

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-000006700-80-01/F
ECHA/SEAC/[Opinion N°(same as opinion number)]

Agreed

5 December 2019

28 November 2019

RES-O-000006700-80-01/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

¹ Delete the unnecessary part(s)

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

Contents

OPINION OF RAC AND SEAC	2
THE OPINION OF RAC	3
THE OPINION OF SEAC.....	3
JUSTIFICATION FOR THE OPINION OF RAC AND SEAC	5
IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK.....	5
Justification for the opinion of RAC.....	5
Description of and justification for targeting (scope)	5
Description of the risks addressed by the proposed restriction.....	5
Information on hazard(s).....	5
Information on emissions and exposures	5
Characterisation of risk(s).....	6
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.....	6
Evidence if the existing regulatory risk management instruments are not sufficient	6
JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS	7
Justification for the opinion of SEAC and RAC	7
JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE.....	8
Justification for the opinion of SEAC and RAC	8
Scope including derogations.....	8
Justification for the opinion of RAC.....	8
Justification for the opinion of SEAC	8
Effectiveness in reducing the identified risks	14
Justification for the opinion of RAC.....	14
Socio-economic impact.....	14
Justification for the opinion of SEAC	14
Costs	14
Benefits.....	21
Other impacts	21
Overall proportionality.....	22
Uncertainties in the proportionality section.....	25
Practicality, incl. enforceability	26
Justification for the opinion of RAC and SEAC	26

Monitorability	28
Justification for the opinion of RAC and SEAC	28
UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC	29
RAC	29
SEAC.....	29
REFERENCES	32

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
<p>a) Octamethylcyclotetrasiloxane EC Number: 209-136-7 CAS Number: 556-67-2 INCI name: Cyclotetrasiloxane or Cyclomethicone <i>Also known as D4.</i></p> <p>b) Decamethylcyclopentasiloxane EC Number: 208-764-9 CAS Number: 541-02-6 INCI name: Cyclopentasiloxane or Cyclomethicone <i>Also known as D5.</i></p> <p>c) Dodecamethylcyclohexasiloxane EC number: 208-762-8 CAS number: 540-97-6 INCI name: Cyclohexasiloxane or Cyclomethicone <i>Also known as D6.</i></p>	<ol style="list-style-type: none"> 1. Shall not be placed on the market: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> a) As a solvent for the dry cleaning of textiles, leather and fur. 3. This restriction shall come into force: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> a) Placing on the market of D4, D5 and D6 for the following uses: <ul style="list-style-type: none"> - 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 - Industrial use in non-metal surface treatment - Industrial use as laboratory reagent in Research & Development activities

Designation of the substances, of the group of substances or of the mixture	Conditions of restriction
	<p>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.</p> <p>c) Placing on the market of D5 for professional use in the cleaning or restoration of art and antiques.</p> <p>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:</p> <p>a) D4 or D5 or D6 in a concentration equal to or less than 1% w/w, for use as adhesives or sealants <i>that cure in situ</i></p> <p>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.</p> <p>c) D4 in a concentration equal to or less than 0.3% w/w for use as protective coatings.</p> <p>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.</p> <p>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.</p> <p>6. By way of derogation, paragraphs 1 and 2 shall not apply to:</p> <p>a) Use of D5 in strictly controlled closed dry cleaning systems for textile, leather and fur where the cleaning solvent is recycled or incinerated.</p>

THE OPINION OF RAC

See the opinion of RAC.

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:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of SEAC.

Description of the risks addressed by the proposed restriction

Information on hazard(s)

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Information on emissions and exposures

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Characterisation of risk(s)

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Uncertainties in the risk characterisation

See the opinion of RAC.

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:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

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 releases throughout the EU/EEA. 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:

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 (Austrian study cited in Danish EPA, 2019). Although D4 will be prohibited in cosmetic products through the EU Cosmetics Regulation, it may still be used 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, SEAC 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

Justification for the opinion of SEAC and RAC

Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

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 as adhesives or sealants that cure *in situ*².
- Mixtures that contain 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 Regulation 2017/745) for dental impression.
- Emulsion concentrates that contain D4 in a concentration equal to or less than 0.3% w/w, for use as protective 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

² The phrase '*cure in situ*' is intended to describe liquid mixtures that become solid during their end use e.g. after bonding materials together or filling voids/gaps.

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.

It is possible that other uses of silicone polymers may also be inadvertently affected. However, the Dossier Submitter does not have sufficient information to suggest further derogations for other uses. If sufficient information is received during the consultation on the draft SEAC opinion, similar derogations may be proposed for other uses.

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 agrees with all of 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).

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 from 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.

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 Dossier 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 feasibility 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:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

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.

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 possible 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 1: 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 note³ 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,

³ Note available at: <https://echa.europa.eu/documents/10162/a3288fcf-928f-795f-8049-ae4da7eab7ee>

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 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 all releases are considered, both to the atmosphere and to the aquatic compartment, this would result in a best estimate of €3 per kg per year of releases abated. If only releases to the aquatic compartment are considered, 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 both the aquatic and 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 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 may be considered as a more suitable basis upon which to estimate cost-effectiveness, at least for these substances, when compared to using releases to the aquatic compartment or releases to both the aquatic and atmospheric compartment. Using only releases to the aquatic compartment would effectively give a weighting of 0% to releases to atmosphere, while using releases to both the aquatic and atmospheric compartment 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 entirely appropriate. Using instead the releases that will remain in the environment after relevant date processes are considered 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 cosmetic product groups, and the results vary substantially between them. Data for releases

that will remain in the environment for individual cosmetic product groups are not available.

Table 2: Cost-effectiveness by broad product group

Broad product group	Cost	Cost
	[€/year/kg] If releases to water only	[€/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:

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 and 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 3 allows comparison of these figures with the central estimates from recent REACH restrictions on PBT/vPvB chemicals.

Table 3: 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. The scope covers the uses of D4, D5 and D6 as a substance or in mixtures used by consumers and professionals. Industrial uses and articles are intended to be 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.

The Dossier Submitter implemented several changes to the text of the conditions of the restriction during the opinion-making, as recommended by RAC and SEAC, to enhance the proposal's practicality.

RAC and 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 and 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.

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 programmes on wastewater treatment plant (WWTP) monitoring on D4 and D5 could be expanded to include D6.

RAC and SEAC conclusions:

SEAC agrees that the restriction is monitorable.

Key elements underpinning the RAC and 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:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

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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