Comments on the SEAC draft opinion and specific information requests

## Specific information requests

1. Please tell us if a two year compliance period will affect the range of cosmetics available to consumers or professionals (e.g. hairdressers or professional make-up artists) on the EU market?

For example, will there be any cosmetic types or categories that will no longer be available as alternative products (that do not contain D4/D5) are not technically or economically feasible?

When answering this question, please be as specific as possible in terms of the cosmetic product category or type that will no longer be available, the intended function of the category or type, the total tonnage of D4/D5 used in these products per year and the justification as to why alternatives on the market are not suitable.

1. Please tell us if it is likely that there are individual companies that only, or predominantly, formulate cosmetic products used or disposed with water containing D4/D5 >0.1% w/w. If so, how many of these companies are there in the EU and what would be the implications of a two year compliance period for them?
2. Is the <60% profit margin cited by SEAC in its opinion representative for the whole of the cosmetics industry?
3. Please tell us if the profit margin for cosmetic products within the scope of the restriction is different to the profit margin for cosmetic products used or disposed with water that do not contain D4/D5? For example, would a conditioner containing D4/D5 have a higher profit margin than a conditioner not containing D4/D5, and if so, how much larger would it be?
4. Besides the costs already included in the SEAC analysis, please quantify any other costs that may be avoided with a longer (e.g. five year) compliance period versus a two year period. Please provide justification that these will occur.

|  |  |  |
| --- | --- | --- |
| **Ref.** | **Date/Name/Org.** | **Comments** |
| 298 | **Date/Time:** 2016/05/12 19:44  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Reconsile REACH Consortium  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  - |
| **SEAC Rapporteurs response:**  Thank you for this comment.  Thank you for the information about the coming updates of the registration dossier, and for the support for the restriction. |

|  |  |  |
| --- | --- | --- |
| 299 | **Date/Time:** 2016/05/13 10:32  **MS name:**  Germany | **Comments on the SEAC draft opinion:**  D4 meets the REACH Annex XIII criteria for both PBT and vPvB. D5 meets the REACH Annex XIII criteria for a vPvB substance. This has been shown in the restriction report and confirmed by the Member State Committee. Due to the hazardous properties of PBTs/vPvBs, both substances need to be considered as SVHC, and hence emission to the environment should be minimized as far as technical possible under socio-economic considerations.  We agree that, based on the hazardous properties of D4 and D5 and the emissions into the environment due to certain wide dispersive uses, action is required on an EU wide basis.  However, we do not agree with the opinion that the suggested restriction is the most appropriate measure. The restriction focuses on the use of the substances in wash-off personal care products which accounts for significant emissions to surface water. However, there are other uses, e.g. contributing also to environmental emissions to a relevant degree. The restriction proposal discusses further emission routes to surface water and we agree with RAC and SEAC that a broader restriction including at least leave-on personal care products would be more appropriate.  In addition to that, the significant emissions of D4 and D5 to air are neglected completely by the restriction proposal. It is stated that D4 and D5 are not deposited from atmosphere due to their physicochemical properties. However, a recent study1 indicates that D4 and D5 are deposited in the Antarctic. Generally, for PBT/vPvB substances all emissions pathways to the environment need to be considered and included in risk management activities.  Consequently, we expect that the restriction will contribute to reduce emissions of the PBT /vPvB substances D4 and D5 to surface water, but we think that additional measures are required to ensure the high level of protection for human health and the environment that is envisaged under REACH.  First, we think that Candidate Listing is important in order to acknowledge the PBT/vPvB status of the substances officially in a way that is transparent for all stakeholders, especially down stream users and the public. This is particularly important as the registrants seem to not accept the PBT/vPvB status of the substances and thus, no risk management measures for minimizing emissions are applied by industry. Candidate Listing is the only way to ensure that the PBT/vPvB properties of D4 and D5 cannot be ignored by industry any longer. One argument brought forward in the proposal is that substitutes would be less well understood and thus potentially more harmful. Only a rather small subset of chemical substances fulfils the PBT or vPvB criteria. Even if substitutes are structurally related, it seems not very probable that they are even more harmful than D4 and D5 as these fulfil the PBT/vPvB criteria.  Second, we think that D4 and D5 should be included in Annex XIV to cover a broader range of emissions. Emission and exposure of the substances are still not completely understood. Inclusion in Annex XIV would require industry to apply for authorization and to prove minimization of emission. Socio-economic consequences need to be communicated by the applicants for each use, and need to be considered before deciding whether authorization is granted. We do not think that applying for authorization is a disproportionate measure as indicated in the text. Actually, it is exactly the measure that is foreseen as a standard for PBTs and vPvBs under REACH.  We do however acknowledge that authorization does not cover risks arising from the presence of the substances in polymers or other siloxanes. However, while authorization is opposed both by the proposal and by the SEAC opinion with the justification that it does not cover all exposure routes, it is obvious that the restriction proposal covers even less exposure routes. A possible option would be to broaden the scope of the restriction to cover all relevant emission routes. However, this would probably require more information on use and exposure.  Another option would be to start Identification as an SVHC after the suggested restriction is adopted. We think that Candidate Listing should be the next step to complement the suggested restriction.  Additionally, given the persistence, bioaccumulation and toxicity of D4 and its potential for long-range transport, we think a nomination of D4 as a POP under the Stockholm Convention should be supported. |
| **SEAC Rapporteurs response:**  Thank you for this comment.  SEAC concludes that the proposed restriction is the most appropriate RMO to prevent emissions of D4/D5 to the aquatic environment, based on the current information. However, as stated in the opinion, there are uncertainties in the emissions estimates in particular when it comes to other sources (mainly leave-on PCPs) and sensitive environmental compartments (i.e. Antarctic), and that is why we recommend a review when there is more information about contribution from other sources.  The text in the opinion has been adjusted to clarify the recommendation of a review. |
| 300 | **Date/Time:** 2016/05/13 12:25  **MS name:**  Germany | **Comments on the SEAC draft opinion:**  The intention of the restriction is to minimize emissions of D4 and D5 to the aquatic environment from their use in personal care products that are washed off under normal use. Although environmental concerns of substances are considered through the application of Regulation (EC) No 1907/2006 we would propose an regulatory approach through Regulation (EC) No 1223/2009 on cosmetic products. In this special case only cosmetic products are concerned of the restriction proposal. The persistence of D4 and D5 is followed by bioaccumulation through the food chain, that means finally a risk for human health. The aspect of protection of human health offers the possibility to regulate concentration limits of D4 and D5 in the Regulation (EC) No 1223/2009.  The benefit would be the regulation in only one field of law and therefore a guaranty of acceptance by the concerned parties (both, companies and administration). |
| **SEAC Rapporteurs response:**  Thank you for this comment. The PBT/vPvB concept under REACH also acknowledges the potential for long-term human exposure to substances through the environment and food.  SEAC notes that RAC considers that human exposure to D4/D5 is mainly caused by direct exposure to consumer products. During the public consultation on the restriction proposal, information was submitted on the cooperation between the German Ministry of the Environment (BMUB) and the German Chemical Industry Association (VCI) launched in 2010 to develop analytical methods for D4, D5 and D6 in humans (see comment # 1425). RAC noted that D4, D5 and D6 have the same metabolite in urine (Me2Si(OH)2) and that the limit of detection is too high to detect relevant quantities. Consequently, it is not possible to distinguish which of these substances causes exposure to humans. It can be concluded that it is currently not possible to determine exposure to D4 and D5 in the general population with human biomonitoring (HBM) programmes. |
| 301 | **Date/Time:** 2016/05/13 21:33  **MS name:**  Sweden | **Comments on the SEAC draft opinion:**  The Swedish CA welcomes the draft SEAC opinion on the restriction dossier on D4/D5 and the conclusions therein, and appreciates the opportunity to provide comments on it.  In the draft SEAC opinion there is a discussion on whether to adopt a 2 year or a 5 year compliance period for the restriction. In our opinion the period should be no longer than 2 years due to the PBT/vPvB properties of D4/D5. The 2 year compliance period will deliver benefits sooner than the 5 year period. The benefits have been estimated to €0.65 billion per year (chapter 1.1.3 in the draft opinion). The estimated value of three additional years of these benefits are many times larger than the expected additional costs related to product reformulation (€15-20 million per year for 20 years, according to Table 1).  The Swedish CA agrees with SEAC on the necessity to review the effectiveness of the restriction in the future. The DS has proposed that the review should take place 10 years after entry into force of the restriction. In our opinion, the review should take place no later than 5 years after the entry into force, because of the uncertainty of the contribution from other sources of D4/D5 to the environmental exposure, for instance from leave-on personal care products. This proposal is in line with the conclusion of the RAC committee. |
| **SEAC Rapporteurs response:**  Thank you for this comment. We note your support for the 2 year compliance period, and the preference for a review after 5 years. The updated opinion keeps the 2 year compliance period and recommends a review 5 years after the end of the compliance period, contingent on the existence of new information.  The rapporteurs would like to point out that the cited quantitative analysis of benefits performed by the dossier submitter was not supported by SEAC, and hence these benefits estimates cannot be used as supporting evidence for a particular compliance period. |
| 302 | **Date/Time:** 2016/05/16 17:27  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Polish Union of Cosmetics Industry  **Org. country:**  Poland | **Comments on the SEAC draft opinion:**  The Polish Union of Cosmetics Industry agrees with the conclusions of the SEAC draft opinion, that the proposed restriction on octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) is the most appropriate EU wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs provided that the conditions are modified as stated in the RAC opinion.  Nevertheless, the Union considers that two years compliance periods is definitely too short for the industry to apply new provisions in proportionate manner. The Polish Union of Cosmetics Industry is advocating for transition period of 5 years.  Please take below arguments for the 5 years compliance period:  The substitution of D4 and D5 by safe and effective ingredients will require 5 years to reformulate and place on the market. D5 siloxane is of key important ingredient for the personal care products industry in Poland and the EU, D4 is present as impurity in other siloxanes.  D5 has a very long history of safe use in personal care products. There are currently no suitable alternatives identified on the market, providing sufficiently similar properties and consumer advantages benefits.  It should be taken into consideration that replacement of D5 should start with search of consumer, industrial and environmental assessment of different potential substitutes.  When substitutes will be identified, the full substitution of D5 will require a long formula design, safety assessment including stability and packaging compatibility assessment, manufacturing process compatibility assessment etc.  Depending on the formulation complexity, replacement costs of D5 may reach amount up to €500,000 per formulation, based on information provided by Cosmetics Europe.  This 5-year transition period is necessary in order to:  • Achieve full substitution of D4/D5 containing wash off products  • Avoid full withdrawal of products on the market as this would require:  o a substantial amount of time  o high removal costs  • Avoid black-listing of D4/D5 as a consequence of product withdrawals. Black listing that would subsequently damage the reputation/image of the cosmetic industry while to allow the cosmetics industry to operate a smooth transition.  The changing replacement of a core formulation ingredient means that the whole product architecture needs to be dismantled, rebuilt and retested to ensure that the consumer benefit is delivered and that the substitution material is safe for both the consumer and the environment. For each formulation where D4 or D5 is currently used, this process will need to be undertaken separately. In many cases, a combination of ingredients will be required to maintain the consumer benefit and legal requirements of the European cosmetic legislation (e.g. durability and safety). Many of the “advertised” alternatives to D5 present manufacturers with a number of important and significant challenges such as different texture and volatility, causing skin irritation by defatting of skin, odour, flammability, etc.  Summarising, 5 year transition period is required because:  • D5 is an important ingredient of several cosmetic products, with no one-to-one substitution candidate identified for all targeted uses,  • Complete substitution requires performance, processing and safety testing, setting up new supply chains, and on-shelf product turn-over (as opposed to active market withdrawal and product destruction). |
| **Specific information 1:**  According to the information from Members of the organization a reasonably long compliance period (5 years) is required to allow the industry to adopt a legal changes.  D5 has a very long history of safe use in personal care products. It is an important ingredient for many categories of products. D5 provides unique properties and a variety of benefits including ease of spreading, volatility to allow release of active ingredients, and a high degree of skin compatibility.  There is currently no one-to-one substitution candidate identified for all targeted uses of D5 in washed off cosmetics. There are currently no suitable alternatives identified on the market, providing sufficiently similar properties and consumer advantages benefits.  Many of the “advertised” alternatives to D5 present manufacturers with a number of important and significant challenges such as different texture and volatility, causing skin irritation by defatting of skin, odour, flammability, etc. |
| **Specific information 2:**  No data. |
| **Specific information 3:**  According to the information from our Members a profit margin cited by SEAC is representative for the cosmetics products “wash-off”. |
| **Specific information 4:**  No data. |
| **Specific information 5:**  A minimum transition period for placing on the market (REACH definition) of 5 years is required, including reformulation, manufacturing of new products, and depletion of non-compliant products from shelves across retailers in the European Economic Area. This is still a challenging timeframe for cosmetic manufacturers to reformulate products and have the previous products exhausted from the market by the end of the transition period. In some cases it may not be possible to reformulate a product with the consumer benefits within the timeframe.  The identification and integration of viable alternatives and replacements for D4 and D5 in wash-off cosmetic products is a complex and lengthy process. There is no one-for-one substitution strategy that will comprehensively address all of the key performance benefits that are derived from these key ingredients. Based on these complexities, it has been conservatively estimated that potential reformulation efforts could take 5+ years, depending on formulation and require in excess of €500000 per formulation to support. Fundamental implications include:  • Research to identify and evaluate potential suitable alternatives and their regulatory compliance and availability,  • Reformulation of products at laboratory level: Dismantling and rebuilding of the product formulation, testing that the formulation is stable and delivers the benefit, testing manufacturing and packaging compatibility etc.,  • Demonstrating that the formulation is safe for consumer use,  • Packaging and labelling modification,  • Industrial development.  Given these complexities, a minimum transition period of 5 years is needed to enable the cosmetics industry to:  • Achieve full substitution (reformulation) of D4 and D5 containing wash off 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 D4 or D5 containing wash-off products that will be on shelf, without active product recall. Many PCPs have a shelf life of several years from production to purchase. Market recall would lead to unnecessary product waste. This 5 years transition period will avoid inappropriate blacklisting of D4 and D5 by audiences, including media, retailers or consumers, as a consequence of product withdrawals.  This would give manufacturers of cosmetic products a chance to place reformulated products on the market by the end of the transition period. However, it is impossible to completely replace products on the shelves across the European Economic Area within 2 years as recently suggested by the Authorities in the Draft Restriction Proposal Report. |
| **SEAC Rapporteurs response:**  Thank you for this comment.  SEAC takes note of the specific information about the time required to achieve full substitution, which is in line with the information provided by other industry actors.  Thank you for confirming the representativeness of the profit margins. |
| 303 | **Date/Time:** 2016/05/16 18:35  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Cosmetics Europe  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  Cosmetics Europe is thankful that the Committees at ECHA have taken into consideration comments previously submitted. Cosmetics Europe feels that the wash-off definition more accurately captures the scope of the products to be included in this restriction. As such, Cosmetics Europe does not support the use of the wording “used or disposed with water” instead of the term “washed-off in normal use conditions” as originally proposed by the Dossier Submitter. “Used with water” would include products that are applied with water but that are not necessarily washed-off with water. Similarly, the term “Disposed with water” is ambiguous and thus may include leave-on products (e.g. body lotions) that are eventually washed-off with water when the consumer takes a shower.  It is the view of Cosmetics Europe that the scope of the restriction as described by the Dossier Submitter should be clearly described in the restriction conditions in order to ensure unequivocal understanding of both, industry and enforcement bodies. Therefore, the description should include the following points:  • The restriction covers cosmetic products that are washed off from the hair and body within several minutes of application in accordance with normal use instructions;  • The rinsage is discharged to the wastewaters.  Additionally we also would like to raise the following points:  • The need for a transition period of 5 years that would still ensure safety whilst not provoking panic and distrust in the sector and allow for reformulation with no negative impacts for the consumer.  • The complexity of substituting of D4 and D5 in cosmetic products  as there is no single, universal replacement therefore a complete reformulation of products is required in order to maintain the consumer benefits which involve a considerable amount of time.  Cosmetics Europe will like to take this opportunity to thank ECHA for the willingness to take into consideration our comments on this important topic.  Cosmetics Europe stands ready to answer any questions you may have. |
| **SEAC Rapporteurs response:**  Thank you for this comment.  SEAC takes note of your comments on the wording of the restriction. The final wording of the restriction will be drafted by the Commission, and the RAC-SEAC opinion will, together with the Background Document, provide supporting information about the intended scope. The opinion text has been updated to outline your comments.  We have noted your suggested use of the EBIT as an alternative affordability measure, and this is now included in the opinion.  See final opinion for updated text on the compliance period. |
| 52x | **Date/Time:** 2016/05/17 08:40 (considered within DL)  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Cefic CES - Silicones Europe  **Org. country:**  Belgium  **Attachments:** | **Comments on the SEAC draft opinion:**  See attachment |
| **SEAC Rapporteurs response:**  Thank you for this comment.  The rapporteurs would like to point out that the emissions presented at the meetings and in the opinion are in line with RAC emission factors, since SEAC does not estimates emissions but directly used the RAC emission estimates. . In the opinion and in the SEAC plenary meeting the share of total emission from leave-on and wash-off products respectively, were also presented, but these should not be confused with the emission factors.  We have updated the opinion to reflect your information on testing costs, development of analytical methods, monitoring and the concentration limit. |
| 53x | **Date/Time:** 2016/05/17 08:44 (considered within DL)  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Reconsile  **Org. country:**  Belgium | **Comments on the SEAC draft opinion:**  See attachment in the confidential version of table |
| **SEAC Rapporteurs response:**  Thank you for this comment. These data were already considered during opinion development. |
| 54x | **Date/Time:** 2016/05/17 08:46 (considered within DL)  **Type:** Industry or trade association  **Org. type:**  Industry or trade association  **Org. name:**  Reconsile  **Org. country:**  Belgium | **Comments on the SEAC draft opinion:**  See attachment in the confidential version of table |
| **SEAC Rapporteurs response:**  Thank you for this comment. These data were already considered during opinion development. |