**Response to comments on the SEAC draft opinion**

**on the Annex XV dossier proposing**

**restriction on**

**Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5); dodecamethylcyclohexasiloxane (D6)**

**EC numbers: 209-136-7; 208-764-9; 208-762-8**

**CAS numbers: 556-67-2; 541-02-6; 540-97-6**

**12 March 2020**

Comments on the SEAC draft opinion and specific information requests

## Specific information requests

1. Paragraph 4 – Derogation for uses of D4, D5 or D6: Paragraph 4 proposes a derogation for certain uses of D4, D5 or D6. For further derogations to be considered for other uses, particularly in medicinal products (whether for human health or veterinary applications), please provide supporting information on:
   1. tonnage and function of D4, D5 or D6 in this use
   2. whether there are alternatives to D4, D5, D6 for these products and if not, what analysis this conclusion is based on.
   3. the impact to society if a derogation or longer transitional period are not agreed to. This includes the financial impact to the companies manufacturing the medicinal products in question and to the companies manufacturing alternatives, but also the potential impact on the users if these products are not available to them.
2. Paragraph 3a –transitional period for uses of D4, D5 or D6 in medicinal products for human health: Paragraph 3a point (iii) is currently only referring to a longer transitional period for medicinal products for human health, as the Dossier Submitter has not received any information on medicinal products for veterinary applications (EU Directive 2001/82/EC) that may be affected by the proposal. For longer transitional periods to be considered for medicinal products for veterinary applications, please provide supporting information on:
   1. tonnage and function of D4, D5 or D6 in this use
   2. whether there are alternatives to D4, D5, D6 for these products and if not, what analysis this conclusion is based on.
   3. the impact to society if a derogation or longer transitional period are not agreed to. This includes the financial impact to the companies manufacturing the medicinal products in question and to the companies manufacturing alternatives, but also the potential impact on the users if these products are not available to them.
3. Paragraph 3a – Transitional period for leave-on cosmetic products: Paragraph 3a proposes a transitional period of 5 years for leave-on cosmetic products (as defined in the Regulation (EC) No 1223/2009 – Preamble to Annexes II to VI). What would be the impact of having a shorter transitional period of 2 years for all leave-on cosmetic products except make-up and lipstick and skin care products?
4. Paragraph 4a – Industrial uses: Paragraph 4a provides a list of registered uses which are proposed to be derogated. Are there any further industrial uses of D4, D5 and D6 that are not included in this list? If so, for a derogation to be considered, please provide supporting information on:
   1. tonnage
   2. use description
   3. information on why the use is not included in the registration dossiers
5. Paragraph 4c - Placing on the market of D5 for professional use in the cleaning or restoration of art and antiques: Paragraph 4c proposes a derogation for D5 for this use, but not for D4. This is because D5 is considered to be an economically and technically available alternative to D4, and has a better toxicity profile. If you have information to the contrary, and would like a derogation for D4 to also be considered for this use, please provide information on:
   1. tonnage and function of D4 for this use
   2. whether there are alternatives to D4 (including but not limited to D5) for this use, and if not, what analysis this conclusion is based on.
   3. the impact to society if no derogation is provided for D4. This includes the financial impact to the companies manufacturing the products in question and to the companies manufacturing alternatives, but also the potential impact on the users and cultural heritage if D4 is not available.
6. Paragraph 5 - Presence of D4, D5 or D6 as residues in silicone polymers used by consumers and professionals: According to the Background Document, it is possible that some silicone polymers mixtures, used by consumers and professionals, may unavoidably contain D4, D5 or D6 residues above 0.1% w/w of each substance. Under the proposed restriction, these mixtures would no longer be allowed to be placed on the market after the proposed transitional period ends.

Information was received during the Annex XV proposal consultation regarding uses of silicone polymers in that situation, and specific concentration limits have been proposed to ensure they are out of scope (see paragraph 5 of the restriction proposal). It is possible that further silicone polymer mixtures are in this situation. For additional derogations to be considered, please provide specific concrete and detailed information in the SEAC opinion consultation on:

* 1. the identity of the mixture (brand name if relevant),
  2. the specific function of the mixture, its sector of use (e.g. construction, dentistry), and the quantity of mixtures placed on the market,
  3. the residual concentration (%w/w) of D4, D5 or D6 in the mixture,
  4. information on why it is not feasible to reduce these concentrations below 0.1% w/w, and
  5. analysis to demonstrate and if possible quantify the negative impact of not derogating the use.

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| **Ref.** | **Date/Name/Org.** | **Comments** |
| 431 | **Date/Time:** 2020/02/03 14:59  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Cefic, CES - Silicones Europe  **Org. country:**  Belgium  **Attachment:**    <redacted>  **Privacy comment:**  This document contains information that should be reviewed by ECHA first. | **Comments on the SEAC draft opinion:**  See attachment below |
| **Specific information 1:**  CES welcomes the inclusion of reference to the Medical Device Directive (MDD) in the proposal to take into account the transition period for medical devices to be placed on the market until May 2024.  Socioeconomic calculations in the restriction proposal are derived for leave-on personal care/cosmetic products and are based on hypothetical costs of ingredient replacement and reformulation of these products.  However, revision and substitution of substances and materials used in medical devices require a very different and much more stringent regulatory path. Devices must be re-tested for function, efficacy, performance, toxicity, and migration and extraction and must be requalified with the appropriate regulatory body. This process requires significant resources, time, and monetary expenditures. It cannot be compared to the cost of finding a suitable new cosmetic ingredient.  The socioeconomic calculations should extend beyond the concept of €/kg product to fully take into account the societal and broader economic consequences of the restriction. Existing medical devices and medical innovations are critical to the UN Sustainability Goal 3 for good health and well-being, and they contribute to healthcare accessibility and reducing costs imposed by illness and disability to individuals, to families and to society. This includes costs to individuals and their families in terms of lost work time and opportunities, as well as physical, emotional, financial, and care-giving costs. Society bears the burden as well in terms of increased social support taxes and burdens on medical resources such as hospitals, therapeutic facilities, and the medical support community as a whole.  As noted in the SEAC Background document (Section 2.6.4., p 79), the risks potentially posed by medical devices that may include D4, D5, or D6 as intentional substances or as residuals in mixtures or polymers are strictly evaluated as a part of the required medical device extraction/migration testing, risk assessment, and risk/benefit calculations. CES agrees with this statement and therefore finds it is unnecessary and inappropriate for medical devices to be included within the scope of the proposed restriction. No environmental benefit would be derived by inclusion in the restriction, as environmental releases would be de minimis, particularly relative to contributions from other sources. When the high costs of moving to alternatives (as described in this same section of the background document) are considered, the failure to exclude medical devices from the scope of the restriction is disproportionate.  It should be noted that there is a discrepancy between the medical devices presented in the SEAC background document and the current derogations listed for medical devices. Although the background document (p89) discusses applications including artificial skin (as used for burn treatments) for which it may not be possible to devolatilize to reach the proposed restriction limit, this application is not covered in any of the listed derogations. These products typically include a very thin silicone membrane which is neither a substance nor a mixture. If a general derogation for medical devices fails to be granted, a derogation should be specifically granted for this very critical application. |
| **Specific information 4:**  The current approach of the draft restriction risks to harm the innovative capabilities of European industry by narrowly defining specific exemptions. This might prove harmful to EU-made innovations as European manufactures are prevented to drive innovation in areas that are not covered by the exemptions. To assume that all future areas of innovation can be foreseen is impossible as past experiences have shown time and time again. To avoid these potential negative impacts to Europe’s industrial base CES proposes to include the following wording&#58;    “By way of derogation, paragraph 1 shall not apply to&#58; a) Placing on the market of D4, D5 and D6 for industrial uses and the industrial production of articles”.  Including such a derogation is consistent with the Commission’s request and would address our worries with regards to future innovations that are not reflected in the proposed list of derogations. |
| **Specific information 6:**  Derogation 5 c.) – protective coatings  The derogation 5 c.) as proposed now reads as follows:  “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  [...]  c) D4 in a concentration equal to or less than 0.3% w/w for use as protective coatings.”    We would like to propose the following change to the derogation:  c) D4 or D5 or D6 in a concentration equal to or less than 0.3% w/w for use as protective coatings.”  Rationale:  CES generally supports the approach taken on derogating protective coatings from the general concentration limit of 0,1 % w/w proposed.  However, removing D5 and D6 from polymers that are used as protective coatings is more challenging than removing D4. This can be established from looking at the physical-chemical properties for D4, D5 and D6 in table 2 of the Annex VX Restriction Report. D4’s higher vapour pressure and lower Henry’s law constant explain that it is more volatile than D5 and D6 and therefore easier to remove from products.  Hence from a technical point of view D5 and D6 should be included to the derogation 5 c.). Only derogating D4 in a concentration up to 0,3% w/w, would pose a technical challenge for the manufacturers.  Derogation 5 f.) – 3D-printing  CES would like to include derogation 5f.) to account for 3D-printing.  f) D4 or D5 or D6 in a concentration equal to or less than 1% w/w, for use in 3D printing  Rationale:  CES would like to propose a derogation for professional and consumer uses in 3D-printing in order to allow for the use of silicone polymers in the diverse existing applications. |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion.  You point out that medical devices are strictly evaluated as a part of the regulatory framework under which they operate. Thus, you find it is unnecessary and inappropriate for medical devices to be included within the scope of the proposed restriction. SEAC, however, concur with the Dossier Submitter that they should be included, since the evaluation within the framework of the medical devices is mainly carried out on the human health risks and not on environmental risks.  The background document mentions artificial skin for burn treatment in section 2.7.9 as a consumer/professional mixture for which achieving concentrations of D4, D5 and D6 below a concentration of 0.1% w/w may be difficult. In the explanation on the derogated uses the Dossier Submitter (DS) remarks it proposes an increase in the concentration limit for the specific uses of silicone polymers for which data is available. The DS explains in section 2.7.3 that no information about concrete cases or about concentrations was received for this application and thus, no derogation was proposed. We concur with the DS that it is difficult to propose derogations for which no data have been received.  SEAC rapporteurs do not concur with the view that the restriction proposal would harm innovation. The effects of the proposed restriction might be on the one hand to limit the possibility to bring innovations based on silicone polymers. However, scientific work is still possible to carry out R&D activities and the entries on the silicone polymers and articles provide enough possibilities to still apply the substances in an industrial production setting. On the other hand the proposed restriction can have a positive effect on innovation and be an incentive to develop new alternatives.  Based on the data provided regarding the presence of D4, D5, and D6 in silicone polymers used in coatings and 3D printing, the DS proposed derogations for these applications in entries 5c and 5j. |
| 433 | **Date/Time:** 2020/02/05 15:50  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Germany  **Company name confidential: Yes**  **Attachment:**  <redacted>  **Privacy comment:**  Protection of confidential business details on product related turnover and other strictly confidential data. | **Comments on the SEAC draft opinion:**  For all comments please see confidential attachment in section V. |
| **Specific information 1:**  See attachment |
| **Specific information 2:**  See attachment |
| **Specific information 3:** |
| **Specific information 4:**  See attachment |
| **Specific information 6:**  See attachment |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion. |
| 434 | **Date/Time:** 2020/02/12 13:20  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Verband TEGEWA e. V.  **Org. country:**  Germany | **Comments on the SEAC draft opinion:**  The association TEGEWA e. V. is representing companies which produce – inter alia - textile, paper, leather and fur auxiliaries and colourants.  Polysiloxanes are produced from cyclic siloxanes and are applied in the production/formulation of textile and leather auxiliaries. These formulations are used in the manufacturing of textiles and leather. The formulations might contain D4, D5 or D6 as residues from the polymerisation process. Currently content of D4, D5, D6 in some of the formulations is still above 1.000 ppm each, industry is working to lower the amount of the residues. The formulations are exclusively used in industrial settings.  With the derogations mentioned under “Conditions of restriction” in the proposed restriction text and considering the statement under “Summery of proposal” (“Industrial uses and articles are intended to be out of scope”) we assume that the uses in textile and leather chemistry will be out of scope. But to avoid any misinterpretation and in order to have a clear and unambiguous regulation – not least important for enforcement bodies – we ask for a clear statement of that the above mentioned uses are definitely out of scope of the planned restriction.  We understand the following derogations as formulated under paragraph 4 of the restriction proposals as applicable to the above mentioned textile, fibre and leather chemistry uses:  - “industrial use in formulation and/or (re)packing of mixtures  - Industrial production of articles  - Industrial use in non-metal surface treatment”  But even though we would assume that textile and leather auxiliary formulations are tackled by these definitions, we would appreciate a more concrete definition where these are explicitly mentioned as “industrial use in formulations for textile, fibre and leather manufacturing”.  Some more details and information about the uses in textile, fibre and leather chemistry applications are to be found under “specific information requests” – derogation for uses. |
| **Specific information 4:**  a. Tonnage;  Regarding the amounts of polysiloxanes we made a (non-representative) survey. We received answers showing that polysiloxanes are used in amounts &gt; 10.000 t/a for leather and textile auxiliaries being produced for the global market. We do not have more concrete numbers and we do not know in what percentage these products are being used in the EUROPEAN market. We neither have information about the amount of IMPORTED polysiloxanes for textile and leather applications into the European market.  b. use desription;  Polysiloxanes are applied in formulations for textile manufacture, e. g. softener preparations, defoaming agents, in coating agents (e.g. for water repellent finish).  Polysiloxanes are also applied in preparations (e.g. fibre fill preparation on PET staple fibres). Furthermore, modified polysiloxanes may be contained as components in spinning preparations as e.g. spreading agent or defoamer.  In leather manufacture, polysiloxanes are used in similar compounds as in textile manufacture. This concerns applications such as; grip, abrasion, water repellency and leather care.  The textile and leather auxiliaries may contain impurities of D4D5, and D6 as residues from the manufacture of the polymers.  As clarification we therefore ask to also consider the following uses under industrial uses of D4, D5 and D6 for a derogation; --&gt; industrial use in formulations for textile, fibre and leather manufacturing  c. Information on whye the use …;  As mentioned before, we believe that the industrial use in formulations for textile, fibre and leather manufacturing is tackled by the definitions given in paragraph 4a of the restriction proposal (“industrial use in formulation and/or (re)packing of mixtures, Industrial production of articles, Industrial use in non-metal surface treatment”) but would appreciate to have it written down in a more precise and unambiguous way. |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion.  SEAC considers that the proposed derogations are already covered under entries in the restriction proposal, as referred to in your comments. SEAC understands that the Dossier Submitter took the wording from the registration dossier as a starting point for the derogations under paragraph 4, and that the wording proposed is broad enough to cover the uses for textile and leather application at industrial sites. |
| 435 | **Date/Time:** 2020/02/13 11:31  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Switzerland  **Company name confidential: Yes**  **Attachment:**  <redacted>  **Privacy comment:**  The confidential document in the attachment includes confidential company sales and volume information. In order to protect our company's commercial interests, this information must not be placed in the public domain. It can only be used by ECHA and the relevant member state competent authorities for the purposes of this restriction assessment. | **Comments on the SEAC draft opinion:**  Please see the attached confidential letter. |
| **Specific information 6:**  Please see the attached confidential letter. |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion. |
| 436 | **Date/Time:** 2020/02/17 10:20  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  France  **Company name confidential: Yes**  **Attachment:** | **Comments on the SEAC draft opinion:**  COMMENTS ON SEAC DRAFT OPINION  Scope of the comment  We, (<redacted> Group) would like to make a comment on the scope of the restriction proposal highlighted in the SEAC draft report.  In both the Annex XV report (version number: 1.1 date: 20 March 2019) and in SEAC draft report (agreed 5 December 2019), the Brief title of the restriction is: ”Restriction of D4, D5 and D6 in consumer and professional products” and industrial uses are not highlighted.  it is also written in the RAC opinion (ECHA/RAC/RES-O-0000006700-80-01/F, adopted 28 November 2019) related to industrial uses (page 10):  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). It specifically targets substances or mixtures intended for end use by consumers or professionals  and also at the same page it is highlighted:  The Commission’s request for a restriction proposal excludes industrial uses of D4, D5 and D6 (such as formulation of mixtures, production of silicone polymers or production of articles) as well as the use of silicone polymers. These are therefore not in the scope of the proposed restriction or of this opinion.  Nevertheless We obsereved significant differences between the new restriction proposal text of the SEAC draft opinion and the ANNEX XV report related to industrial uses.  The Annex XV restriction report of D4, D5 and D6 stated in the original proposed text of the restriction among the derogations (page 4):  3. By way of derogation, paragraph 1 shall not apply to:  a) Placing on the market for use at industrial sites (except for dry cleaning industrial sites), and use as a transported isolated intermediate, provided that the conditions in points (a) to (f) of Article 18(4) of the REACH Regulation are met  While in the SEAC DRAFT OPINION page 2-3 it is stated:  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  - Industrial use in non-metal surface treatment  - Industrial use as laboratory reagent in Research & Development activities  The new text in the SEAC draft report gives the possibility of some confusion whether industrial uses are generally exempted or just the highlighted specific industrial uses are exempted.  In addition, the highlighted industrial uses do not cover all segments of the industry and there can be also new industrial uses identified in the future.    Request for clarification of the scope of the restriction  We suggest that the restriction makes it clearer that the exemption for industrial uses is a general exemption and not just an exemption for some certain industrial uses  In addition, we would like to also ask to add into the industrial uses examples part of the restriction proposal the following uses:  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 of D4, D5 and D6 (as residual monomers) in polymers as part of mixtures used as anti-foaming agents  which is a critical use in biological medicine production in the pharmaceutical industry (the polymers applied in the anti-foaming mixtures can contain a residual quantity of D4, D5 and D6 above 0,1%)  and  • Industrial production of articles (including medical devices)  This change would indicate that manufacturing can be done with a raw material containing D4/D5/D6 above 0.1 % on the condition that the concentration of D4/D5/D6 in the marketed products does not exceed 0.1 %  These proposals would make the restriction clearer and would help the industry to better identify their duties related to this new regulatory obligation.  Compiled and submitted by the <redacted> Group  17.02.2020 |
| **Specific information 4:**  Our general comment deals exactly with this part of the proposed restriction; In both the Annex XV report (version number; 1.1 date; 20 March 2019) and in SEAC draft report (agreed 5 December 2019), the Brief title of the restriction is; ”Restriction of D4, D5 and D6 in consumer and professional products” and industrial uses are not highlighted.  it is also written in the RAC opinion (ECHA/RAC/RES-O-0000006700-80-01/F, adopted 28 November 2019) related to industrial uses (page 10);  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). It specifically targets substances or mixtures intended for end use by consumers or professionals  and also at the same page it is highlighted;  The Commission’s request for a restriction proposal excludes industrial uses of D4, D5 and D6 (such as formulation of mixtures, production of silicone polymers or production of articles) as well as the use of silicone polymers. These are therefore not in the scope of the proposed restriction or of this opinion.  Nevertheless We obsereved significant differences between the new restriction proposal text of the SEAC draft opinion and the ANNEX XV report related to industrial uses.  The Annex XV restriction report of D4, D5 and D6 stated in the original proposed text of the restriction among the derogations (page 4);  3. By way of derogation, paragraph 1 shall not apply to;  a) Placing on the market for use at industrial sites (except for dry cleaning industrial sites), and use as a transported isolated intermediate, provided that the conditions in points (a) to (f) of Article 18(4) of the REACH Regulation are met  While in the SEAC DRAFT OPINION page 2-3 it is stated;  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  - Industrial use in non-metal surface treatment  - Industrial use as laboratory reagent in Research &amp; Development activities  The new text in the SEAC draft report gives the possibility of some confusion whether industrial uses are generally exempted or just the highlighted specific industrial uses are exempted.  In addition, the highlighted industrial uses do not cover all segments of the industry and there can be also new industrial uses identified in the future.    Request for clarification of the scope of the restriction  We suggest that the restriction makes it clearer that the exemption for industrial uses is a general exemption and not just an exemption for some certain industrial uses  In addition, we would like to also ask to add into the industrial uses examples part of the restriction proposal the following uses;  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 of D4, D5 and D6 (as residual monomers) in polymers as part of mixtures used as anti-foaming agents  which is a critical use in biological medicine production in the pharmaceutical industry (the polymers applied in the anti-foaming mixtures can contain a residual quantity of D4, D5 and D6 above 0,1%)  and  • Industrial production of articles (including medical devices)  This change would indicate that manufacturing can be done with a raw material containing D4/D5/D6 above 0.1 % on the condition that the concentration of D4/D5/D6 in the marketed products does not exceed 0.1 % |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion.  The entries in both the RAC opinion and the Background Document are identical to those in the SEAC draft opinion.In your comment, you are comparing the restriction wording in the SEAC draft opinion with the one from the Annex XV report (version number; 1.1 date; 20 March 2019). This document is obsolete. Based on the comments received during the Annex XV consultation, and the feedback from the Forum, the Dossier Submitter has updated the Annex XV report to the Background Document (version number 1, date 5 Decembre 2019). The Background Document has been published together with the SEAC draft opinion.  In the Background Document, the wording from the REACH registered uses (by the lead registrants of D4, D5 and D6) has been used to describe the current entries which also include uses that were identified during the restriction proposal process. SEAC concur with the Dossier Submitter, which followed the FORUM advice in that, to list the identified industrial uses of D4, D5 and D6. SEAC assumes that both applications mentioned above, polymers as a part of mixtures used as antifoaming agents and the production of articles are already covered under paragraph 4 of the restriction proposal. |
| 437 | **Date/Time:** 2020/02/17 12:03  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Japan Cosmetic Industry Association  **Org. country:**  Japan  **Attachment:** | **Comments on the SEAC draft opinion:**  It would be a great pleasure to have an opportunity for Japan Cosmetic Industry Association to submit comments regarding the draft opinion of he Committee of Socio-economic Analysis (SEAC). Please find attached one document and one table. Specifc comments are also posted accordingly in the columns.  We sincerely hope SEAC to take our comments into consideration.  Thank you very much in advance. |
| **Specific information 1:**  1. Lack of appropriate Alternatives  The list of alternatives shown in Table 35 in Annex to the Background Document includes 100 ingredients as potential alternatives in cosmetics. However, these are only positioned as potential alternatives and it does not necessarily mean that Cyclosiloxanes in every product can be replaced by them without concerns. Experts from JCIA member companies evaluated whether the all ingredients listed in Table 35 can be alternatives to Cyclosiloxanes one by one, and the results are shown in attached Table 1 (please see the table attached). Most of ingredients listed cannot be an alternative, because they have different physiochemical properties from Cyclosiloxanes with respect to volatility, solubilization property, spreadability etc. which are key characteristic elements of Cyclosiloxanes. At least, it is obvious that simple one-for-one replacement to Cyclosiloxanes is impossible. Fundamental reformulation work using several alternatives and other ingredients is necessary to accomplish the product performances that consumers expect. In addition, there could be a cost and supply issue. Some of these alternatives would have much higher unit prices than Cyclosiloxanes, while their supply amount would not be enough as their demand exceeds supply. Furthermore, some alternatives either show toxicological concerns like skin irritancy or aquatic toxicity, or do not provide sufficient toxicological data to conclude as safe at present. Although most of them may have not been identified as PBT/vPvB nor are under regulatory scrutiny so far, safety concerns have been raised for some ingredients already. Thus, it is not guaranteed that these alternative candidates will not be regulated in the future because they are not currently regulated to date.  In general, each company and each brand offer variety of cosmetic products depending on consumer preferences and marketing strategies, and it enables cosmetic companies to satisfy broad range of consumers by providing products which meet each consumer’s expectation. That is particularly important value of cosmetics. Thus, the fact that a significant proportion of products on market are formulated without Cyclosiloxane cannot be an evidence that most existing products can be replaceable. Inappropriate alternatives spoil some functions and cost performance of existing products. As a result, European consumer’s benefit will be spoiled and European cosmetics market will be shrinking as well. However, this loss of economic value is not considered in SEAC opinion.  Here shows a survey result by some JCIA member companies. The Table 2 posted in the attached document shows the results of a comparison of the average annual sales per product between a product group with Cyclosiloxanes and a product group without them. According to the results, when comparing the sales amount of per product by product category, the values of products without Cyclosiloxanes compared to the values of products with Cyclosiloxanes were 23-88% for body care (including sunscreen) category and 67-69% for make-up category, respectively. These data show that switching to a product with Cyclosiloxanes to without Cyclosiloxanes could reduce its economic value from 12% to 77% at maximum depending on a product or a product category. In this regard, we believe that a similar survey should be conducted in the EU market and thus, its survey result will be helpful to take into consideration in order to estimate cost-effectiveness assessment of Cyclosiloxane more precisely.  As stated in the above, we don’t think that the SEAC opinion fully considers the lack of adequate alternatives, the deterioration of product performance due to lack of Cyclosiloxanes, and the economic losses expected in these regards. We hope that re-examination of alternative raw materials and economic losses will be conducted to reflect the results in cost-effectiveness evaluation. We believe these considerations should lead a more appropriate regulatory decision.  2. Proportionality on the Number of Reformulation  Referring to Annex to the Background Document to the Opinion on page 71, following assumptions are applied to estimate total number of reformulations:  The specific assumptions used were as follows:  - For subcategories where products containing D4, D5 and D6 represent less than30% of the market, the alternatives are expected to take over their market share and very few of these products are expected to be reformulated (assumed 5%).  - For subcategories where products containing D4, D5 and D6 represent between30% and 70% of all products, it is assumed that half of these products would be reformulated. The remaining 50% of products are expected to be discontinued.  - For subcategories where products containing D4, D5 and D6 represent over 70%of all products, it would be assumed that 95% of those products would be reformulated. However, no subcategories in the data show such high prevalence of products containing D4, D5 and D6.  In particular, the number of necessary reformulation is considered to be underestimated in categories where the proportion of products containing Cyclosiloxanes is low. Products containing Cyclosiloxanes as described above have superior values regarding consumers’ benefits. The lower ratio of those products in a category does not become a reason that those products are not necessary to reformulate. Such a calculation method is not well grounded. It should be estimated by assuming that all of formulations containing Cyclosiloxanes will be reformulated. Therefore, we would cordially ask SEAC to reconsider the methodology of cost-effective assessment for a cosmetic ingredient taking our comments into consideration.  Going back to the original point, it is described that "D4, D5 and D6 have been formally identified as PBT/vPvB and listed as SVHC substances, which justifies the goal to minimize all emissions to the environment." on page12 of SEAC opinion. This way of thinking has not been mentioned in ANNEX XV RESTRICTION REPORT Proposal for a Restriction. Designation as SVHC does not directly mean that any potential impact by Cycloxiloxanes for environment and human has changed from the time when wash-off cosmetic products containing them were restricted. As atmospheric half-lives for cyclic volatile methyl siloxanes is very short (D4：4.5 days, D5:4.2 days at 25℃）[NICNAS (2018)], the residual ratio in atmospheric environment is extremely smaller than that in aquatic environment. It seems inappropriate to place greater emphasis on the hazard due to the SVHC designation itself and to consider release to aquatic environment as having the same risk as release to atmospheric environment. Therefore, we believe that the effectiveness was overestimated in cost-effectiveness assessment in the SEAC report.  In conclusion, we respectfully request derogation of Cyclosiloxane use, especially D5, in leace-on cosmetic products. |
| **Specific information 3:**  As mentioned in an attached document and a table, we think listed potential alternatives proposed by ECHA are insufficient as an alternative to Cyclosiloxanes. Reformulation should start from development of appropriate alternatives, which will surely take more than 5 years of transition period proposed by ECHA for cosmetics. There are lots of uncertain factors estimating time for developing appropriate alternatives, however they are not considered in the current proposal. At least 10 years should be added to transition period for screening potential alternatives, safety assurance, securing of sufficient supply and so on. Furthermore, if restriction on microplastics for leave-on cosmetics and Cyclosiloxanes for cosmetics entry into force at the same timing, multiple reformulation can be avoided in order to reduce reformulation cost, which is a heavy burden for each company. SEAC evaluates the impact for whole society, however the impact for each business is more critical in practice particularly in the industry. Therefore, we hope that the restriction on Cyclosiloxanes for cosmetics entries into force would be coordinated with the timing of restriction on microplastics for leave-on cosmetics only after development of alternative ingredients has been completed. |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion.  The obligation to minimise emissions and exposure has been mentioned in section 1.2 of the Background Document, as well as in the final RAC opinion.  Your comment indicates that the cyclosiloxanes cannot be replaced in every product without concern and further, that none of the 100 identified potential alternatives can be used to replace the cyclosiloxanes in any of the applications as a simple one-for-one replacement.  The SEAC rapporteurs acknowledge that replacement in the leave-on cosmetics may be a challenge in certain products as indicated by JCIA and that a simple one-for-one replacement to cyclosiloxanes is not possible in all cases. However, SEAC rapporteurs think this situation has been correctly taken into account in the cost assessment (as the Dossier Submitter assumes that reformulations would be required for every substitution), and believe that a move to cyclosiloxane-free products is possible within the time span proposed in the restriction proposal.  Your comment states that performance loss may occur and that the loss of economic value is not considered in the SEAC opinion. SEAC is well aware that performance loss and consumer surplus loss may take place, However, SEAC pointed out in the Draft Opinion that the potential impacts on the performance loss and consumer surplus loss are difficult to quantify with the data currently available. These topics are dealt with in the sections ‘Consumer costs associated with performance loss’ on page 17 and ‘Performance/Consumer surplus losses’ on page 18.  The SEAC rapporteurs also note your disagreement with the assumption made by the Dossier Submitter that not all products will be reformulated. However, SEAC rapporteurs would like to remind you that the Dossier Submitter carried out sensitivity analysis on this topic in Appendix D.2.4: “Effect of using different assumptions regarding what proportion of formulations containing D4, D5 and D6 would be reformulated” (even analysing the impact of assuming 100% of formulations containing D4, D5 and D6 would be reformulated), and this was taken into account in the SEAC opinion. |
| 438 | **Date/Time:** 2020/02/17 12:47  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  DuPont de Nemours (Belgium) BVBA  **Org. country:**  Belgium  **Attachment:**  <redacted>  **Privacy comment:**  This submission contains volumes information specific to DuPont's supply chain. This information should be maintained confidential. | **Comments on the SEAC draft opinion:**  Submission will be made confidentially. Please refer to the confidential section |
| **Specific information 1:**  please refer to the document submitted in the confidential section |
| **Specific information 2:**  please refer to the document submitted in the confidential section |
| **Specific information 3:** |
| **Specific information 4:**  please refer to the document submitted in the confidential section |
| **Specific information 5:** |
| **Specific information 6:**  please refer to the document submitted in the confidential section |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion. |
| 439 | **Date/Time:** 2020/02/18 13:24  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  BAH Bundesverband der Arzneimittelhersteller  **Org. country:**  Germany | **Comments on the SEAC draft opinion:**  The proposed limits are to low (constituents in mixtures in a concentration equal to or greater than 0.1% w/w) because the manufacturers of for example simeticone (as active ingredient) are not able to produce this substance in the grade of purity. The coming into force of the restriction with at least 5 years after publication in the Official Journal is to short for changing the production processes. We propose to extend this period to a length of 7 years.  Another problem is that there is an inconsistency in page 2: Conditions of restriction, point 3.  This restriction shall come into force:  a) On DD/MM/YY [at least 5 years after  publication in the Official Journal] for .. (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..  If we apply these restrictions, medical devices, certificated under the Directive 93/42/EEC for example dental impressions, will have a longer transition period (at least 5 years) than the same product which is certificated under the Regulation (EU) 2017/745. For these products only a transition period for 2 years is applied. This transition period is too short with respect to the need to do a lot of R&D Work (research and development work) and to maintain shelf life tests. For these products are also a transition period of art least 5 years is necessary. The phase “in the classification rule 21 set in Annex VII” should be deleted.  This is also applicable for point 5e). |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion.,  With regard to your comment on medicinal products for human health (as defined in EU Directive 2001/83/EC) and veterinary medicinal products (as defined in EU Directive 2001/82/EC or in Regulation (EU) 2019/6) the transitional period proposed has been prolonged to 7 years by the Dossier Submitter (paragraph 3b). Note that the restriction proposal, and associated transitional period, would apply to the placing on the market of medicines containing D4, D5, D6 as an ingredient in a concentration above 0.1% w/w in the medicine’s formulation. The example you are providing on Simethicone does not seem to fall under the scope of the restriction proposal. Indeed based on the information available in the Background Document (cf. section 2.7.3), Simethicone (i) is a silicone polymer containing residues of D4, D5, D6, (ii) it is used in industrial uses (formulation of medicines), (iii) and after formulation the concentration of D4, D5, D6 residues in the final medicine would be below 0.1% (due to dilution with other ingredients).  With regard to your comments on the 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) a transitional period of 5 years is indeed proposed (paragraph 3a(ii)). The 5-years transitional period is targeted to (substance-based) medical devices only, as no information has been received during the consultations on potential (direct) use of D4, D5 or D6 substance in other types of Medical Devices.  Note as well, that for 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) where the presence of D4, D5, D6 would result from residues/impurities in silicone polymers, the Dossier Submitter has proposed a concentration limit of D4, D5 and/or D6 up to 0.2% (paragraph 5e), whereas for medical devices for dental impression D5 or D6 concentrations (resulting from residues in silicone polymers) are allowed up to 0.3% and 1% respectively (paragraph 5b).  SEAC concur with the Dossier Submitter’s proposal of these derogations, based on the fact that the intention of the restriction was not to include silicone polymers and base these derogations on data submitted during the consultation and call for evidence. |
| 440 | **Date/Time:** 2020/02/18 13:35  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Germany  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  Our problem is that there is an inconsistency in page 2: Conditions of restriction, point 3.  This restriction shall come into force:  a) On DD/MM/YY [at least 5 years after  publication in the Official Journal] for .. (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..  If we apply these restrictions, medical devices, certificated under the Directive 93/42/EEC for example dental Impression materials, will have a longer transition period (at least 5 years) than the same product which is certificated under the Regulation (EU) 2017/745.  For these products only a transition period for 2 years is applied.  This transition period is too short with respect to the need to do a lot of R&D work (research and development work) and to maintain shelf life tests.  For these products are also a transition period of art least 5 years is necessary.  The phase “in the classification rule 21 set in Annex VII” should be deleted.  This is also applicable for point 5e). |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion.  Please see the response provided to the comment #439, which covers the answer to your question as well. |
| 441 | **Date/Time:** 2020/02/18 14:26  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  <redacted>  **Org. country:**  Belgium  **Company name confidential: Yes** | **Comments on the SEAC draft opinion:**  Na |
| **Specific information 1:**  It is unclear if paragraph 4. a) of the proposal (that includes ‘Industrial use in formulation and/or (re-)packing of mixtures’ and „Industrial production of articles”) would be an exemption that could cover the production of pharmaceutical products to be placed on the market. |
| **Specific information 2:**  We believe that the SEAC opinion does not clearly differentiate between medical devices and pharmaceuticals (see page 13).  We believe that SEAC should also address the pharmaceuticals because medical use should not only refer to medical devices. Based on the document it is not clear for us what SEAC’s opinion is on pharmaceuticals. Further clarification would be required.  Page 13: „considerable amount of comments were received during the consultation on the various medical applications. These comments contained further details of the medical applications containing D4, D5 and D6, including information on the concentrations present and the total amount used within the medical sector. The submissions confirmed the Dosser Submitter’s estimations on the quantities used and provided insight on the time needed for substitution. Thus, the comments resulted in a longer transition period for medical devices than that which was originally proposed by the Dossier Submitter.”  Looking at the below section (page 20) and based on its content we believe that SEAC is not fully aware of the costs involved in the reformulation of a pharmaceutical products. Our opinion is that this should also be addressed because based on our calculation – contrarily to SEAC’s opinion - there is considerable cost. Our calculations show that the cost of reformulation of a topical pharmaceutical product is in the range of 14-27 million euros per indication depending on the complexity and number of clinical studies. This is considerably higher than that detailed in the document and it should also be noted that this is for one indication and it is quite common that two, three or more indications will be studies in such formulations.  page 20: “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.”  It is also not yet clear to us if SEAC took into consideration that the use of pharmaceuticals and thus the D5 output from these products in considerably lower than that of other uses. Furthermore the pharmaceutical products in question are not wash-off products, contrarily, the use of D5 in these products is based on its ability to evaporate, thus D5 from these products does not pollute water. |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion.  SEAC assumes that the production of medicinal products is covered under paragraph 4 of the restriction proposal.  SEAC concurs with the Dossier Submitter’s proposal of a longer transitional period of 7 years for medicinal products for human health and veterinary medicinal products as indicated in the current paragraph 3b of the restriction proposal. |
| 442 | **Date/Time:** 2020/02/18 16:59  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  The Polish Union of the Cosmetics Industry  **Org. country:**  Poland  **Attachment:** | **Comments on the SEAC draft opinion:**  In April 2017, ECHA initiated a new Restriction Process for the use of D4, D5 and D6 above 0.1% in leave-on and other consumer and professional products.  The cosmetics Industry would like to reiterate the significant decline of emissions to the aquatic environment following the introduction of the D4 and D5 wash-off REACH restriction in January 2018 (2018/35/EC). This is supported by environmental monitoring data submitted to ECHA by CES and Unilever. The downward trend is expected to continue following the deadline of the wash-off Restriction (Jan 2020). As a result, the Cosmetic Industry believes that this significant reduction should be taken into account, demonstrating that cosmetic leave on products are not a significant source of aquatic emission. Therefore it would be more appropriate to assess whether further regulatory action for D4, D5 and D6 use in cosmetic leave on products is actually required by reviewing the aquatic emissions of D4, D5 and D6 in future to see whether additional risk management requirements are necessary for cosmetic leave on products.  The cyclic methyl siloxanes Decamethylcyclopentasiloxane (D5) and Dodecamethylcyclohexasiloxane (D6) are key ingredients in many categories of cosmetic products, such as make-up products, hair care products or facial products. In certain products silicones are present in concentrations up to 100%, so they are the only component of the product. Examples of product groups containing more than 70% of siloxanes are make-up products (primers, bases applied under make-up), make-up removers, hair serums and oils. Make-up foundations are important and specific product category where silicones are particularly difficult to replace. The content of D5 and D6 in foundation is 5-15% only, but these are main ingredients of the oily phase of the emulsions. Moreover, silicones are used as emollient ingredients (skin conditioning), hair conditioning, cleaning and as solvents.  It should be noted that cyclic silicones are characterized by specific polarity, which affects their unique physico-chemical properties. Silicones D5 and D6 have a unique effect on the sensory properties of the product − due to their volatility they do not cause the "greasiness" effect and do not create an oily, sticky layer on the surface of the skin or hair. They give a "silky touch" effect on the skin / hair.  The described in-use properties of products due to the silicones use are particularly appreciated and highly desired by the consumers and essential for certain product types. There is currently no universal and direct one-for-one available substitutes for D5 and D6. Replacing D5 and D6 in different personal care product types needs to be addressed on a case-by-case basis and requires a new formulation approach with the creation of a new products architecture in order to achieve a products which matches the desired performance characteristics and sensory benefits of a specific original D5 and D6 containing finished products.  The use of more than one alternative substance could be required per formulation and many alternatives across a product portfolio. Many criteria such as regulatory compliance, human safety risks, environmental safety risks, availability, quality, technical and economic feasibility need to be taken into account. Most of the screened alternatives do not meet or comply with the above-mentioned criteria and therefore were not identified as appropriate alternatives. In addition, many of the potential alternatives have emollient properties, but cannot be used on their own to replace D5 and D6due to a number of challenges (different texture and volatility, causing skin irritation by defatting of skin, odour, flammability, etc). What further raises our concern available alternatives are much more expensive than currently used silicones.  The Union cannot agree with the conclusion made by ECHA that the presence on the market of products with and without D5 and D6 indicates that they can be replaced in all product categories. The Union believe that it is not only possible, as the SEAC draft opinion notes, but also likely that inferior substitutes to D5 and D6 will lead to products of inferior quality and subsequent consumer loss. SEAC notes the inability to quantify this consumer loss however qualifies it as moderate but makes no further effort to counterbalance the total cost of the proposed restriction.  Therefore, transitional period (5 years) proposed by ECHA raises our concerns and doubts. Based on these complexities, we assume that potential reformulation efforts could take longer than 5 years in case of certain products of product categories. Product categories such as makeup products, makeup removers, hair products, due to the lack of suitable alternative raw materials, will need longer time for reformulation. The time that will be needed is difficult to indicate as it depends on the availability of alternative raw materials. Therefore, not only internal producer departments (R&D) would be engaged but the producer is dependent on external stakeholders. Some alternatives are currently being tested, but the test results are unsatisfactory. Unusual, reactions of the product mass with packaging were frequently observed during D5 and D6 replacement. Products ingredients pass through the packaging e.g. off polypropylene, polyethylene, they also frequently damage the packaging.  It is also important to draw attention that the definition of ‘placing on the market’ under the Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is different than the one under the Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. The Cosmetics Regulation also defines the definition of ‘making available on the market’. The vast majority of regulatory proposals for cosmetic ingredients distinguish between transitional periods for placing products on the market and making them available.  Given these facts, a longer transitional period is needed to enable the cosmetics industry to:  - Achieve full substitution (reformulation) of D5 and D6 containing leave-on products. If insufficient time is allowed for complete reformulation the implication will be removal of products from market leading to significant disruption in product availability to the consumer and cost to industry,  - Achieve timely turnover of D5 and D6 containing leave-on products already placed on the market and available in the delivery chain. Many personal care products have a shelf life of several years. The withdrawal of cosmetic products already placed on the market for the implementation of the new regulation is not justified. That would lead to unnecessary product waste and have a significant environmental impact.  All these necessary steps will require considerable amount of human work and costs that cosmetic products producers will have to bear.  It is important for the cosmetics industry while replacing D5 and D6 in leave-on cosmetic products − to keep and ensure the high quality of products expected by the consumers. The reformulation process should not limit the consumers’ choice and acceptance of products, especially make-up and hair products, as those categories are expected to the most challenging in reformulation process. If producers do not have sufficient time to carry out reformulation process and final placed products do not correspond with consumers preferences, this may lead to develop of a "grey area". Consumers could massively start to buy products containing D5 and D6 online from outside the EU, as these product would have much better sensorial properties.  It is worth paying attention to fact that restriction report provides details and an analysis of the cosmetic Industry use of D4, D5 and D6 from an “app” called CosmEthics in preference to the data which Industry submitted public consultation. The CosmEthics App is a consumer app and has not been developed for the purposes of data collection for regulatory purposes and as such it is inappropriate to use these unvalidated data in preference to those submitted industry.  The Union would also like to refer to the positive assessment of D5 in Canada, US and Australia. In February 2012, the Canadian Authorities concluded that no action should be taken to restrict D5 as “it does not pose a danger to the environment”. This conclusion was made following the results of an independent scientific review. |
| **Specific information 3:**  Longer transitional period (minimum 5 years) for all leave-on cosmetics products is needed to enable the cosmetics industry to achieve full substitution (reformulation) of D5 and D6 containing leave-on productsa and achive timely turnover of D5 and D6 containing leave-on products already placed on the market and their availability in the delivery chain.  If insufficient time is allowed for complete reformulation the implication will be removal of products from market leading to significant disruption in product availability to the consumer and cost to industry. Many personal care products have a shelf life of several years. Short transitional period will force the withdrawal of cosmetic products already placed on the market for the implementation of the new regulation what is not justified. That would lead to unnecessary product waste and have a significant environmental impact. |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion.  The comment requests a longer transitional period for cosmetic products. SEAC acknowledges that substitution of the cyclosiloxanes may be challenging, certainly in products consisting of 100% silicones and that a simple one-for-one replacement to cyclosiloxanes is not possible in all cases. SEAC would further refer to the response provided to comment #437. SEAC is also aware of the obligation to minimise the emissions of D4, D5 and D6 because they have been identified as SVHC (see section 1.2 of the Background Document) and products using such a high percentage of D4, D5 and D6 are then certainly relevant to address. The Dossier Submitter and SEAC took note of the progress made in implementing the UK restriction for D4 and D5 in wash-off cosmetics (see section 1.4.2.1 of the Background Document) indicating that most applications with D4 and D5 have been withdrawn from the market 5 years after the restriction process started. SEAC assumes this scenario also possible for the current proposal, considering that producers are already aware of the current restriction proposal for some time. SEAC believes that a move to cyclosiloxane-free products is possible within the time span proposed in the restriction proposal.  SEAC took note of the remark that the definitions in the REACH Regulation (EC) No 1907/2006 and the Cosmetic Regulation (EC) No 1223/2009 differ. Placing on the market within the Cosmetic regulation means the first making available of a cosmetic product on the Community market (see article 2 of the Regulation), whereas under the REACH Regulation it means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall also be deemed to be placing on the market. The current proposal follows the definition under the REACH regulation concerning ‘placing on the market’. As ‘placing on the market’ comprises supplying or making available, SEAC assumes that it is clear what is covered under this paragraph in the proposal. In SEAC’s view this is comparable to ‘making available on the market’ as defined under the Cosmetic Regulation and the transitional period in the current proposal is applicable to all downstream users. Thus, it covers both the sales to distributors as well as that to consumers.  The Dossier Submitter explains in 2.5.1.1.on page 42 of the Background Document (BD) how data are gathered for the CosmEthics app, indicate on page 9 that also data from other sources have been used and on page 14 that these data are broadly consistent with data provided by other stakeholders. Furthermore, it is not made clear in your comment why the CosmEthics database should not be used to indicate which products are on the European market, nor why the data provided by the stakeholders should be better qualified. SEAC has no reason to doubt that the data used by the Dossier Submitter is appropriate.  SEAC rapporteurs note your comment that you disagree with the Dossier Submitter’s conclusion that the existence of products with and without D4, D5 and D6 mean they can be replaced, and that you consider it likely that replacement with alternatives would lead to consumer loss. SEAC is well aware that performance loss and consumer surplus loss may take place, However, SEAC pointed out in the Draft Opinion that the potential impacts on the performance loss and consumer surplus loss are difficult to quantify with the data currently available. These topics are dealt with in the sections ‘Consumer costs associated with performance loss’ on page 17 and ‘Performance/Consumer surplus losses’ on page 18. |
| 443 | **Date/Time:** 2020/02/18 18:04  **Type:** MemberState  **MS name:**  Sweden | **Comments on the SEAC draft opinion:**  As mentioned in the previous consultation, the Swedish CA proposes that the implementation period is reduced to two years for three cosmetic product categories (Deodorants and antiperspirants; Hair styling (“LEAVE-ON”) and other; and Wash-off).  D4, D5 and D6 have been identified as SVHC substances with PBT/vPvB properties and therefore give rise to specific concerns. Measures to reduce emissions of PBT/vPvB-substances to the environment should be implemented as quickly as possible. Prolonged implementation periods can be considered proportional if they lead to avoidance of considerable compliance costs. The information provided in the background document does not indicate that restricting the use of D4, D5 and D6 in the three cosmetic product categories listed above within two years would lead to considerable costs.  According to the background document, the three cosmetic product categories account for 89% of releases to water and 77% of releases to all compartments from cosmetic products, while they account for only 6% of the expected product reformulations required due to the proposed restriction.  Based on the information provided in the background document, restricting the use in these three product categories is considerably more cost-effective in terms of cost per unit of emission reduction to water than the existing restriction of D4 and D5 in wash-off products. This holds even if the implementation period is reduced from five years to two years (which is the implementation period proposed for all other uses apart from cosmetic products, dry cleaning applications and the uses covered by derogations). The relative cost-efficiency in terms of cost per unit of emission reduction to all compartments is even greater. An implementation period of two years for these cosmetic product categories should therefore be considered proportional. |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion.  The SEAC rapporteurs understand the rationale behind the Swedish proposal. Sweden indicates that the BD does not indicate that restricting the substances within two years would lead to considerable costs. That is correct, but it neither indicates the opposite; the effect of a 2 year derogation period compared to a 5 year derogation period is currently only available for the complete group of cosmetics and not for these specific categories. Such data were not provided in the comment, either. SEAC would also refer to the following statement regarding the costs estimated by the Dossier Submitter for a transitional period of 2 years (section 2.5.1.5 of the Background document): “The Dossier Submitter notes, however, that this estimate is based on the assumption that it is feasible to complete all the needed reformulations in 2 years. Evidence obtained in the consultation casts doubt on whether that would be possible to do at all, and if it is, whether the cost per reformulation would be the same (reformulating in only 2 years may require increasing resources to tackle in parallel reformulations which would otherwise have been done consecutively). The estimate for the cost of reformulations with a 2-year transitional period is therefore likely an underestimate, and it could be significantly higher.”  Sweden mentioned the percentages of the expected reformulations. However, these does not necessarily provide an insight into the effort that has to be put into reformulating the products, see for instance comment #442 on make-up foundations and other specific product categories. Most industry stakeholders that reacted in this PC on the SEAC opinion indicated that substitution can be time consuming and may take up to 10 years (e.g. #437. #442 (which also indicate the challenge to reformulate hair products) and #446). Thus, SEAC has not recommended to reduce the transitional period fort these three cosmetic products categories from five to two years. |
| 444 | **Date/Time:** 2020/02/18 18:17  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Hungary  **Company name confidential: Yes**  **Attachment:**  <redacted>  **Privacy comment:**  The information in this letter and its appendices includes volumes, compositions and application related information which are confidential to our Company. Confidentiality is requested to protect the commercial interest and intellectual property of <redacted>  Therefore, information included in this letter and its appendices must not be placed in the public domain. It can only be used by relevant experts of ECHA and the relevant Member State Competent Authorities for the purposes of the restriction assessment. | **Comments on the SEAC draft opinion:**  We intend to comment on (i) the clinical, toxicological, and financial impact of reformulation of medicinal products, and (ii) loss of functionality and (iii) the consequent negative effects of EU patients' quality of life caused by the proposed restriction of D5 as pharmaceutical excipient.  Please note that we intend to submit a two-part comment, complete with two attachments. (This part one of the comment.) |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion. |
| 445 | **Date/Time:** 2020/02/18 18:26  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Hungary  **Company name confidential: Yes**  **Attachment:**  <redacted>  **Privacy comment:**  The information in this letter and its appendices includes volumes, compositions and application related information which are confidential to our Company. Confidentiality is requested to protect the commercial interest and intellectual property of <redacted>.  Therefore, information included in this letter and its appendices must not be placed in the public domain. It can only be used by relevant experts of ECHA and the relevant Member State Competent Authorities for the purposes of the restriction assessment. | **Comments on the SEAC draft opinion:**  We intend to comment on (i) the clinical, toxicological, and financial impact of reformulation of medicinal products, and (ii) loss of functionality and (iii) the consequent negative effects of EU patients' quality of life caused by the proposed restriction of D5 as pharmaceutical excipient.  Please note that we intend to submit a two-part comment, complete with two attachments. (This part two of the comment.) |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion. |
| 446 | **Date/Time:** 2020/02/18 18:47  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Personal Care Products Council  **Org. country:**  United States  **Attachment:** | **Comments on the SEAC draft opinion:**  Tuesday, February 18, 2020  Personal Care Products Council Comments on the Consultation on the draft opinion of the Committee of Socio-economic Analysis on the Proposed Restrictions for Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5) ; Dodecamethylcyclohexasiloxane (D6) in Leave-On Cosmetic Products  On behalf of the Personal Care Products Council (PCPC), we are pleased to submit the following comments on the draft opinion of the Committee of Socio-economic Analysis regarding the proposed restriction of Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5); and Dodecamethylcyclohexasiloxane (D6) in leave on cosmetic products that was issued as a public consultation on the ECHA website.  Our previous submission focused on the significant issues that arise from the scientific process that has been followed by ECHA, and our concerns with the ensuing proposed restriction. Beyond these concerns, we provided additional input on the highly detrimental economic effect that the proposed restriction would also have on the cosmetic and personal care products industry. Below we offer our concerns with what we believe is a skewed economic analysis of the potential costs and benefits of the proposed restriction.  The proposed restriction would require manufacturers to undertake significant reformulations to a wide variety of leave-on products. As acknowledged by the Dossier Submitter, the reformulation process is financially very costly. Previously, PCPC undertook a survey of our members to evaluate the expected impact of the proposed restriction. Based on the responses to this survey, we estimate an average 19% of all SKUs that PCPC members market in the European Union would need to be reformulated. Therefore, based on 2018 data, we estimate that the proposed restriction would negatively affect over $720 million of U.S. exports to the EU. We believe that this estimate is fairly close to the relevant Annex XV restriction proposal for the use of D4 and D5 in wash-off cosmetics (UK, 2015) which estimated that products based on D5 account for around 20-30% by value of all cosmetics on the EU market and better captures the magnitude of the impact on our industry and the number of products that would need to be reformulated.  The SEAC draft opinion mistakenly supports the Dossier Submitter in arbitrarily disregarding the above data in favor of the figures provided by the CosmEthics database and other apps which do not accurately depict the state of the cosmetics market and often include characterizations that are not underpinned by sound, risk-based, scientific evidence. More importantly, the SEAC draft opinion agrees with the Dossier Submitter that the “lower the proportion of products that contain D4, D5 and D6 within a subcategory, the lower the proportion of products within a subcategory that will actually be reformulated in the event of a restriction .” The rationalization for this critical opinion does not take into consideration the relative importance of the product in a company’s portfolio, including sales and consumer interest. Thus, the calculation the Dossier Submitter estimate of the fraction of products that would be reformulated in the event of the proposed restriction is largely understated. In fact, it is our industry’s strong view that the overall estimate of the costs of proposed restriction as estimated in the SEAC draft opinion are vastly understated.  Additionally, the Dossier Submitter notes that certain reformulations will fail, raising the total reformulation cost per new product. However, SEAC notes the inability to quantify these costs and subsequently justifies not including these costs in the final cost/benefit calculations by assuming technological improvements that will counterbalance such failures.  The SEAC draft opinion accepts the potential upper limits for the cost of substitute raw materials and agrees that the potential cost could be up to 33% (a third) higher. However, we note that SEAC does not include this potential additional cost in its analysis. The draft opinion accepts the inability to quantifying this cost, and characterizes the cost as being very likely to be small in comparison to the total reformulation cost. However, in absolute amounts a 33% cost increase in raw materials is potentially very impactful.  Moreover, we believe that it is not only possible, as the SEAC draft opinion notes, but also likely that inferior substitutes to D5 will lead to products of inferior quality and subsequent consumer loss. SEAC notes the inability to quantify this consumer loss however qualifies it as moderate but makes no further effort to counterbalance the total cost of the proposed restriction.  In all of the above cases, SEAC acknowledges potential costs however claims the lowest possible impact for the restriction. Cumulatively, these costs more accurately estimate the impact of the proposed restriction. We would like to reiterate that, in addition to costs incurred, any reformulation process is also extremely time consuming. This process includes product redesign; efficacy testing; procurement of new ingredients; new safety assessments; and scaling up, among other activities. Even when there is a direct substitute for the ingredient in question, the reformulation process normally averages 4.5 years. However, when a direct substitute does not exist, such as the case with D5, fundamental research would be needed to ensure the substitute ingredient’s stability, efficacy and safety in the product, as well as consumer acceptance. Such research requires significantly more time, potentially adding 8-10 years to the product development process.  This burden would be further exacerbated by the concurrent restriction on the use of intentionally added microplastic particles in consumer or professional use products of any kind, which will also necessitate research and development and reformulation of vast numbers of product formulas.  Indeed, ECHA acknowledges these additional costs and increased complexity in its report on the “Potential overlap between proposed restrictions on D4, D5, D6 and microplastics.” However, in our view, ECHA does not accurately take these additional costs and complexities into account in the report’s conclusions. Moreover, ECHA does not assess whether the functions provided by D4, D5, D6 together with the potentially restricted microplastics can be achieved by other ingredients or technologies or if additional primary research would be necessary to replace the synergies that these ingredients offer in combination.  As such, we believe the report erroneously concludes that the real costs faced by industry will be less than the sum of the estimates suggested by the Dossier Submitters. In reality, the concurrent restriction being proposed for microplastics would compound the impact of the D4, D5, D6 leave-on restriction on our industry.  Given the significant concerns that have been raised with the risk assessment process that has been followed by ECHA, as well as the serious economic harm and trade disruption that is expected, we urge ECHA to reconsider the proposed restriction. However, should ECHA decide to finalize the proposed restriction as currently envisioned, we would strongly urge that the implementation period be extended to at least 10 years.  We greatly appreciate the opportunity to provide these comments regarding the proposed additional restriction of these substances. We hope that ECHA will review and consider the points that we have raised in this submission and provide the necessary extension to the implementation period.  Sincerely,    Francine Lamoriello  Executive Vice-President  Global Strategies |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion.  The Dossier Submitter has explained the approach to estimate the reformulations in subsections ‘C) Number of formulations containing D4, D5 and D6’ and ‘D) Number of reformulations expected’ of section 2.5.1.1 and indicated that they deviated from the approach earlier applied in the UK restriction. SEAC concur with the approach followed by the Dossier Submitter in assuming that in product categories when a larger percentage of products does not contain D4, D5 or D6, it can be expected that a lower proportion of products containing D4, D5 and D6 will be reformulated. SEAC rapporteurs would also like to remind you that the Dossier Submitter carried out sensitivity analysis on this topic in Appendix D.2.4: “Effect of using different assumptions regarding what proportion of formulations containing D4, D5 and D6 would be reformulated” (even analysing the impact of assuming 100% of formulations containing D4, D5 and D6 would be reformulated), and this was taken into account in the SEAC opinion As indicated in other response to comments, SEAC is aware that for certain products substitution may be a challenge.  Concerning the comment on the raw material prices SEAC would refer to the text of the draft opinion which states under Raw material costs and the substitutes on page 17 the following: ‘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**.’ Additional text is to be found under the heading ‘Raw material price’ on page 19 that states “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.’  Analysis on the potential impact of failed reformulations is provided in the Background Document in section 2.5.1.1. Reformulation costs, under subsection B) Costs per reformulation. SEAC indeed concur with the Dossier Submitter on how these costs are currently taken into account, as specific information on this topic is not available and is also not submitted in the current comment.  The restriction proposal for wash-off cosmetics was submitted by the United Kingdom on 17 April 2015, which is almost 5 years ago. SEAC assumes that, if not already involved in substitution, stakeholders may have started with substitution shortly after that (although the current products are different from the wash-off products in the UK proposal). Although SEAC acknowledge that there may be challenges in substitution, SEAC assumes that for a considerable part companies may benefit from the experiences gained by substituting the cyclosiloxanes in the wash-off products. See also the answer to #437.  The Dossier Submitter explains in 2.5.1.1.on page 42 of the Background Document (BD) how data are gathered for the CosmEthics app, indicate on page 9 that also data from other sources have been used and on page 14 that these data are broadly consistent with data provided by other stakeholders. Furthermore, it is not made clear in your comment why the CosmEthics database should not be used to indicate which products are on the European market, nor why the data provided by the stakeholders should be better qualified. SEAC has no reason to doubt that the data used by the Dossier Submitter is appropriate.  Regarding the consequence of having potentially underestimated substitution costs, SEAC rapporteurs would like to remind you that the Dossier Submitter carried out sensitivity analysis which has shown, as reported in our opinion document, that the proposed restriction would remain cost/effective even if the costs had been severely underestimated.  Concerning the transition period, SEAC does believe that a move to cyclosiloxane-free products is possible within the time span in the restriction proposal. |
| 447 | **Date/Time:** 2020/02/18 20:27  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Cosmetics Europe  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  Please see our comments in the non-confidential attachent uploaded. Thank you. |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thanks for the comments provided on the SEAC draft opinion.  The SEAC rapporteurs acknowledge that replacement in the leave-on cosmetics may be a challenge in certain products as indicated by Cosmetics Europe and that a simple one-for-one replacement to cyclosiloxanes is not possible in all cases. We also concur that in some cases major reformulation may be needed and that the use of more than one alternative substance could be required per formulation. However, the SEAC rapporteurs think this situation has been correctly taken into account in the cost assessment (as the Dossier Submitter assumes that reformulations would be required for every substitution), and believe that a move to cyclosiloxane-free products is possible within the time span proposed in the restriction proposal.  The Dossier Submitter explains in 2.5.1.1.on page 42 of the Background Document (BD) how data are gathered for the CosmEthics app, indicate on page 9 that also data from other sources have been used and on page 14 that these data are broadly consistent with data provided by other stakeholders. Furthermore, it is not made clear in your comment why the CosmEthics database should not be used to indicate which products are on the European market, nor why the data provided by the stakeholders should be better qualified. Thus, SEAC has no reason to doubt that the data used by the Dossier Submitter is appropriate. |
| 448 | **Date/Time:** 2020/02/18 23:57  **Type:** BehalfOfAnOrganisation  **Org. type:**  International NGO  **Org. name:**  European Environmental Bureau  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  We strongly endorse the proposal to restrict D4/D5/D6. The inclusion of D6 under the scope of this restriction will prevent this potential regrettable substitution.  We would also like to support SEAC in its rejection to requests for longer transition periods that have not been substantiated with sufficient reliable data.  We would also like to encourage SEAC to consider the concept of essential uses when assesing requests for derogations and for longer transtitional periods.  The concept of essential use for PFAS has been developed by Cousins et al.1 Following the example of the Montreal Protocol  This approach is based on the example of the Montreal Protocol, which phased out the use of ozone-depleting chlorofluorocarbons except for certain ‘essential’ uses, and which defined the concept of ‘essential use’ in Decision IV/25.19 The two elements of an essential use are that a use is “necessary for health, safety or is critical for the functioning of society” and that “there are no available technically and economically feasible alternatives”.  Following this approach, no derogations or longer transitional periods should be allowed for uses of and proposes stopping the use of D4/D5/D6 which are not essential or when safer alternatives exist.  For cosmetic products, it is clear that effective alternatives to D4/D5/D6 exist. For example, products bearing the Nordic Swan ecolabel cannot contain these SVHCs. Nor is there any indication of reduced performance when alternatives are used. Clearly, there is no reason for any exemptions for any cosmetics in using these SVHCs.  Ordinarily we would argue that "high risk" products should have shorter transition times. Here, "risk" is estimated by the amount in the environmental stock/compartment (direct risk to the consumer is not a concern). The restriction proposes very long (5 year) transitional period for cosmetic products, and some industry comments ask for still longer transition times. Against this claim, we must reiterate that widely dispersive leave-on products account for 90+% of the "risk" (emissions to the environment) from these known SVHCs, and should be replaced as soon as possible.  Leave-on cosmetic products are a high risk non essential use and alternatives are available in the market, therefore the requested transitional period of 5 years should not be accepted.  SILICONE  Industry has argued (in many of the PC comments) that D4/D5/D6 have no intended use in the product, but are residuals in the manufacture of silicone polymer. Thus the product formulator has little control over the residual D4/D5/D6 level. Of course, a residual cannot be considered an essential use.  Industry's own statements demonstrate clearly that low-residual silicone polymer is available. For example, Bayer (comment 2248) say explicitly that their products contain < 0.1% of D4 and D5, and note correctly that these products therefore do not fall under the scope of the restriction. Moreover, no (non-confidential) comments stated that the low-residual polymers would be more expensive. Therefore the problem of D4/D5/D6 residuals is one that should be communicated by formulators to their suppliers.  We suggest that ECHA consider engaging directly with silicone polymer manufacturers, both to get better data on residual concentrations, and to alert them to the impending necessity of keeping residuals below the 0.1% limit.  REFORMULATION TIME  Reformulation time and cost has been extensively reviewed in the (revised) Background Document.  It is estimated that about 11% of cosmetics formulations would need to be reformulated to eliminate D4/D5/D6 (or between 8% and 16% per the DS) [BD p48]. The BD expresses concerns whether reformulations can be completed in time if many products need to be reformulated. Resource limits (e.g., expertise within one company) might mean that more time is required to reformulate a large set of products.  However, these reformulations should not be considered independently. It is quite likely that, in most cases, a reformulation of one product will inform other reformulations in the same category. Even with D5, for which some commentors assert that there is no single drop-in substitute, reformulation is required for a fairly small number of uses and technical functions. Moreover, the push to reformulation across the entire industry, and especially the widespread presence of products on the market that \*already use non-restricted alternatives\*, should result in a relatively short reformulation time.  It must be reiterated that the proposed restriction is not a new idea; industry has had years to anticipate these reformulations. D4 and D5 were identified by the MSC as meeting vPvB criteria in April 2015 [BD p6]. D4, D5, and D6 were formally identified as SVHC compounds in June 2018 [BD p7]. Thus, the industry has known for almost five years that these compounds would be subject to restriction as SVHC. Manufacturers have been legally required to advise downstream users on risk management for a year and a half (and arguably should have been doing so for the last five years). It is clear that known vPvB substances should not be used in "widely dispersed" products like cosmetics. We echo the words of the BD: "the reformulation should have occurred already under existing legal obligations" [BD p31] |
| **SEAC rapporteurs response:**  The SEAC rapporteurs thank you for the comments provided on the SEAC draft opinion.  The derogations proposed for those applications which were uses of silicone polymers where D4, D5 and D6 impurities were above 0.1% w/w conform the request of the European Commission. The Dossier Submitter followed the principle that derogations for applications for which no data had been received would not be proposed, whereas data submissions containing concentration data could result in concentration limits. SEAC concur with these lines followed by the Dossier Submitter. |