonnages of D4, D5 and D6 used (e.g. #2034, #2052, #2177, #2344, #2387, #2469, #2481, #2736) and indicate an agreement with the tonnages of D4, D5 and D6 used in the Background Document. These comments focused on clarifying the tonnages used, identifying missing uses (#2034), reporting the residual concentrations of D4, D5 and D6 in final products, as well as highlighting the efforts of industry to reduce residual traces of cyclic siloxanes in polymers and mixtures to below 0.1 %.

Some comments confirmed the tonnages used for some specific uses, such as the use of D5 in head lice treatments (#2052) or the use of D5 and D6 in health care applications (#2052). One comment indicated that rigid PU foam is not a 'direct' use (#2344), which resulted in an update of the Background Document (tonnage used for this use was revised to zero).

Comment #2034 indicated the tonnage of D4 (0.4 t) used in the motor vehicle and motorcycle repair and maintenance sector, while comment #2177 provided clarification on the tonnage of silicone polymers used in cosmetics. Comment #2481 refines the total amount of D4, D5, and D6 present in mixtures sold to the medical device producers or related industrial actors. A company producing sealant polymers (#2736) specified the total tonnage of D4, D5, and D6 and also provided residual concentration of cyclosiloxanes in final products.

Some stakeholders challenged the release estimations by comparing them with measurements in WWTP influents obtained from a recently commissioned industry monitoring programme. Based on environmental monitoring data and information on D5 releases to waste-water from leave-on cosmetic products, comments # 2191 and #2638 claim that there is a significant decline in emissions to the aquatic environment following the introduction of the restriction on D4 and D5 in wash-off cosmetic products in January 2018 (2018/35/EC).

Two comments contain studies on WWTP monitoring data (#2177 for D4 and D5; #2469 for D6) for six locations (DE, SP, PO, SW, UK) in the EU. Information on the estimated mass loading in municipal WWTP influent are given. These comments generally support the release modelling reported by the Dossier Submitter, but RAC notes that extrapolating the results from six sampling points to the EU scale has its limitations due to the representativeness of the sampling locations.

Overall, RAC notes that the reported release factors to waste water for leave-on cosmetics are within the range used by the Dossier Submitter (#2191, #2519, #2638). Furthermore, the estimated mass load in WWTP influent based on monitoring data are in the same order of magnitude as those estimated by the Dossier Submitter. They are (with the exception of the lower estimate for D4) within the upper and lower estimates provided. Comments #2191 and #2638 seem to confirm the decline of D4 and D5 emissions from wash-off cosmetic products. For D6 the estimated mass load based on monitoring data is slightly lower than estimated by the Dossier Submitter. This may be related to a potential overestimate on D6 tonnages by the Dossier Submitter. Indeed, while D4 and D5 have been under regulatory scrutiny for several years, during which the quality of use and tonnage information available has progressively improved, this is not the case for D6, which has only relatively recently been under enhanced regulatory scrutiny.

RAC concludes that the consultation provided additional evidence and confirmed that D6 is released into waste water. The evidence provided seems, on one hand, to demonstrate the effectiveness and monitorability of the existing restriction on D4 and D5 in wash-off cosmetic products and on the other hand provides evidence that further risk management for D4, D5 and D6 is needed.

Characterisation of risks

Summary of proposal:

PBT/vPvB substances give rise to specific concerns based on their potential to accumulate in the environment and cause effects that are unpredictable in the long-term and are impossible to reverse even when releases cease. Therefore, the risk from PBT/vPvB substances cannot be adequately addressed in a quantitative way, e.g. by derivation of risk characterisation ratios. Emissions and subsequent exposure, in the case of a PBT/vPvB substance, are therefore considered as a proxy for risk.

Recent research (Gabbert & Hilber 2016; Gabbert et al., 2018), undertaken for the European Commission, on socio-economic analysis for PBT/vPvB substances in the REACH authorisation and restriction procedures, has reported that a 'stock pollution approach' could provide additional useful information within a socio-economic analysis compared to simply considering releases to environmental compartments.

Therefore, in addition to the 'low' and 'high' release scenarios, a complementary 'environmental stock pollution' scenario was developed by the Dossier Submitter for D4, D5 and D6. This scenario is based on multi-media environmental fate and distribution modelling using the widely used SimpleBox 4.0 model parametrised with relevant environmental fate parameters for the three substances identified from registration dossiers or the recent SVHC decisions for D4, D5 and D6.

Table 3: Steady-state environmental stock pollution associated uses of D4, D5 and D6

Use	Annual use tonnage [tpa]	Steady-state environmental stock pollution [t]
All uses	19 946	493 – 509
Use in cosmetics only (D4, D5 and D6, and impurities)	17 838	463 – 474

RAC conclusions:

RAC concludes that, in general, an 'environmental stock pollution approach' provides additional useful information for the characterisation of the risks posed by PBT/vPvB substances compared to data on the estimated emissions alone. In the case of D4, D5, and D6 the multimedia modelling showed that, in addition to release to water, releases to the atmosphere contribute to a steady-state environmental stock of D4, D5 and D6 and may lead to accumulation in other environmental compartments (including soil and aquatic sediments). Consequently, all releases of D4, D5 and D6 to the environment are of concern, not just those releases that occur to wastewater.

RAC concludes, that total releases of D4, D5 and D6 into the environment should be used as a proxy for risk.

Key elements underpinning the RAC conclusions:

RAC focussed its assessment on the emissions as a proxy for risk with the same scientific argumentation as e.g. in the opinion on the proposed restriction on C9-C14 PFCAs (perfluoroalkyl carboxylic acids: PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA, PFTDA; their salts and precursors (EC#: 206-801-3, 206-400-3, 218-165-4, 206-203-2, 276-745-2, 206-803-4)[5]).

The REACH Regulation recognises that the hazard and exposure assessment of PBT/vPvB substances (i.e. substances that fulfil the REACH Annex XIII criteria) cannot be carried out with sufficient reliability for a quantitative characterisation of risks. Therefore, REACH registrants of PBT/vPvB substances are required to undertake an 'emissions characterisation' and implement or recommend to downstream users risk management measures that minimise emissions into the environment and consequently minimise exposures to humans

[5] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18195edb3

and the environment, throughout the lifecycle of the substance (Annex I).

Annex I of REACH does not differentiate between the environmental compartments that should be considered when undertaking an emission characterisation or minimising releases for a PBT/vPvB substance. Guidance R.11 also specifies that if a 'P' or 'vP' conclusion is reached for one compartment, no further testing or assessment of persistence of other environmental compartments is normally necessary, acknowledging in this way the fact that a conclusion for one compartment has broader environmental implications.

In response to the proposed restriction on D4, D5 and D6, some stakeholders stated in their comments that releases to air are not associated with a concern and consequently do not need to be minimised. Instead, these stakeholders contend that the majority of D4, D5 and D6 in the atmospheric compartment will remain in the atmospheric compartment until it is degraded and although some redeposition will occur to surface media from the atmosphere the concentrations predicted in surface media can be assumed be negligible (as they are below concentrations associated with ecotoxicological effects). On this basis they conclude that releases to the atmosphere can be considered to be irrelevant in terms of risk.

RAC notes that such a conclusion is not consistent with the risk assessment approach for PBT/vPvB substances under REACH, outlined above, as the concentrations of PBT/vPvB substances in individual environmental compartments cannot be assumed to result in negligible risk. Such a conclusion would only be possible for substances where quantitative characterisation of risks can be considered to be reliable.

Multi-media environmental fate modelling was performed by the Dossier Submitter to estimate the proportion of the releases of D4, D5 and D6 that remain 'unrelated' in the environment under steady-state conditions. The model takes into account the predicted partitioning behaviour (between environmental compartments e.g. water and sediment) of D4, D5 and D6 as well as degradation. In simple terms, the modelling estimates the quantity (mass) of D4, D5 and D6 that remains in the environment (in all compartments, including the atmosphere) under steady-state conditions assuming the baseline releases (estimated in Section 1.5.3.2 of the Background Document). The results of the modelling is reported in Section 1.5.4 of the Background Document. Similar modelling has also been performed by the REACH registrants in their CSR.

Annex B.4.1 of the Background Document describes the key assumptions and input parameters used in the multi-media fate modelling. The input parameters are publicly available or have been commented during the consultation. RAC did not evaluate these input values since the most relevant intrinsic substance properties like persistence in the different environmental compartments was already assessed by MSC and/or ECHA's PBT EG.

For D4, D5 and D6, the Dossier Submitter estimated a steady-state stock pollution in the EU environment of approximately 500 tonnes. This fraction comprises a (relatively high) proportion of the total releases that occurred to water and a (much smaller) proportion of the total releases that occurred to air. RAC notes that while only high-level estimates incorporating certain product categories are available, this approach does add valuable qualitative information on the fate and behaviour of D4, D5 and D6 in the environment. As a consequence, RAC concludes that based on the fate of D4, D5 and D6 in the environment, the releases to all compartments (including air) are relevant and cause a concern as they contribute to a steady-state stock pollution of D4, D5 and D6 in the environment.

RAC notes that it is not possible to determine quantitatively the contribution that emissions into air make to the aquatic environment. In the case of D4, D5 and D6 a minor fraction of the high releases to air is expected to accumulate in water and sediment. However, since D4, D5 and D6 are PBT/vPvB substances, and as a consequence of the results from the environmental stock pollution modelling, total emission of D4, D5 and D6 to all compartments environment can best be used as a proxy of risk.

The consultation indicates that, in general, the SimpleBox model is an appropriate tool to explore the fate and partitioning of D4, D5 and D6 (# 2141, #2170, #2177, #2196, #2469, #2705, #2716, #2724). Although some respondents claim that they cannot reproduce the results of the modelling, its reproducibility was confirmed by other respondents (#2191). Comment #2141 questioned the use of the SimpleBox 4.0 in general and comment #2177 and #2213 specifically the use of weight/time, as the output of SimpleBox generates masses on a weight basis only. Comment #2213 criticises the fact that the modelling was not reported in accordance with the principles of "Good Modelling Practice (GMP)".

RAC notes that the Dossier Submitter used a publically available version of a widely used and established multimedia fate model (SimpleBox, version 4.01) precisely to increase the transparency and reproducibility of the simulations. In addition, Tables 2 and 3 in the Background Document recorded the most sensitive input parameters, namely compartmental emissions (total and percentile contributions), key physical-chemical parameters and degradation rates in air.

While the key input parameters mainly originated from the published SVHC identification dossiers, comments on the input parameter degradation rate in air (#2170, #2141 and #2196) indicate that the atmospheric degradation rate constants for cVMS might be greater than assumed by the Dossier Submitter (Whelan et al., 2004). RAC notes that the degradation rates used for the environmental fate and behaviour modelling (see Background document Annex B 4.1.3) were updated by the Dossier Submitter based on these comments. These changes have only a minor impact to the atmospheric concentration of D4, D5 and D6 and thus, on the estimated stock pollution.

The K_{ow} value for D6 was commented (#2177, #2469) although this value is provided in the REACH registration dossiers and disseminated on the ECHA website[6]. However, the value has no impact on the calculation of WWTP efficiency (using SimpleTreat 4), nor on the stock modelling (using SimpleBox 4.0) as the models used calculated Koc values.

Some stakeholders challenged the risk characterisation in general. Comment #2177 presents a quantitative risk assessment using risk characterisation ratios (RCRs) that reports that exposure to D4, D5 and D6 does not lead to a risk being identified for humans (via inhalation) or for freshwater and marine water species.

As pointed out above, RAC notes that the concern for D4, D5 and D6 is caused by their PBT/vPvB properties. For PBT/vPvB substances, a "safe" concentration in the environment cannot be established with sufficient reliability using the methods currently available. Consequently, an acceptable risk must not be determined with a quantitative risk assessment. As a consequence, from a risk point of view there are no acceptable emissions into the environment for PBT/vPvB substances.

Comment #2469 and #2716 questioned the reliability of the Sanchis et al. (2015a) study on

[6] ECHA brief profile accessed on 7 November 2019: https://echa.europa.eu/brief-profile/-/briefprofile/100.007.967

the detection of volatile dimethylsiloxanes in antarctic soils, vegetation, phytoplankton and krill. Similar comments were also made during the evaluation of the previous restriction proposal on D4 and D5 in wash-off cosmetic products and already addressed in that RAC opinion (ECHA, 2016). RAC concluded at that time that further research on the rate of redeposition of D4 and D5 during the polar night is needed. RAC further noted that as the atmospheric releases of D4 and D5 were large even only extremely low rates of redeposition would still be of concern.

RAC notes that because of the PBT/vPvB properties of D4, D5 and D6 atmospheric redeposition does not need to be a significant source of D4, D5 and D6 to cause concern and to require minimisation of the emissions into the atmosphere. For volatile compounds released to air there will always be some partitioning between air and surface media.

In the absence of follow-up monitoring studies in the Antarctic, the conclusion of RAC 2016 remains valid, and would also likely to be valid for D6 because of their similar physical-chemical properties. RAC agrees with the Dossier Submitter that the environmental stock pollution modelling is not intended to provide a definitive estimate of the environmental behaviour of D4, D5 and D6 but rather indicative estimates of the proportion of substance releases that remains "unreacted" in the environment after relevant fate processes are taken into account. Because of the remaining limitations regarding the amount of redeposition to surface media following air emissions RAC is unable to conclude about the extent to which air emissions may lead to accumulation in aquatic sediments although this accumulation is likely to take place.

Uncertainties in the risk characterisation

In section 3 ‘Assumptions, uncertainties and sensitivities’ as well as in Appendix D, the Dossier Submitter describes in detail the assumptions in the exposure assessment that contribute to uncertainties in the risk characterisation. The main reason is the limited information provided in the CSR and in the replies to the calls for evidence. As indicated above, the comments received in the consultation added confidence to the assumptions made by the Dossier Submitter.

The Dossier Submitter has provided a sensitivity analysis to characterise the impact of the identified uncertainties on the release estimates. A change in the connection rate to waste water treatment plants (WWTP) in Europe from 80% to 90% leads to a reduction in surface water emissions of 45 % but a reduction in overall emissions of less than 1%. An improvement of a few percentage points in the efficiency of the WWTP leads to ca. 20 % reduction in surface water emissions, and less than 0.1 % reduction in overall emission (water + air). Also, the proportion of discarded packaging containing remaining D4, D5 and D6 is a sensitive parameter for the calculation of the releases to surface water for the relevant uses (cosmetics, pharmaceuticals, medical devices, waxes and polishes). On the other hand, the effect on the estimated overall releases (water + air) is negligible.

RAC notes that it is uncertain to estimate an environmental concentration that may arise in the aquatic environment from redeposition based on emissions into air or from a concentration estimated for the atmospheric compartment.

RAC notes that the risks of D4, D5 and D6 have been demonstrated in the aquatic food chain (e.g. De-Gao Wang, et al. 2017). Other risk cannot be excluded because of missing evidence, e.g. there remains uncertainty on the likelihood of adverse effects in humans and organisms

from exposure via air.

Evidence if the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk

Summary of proposal:

Consumer and professional uses of D4, D5 and D6 result in releases to the environment which are dominated by releases from wide-dispersive uses in cosmetic products (under both low and high release scenarios). Releases to all compartments are relevant as they contribute to a steady-state stock pollution of D4, D5 and D6 in the environment. The Dossier Submitter considers that risks are not adequately controlled and that uses of D4, D5 and D6 are not minimised throughout their life-cycle, as required for PBT/vPvB substances according to paragraph 6.5 of Annex I to REACH.

RAC conclusions:

RAC agrees with the Dossier Submitter that risks are not adequately controlled and that uses of D4, D5 and D6 are not minimised throughout their life-cycle.

RAC concludes that consumer and professional uses of D4, D5 and D6 result in releases to the environment which are dominated by releases from wide-dispersive uses in cosmetic products (under both low and high release scenarios). RAC concludes that risks from consumer and professional uses of D4, D5 and D6 are not adequately controlled since emissions are not minimised.

RAC agrees with the Dossier Submitter that the risk management measures adopted are not sufficient and that uses of PBT/vPvB substances are not minimised throughout their life-cycle, as required according to paragraph 6.5 of Annex I to REACH.

RAC has not assessed the emissions and the risk resulting from any uses outside the scope of this restriction as set out by the request of the EU Commission or by other sources of environmental releases of D4, D5 and D6 like the break-up and degradation from silicone polymers during the use phase or during the waste phase.

Key elements underpinning the RAC conclusions:

Annex I to REACH obliges registrants of PBT/vPvB substances to implement or recommend to downstream users risk management measures that minimise the releases of substances to environmental compartments and the workplace throughout the life-cycle of the substance. RAC concludes that the use of a PBT/vPvB substances in a consumer product that is ‘widely dispersed’ during use (either released to atmosphere or to wastewater), such as a cosmetic product, is not consistent with the concept of minimisation.

The identification of D4, D5 and D6 as SVHC is sufficient justification in itself for producers to reformulate cosmetic products that contain them as ingredients.

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of the proposal:

The possibility to address the risks posed by the use of D4, D5 and D6 under other sector-specific existing EU legislation was examined in Appendix C.1.2 of the Background Document. Possible EU-wide risk management measures other than a restriction were assessed:

- Control of emissions under the IED and/or Water Framework Directive and waste legislation
- Taxation on D4, D5 and D6 content
- Sector-specific legislations such as: Medicines Regulations (Directive 2001/82/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004), Detergents Regulation ((EC) No. 648/2004), Construction Products Regulation, Medical Devices and in vitro diagnostic Medical Devices Regulations ((EC) 2017/745 and (EC) 2017/746), Cosmetics Regulation (EC) 1223/2009
- General Product Safety Directive 2001/95/EC
- Persistent Organic Pollutants Regulation (POP) 850/2004
- Update of REACH registration dossiers
- REACH Authorisation process

It was concluded on the basis of effectiveness, practicality and enforceability that none of these are a realistic, effective and balanced means of address the identified risk.

Whilst it was recognised that some existing or proposed EU legislation or other measures could have an impact on the risk management of certain sectors, these were assessed as inappropriate to address *all* of the sectors and products contributing to the risk that was not adequately controlled. This is due to the types of uses and releases addressed by the restriction proposal which could not be addressed holistically by the other legislation.

RAC conclusions:

RAC agrees with the analysis of existing regulatory risk management instruments by the Dossier Submitter in Appendix C 1.2. RAC concludes that the existing regulatory risk management instruments are not sufficient to address the risk.

JUSTIFICATION THAT ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

The Dossier Submitter concluded that action is required on a Union-wide level. Products containing these substances are formulated and used throughout the EU/EEA, resulting in similarly widespread releases. Thus, only action on a Union-wide basis would effectively reduce the environmental exposure to D4, D5 and D6 in the EU, limit the potential for trans-boundary exposure to D4, D5 and D6 from EU sources and avoid trade and competition

distortions.

SEAC and RAC conclusions:

Based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC support the view that any necessary action to address risks associated with D4, D5 and D6 should be implemented in all MS.

Key elements underpinning the SEAC and RAC conclusions:

See section 1.6 'Justification for an EU wide restriction measure' from the Background Document.

D4, D5 and D6 are cyclic volatile methyl siloxanes which are manufactured and used in a variety of sectors throughout the EEA. The three substances are regulated under REACH through their inclusion in the candidate list in June 2018 due to their vPvB (D5 and D6) or their vPvB and PBT properties (D4). Although REACH aims at limiting the emissions of vPvB and PBT substances, the inclusion in the candidate list does not per se ensure significant and irreversible decline in production and use of the substances (Danish EPA, 2019). Although D4 will be prohibited in cosmetic products through the cosmetics Regulation it may still be applied in other applications, D5 and D6 are still widely used in cosmetics and other products and risks may therefore arise in all EU Member States.

Consumer products (including cosmetics), other substances, and mixtures containing D4, D5 and/or D6 are manufactured and placed on the market in all EU Member States. Therefore, to avoid market distortion among companies within the EU, RAC agrees that action is needed on a union-wide basis, and that the proposed restriction enables a uniform approach for the three siloxanes among different applications throughout the EU.

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

Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

The proposed scope of the restriction aims at preventing the placing on the market of D4, D5 and D6 either as a substance as such, as a constituent in another substance or in a mixture. The scope does not include (i) articles or (ii) industrial uses of D4, D5 and D6 (such as formulation of mixtures, production of silicone polymers, or production of articles), by having a specific derogation for these uses.

Several derogations from the proposed restriction are recommended for specific types of products (i.e. D5 in certain medical devices) and uses (i.e. D5 in dry cleaning as long as appropriate risk management measures are in place and the use of D5 by professional users for the cleaning of art and antiques). The Dossier Submitter also identified that specific derogations for the use of silicone polymers in mixtures that potentially contain relatively high concentrations of D4, D5 and D6 as impurities would be justified. As some specific applications may be inadvertently impacted by the restriction, and more specifically by enforcement which

would not be able to distinguish if the presence of D4, D5 and D6 detected above the concentration limit of 0.1% w/w is due to the presence of D4, D5 and D6 themselves or from the presence of impurities in silicone polymers.

RAC conclusions:

RAC took note of the advice of the Forum on the enforceability from 24 June 2019 and the opinion of FORUM that the scope of the original restriction proposal was not fully clear and that some definitions were missing. As a consequence, the Dossier Submitter revised the text of the restriction to provide further clarifications. RAC notes that these modifications did not change the intended scope of the proposed restriction.

RAC concludes that the updated conditions of the restriction are appropriate to reduce emissions to the environment from the uses within the scope set in the request to the Dossier Submitter from the European Commission.

The proposed restriction includes a concentration limit, justified derogations, and transitional periods of different durations (2, 5, 10 years) which starts after entry into force of a restriction. Some derogations are specifically targeted to D5 and D6 only, because D4 has reprotoxic properties.

From a risk point of view, because of the PBT/vPvB intrinsic substance properties of D4, D5 and D6, a restriction with no concentration limit, no derogations and no transitional period would be the optimum instrument to immediately minimise emissions of D4, D5 and D6 into the environment. Nevertheless, RAC agrees with the Dossier Submitter that the proposed scope, even if not totally preventing emissions of D4, D5 and D6 into the environment, would further minimise them.

RAC notes that all concentration limits in the text of the restriction are separate for D4 or D5 or D6 and are not intended to be cumulative. This is justified in the Background Document section 2.2.2. The proposed concentration limit of 0.1 % w/w is the same as currently implemented for the restriction on D4 and D5 in wash-off cosmetic products. It prevents intentional uses of D4, D5 and D6 whilst also facilitating the enforceability of both restrictions.

After the restriction has been adopted and after the end of the longest transition period, the releases of D4, D5, D6 will not cease completely: some releases will remain because of the derogated uses, industrial uses and the presence of D4, D5 and D6 impurities in silicone polymers. The Dossier Submitter has estimated these remaining releases to be ca. 1 212 – 1 352 tpa post restriction (Section 2.4.1 of the Background Document).

RAC notes that in each derogation it is specified for which substance it applies. For example in some derogations D4 is excluded because it is toxic while e.g. other derogation are limited to D5 because it was not justified for D4 or D6 by stakeholders. Detail arguments are given in the Background Document section 2.2.

More specifically, the derogated uses as proposed in paragraph 4b and 4c are assumed to result in emissions accounting for less than 4 % of the total remaining releases (i.e <50 tpa). The formulation of mixtures containing D4, D5 and D6, which are industrial uses out of scope of this proposed restriction, are estimated to contribute approximately 0.2 % of total remaining releases to the environment of D4, D5 and D6 (ca. 2 tpa). Over 95% or ca. 1 300 tpa of the remaining emissions will be caused by consumer and professional uses of mixtures containing silicone polymers with residual amounts of D4, D5 and D6 at concentrations below

0.1%. These figures might be overestimated as the Dossier Submitter has taken a worst case scenario approach, in the absence of more refined release data, to estimate the releases post restriction from this source.

For PBT/vPvB substances the length of the transitional period is the most critical point from a risk point of view as more emissions are caused the longer the transitional period is. As with other PBT/vPvB substances, for RAC, it is also in the case of D4, D5 and D6 important that the transitional period is short.

In chapter 2.1. Analysis of risk management options (RMOs) and in chapter C.1 of the Appendix the Dossier Submitter has conducted an analysis of a series of diverse risk management options to identify the most appropriate one to address the identified risks. RAC agrees with the conclusions of the Dossier Submitter.

RAC agrees with the Dossier Submitter that the proposed restriction is the most appropriate EU-wide measure to limit the emissions of D4, D5 and/or D6 into the environment.

Justification for the opinion of SEAC

Summary of proposal:

Uses of D4, D5 and D6 in cosmetic products are estimated to account for over 90% of total releases. All the derogations proposed are for other minor uses, which the Dossier Submitter has assessed qualitatively. Each of these minor uses was evaluated against the following criteria (described in detail in section 2.6 of the Background Document):

- Whether functionality would be maintained in the case of a restriction
- The sustainability of alternatives
- The magnitude of releases that would be prevented by a restriction
- The proportion of expected releases from that use going into the atmospheric compartment (rather than into the aquatic compartment)

Information on potential impacts were presented and summarised, but no quantitative estimates of the cost of a potential restriction for the derogated uses were made.

The derogations proposed are justified as follows:

- The derogation proposed for the placing on the market of medical devices for scar/wound treatment or wound prevention and the care of stoma is justified on the grounds that alternatives may not provide the required technical function, and that this would affect vulnerable populations, such as the old and infirm (particularly patients with burns). Additionally, the tonnages for this use are estimated to be relatively low compared to the uses in cosmetic products, with a low proportion of releases directly to the aquatic compartment.
- A transitional period for uses of D5 and D6 in all other medical devices of five years (consistent with that for leave-on cosmetics) is justified on the grounds that (i) the reformulation of these products would be very similar to the reformulation of leave-on cosmetics, and (ii) the process required to reformulate these may be at least as onerous as that for leave-on cosmetics.

- The derogation proposed for the placing on the market of D5 for professional use in the cleaning or restoration of art and antiques is justified on the grounds that use of typical alternatives would not achieve an overall reduction in risk and that there is potential for damage or loss of cultural property if D5 is not used. Additionally, the tonnages of D5 used are low, and with a low proportion of releases to the aquatic compartment. D5 can be used as an alternative to D4, and therefore the derogation proposed is limited to D5 because of the harmonised classification of D4 for human health.

- The time limited (10 year) derogation for placing on the market and use of D5 for dry cleaning of textiles, leather and fur, is justified on the grounds that likely alternative substances or technologies would not result in an overall reduction in risk (e.g. flammability or the potential for the release of microplastics). In addition, the tonnages used that are estimated to be relatively low and with a low proportion of releases to the aquatic compartment. Placing on the market and use after the transitional period would only be permitted when strict operational conditions and risk management measures are adopted (e.g. use of closed systems).

The Dossier Submitter has also identified uses of silicone polymers in mixtures that potentially contain relatively high concentrations of D4, D5 and D6 as impurities. In order to prevent them from being inadvertently affected by the restriction, the Dossier Submitter considers that there is a need for specific concentration limits for these uses. Based on information received during the consultation, the following derogations are proposed:

- Mixtures that contain D4 or D5 or D6 in a concentration equal to or less than 1% w/w, for use in adhesion, sealing, gluing and casting.

- Mixtures that contain D5 in a concentration equal to or less than 0.3% w/w or D6 in a concentration equal to or less than 1% w/w, for use as medical devices (as defined in Regulation 2017/745) for dental impression.

- Mixtures that contain D4 in a concentration equal to or less than 0.5% w/w, or D5 or D6 in a concentration equal to or less than 0.3 % w/w for use as protective coatings (including marine coatings).

- Mixtures that contain D5 in a concentration equal to or less than 1% w/w or D6 in a concentration equal to or less than 3% w/w, for (i) rapid prototyping and mould making, and (ii) high performance uses stabilised by quartz filler.

- Mixtures that contain D4 or D5 or D6 in a concentration equal to or less than 0.2% w/w, for use as medical devices as defined in the classification rule 21 set in Annex VIII to the Regulation (EU) 2017/745.

- D4 in a concentration equal to or less than 0.2% w/w, or D5 or D6 in a concentration equal to or less than 1 % w/w for use as silicone insoles for horses, or as horseshoes.

- D4 or D5 or D6 in a concentration equal to or less than 0.5 % w/w, for use as adhesion promoters.

- D6 in a concentration equal to or less than 1 % w/w, for professional use in the cleaning or restoration of art and antiques.

- D5 or D6 in a concentration equal to or less than 1 % w/w, for use in pad printing, or manufacturing of printing pads.

- D4, or D5, or D6 in a concentration equal to or less than 1 % w/w, for use in 3D-printing.

The Dossier Submitter has suggested changes in the first four proposed derogations and added the last five new derogations based on the information received during the consultation on the draft SEAC opinion (#431 and other confidential responses).

SEAC conclusions:

SEAC concludes that the proposed scope is appropriate to achieve the aim of reducing the emissions to the environment. SEAC agrees with the Dossier Submitter that a restriction is the most appropriate EU-wide measure to address the concern caused by emissions of D4, D5 and/or D6 to the environment and that the choice of the proposed restriction option is justified.

Different restriction options under REACH, risk management under other EU legislation and risk management via non-legislative (voluntary) measures are discussed in Section 2.1 of the Background Document and in Section C.1 of the appendix to the Background Document. SEAC agrees with the comparison and prioritisation of the different RMOs and the conclusions of the Dossier Submitter on the preferred management option.

Overall, the analysis conducted has provided sufficient justification for SEAC to conclude that the proposed restriction is the most appropriate EU-wide measure to limit the emissions to the environment and reduce the stock. SEAC agrees with the Dossier Submitter's conclusion that the other risk management options assessed are not as appropriate as a restriction under REACH due to limitations in scope and effectiveness. SEAC also agrees that among the different possible REACH restriction options that have been assessed by the Dossier Submitter, the proposed restriction is the most appropriate.

SEAC notes that the Dossier Submitter waited for information submitted in the consultation to fine tune the scope of the restriction and to adapt the entries when necessary. SEAC agrees with these adaptations.

SEAC concur with the proposed derogations (dry cleaning, medical devices for scar/wound treatment, wound prevention and the care of stoma, D5 in the cleaning or restoration of art and antiques), as well as the changes made after the SEAC draft opinion consultation and the new additions. SEAC notes that some of the requested derogations are already covered under entries in the restriction proposal such as the use of antifoaming agents in the pharmaceutical industry (#436), textiles, (#434), and the use for dental impressions (#439, #440), therefore SEAC agrees with the Dossier Submitter that no additional derogations need to be added. There were three other responses to the consultation referring to potential additional derogations. Two were derogation requests (both confidential), and SEAC agrees with the Dossier Submitter that they should not be proposed, based on the fact that the claims made in the responses were not substantiated. The other (#431) pointed out that there is a reference in the Background Document to a use of silicone polymers (artificial skin) which could be affected, but no derogation is proposed for it. The Dossier Submitter explains that this is because no information on particular cases of this use or data on residual concentrations were provided. SEAC therefore agrees that a derogation should not be proposed for this use of silicone polymers.

Key elements underpinning the SEAC conclusions:

The restriction proposal is targeted at reducing the emissions of D4, D5 and D6. The Dossier Submitter indicates that emissions will not totally cease, as releases will remain from D4, D5 and D6 present in silicone polymers below the limit proposed in the restriction, but that an emission reduction of 90% can be obtained through the restriction. Overall, SEAC agrees that the proposed scope is appropriate to achieve the aim of reducing the emissions to the environment by:

a. Covering all the sources of release to water and air

b. Limiting the concentration to 0.1 % (w/w) in other substances and in mixtures

SEAC agrees with the conclusions of the Dossier Submitter on the comparison of different RMOs and the prioritisation made resulting in the proposed restriction as the preferred risk management option.

Different options under REACH, risk management under other legislation as well as risk management using non-legislative (voluntary) measures, are discussed in Section 2.1 of the Background Document and in Section C.1 of the appendix to the Background Document. Section C 1.2 deals with Union-wide risk management options other than restriction.

SEAC agrees with the line of argumentation presented by the Dossier Submitter that voluntary agreements, the cosmetic products regulation, the Industrial Emission Directive, the Water Framework Directive, the POPs Regulation and other measures under REACH (updating registration dossiers and authorisation) would be a less effective, or more costly, means to reduce emissions of D4, D5 and D6 compared to the proposed REACH restriction.

The Cosmetic Products Regulation ((EC) No. 1223/2009), for instance, governs the safety of substances used in cosmetic products from a consumer health perspective, but environmental safety is explicitly excluded (this specifically intended to be covered by REACH). The Water Framework Directive (2000/60/EC) currently has no specific provisions for D4, D5 or D6 and is mainly directed to water emissions. D4 may be included in the POP Regulation in the future, but may be a long and unpredictable process. D5 and D6 cannot be listed as POPs as they are not identified as ‘toxic’.

SEAC agrees with the Dossier Submitter that update of registration dossiers or authorisation under REACH would be a less effective way to reduce the releases of D4, D5 and D6 to the environment form the uses within the proposed scope.

Based on contacts with Cosmetics Europe and some other stakeholders, the Dossier Submitter indicates in the appendix of the Background Document that large retailers increasingly reject ingredients under regulatory scrutiny. However, an Austrian study cited in Danish EPA (2019) found that inclusion in the candidate list had, in general, no visible impact on substitution efforts and use volume of SVHC. Some companies express the intention to phase out SVHCs if feasible, but others indicate that the candidate list does not require elimination of chemical substances from any products and point to the legal obligations related to the listing.

Therefore, SVHC listing is not expected to address the risks and minimise emissions to the environment of D4, D5 and D6. In the framework of REACH, subsequent risk management after candidate listing is achieved via either authorisation or restriction. Furthermore, the possible effect on emission and risk of voluntary phase-out by some stakeholders has been considered by the Dossier Submitter in the baseline scenario as part of sensitivity analysis.

Two of the risk management options assessed by the Dossier Submitter are a voluntary

industry agreement to either restrict the use of D4, D5 and D6 in professional and consumer products, or a voluntary agreement for industry to label mixtures containing D4, D5 and D6. SEAC assumes that in the various sectors a large number of formulators are active (e.g. cosmetic products, pharmaceuticals and medical devices), which makes it uncertain as to whether this would be an effective approach.

SEAC concurs with the Dossier Submitter that substituting the use of D4, D5 and D6 in the absence of a restriction is highly unpredictable and unlikely to be effective. SEAC carried out a literature review using search terms related to advertisement, labelling and effects on substitution of chemicals. Although there is quite some information on label and advertising claims, mainly on food and drugs, limited information seems to be available to scientifically underpin the effect of such claims on the substitution of hazardous substances.

Considering the control of emissions under the Industrial Emission Directive and/or Water Framework Directive and waste legislation. SEAC agrees with the Dossier submitter that these pieces of legislation are very effective in controlling point sources, but are less effective in controlling emissions from diffuse sources (including to air) as in the case of the uses of D4, D5 and D6 considered in this restriction proposal.

Even though it was difficult to judge from the limited assessment provided in the Background Document, SEAC tends to agree with the Dossier Submitter that using a large number of different sector specific legislation would be a resource-intensive means to address the risks, and further notes that a number of these directives and regulations do not currently focus on environmental issues. Furthermore, such legislation does not exist for all relevant sectors identified as sources of D4, D5 and D6.

The Dossier Submitter concludes that an information campaign for consumers to avoid buying 'products' containing D4, D5 and D6 does not seem to be sufficiently effective as it will be difficult for consumers to identify the mixtures that contain D4, D5 or D6. The Dossier Submitter does not mention the EU Ecolabel regulation in its assessment, although the Nordic Swan Ecolabel is used further on as an argument that cosmetic products in relevant product categories are available on the market. *The Nordic Swan Ecolabel: "there are 3 469 cosmetic products across various categories that fulfil the Nordic Swan Ecolabel criteria that 'D4, D5 and D6 must not be present in the product or raw material'".* However, SEAC has no information of the impact on the Nordic Swan Ecolabel on consumer behaviour in relation to the preference for D4, D5 and D6-free cosmetic products. Thus, the effectiveness of the label in terms of transfer to alternatives and emission reduction is also not clear.

SEAC also verified that the proposed restriction was justified despite the existence of the existing restriction on the use of D4 and D5 in wash-off cosmetic products, which will become effective on 31 January 2020. At the time of drafting the original proposal (submitted by the UK), emissions of D4 and D5 to water were considered to be sufficient by themselves to justify action at EU-level; releases to air were therefore not assessed in detail. In addition, releases to water from uses of wash-off cosmetics contributed 'a significant amount' of the total releases of D4 and D5 to surface water. The Annex XV report proposing the restriction had concluded that the emissions to the aquatic environment from leave-on cosmetics were negligible (although this conclusion was not supported by RAC). Since then, D4, D5 and D6 have been formally identified as PBT/vPvB and listed as SVHC substances, which justifies the goal to minimise all emissions to the environment.

Derogations

The Dossier Submitter assessed the need for derogations for specific uses by means of a multi-criteria analysis including both quantitative and qualitative information. This is

described in Section 2.6 of the Background Document. Each of the non-cosmetics uses was evaluated against the following criteria:

- Whether functionality would be maintained in the case of a restriction
- The sustainability of alternatives
- The magnitude of releases that would be prevented by a restriction
- The proportion of expected releases from that use going into the atmospheric compartment (rather than into the aquatic compartment)

Based on the multi-criteria analysis, the Dossier Submitter proposed two derogations based on the fact that a loss of functionality with currently available alternatives would adversely affect vulnerable populations (case of medical devices for scar/wound treatment, wound prevention and the care of stoma) or damage valuable cultural property (case of use of D5 in the cleaning or restoration of art and antiques). A third derogation for dry cleaning of textiles, leather and fur (process-limited, and transition of 10 years) is based on the grounds that some of the likely alternative substances would not result in an overall reduction in risk (e.g. flammability). For all three of the proposed derogations, tonnages are low compared to the totals addressed by the rest of the restriction. On the basis of input during the consultation, a longer transitional period of five years was proposed for medical devices that were not covered by the derogation, which was justified by the fact that reformulation was considered to be very similar to that of the leave-on cosmetics, and because the reformulation process required was considered to be at least as onerous as that for leave-on cosmetics.

SEAC agree with the assessment of these derogations and considers that the above elements and especially the need to avoid a transfer of risks are sufficient to justify the three proposed derogations. Based on input during the consultation on the SEAC Draft Opinion (#439 and other confidential responses), SEAC recommends prolonging the derogation period for medicinal products as defined in EU Directive 2001/83/EC, as well as for veterinary products defined under Regulation (EU) 2019/6 (previously directive 2001/82/EC) to seven years. This can be substantiated by the relatively long qualification and registration periods needed for such products compared to for instance cosmetics. There were a few requests to prolong the derogation period for cosmetic products (#437, #442, #446), as well as requests to grant a shorter derogation period for certain cosmetic product groups (#443).

One of the comments (#437) indicated that although alternatives have been identified by the DS, it does not mean that the cyclosiloxanes can be replaced easily in every product. The proportion of products without cyclosiloxane cannot be used as evidence for substitution of cyclosiloxanes within that group according to that comment (#437). Another comment (#442) indicated that cyclosiloxanes are key ingredients in certain categories of cosmetic products in which cyclosiloxanes may be present in high concentrations. According to that comment, reformulation will take more time where suitable alternatives are lacking (#442).

The proposal to reduce the transitional period from five to two years for some cosmetic product categories indicated that these product groups contributed most to the emissions and accounted for a limited amount of the reformulations. Although the background document contained data on the effect of reducing the derogation period from five to two years for all cosmetic products together, the Dossier Submitter did not calculate specific costs associated with reducing the transitional period to 2 years for these product groups, and neither did the submitted comments (#437, #442, #443). Additionally, SEAC notes that the Dossier Submitter (in section 2.5.1.5 of the Background Document) explains that the estimate provided in the Background Document of costs for a 2-year transitional period for all cosmetics is based on the assumption that it is feasible to complete all the needed reformulations in 2 years. The Dossier Submitter warns that evidence obtained in the consultation casts doubt on

whether that would be possible to do at all, and if it is, whether the cost per reformulation would be the same (since reformulating in only 2 years may require increasing resources to tackle in parallel reformulations which would otherwise have been done consecutively). The Dossier Submitter considers that the estimate for the cost of reformulations with a 2-year transitional period is therefore likely an underestimate, and it could be significantly higher. Given the doubts regarding the potential impacts of shortening the transitional period for 2 years, SEAC lack the underpinning data to make a clear statement on the effects of doing so, including on the effect on practicality or enforcement issues. Thus, SEAC concur with the dossier submitter to propose a transitional period of five years for all leave-on cosmetic products.

For head lice treatment, it appears from the information provided by the Dossier Submitter, that there are existing and efficient alternatives, including alternatives not using insecticide. The same conclusion applies regarding the availability of alternatives for lubricants, massage gels and topical treatments. Additionally, also considering the relatively significant releases to the environment, SEAC agree to not derogate these uses.

A considerable amount of comments were received during the consultation on the various medical applications. These comments contained further details of the medical applications containing D4, D5 and D6, including information on the concentrations present and the total amount used within the medical sector. The submissions confirmed the Dosser Submitter's estimations on the quantities used and provided insight on the time needed for substitution. Thus, the comments resulted in a longer transition period for medical devices than that which was originally proposed by the Dossier Submitter.

SEAC agrees with the proposal by the Dossier Submitter not to derogate the use of D5 and D6 in detergents, household care and vehicle maintenance products, on the grounds that there are existing alternatives with lower risk and same level of performance. The Dossier Submitter could only identify two companies that use D5 or D6 in air fresheners and car products and overall they seem to be able to find alternatives within the proposed transition period (five years).

The Dossier Submitter's justification for the derogation on the placing on the market of D5 for the cleaning or restoration of art and antiques was supported during the consultation. Cleaning and restoration would either become impossible or replacement of D5 would involve noxious materials (chlorinated solvents). As indicated by the Dossier Submitter, the use of these solvents as alternatives to D5 are thought not to result in an overall reduction of risk.

Regarding the proposal to not derogate D4 in the restoration of art and antiques, SEAC notes that D4 is more toxic than D5, and that the use of D5 has been promoted as a replacement for D4 in Europe. Although SEAC notes there is very limited information on technical feasibly on D5 as an alternative for D4 and lack of clarity that D5 has been found as a suitable alternative in general it can support the proposal of the Dossier Submitter not to grant a derogation for D4 for this specific use.

One of the aims of the consultation was to receive information on the content of D4, D5 and D6 in silicone polymer mixtures, used by consumers and professionals, as it was assumed that they may unavoidably contain D4, D5 or D6 residues above 0.1% w/w of each substance. The information submitted during the consultation was used by the Dossier Submitter to adapt the conditions of the restriction and resulted in a further specification of the percentages mentioned in the restriction.

One stakeholder indicated during the consultation that for their application the restriction provides the most targeted and appropriate approach to the risk and ensures that the risk

reduction capacity is significant in comparison to other regulatory approaches (RMOs) including potential authorisation.

SEAC agrees with the approach followed by the Dossier Submitter during the consultation and the adaptations made.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

The Dossier Submitter has identified and assessed five different risk management options, and has concluded that the proposed restriction on the placing of D4, D5 and D6 on the market (concentration limit of 0.1% w/w) in consumer and professional products including justified derogations was the most effective option to reduce the identified risks.

The Dossier Submitter estimates that a total reduction of emissions of ca. 90% for all compartments could be obtained through the Annex XV restriction proposal (from releases of 17 994 – 18 485 tpa of D4, D5 and D6 to releases of 1 212 – 1 352 tpa post restriction).

The Dossier Submitter has also assumed that in case a restriction is adopted for professional and consumer products, this will have consequences on the upstream supply chain, hence the releases to the environment from the formulation steps will also be reduced.

The Dossier Submitter notes that emissions of D4, D5 and D6 in the environment will not totally cease and will remain from some consumer and professional products containing silicone polymers with residual amounts of D4, D5 and D6 at concentrations below 0.1%, as well as a small quantity of emissions from derogated uses (accounting for less than 4 % of the remaining releases).

RAC conclusions:

RAC concludes that the estimated reduction in the total releases of D4, D5 and D6 into the environment (water and air) achieved by the proposed restriction can be used as an estimate of the effectiveness (risk reduction capacity) of the proposed restriction.

RAC agrees with the Dossier Submitter that the proposed restriction is the most effective option to reduce the identified risks.

RAC concludes that the majority of suitable alternatives have significantly fewer health and safety concerns and are of lesser environmental concern than D4, D5 and D6 and that the majority of substitution options is likely to be beneficial.

Key elements underpinning the RAC conclusions:

In section 2.1 “Analysis of risk management options (RMOs)” the Dossier Submitter discusses various Risk Management Options (RMOs) vs their potential for risk reduction. In section 2.4.1 “Effectiveness and risk reduction capacity of the proposed restriction” the Dossier Submitter demonstrates that the majority of releases of D4, D5 and D6 to the environment (all compartments) can be reduced through a restriction focussing on uses.

According to Table 16 in the Background Document, a total emissions reduction for all compartments of ca. 90% from releases of 17 994 – 18 485 tpa to releases of 1 212 – 1 352

post restriction could be obtained.

Some consumer and professional products that are mixtures will contain silicone polymers with residual amounts of D4, D5 and D6 at concentrations below 0.1%7. The resulting emissions would not be affected by the proposed restriction. This would also be the case for articles where the residual amount of D4, D5 and D6 is below 0.1%.

The Dossier Submitter assessed the sustainability of alternatives and summarised the assessments by using a Red-Amber-Green rating system. If the likely alternatives was considered to be more hazardous, the assessment would be a RED. If similarly hazardous, the conclusion of the assessment would be AMBER. If less hazardous, the conclusions would be GREEN. When the use of alternatives would not result in an overall reduction in risk, or where the restriction would appear to be disproportionate from society's perspective, the Dossier Submitter has proposed derogations from the proposed restriction. Some derogations are specifically targeted to D5 only, because D4 is hazardous for human health, and D5 can be used as an alternative to D4. However, some alternatives have a greater health hazard than D4.

In Appendix C.2 the Dossier Submitter documented a total of 100 potential alternatives for cosmetic products. This includes, substances on their own, as well as substances in mixtures. The alternatives have different profiles with regards to risks. The Dossier Submitter notes that some alternatives might not be suitable for substitution due to environmental concerns, and are under regulatory scrutiny because of PBT concerns (e.g. linear siloxanes). However, most alternatives appear to have no health and safety concerns and are of less environmental concern than D4, D5 and D6.

There are 3 469 cosmetic products across various categories that fulfil the Nordic Swan Ecolabel criteria that 'D4, D5 and D6 must not be present in the product or raw material' (Nordic Swan Ecolabel, 2018). To obtain the Nordic Swan Ecolabel, products should pass 'efficiency testing' which, in cosmetics, consists of consumer acceptability tests. For sun-protection products, the Nordic Swan Ecolabel also requires that the performance of the product, as outlined in recommendation 2006/647/EG, also has demonstrated. Products that have been granted an ecolabel certificate should demonstrate that the sales of the products are increasing or stable during three consecutive years – this is requested by the Nordic Swan Ecolabel organisation to document that the certified product is accepted by the consumers for its primary function (revised Background Document, section 2.5.1.1.D).

Socio-economic impact

Justification for the opinion of SEAC

Costs

Summary of proposal:

The restriction proposal would require companies undertaking non-derogated uses to stop using D4, D5 and D6. The costs associated with this have been calculated for cosmetic products, but not for other uses, which have been assessed using a qualitative approach.

[7] It includes also mixtures that are made of silicone polymers with residual amounts of D4, D5 and D6 above a concentration of 0.1%: after formulation and dilution with other ingredients, the residual amounts of D4, D5 and D6 in the final products used by the consumers and professionals could be in concentrations below 0.1%.

For uses in cosmetics, the costs identified are as follows:

Reformulation costs: As no one-for-one, drop-in alternative substances have been identified, a large proportion of the costs to companies are expected to arise due to the reformulation efforts required to remove D4, D5 and D6 from products. The approach taken to estimate these efforts is closely based on the methodology applied in the UK Annex XV report proposing a restriction on the use of D4 and D5 in wash-off cosmetics, which has already been positively evaluated by SEAC. The Dossier Submitter deviated from the UK methodology, as follows:

- Number of formulations containing D4, D5 and D6 on the market: The UK used a top-down estimate of the proportion of cosmetic products by value that contained D4 and D5, an approach that was acknowledged at the time to likely result in a significant overestimate. The Dossier Submitter estimated the number of formulations on the market by using data from several databases which have information on products on the market today and include data on their ingredients, as well as data from a specially-commissioned market survey of three EU MS.

- Number of reformulations expected in response to the restriction: The UK used an implicit assumption that every formulation containing the restricted ingredients would be reformulated as a result of the restriction. The Dossier Submitter considers that there are good reasons to believe this may not be the case, and companies (particularly large ones, which are also likely to produce alternative formulations within the same category) will accept that customers will switch to an existing alternative product rather than invest in reformulation. The Dossier Submitter uses the detailed data available from the databases mentioned above to estimate the proportion of products containing D4, D5 and D6 that would actually be reformulated, using the proportion of products in a subcategory that do not contain D4, D5 or D6 as a proxy for the availability to consumers of products without D4, D5 and D6. It is assumed that with increasing availability of alternatives to consumers in a subcategory, the lower the proportion of D4, D5 and D6-containing formulations that would be reformulated.

The best estimate for total reformulation costs is an average annual cost of €54 million, with a 20-year NPV of €605 million.

Raw material costs: Very limited information has been provided on which alternative substances will to be used to replace D4, D5 and D6, but industry has provided a list of substances that have been identified as potential alternatives for D5. Some had similar prices, but the majority were more expensive, some substantially so. This could be expected to result in increased costs of raw materials for any reformulated products. Due to these uncertainties, the Dossier Submitter followed the same approach as in the D4/D5 wash-off proposal, and assumed the unit price for the alternative would be twice that of D4, D5 and D6.

The best estimate for total additional raw material costs is an average annual cost of €9 million, with a 20-year NPV of €98 million.

Consumer costs associated with performance loss: If, as assumed, not all products are reformulated, or some are reformulated but to a lower quality, this could lead to the products available to consumers being of a different quality of those currently available and containing D4, D5 and D6. For instance, they may not feel as silky on the skin, may leave hair and skin less smooth, may leave a residue or may not dry as quickly. It was not possibly to quantify these potential impacts on consumers.

TOTAL MONETISED COSTS: The best estimate for total quantified and monetised costs is average annual costs of €63 million, with a 20-year NPV of €703 million.

The Dossier Submitter was also able to disaggregate the quantified costs associated with the use of D4, D5 and D6 in cosmetics by broad product group. The results are as follows:

Table 4: Costs by broad product group

Broad product group	Average annual cost (€ million)	20-year NPV (€ million)
Make-up and lipsticks + Skin care	53	586
Deodorants and antiperspirants	5	59
Hair styling and other	3	37
Wash-off	1.1	12.1
Sun/self-tanning	0.8	8.4

SEAC conclusions:

SEAC agrees with the approach taken by the Dossier Submitter to estimate the substitution costs of the proposed restriction in the cosmetic sector, and finds that the proposed cost estimate provides a good indication of the order of magnitude of the total costs (for all sectors currently under the scope not proposed for derogation).

Key elements underpinning the SEAC conclusions:

SUBSTITUTION COSTS: COSMETICS

Availability of alternatives

SEAC reviewed the evidence and analysis provided by the Dossier Submitter regarding the existence and availability of alternatives to D4, D5 and D6 focusing on

1) leave-on cosmetics using a confidential survey carried out by the cosmetic industry.

2) uses of D4, D5 and D6 in sectors other than cosmetics

3) uses of silicone polymers that may contain D4, D5 and D6 as impurities above the proposed 0.1% w/w threshold.

A review by the Dossier Submitter identified a list of 100 possible alternatives (see C.2.2) of which a considerable number have not been identified as PBT/vPvB nor are under regulatory scrutiny, and are therefore not subject to availability issues related to future regulation. Regarding (leave-on) cosmetics, the information comes from the trade press, from information received from trade associations and from an industry survey carried out in 2017 (updating a 2013 survey). In general, from that survey, it seems that there are alternatives available in each product category.

The Dossier Submitter also used databases on cosmetic product formulations to examine if, for any given product category, a significant proportion of products are formulated without D4, D5 or D6. Since products with D4, D5 and D6 are always a minority (except for one product category), this qualitatively strengthens the conclusion that there are alternatives available. Another indication provided by the Dossier Submitter on the availability of alternatives is that products with the “Nordic Swan” ecolabel do not contain D4, D5 or D6 and

are available in most cosmetic product categories.

On the basis of available evidence, the Dossier Submitter concludes that substitution of D4, D5 and D6 with alternatives is both technically and economically feasible for many cosmetics, although effort may be needed for some specific products. Further to the fact that the industry survey did not report major issues, SEAC considers that the restriction would be an incentive to alternative suppliers to increase their offer of alternatives. The consultation indicated that alternatives are currently being tested by cosmetic manufacturers.

Performance/Consumer surplus losses

The industry survey tends to show that no identified alternative could provide the same performance level, at the same cost, or without any possible disadvantage in terms of environmental/health risks or safety (flammability). Performance losses in terms of feel, smell or durability are expected by industry, with therefore some consumer impacts in terms of lower satisfaction (consumer surplus losses) and possibly some reduced demand in some cases.

SEAC agrees with the Dossier Submitter that there is not enough information to quantify consumer surplus losses. Based on the information from the industry survey, SEAC consider that this impact on consumers appears to be low to moderate, in particular because the Call for Comments and Evidence and the consultation did not reveal new concerns in terms of the performance of alternative formulations from industrial stakeholders or consumers. Another indication for a low/moderate performance loss is that the alternatives (present in each cosmetics category) that have the Nordic Swan ecolabel had to pass tests in terms of technical performance and customer acceptance. Finally, performance gains thanks to advances during reformulation are possible as well.

Raw materials costs

As in the proposal for a restriction of D4 and D5 in wash-off cosmetics, the Dossier Submitter assumed that the unit price of the alternative will be twice that of D4, D5 and D6 and that the same quantities are required of the alternative and of D4, D5 and D6.

The industry survey (in 2017) reports price differences of alternatives, between 0 up to 1 000%, with quantities required being in general slightly lower. It is difficult to compare the information from the survey with the assumption for raw material price difference proposed by the Dossier Submitter, but it seems reasonably realistic to SEAC. It is possible that raw material costs are underestimated by the Dossier Submitter, but the sensitivity analysis carried out by the Dossier Submitter shows that even if the price difference was 200% (or even 300%), this would not change the total costs of the restriction by more than a third (for 300%). SEAC notes that this survey does not consider D6, but since D6 has minor use in cosmetics, this does not add significant uncertainty to the costs estimate.

SEAC concludes that, although difficult to estimate, these costs are very likely to represent clearly a minor share of the total substitution costs compared to reformulation, and that the proposed estimate and sensitivity analysis provided by the Dossier Submitter is appropriate when considering proportionality.

Process / packaging adaptation costs

Process or packaging adaptation needs (chemical compatibility issues between existing package material and alternatives) have been noted in the industry survey for some instances. The Dossier Submitter did not quantify or qualify these costs. However, it seems they would only occur in a limited number of cases. Part of these costs are likely to be avoided since process/packaging issues are considered during reformulation, and they could therefore

be partly included in reformulation costs. SEAC rapporteurs consider these costs are probably negligible compared to other costs considered in the assessment.

Reformulation costs

SEAC agrees with the method consisting basically in multiplying the number of reformulations for D4, D5 or D6 (as was carried out in the Restriction proposal on D4 and D5 in wash-off cosmetic products) with the unit cost for one reformulation.

Costs per reformulation

Reformulation costs for large companies are estimated to be €365 000 per reformulation, without other changes from the costs in the 2016 Background Document (D4/D5 restriction on wash-off cosmetics) than adjustment for inflation to 2017.

SEAC agrees with the Dossier Submitter's rationale concluding that the per reformulation cost for small companies is significantly lower than that assumed for the wash-off restriction proposal, and to use the new figure of €42 000 per reformulation (based on information by the Cosmetics industry).

Based on additional calculations, making use of data from Cosmetics Europe and EuroStat data on R&D spending in the cosmetics industry, the Dossier Submitter estimates that the costs for reformulation are overestimated.

There is, however, also an underestimation factor in that not all reformulations are necessarily successful. The Dossier Submitter argues that even if a share of reformulations are not successful, they will provide a learning effect and reduce the costs of successful reformulations, and that these two effects cancel each other out. SEAC is not sure of the significance of this effect (no evidence provided, and doubts that experience on reformulation would be shared outside each company). The learning effect might already be accounted for by industry in the figures provided.

It is not possible with the information at hand to know the relative magnitudes of possible overestimation and underestimation for unit reformulation cost, and SEAC agrees to use the estimates proposed by the Dossier Submitter, having not enough evidence that conclude if they are overestimated or underestimated.

Number of reformulations

The number of reformulations is assessed by combining the total number of formulations with D4, D5 or D6 on the market, combined with information on the proportion of products actually containing D4 D5 or D6 in each product category. The reasoning by the Dossier Submitter is that that the lower the proportion of products that contain D4, D5 and D6 within a subcategory, the lower the proportion of products within this subcategory that will actually be reformulated, because more readily available formulations without D4, D5 and D6 already exist.

Regarding the total number of formulations with D4, D5 or D6, the market research making use of CosmEthics and other databases plus the mystery shopping exercise gives a good impression of the market for cosmetics. SEAC agrees with the assumptions made in the Background Document to estimate the total number of formulations containing D4, D5 and D6 on the market. The range provided to estimate the number of formulations, based on the CosmEthics and other database data sources, is convincing. SEAC note that the number of formulations provided by industry (60 000), despite being apparently based on relatively arbitrary assumptions, is within the range used by the Dossier Submitter (34 400 to 68 800).

Regarding the way the number of reformulations is derived, SEAC agrees with the principle

adopted by the Dossier Submitter explained above. However, SEAC notes that existing products without D4, D5 and D6 might belong to another company than the one needing to reformulate and that the Dossier Submitter approach might be somewhat optimistic in that it assumes companies will in general have access to existing reformulations. There is some uncertainty regarding the possibility that new formulations will be available to all industrial stakeholders, and that reformulation costs will be avoided by those stakeholders who have not reformulated so far.

The Dossier Submitter also assumes that a share of cosmetic product formulations with D4, D5 and D6, if not reformulated without D4, D5 and D6, will be terminated, therefore considering that in that case industrial stakeholders will cease production (and not reformulate). This could lead to either consumer surplus losses if those products have no equivalent on the market or reduced choice. In case an equivalent product is reformulated by a competing company remaining on the market it would be only a distributional cost, but it is unclear whether and how these cases are accounted for in the Dossier Submitter's cost estimates.

In summary, the rationale and methodology appear to be sound and an improvement relative to the D4 and D5 restriction in wash-off cosmetics. SEAC notes, however, that the share of products being reformulated or terminated, respectively, appear to have been chosen relatively arbitrarily by the Dossier Submitter, given the lack of information and the difficulty to predict companies actual and accurate response to the proposed restriction, with consequences in terms of uncertainties.

SEAC has limited information to assess whether this would lead to an overestimation or an underestimation of reformulation costs, but the assumptions surrounding access to reformulations and product termination without reformulation might underestimate the costs.

SEAC agrees with the way the Dossier Submitter further reduces the number of reformulations by withdrawing the ones that would have happened anyway without the restriction during the transitional period, or only taking into account the cost of bringing forward during the transitional period the ones that would have happened within five years after entry into force without the restriction. SEAC also approves that the Dossier Submitter took into account comments made by SEAC for wash-off restriction and did not assume coordination of baseline reformulations occurring later than six years after the end of the transitional period.

The Dossier submitter, in addition to what was done for the D4 and D5 restriction in wash-off cosmetic products, also considers that the cost of minor reformulations will also be saved during the transitional period, because they will be added to the major reformulations required by the proposed restriction, at no extra cost. While the assumption of merging and postponing minor reformulations during the transitional period is sensible in view of SEAC, because it can indeed be expected that companies will try to minimise reformulation costs, it is unclear why this merging of minor with major reformulation will incur rigorously no cost (more experimental work could be necessary for instance). Another assumption might have been possible, though with probably low impact of the total cost assessment.

Other costs related to cosmetic products

The costs taken into account in this proposal deviate from the methodology used in the proposal for the restriction of D4 and D5 in wash-off cosmetic products as test costs and cost savings for the EU anaerobic digestion plants are included in the previous analysis but not in the present proposal. SEAC considers that the omission of these cost savings is not significant in this case as the emissions of leave-on cosmetic products are mainly to air instead of to water.

SUBSTITUTION COSTS: OTHER USES

For uses other than in (leave-on) cosmetics, the Dossier Submitter did not systematically assess the costs quantitatively because of a lack of information and because the objective is to assess the potential for derogations as a whole under a multi-criteria qualitative analysis.

Substitution costs are provided for only a very limited number of these other uses and are not sufficiently comprehensive to provide a good indication of substitution costs in these sectors.

SEAC has assessed the derogations in the dedicated section of this opinion and will not use the cost information for other uses in the cost assessment. However, for sectors that are not proposed for derogation (or whose derogation is time-limited) by the Dossier Submitter (e.g. dry cleaning, several medical devices), costs estimates are not available, and SEAC currently lack information and analysis to quantitatively address their inclusion in the cost of the proposed restriction.

However, the tonnages involved in all other non-derogated uses (in the proposed scope) except for silicone polymers are several orders of magnitude lower than for leave-on cosmetic products, so SEAC considers that the substitution costs are negligible compared to leave-on cosmetic products. If the substitution costs for these sectors were several orders of magnitude greater than for cosmetic products SEAC considers that this would have been identified during the preparation of the Annex XV report by ECHA (i.e. in the call for evidence) or during the consultation after the submission of the proposal.

For uses of silicone polymers the tonnages used are not negligible and there is at present only broad information (and some lack of economic information on costs) as recognised by the Dossier Submitter on the consequences of the proposed restriction and the need for this industrial sector to eventually find alternatives, and the consequences in terms of costs.

ENFORCEMENT COSTS

Enforcement includes both administrative and testing costs.

Administrative costs have been assessed by the Dossier Submitter using the “fixed budget approach” developed by ECHA. The Dossier Submitter lacked information to assess testing costs and assumed that they could be equal to the administrative costs.

SEAC agrees that the proposed restriction is not particularly complex compared to others, and that the previous restriction on D4 and D5 in wash-off cosmetic products will ensure that stakeholders are familiar with the proposed restriction. Therefore, fixed annual administrative costs of €55 000 appear to be a reasonable estimate. However, given the uncertainties related to the extrapolation of the “fixed budget” to this particular case, it is not possible for SEAC to agree with the Dossier Submitter that this value is an overestimation.

The assumption by the Dossier Submitter that testing costs would be equal to administrative costs does not appear to be well founded. SEAC does not support this assumption, therefore, concludes that enforcement costs, assessed only in terms of administrative costs, are underestimated.

Benefits

Summary of proposal:

The benefits from the restriction arise from reduced emissions of D4, D5 and D6. As the substances are PBT/vPvB, the reduction in risk is not quantified, and reduction in emissions and 'releases that remain in the environment' are used as a proxy for the reduction in risk. These benefits have not been quantified or monetised.

It is also possible that D4, D5 and D6-containing products that were reformulated will have improved quality and provide a performance gain to consumers. However, this does not seem likely (or would not affect a significant number of products).

SEAC conclusions:

SEAC agrees that as the substances are PBT/vPvB it is not feasible to assess quantitatively the benefits in terms of avoided impacts on human health and on the environment. SEAC also agrees that reduction in emissions and in releases that remain in the environment can be used as proxies for risk in the cost-effectiveness analysis.

Key elements underpinning the SEAC conclusions:

SEAC's conclusion is first of all founded on the agreed general approach by ECHA for the assessment of PBT/vPvB substances.

SEAC also took note that RAC is of the opinion that the releases of D4, D5 and D6 to all compartments (including air) are relevant. SEAC will therefore use in preference total emissions reductions as a proxy for risk rather than only emissions to water (the latter will be used as a sensitivity case in the proportionality assessment). SEAC also agrees that the reduction in releases that 'remain in the environment' is another possible proxy for risk that is complementary to the one based on emissions reduction, without clear indication that one would be more closely related to actual risk or impact than the other.

Other impacts

Summary of proposal:

If a restriction on the intentional use of microplastics is adopted on a similar date as the proposed restriction on D4, D5 and D6, this would have an impact on reformulation costs in the cosmetics industry. A proportion of products will contain both microplastics and D4, D5 and D6, and if the costs of reformulation are counted separately in each impact assessment, then this will likely represent double counting, at least for a proportion of the costs. A note[8] has been published analysing the extent of potential overlap. Feedback from industry in the consultation of this restriction proposal indicated that the 'double-counting' effect would be limited.

SEAC conclusions:

SEAC agrees with the Dossier Submitter that some double-counting of reformulation costs between the proposed restrictions on microplastics and this restriction is possible. However, SEAC has limited information to assess the specific economic effect of having two proposed restrictions in the same sector at the same time (leave-on cosmetics), but it seems that it will

[8] Note available at: https://echa.europa.eu/documents/10162/a3288fcf-928f-795f-8049-ae4da7eab7ee

remain limited.

Key elements underpinning the SEAC conclusions:

SEAC agrees that since microplastics and D4, D5, and D6 are both used in leave-on cosmetics, some of reformulations of leave-on cosmetics could, in case both restrictions are adopted, be carried out simultaneously for products containing microplastics and D4, D5 or D6, and that this would reduce overall total reformulation costs of both restrictions.

SEAC did not analyse the specific economic effect of having two proposed restrictions in the same sector at the same time (leave-on cosmetics). Apart from positive synergies in reformulations, in theory there could also be negative aspects for supply chains (e.g. additional need for financing and higher financing costs). SEAC notes, however, that at the current stage of both opinion-making processes the restriction cost for leave-on cosmetics is roughly one order of magnitude greater for microplastics than for D4 D5 and D6, and believes that overall, all synergistic effects would remain limited.

Overall proportionality

Summary of proposal:

As D4, D5 and D6 are PBT/vPvB substances, proportionality has been assessed by considering the cost-effectiveness of the restriction.

Depending on whether releases to the atmospheric compartment are considered to be significant, the costs per kg of D4, D5 and D6 abated are very different. If the Dossier Submitter considers all releases, both to the atmosphere and directly to the aquatic compartment, this would result in a best estimate of €3 per kg per year of releases abated. If the Dossier Submitter was to consider only releases to the aquatic compartment, the abatement costs would be greater: €1 000 per kg per year.

However, it is also possible to analyse cost-effectiveness based on the releases that will remain in the environment resulting from the releases of D4, D5 and D6 to the aquatic compartment and the atmospheric compartment. The cost-effectiveness in this case is underpinned by the cost per kg of D4, D5 and D6 releases that will remain in the environment, and that would be avoided if a restriction were implemented. When considering these releases, abatement costs would be €104 per kg per year.

Using the releases that will remain in the environment that would be avoided may be considered as a more suitable basis upon which to estimate cost-effectiveness, at least for these substances, when compared to using only releases to the aquatic compartment or releases to the aquatic compartment plus the atmospheric compartment. Using only releases to the aquatic compartment would effectively give a weighting of 0% to releases to atmosphere, while using releases to the aquatic compartment plus atmosphere would give releases to the atmospheric compartment a weighting of 100%. Considering feedback received by the Dossier Submitter from the ECHA PBT expert group, neither of those extreme scenarios seems appropriate. Using instead the releases that will remain in the environment gives some weighting to the releases to the atmosphere, but not as much as releases to the surface water.

The Dossier Submitter has also calculated measures of cost-effectiveness for different cosmetics product groups, and the results vary substantially between them. At the time of submission, there was no data available by product group for releases that will remain in the environment.

Table 5: Cost-effectiveness by broad product group

Broad product group	Cost [€/year/kg] If releases to water only	Cost [€/year/kg] If releases to all compartments
Make-up and lipsticks + Skin care	8 615	10.2
Deodorants and antiperspirants	275	0.5
Hair styling and other	245	0.5
Wash-off	49	9.5
Sun/self-tanning	-	99.1

RAC conclusions:

RAC concludes that from a risk point of view, because of the PBT/vPvB properties of D4, D5 and D6, emissions of D4, D5 and D6 into the environment (all compartments) should be minimised within a short transitional period. RAC notes that for the restriction on D4 and D5 in wash-off cosmetic products proposed by the UK a transitional period of two years was granted. Within the scope of this proposed restriction any residual emissions of D4, D5 and D6 resulting from derogations should be well justified.
RAC concludes that total releases of D4, D5 and D6 into the environment (all compartments) may be used as a proxy for risk and consequently RAC concludes that the cost-effectiveness of the proposed restriction should be calculated using the estimation of total releases of D4, D5 and D6 into the environment (all compartments).

SEAC conclusions:

SEAC agrees with the cost-effectiveness analysis conducted by the Dossier Submitter for the cosmetics sector and concludes, based on the range of cost-effectiveness estimates for emissions reduction, that the proposed restriction is proportionate.

Key elements underpinning the RAC conclusions:

Because of the PBT/vPvB intrinsic substance properties of D4, D5 and D6 any emission into the environment (all compartments) is to be minimised, since they add to the concern. In Section 2.5.4. “proportionality” the Dossier Submitter discusses two different transitional periods, two years and five years and estimated the releases to water and air prevented over 20 years. The 2 year transitional period would reduce significant more releases than a 5 year transitional period. It is requested, that that a restriction is ‘capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk’. In the case of PBT/vPvB substances this means to minimise emissions in the shortest possible transitional period, because of the non-threshold nature of the risk.

Key elements underpinning the SEAC conclusions:

SEAC has reviewed and agreed with the cost assessment reported by the Dossier Submitter and takes note that RAC agrees with emissions reduction calculated by the Dossier Submitter. Therefore, SEAC agrees with the C/E ratios presented by the Dossier Submitter.

Under the central estimate (based on a five-year transitional period), the C/E ratios spread over a very wide range between 3€/kg when all emissions are considered and 1 000 €/kg if only emissions to water are considered. Table 6 allows comparison of these figures with the central estimates from recent REACH restrictions on PBT/vPvB chemicals.

Table 6: Cost effectiveness of recent REACH restrictions on PBT/vPvB chemicals

	€/kg central value
Lead in shot in wetlands	9
Lead in PVC (under decision-making)	308
D4, D5 in wash-off cosmetics	415
DecaBDE	464
Phenylmercury compounds	649
PFOA-related substances	734
PFOA	1 649

Estimations for the releases that will remain in the environment are presented in Section B.4.1 of the Background Document. The estimations take degradation in both the water and air compartments, as well as other chemical fate processes into account. The Dossier Submitter considered the cost per kg of preventing releases that will remain in the environment to be the most appropriate effectiveness indicator, which was estimated to be €104 per kg of releases abated.

Unfortunately, it is not possible to compare the current restriction proposal directly with previous ones as this is the first proposal in which releases that will remain in the environment have been estimated. However, assuming degradation of lead and PFOA to be minimal, this would indicate that a cost of €104 per kg of releases abated is cost-effective compared to the lead in PVC and the PFOA restriction.

To be able to make the proportionality assessment by comparing the cost-effectiveness with recent REACH restrictions, a unit of emission (e.g. kg) of any PBT or vPvB substance is considered to be the same in terms of the potential damage to human health and environment (see ECHA, 2016). Another assumption is that no decay takes place, as that would lead to differences in the amounts of the substances released that finally lead to impact. ECHA (2016) indicates

"that while weighting on the basis of (expected damage) is not currently possible systematically using numerical approaches, it is often feasible to describe factors or situations where the properties of a particular PBT or vPvB would be likely to cause more or less damage. Examples of such factors and situations are listed in Annex 1 [of ECHA (2016)]. These include the possibility to use information on P, B and T properties."

In the approach followed in the D4, D5 and D6 restriction proposal, characteristics on persistency (decay rate) have been used for fine tuning. Comparing the results of this approach, expressed in releases that remain in the environment, with previous restrictions is only possible assuming the decay of the substances in previous restrictions to be zero.

On the one hand, SEAC agrees with the Dossier Submitter that the reduction in emissions that would remain in the environment might be a more suitable proxy for C/E analysis than avoided emissions. On the other hand, SEAC has some reservations, for example because the estimate of releases that would remain in the environment is provided by generic modelling of steady-state stock that is known to be uncertain and cannot be validated with observations, whereas emissions come more directly from observations. Without further information, SEAC is unable to make a definite conclusion about the use of this proxy.

Even in the less favourable case of only considering water emissions, the C/E ratio of the proposed restriction lies within the range of C/E ratios of past proportionate restrictions for PBT/vPvB chemicals. The comparison with the C/E for PFOA is not straightforward since it relates to the initial proposal before derogations that were recommended by RAC and SEAC to improve the C/E of the restriction. It should also be noted that SEAC concluded that cost could be somewhat underestimated because there was no assessment of testing costs.

If compared to the closest restriction (the UK restriction on D4 and D5 in wash-off cosmetic products) in terms of cost per avoided emissions to water, the proposed restriction is less cost-effective (€ 415 / avoided D4 and D5 kg emitted to water for the UK restriction, vs. € 1 000 / avoided D4, D5 and D6 kg emission for the proposed restriction). However, this is understandable since the first restriction logically targeted water emissions (given knowledge regarding their significance at that time), and the most cost/effective reduction targets, while this second restriction includes cases of more expensive substitution (especially lipsticks, skin care, sun/self-tanning). Because the UK restriction targeted only wash-off products and the proposed restriction includes a large proportion of leave-on products, it is likely that air emissions contribute proportionally significantly more to all emissions for the proposed restriction than for the restriction on wash-off cosmetic products, and therefore this puts the difference in cost-effectiveness into perspective. Furthermore, SEAC considers that the proposed restriction does not need to be especially compared to the restriction of D4 and D5 in wash-off cosmetics, but to the range of all past restrictions under REACH.

The Dossier Submitter also assessed the impact of uncertainties through sensitivity analysis regarding the number of reformulations, and the price of alternative raw materials. Assuming that alternative raw materials are not twice but three times more expensive leads to an increase of 14% of the C/E ratio. The C/E ratio is directly proportional to what proportion of formulations with D4, D5 and D6 are assumed to be reformulated. In the worst case it is assumed that all formulations containing D4, D5 and D6 would be reformulated, the C/E ratio would increase to €5 500 per kg of releases to water prevented. This figure is by far exceeding the highest value appearing in Table 5, but this value for PFOA is a central value, and the upper value for the C/E of the PFOA restriction was €6 511/kg of avoided release, which is higher than €5 500.

Overall, consideration of uncertainties, of the related sensitivity analysis and its impact on the C/E ratios does not change SEAC conclusions that under a C/E perspective, the proposed restriction is proportionate.

The C/E ratio is also sensitive to the choice of the transitional period. The Dossier Submitter calculated the impact on costs of shorter transitional periods (down to 1 year) for cosmetic products. In case the transitional period is shortened to one year, the cost per kg would increase by around 13%, which would not change conclusions based on C/E (other aspects related to the transitional period are discussed in next section of the draft opinion).

Uncertainties in the proportionality section

SEAC endorses that intermediate use of the siloxanes probably mainly takes place at industrial sites as assumed by the Dossier Submitter, and that emission control is probably better regulated at industrial sites than at other sites. However, SEAC notes that this unlikely to be similarly organised in all Member States.

Main uncertainties in the C/E analysis have been reported and discussed above, alongside the description of key elements underpinning SEAC conclusion.

Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter considers the proposed restriction implementable for industry: alternatives to D4, D5 and D6 are already available on the market, and economically feasible for the different uses. In addition, the reformulation or transition to alternatives is feasible if sufficient transition time is given.

With regard to enforceability, the Dossier Submitter considers that the scope of the proposed restriction is clear and unambiguous: it covers the uses of D4, D5 and D6 as a substance or in mixtures used by consumers and professionals. Industrial uses and articles are out of scope. In addition, standardised laboratory methods for measuring D4, D5 and D6 exist (they have been developed in response to the restriction on D4 and D5 in wash-off cosmetic products). In addition, for cosmetic products, a simple preliminary check if the restricted substances are included can already be done by reading the INCI ingredients list on cosmetics packaging.

RAC conclusions:

RAC's view is that the proposed restriction is implementable, enforceable and manageable, as it is largely comparable to the current restriction on D4 and D5 in wash-off cosmetic products which was considered to be practical. For the non-cosmetic uses identified, measures are expected to be practical as well.

SEAC conclusions:

SEAC's conclusion is that the proposed restriction is implementable, enforceable and manageable, as it is largely comparable to the previous restriction on D4 and D5 in wash-off cosmetics, which was considered to be practical. For the non-cosmetic uses identified, measures are expected to be practical as well.

Key elements underpinning the RAC conclusions:

In section 2.8 "Practicality" (cf. Annex C for alternatives on cosmetics, and the relevant sections in 2.6 for the other uses) the Dossier Submitter has demonstrates that alternatives to D4, D5 and D6 are available and economically feasible. D4 has recently been listed on ANNEX II to the cosmetic regulation covering substances prohibited in cosmetic products ((EU) 2019/831).

In the consultation, the Danish EPA confirmed that reformulation and substitution of various products covering different product categories are already taking place. A random sample of historical data going back to 2015 collected in the database of The Danish Consumer Council's app "Kemiluppen" shows that out of 27 products declared to contain D4, D5, D6 and/or cyclomethicone, the composition of cyclic siloxanes has been changed in 26% (7 products) products and 19 % are now completely cyclomethicone free. These products represent diverse product types of both leave on and rinse off products (foundation, hair conditioner, sunscreen and deodorant).

Standardised laboratory methods for measuring D4, D5 and D6 have been developed in response to the restriction proposal in wash-off products. One of these laboratory methods is Gas Chromatography, which enables accurate measurement of D4, D5 and D6 down to 0.1% w/w in mixtures such as cosmetic products. Recent publication in 2017 (Brothers et al., 2017) have indeed demonstrated the accuracy and reliability of such simple analytical methods as

well as importance of proper sample preparation, for example QuEChERS (quick, easy, cheap, effective, rugged, and safe) sample preparation procedure commonly used for analysis in food and agricultural products is not recommended.

RAC took note of the advice of the Forum on the enforceability from 24 June 2019 and the opinion of FORUM that the scope of the originally restriction proposal was not fully clear and that definitions were missing. As a consequence, the Dossier Submitter substantially adjusted the text of the restriction without changing the originally intended scope.

Key elements underpinning the SEAC conclusions:

SEAC considered that the scope of the restriction, as initially proposed, could have been phrased more clearly in a number of instances. During the opinion-development process, SEAC recommended that the Dossier Submitter revise the text of the conditions of the restriction to enhance the practicality and enforceability of the proposed restriction.

These recommendations related to the use of the terms “industrial sites”, rinse-off vs wash-off cosmetic products, medical devices and dry cleaning. Similar recommendations were made by Forum. The text of the Background Document was adapted accordingly and this has led to a clearer description of the activities on “industrial sites” and a clearer description concerning the dry cleaning and the restrictions considering emissions. Forum concludes that the new wording improves, in general, the proposed conditions of the Annex XV restriction proposal.

During the consultation on the SEAC draft opinion, questions were raised regarding whether certain uses were covered by the current entry on ‘industrial uses’ (entry 4(a)) and some of the comments requested a more open description (#431, #436, and other confidential responses). SEAC agrees with the current description provided by the Dossier Submitter (based on registered uses) which provides more clarity on the activities to be covered by the restriction. SEAC assumes that most production activities will be covered under ‘industrial use as a monomer in the production of silicone polymer’ and ‘industrial production of articles.’ This also corresponds with the Forum advice to specify the activities.

SEAC concludes from the information in the dossier that alternatives are available for all uses within the scope of the restriction and that actors involved are familiar with these alternatives. SEAC finds it possible to replace D4, D5 and D6 in leave-on and rinse-off cosmetics with alternatives that seem to be both technically and economically feasible, although this may result in some product performance loss.

For certain categories of cosmetics and mixtures used in other sectors, there are already alternatives available on the market which do not contain D4, D5 and D6. Therefore, SEAC considers the proposed restriction to be implementable.

SEAC considers that the sampling of products to check the presence of D4, D5 and D6 is feasible. For cosmetics, a simple preliminary check can already be done by reading the INCI ingredients list on the packaging of the cosmetics. In checking the presence of D4, D5 and D6 the Enforcement Authorities may request information about the product composition from the suppliers of the other products.

The Dossier Submitter indicates that standardised analytical methods for D4, D5 and D6 to verify the concentration in mixtures, including cosmetics, have been developed to support the implementation of the D4/D5 restriction on wash-off cosmetics. Based on recent studies, accurate measurement of D4, D5 and D6 down to 0.1% w/w in mixtures such as cosmetic products is possible. The Dossier Submitter indicates in the appendix to the Background document that the detection limit is reported to be 0.1 mg/kg, which is far below the proposed limit of 1 000 mg/kg (0.1% w/w). Although not explicitly mentioned in the Background Document, as also noted by Forum, SEAC expect that the analytical methods mentioned are

easy to apply on a daily basis and able to reach the limit value proposed. A reference to the analytical method(s) available as recommended by Forum is supported.

In the consultation for the 2016 restriction it was indicated that there were challenges in measuring D4/D5 at a 0.1% w/w concentration level in cosmetics. These challenges were related to inference between the siloxanes and particularly the silicone polymers. In that case, SEAC took note of these challenges and concluded that the restriction could be considered enforceable. The study referred to in this Background Document on D4, D5 and/or D6 indicates the potential for interferences and provide recommendations to reduce such interferences.

The initially proposed restriction required a zero emission from the dry-cleaning sector using D5 in order for the derogation to apply. Both SEAC and Forum considered that it would be unrealistic to realise the zero emission due to opening of the dry cleaning equipment and doubted whether the measures can be fully implemented and enforced.

Currently, the entry for dry cleaning has been phrased in a more realistic way, although improvements are still possible. SEAC support a further clarification of “strictly controlled conditions” or “controlled dry cleaning systems” as proposed by Forum. In its advice, Forum suggested to improve the scope, details in the dossier and wording to improve the practicality and enforceability. Most of these suggestions have been addressed in the most recent update of the Background Document.

Based on these considerations, SEAC concludes that the proposed restriction is enforceable.

Alternatives to D4, D5 and D6 exist for the majority of the identified uses. The reformulation or transition to alternatives is considered to be feasible if sufficient transition time is given. The Dossier Submitter has incorporated a justification for the transition period in the Background Document. The impact assessment carried out for cosmetics and other product categories, led to proposals for transitional periods of different durations to avoid disproportionate socio-economic impacts. The analysis of the impact of two and five year transitional periods for the cosmetics is presented in the Background Document, and the Appendix shows full analysis between 1 and 10 years.

When describing the reformulation process, the Dossier Submitter states that there are no major impacts and therefore that no consideration needs to be taken to the time for reformulation. Thus, companies could plan for their implementation of the restriction, and organise the products removal from the shelves. The consultation delivered proposals for both longer transition times (10 years) as well as for shorter transition times (two years). Some cosmetic companies or their trade organisations indicated that a five year transitional period was possible in the case of the availability of a direct substitute, but indicated a longer duration would be necessary in case of reformulation.

The Dossier Submitter has considered all information submitted during the consultation and reflected their considerations in the Background Document (Section 2.5.5) providing argumentation for the five year transition period for the leave-on cosmetics. In SEAC’s view, the arguments support maintaining the five year period earlier proposed for the leave-on cosmetics.

SEAC concludes that, considering earlier experiences with the restriction of D4 and D5 in wash-off cosmetics and the transition times proposed, the proposed restriction is manageable.

Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The presence of cosmetics on the market containing D4, D5 and D6 could be monitored using databases or applications such as the ones that were used as sources for this Annex XV report preparation (CosmEthics, QueChoisir, CodeCheck, etc…). Mystery shopping campaigns could also be used for the same purposes. Additionally, Voluntary Industry programmes on waste water treatment plants (WWTP) monitoring on D4 and D5 could be expanded with D6.

RAC and SEAC conclusions:

RAC and SEAC conclude that the proposed restriction is monitorable.

Key elements underpinning the RAC conclusions:

The Dossier submitter has laid out in Section 2.9 “Monitorability” several arguments. RAC agree with the Dossier Submitter that presence of cosmetics on the market containing D4, D5 and D6 could be monitored using databases or applications as well as analytical method with suitable threshold.

Information from the consultation confirmed that the sampling and measurement of D4, D5 and D6 in municipal WWTP influents are feasible to monitor the effectiveness of the proposed restriction on cyclic siloxanes. Because the concentrations of cyclic siloxanes in the wastewater is very low (µg/L), the limit of detection of used analytical method is far below the limit in the proposed restriction.

Key elements underpinning the SEAC conclusions:

Due to the characteristics of PBT/vPvB substances, risks cannot be adequately addressed in a quantitative way. Therefore, emissions and subsequent exposure, are considered as a proxy for risk. Monitoring the effectiveness of the proposed restriction in reducing the emissions to water and air can in first instance be carried out by monitoring the emissions to water or the emissions from waste water treatment plants (see Sections B.4.1.5 and B.9.2.3 in the Background Document). These reductions in emissions and/or releases that remain in the environment have also been used in the model estimations to estimate the effectiveness of the restriction.

For cosmetic products, a simple check can already be done by reading the INCI ingredients list on the packaging of the cosmetic product. The Dossier Submitter indicates that standardised analytical methods for D4, D5 and D6 to verify their concentration in mixtures, including cosmetics, have been developed to support the implementation of the D4/D5 restriction of wash-off cosmetics. The Dossier Submitter indicates in the appendix to the Background Document that the detection limit is reported to be 0.1 mg/kg, which is far below the proposed limit of 1 000 mg/kg. Thus, it is expected that monitoring the presence of D4, D5 and/or D6 above the proposed limit is feasible. No comments on the monitorability were received during the consultation, although one that indicate a problem with the monitorability of the restriction. One submission recommended to include D6 in the voluntary monitoring programme for water and to extend the monitoring with air samples.

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

RAC

Summary of proposal:

A number of uncertainties (e.g. tonnage of certain uses such as in detergents, household care and vehicle maintenance products) have been identified and listed by the Dossier Submitter in the Background Document (section 3 of the report and in Annex D). The Dossier Submitter is relying on the information provided by the registrants, the sector associations, and gathered during the market research study. These uncertainties do not have a significant impact on the overall releases estimates.

It should also be noted that, due to the lack of reliable measurement data, the estimated releases could not be compared with monitoring data.

It remains unclear to what extent mixtures containing silicone polymers used as medical devices and as sealants used in the construction sector would be affected by the proposed restriction, where these contain D4, D5 and D6 as impurities above 0.1% concentration.

RAC conclusions:

RAC agree with the identified uncertainties and the sensitivity analysis performed by the Dossier Submitter.

Key elements underpinning the RAC conclusions:

RAC agrees with the evaluation of the Dossier Submitter that not all uses of D4, D5 and D6 might have been captured in the tonnage reported in the Annex XV restriction report in which the main sources of information were the call for evidence, market survey and REACH registration dossiers. The companies reporting to the product registries are placing mixtures on the market that might not reach the 1 tpa threshold for REACH registration obligations; this might be a reason why some uses are not captured in the REACH Registration dossiers. Also, D4 has recently been listed on ANNEX II in the cosmetic regulation covering substances prohibited in cosmetic products ((EU) 2019/831).

But the overall tonnages are small and from the view point of risk assessment the resulting impact on the proposed restriction is negligible.

SEAC

Summary of proposal:

For cosmetic products, sensitivity analysis was performed for key variables for which significant uncertainty remains (see Appendix D.2 in the Background Document):

- Assumptions regarding what proportion of formulations containing D4, D5 and D6 would be reformulated: this is a key area of uncertainty in the analysis, and little supporting information is available. Sensitivity analysis reveals that the total cost (and cost effectiveness) of the restriction is directly proportional to changes in the number of reformulations. In the most extreme scenario, where 100% of formulations containing D4, D5 and D6 are assumed to be reformulated, the costs (total costs of the restriction and costs per kg of releases that would remain in the environment abated) would be five times higher i.e. the annual cost per kg of releases prevented would increase to €7 350 if only releases to water were considered, and to €20 if releases to air and water were considered. If considering D4, D5 and D6 releases that would remain in the environment, abatement costs would increase to €450 per kg per annum.

- Prices of raw materials used to replace D4, D5 and D6: Industry are considering a wide variety of substances as alternatives to D4, D5 and D6, but it is not known which will be taken forward. Sensitivity analysis shows that as the additional costs of raw materials are only a small proportion of total costs, increasing the assumed cost of the alternative raw material would lead to relatively small increases in total costs. For instance, assuming alternative raw materials would be 3 times as expensive as D4, D5 and D6, rather than 2 times, leads to an increase in total costs of 14%.
- Variations in the price of raw materials used in alternative products: the Dossier Submitter has assumed that input costs for alternative products (i.e. those that do not contain D4, D5 or D6) would not change as a result of potential increased demand due to the restriction. Sensitivity analysis shows that should there be an increase, each 10% increase in raw material costs would lead to a 5% increase in total costs of the restriction.
- Behaviour of industry under the baseline: There are indications that there could be a voluntary move away from D4, D5 and D6 by industry, even without the restriction (e.g. in response to the SVHC identification of D4, D5 and D6). This would reduce both the costs and benefits that could be attributed to the restriction. As has been explained above (Justification that Action is required on an EU-Wide basis), as such, this is not likely to have a significant effect on the cost-effectiveness estimates.

SEAC conclusions:

SEAC concludes that the uncertainties have been adequately assessed and presented by the Dossier Submitter. SEAC considers that major uncertainties are related to the proportion of reformulations, the price and variation in price of raw materials and how industry will react to the restriction, which have already been addressed in parts of the opinion where relevant.

Key elements underpinning the SEAC conclusions:

In the consultation the Dossier Submitter specifically requested data on substituting D4, D5 or D6 in cosmetic formulations, and experiences different from the assumptions outlined in section 2.5.1 of the Annex XV report. These assumptions considered the formulation costs, the raw material costs and the consumer costs associated with performance loss. As indicated above in the summary, uncertainties could mainly be related to reformulation costs and the raw materials costs. The reformulation costs are based on the number of total cosmetic product formulations on the EU/EEA market, the costs per reformulation, the number of formulations containing D4, D5 and D6 and the number of reformulations expected.
The consultation resulted in some input indicating that the reformulation process is complex, financially costly and also time consuming. However, the amount of qualitative information provided was limited. One submission (#2636) indicated that the estimated number of reformulations would be 19% of all SKUs (stock keeping unit). This seems to be in good agreement with the 34 400 to 68 800 formulations with D4, D5 and D6 (best estimate 47 300 formulations) among the 430 000 formulations on the market as described in Section 2.5.1.1 of the Background Document. One submitter (#2672) indicated that reformulation for certain products groups, such as make-up, make-up removers and hair products, would be more challenging and would take more effort than others and added that alternatives may be different in various products. This claim could not be further scrutinised. The Dossier Submitter presented in the Background Document a simple weighted average between major reformulations and reformulations by SMEs would hence result in an estimate for reformulation costs of €135 000 - €200 000 per item and concluded that this is significantly lower than the € 350 000 assumed in the assessment of the proposed restriction on wash-off cosmetic products. One comment on cost elements submitted during the consultation (#2177) provided a central estimate of €240 000 for the total reformulation cost to replace

D5 per personal care product with a low and a high estimate of €110 000 and €360 000 respectively. This is in the same range as the values presented by the Dossier Submitter. No further data on these elements were submitted, and thus SEAC consider a further reduction of the uncertainties around these items not achievable.

Although some information on possible alternatives was provided during the consultation, information on the price of raw materials was not received. Information on the most probable alternatives and the amounts of these alternatives needed to replace D4, D5 and D6 were lacking which prevents SEAC to further scrutinise the assumptions made concerning the raw material costs.

As already indicated in the section on Justification that Action is required on a EU-Wide basis, SEAC does not assume that inclusion in the candidate list has in general a visible impact on substitution efforts and use volume of the substance. Some companies express the intention to phase out SVHCs if feasible, but others indicate that the candidate SVHC list does not require elimination of chemical substances from any products and point to the legal obligations related to the listing.

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