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/[Opinion N°(same as opinion number)]

Adopted

28 November 2019

28 November 2019

RES-O-0000006700-80-01/F

5 December 2019

[SEAC opinion number]

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 **[date of adoption of the opinion]**. **[**The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]]**[1].

[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.**] [**No comments were received from interested parties during the consultation in accordance with Article[s 69(6) and][3] 71(1)**]**[6].

The opinion of SEAC was adopted **by [consensus**.**][a simple majority]** of all members having the right to vote. [The minority position[s], including their grounds, are made available

[1] Delete the unnecessary part(s)

in a separate document which has been published at the same time as the opinion**.]**[6].

Contents

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), (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 (iii) medicinal products for human health as defined in EU Directive 2001/83/EC. b) 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. c) 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 - Industrial use in formulation and/or (re-)packing of mixtures - Industrial production of articles

Designation of the substances, of the group of substances or of the mixture	Conditions of restriction
	- 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 as adhesives or sealants *that cure in situ* b) D5 in a concentration equal to or less than 0.2% 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 0.3% w/w for use as protective 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. 6. By way of derogation, paragraphs 1 and 2 shall not apply to: 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

See the opinion of SEAC.

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 methyl siloxane (cVMS) 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[2]); 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[3]. 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.

[2] D4 is also identified as a PBT substance

[3] 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[4]). 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[5]).

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)

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

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 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 REACH Annex XIII 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)[6]).

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 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

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

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[7]. 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 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

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

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 reprotoxicity 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:

See the opinion of SEAC.

SEAC conclusions:

See the opinion of SEAC.

Key elements underpinning the SEAC conclusions:

See the opinion of SEAC.

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%8. 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

[8] 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%.

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:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Benefits

Summary of proposal:

See the opinion of SEAC.

SEAC conclusions:

See the opinion of SEAC.

Key elements underpinning the SEAC conclusions:

See the opinion of SEAC.

Other impacts

Summary of proposal:

See the opinion of SEAC.

SEAC conclusions:

See the opinion of SEAC.

Key elements underpinning the SEAC conclusions:

See the opinion of SEAC.

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 4: 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 and SEAC 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).

Key elements underpinning the RAC and SEAC 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.

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 and SEAC 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.

Key elements underpinning the RAC and SEAC 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.

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 concludes that the proposed restriction is monitorable.

Key elements underpinning the RAC and SEAC 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.

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:

See the opinion of SEAC.

SEAC conclusions:

See the opinion of SEAC.

Key elements underpinning the SEAC conclusions:

See the opinion of SEAC.

REFERENCES

ECHA (2017). ECHA study on enforcement costs. Helsinki, ECHA. SEAC/35/2017/02.