Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

OCTAMETHYLCYCLOTETRASILOXANE,
DECAMETHYLCYCLOPENTASILOXANE

Draft

11 March 2016

(Draft)

11 March 2016

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name:	**OCTAMETHYLCYCLOTETRASILOXANE**
EC No.:	**209-136-7**
CAS No.:	**556-67-2**
Chemical name:	**DECAMETHYLCYCLOPENTASILOXANE**
EC No.:	**208-764-9**
CAS No.:	**541-02-6**

This document presents the opinion adopted by SEAC. The Background Document (BD) provides support to both RAC and SEAC opinions, giving detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINIONS

United Kingdom has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at: http://echa.europa.eu/web/guest/restrictions-under-consideration
on ***18 June 2015.*** Interested parties were invited to submit comments and contributions by ***18 December 2015.***

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on ***11 March 2016.***

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

The draft opinion was published at http://echa.europa.eu/web/guest/restrictions-under-consideration on ***16 March 2016.*** Interested parties were invited to submit comments on the draft opinion by ***16 May 2016.***

THE OPINION OF SEAC

The restriction proposed by the Dossier Submitter is:

Designation of the substances, of the group of substances or of the mixture	Conditions of the restriction
a) Octamethylcyclotetrasiloxane EC Number: 209-136-7 CAS Number: 556-67-2 **b) Decamethylcyclopentasiloxane** EC Number: 208-764-9 CAS Number: 541-02-6	1. Shall not be placed on the market or used in concentrations equal to or greater than 0.1% by weight of each in personal care products that are washed off in normal use conditions. 2. Personal care products shall be taken to mean any substance or mixture intended to be placed in contact with the various external parts of the human body (epidermis, hair, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition. 3. Normal use may be determined by packaging instructions, indicating the purpose of the product and how it is to be used. 4. This restriction shall come into force on DD/MM/YY [at least 2 years after publication in the Official Journal]. 5. By DD/MM/YY [ten years after entry into force] the Commission shall carry out a review of the other sources of these substances to investigate whether any further emission reduction measures are necessary. On the basis of this review, the Commission shall, if appropriate, present a legislative proposal to extend the restrictions in paragraph 1.

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on information related to socio-economic benefits and costs documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the 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.

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the background document. RAC considers that the proposed restriction on ***octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5)*** is the most appropriate EU wide measure to address the identified risks in terms of the effectiveness in reducing the risks provided that the conditions are modified.

The conditions of the restriction proposed by RAC are:

Designation of the substances, of the group of substances or of the mixture	Conditions of the restriction
a) **Octamethylcyclotetrasiloxane** EC Number: 209-136-7 CAS Number: 556-67-2 **b)** **Decamethylcyclopentasiloxane** EC Number: 208-764-9 CAS Number: 541-02-6	1. Shall not be placed on the market in cosmetic products used or disposed with water intended for consumer or professional use in concentrations equal to or greater than 0.1% by weight of each of the substances. 2. Cosmetic products are defined as being within the scope of Regulation (EC) 1223/2009 3. This restriction shall come into force on DD/MM/YY [18 months after publication in the Official Journal].

The term 'personal care product (PCP)' is used throughout the background document and opinion and is intended to have the same meaning as 'cosmetic product' in this context.

JUSTIFICATION FOR THE OPINION OF SEAC

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

Summary of the proposal:

D4 is a PBT/vPvB substance and D5 is a vPvB substance. As such, minimisation of emissions is required under REACH. The objective of the restriction proposal is to effectively reduce emissions, and implicitly the risks, of D4 and D5 to the aquatic environment across all EU Member States. Whilst these substances are used in a wide variety of uses and products, the Dossier Submitter argues, based on the result of a risk assessment, that a targeted restriction of the use of D4 and D5 in a specific category of personal care products (wash/rinse-off products) will effectively eliminate emissions to the aquatic environment. To justify that action is required on an EU wide basis to reach this goal, the Dossier Submitter argues that Personal Care Products (PCP) are produced, used and transported across Member States. This implies that an EU wide restriction is necessary to minimise the risks. It is also highlighted that an EU wide restriction would remove any potential distorting effects that national restrictions might have on the free circulation of goods on the common market, thereby ensuring a level playing field for all the actors in the internal market.

SEAC view

SEAC agrees that action is required on an EU wide basis.

Key elements underpinning the SEAC view

SEAC recognises that action is required to reduce the risks from PBT and vPvB substances. The use of D4 (PBT and vPvB) and D5 (vPvB) in PCPs occurs across the EU. Specifically, D4 or D5 in PCPs produced in one MS can be transported and used in another MS. Equally, a Member State may receive emissions from uses in another Member State. This means that any action taken should also be EU wide. Securing the free movement of goods within the EU to ensure that the internal market functions properly also underpins the necessity of union wide action.

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

Summary of the proposal

Section E of the Background Document contains a short analysis of other EU wide legislative measures that could have been utilised to control the risks of D4 and D5 to the aquatic environment as an alternative to the proposed, targeted, restriction:

<u>Updates to existing REACH Registration dossiers</u>

The Dossier Submitter notes that registrants should (in theory) update registrations to reflect the PBT/vPvB status of D4 and D5 and recommend risk management measures (RMMs) to minimise emissions, potentially choosing no longer to support certain uses (use advised against). The Dossier Submitter concludes that this risk management option has potential to significantly reduce environmental emissions, but that it is not guaranteed to do so because downstream users could still use the substance in PCPs even if such use is not supported by the registrants (after notification to ECHA and preparation of a downstream

user Chemical Safety Report). In addition, registrants are only legally obliged to consider the tonnage they supply individually, not collectively.

REACH Authorisation (including candidate listing)

The Dossier Submitter outlines several reasons why it considers that REACH authorisation and candidate listing (formal identification as a substance of very high concern) is not an appropriate risk management option for D4 and D5. Primarily, the Dossier Submitter considers that a listing on Annex XIV of REACH would not control the presence of D4 and D5 in silicon polymers or other siloxane homologues (such as D6) as impurities[1], which can lead to the presence of D4 and D5 in wash-off PCPs. In addition, the Dossier Submitter considers that candidate listing could have a "black-listing" effect and promote unnecessary substitution in uses with low environmental risks, potentially with substances with less well understood hazard properties. The Dossier Submitter also considers that as modelling suggests that reductions in D4 and D5 concentrations in water and sediment can be reduced by targeting emissions to the aquatic compartment only, Authorisation, which would affect uses with emissions to all compartments, would be a disproportionate regulatory response for these specific substances, as it would cover uses which would induce no or insignificant risks to the aquatic environment.

Regulation No 850/2004 on persistent organic pollutants (POP)

Regarding the POPs Regulation, the Background Document notes that identification of D4 and D5 as POPs may not be straightforward as the potential for harm posed by these substances, in the context of remote environments, is lower than substances that are currently considered to be POPs (e.g. some halogenated pesticides, dioxins and polychlorobiphenyls) and highlights that negotiations with countries outside the EU may take several years to complete, would require extensive socio-economic information (beyond that collated for this restriction) and is not guaranteed to reach consensus. The Dossier Submitter does not consider that identification of either D4 or D5 as a POP is necessary to ensure a proportionate level of environmental protection in the EU.

Regulation under the Water Framework Directive

The Dossier Submitter notes that neither of the two substances are currently considered as priorities under the Water Framework Directive (i.e. designation as either priority substances or priority hazardous substances), but they are presently under consideration. The Dossier Submitter considers that should either D4 or D5 be prioritised this would result in the setting of an EU wide environmental quality standard (EQS), but would be unlikely to provide an effective way to reduce aquatic emissions as it could not directly prevent the use of D4 and D5 in PCPs. Rather, Member States would have to carry out measures (i.e. usually improved wastewater treatment) to achieve the EQS in the aquatic environment (when it is technically feasible and not disproportionately costly to do so). As it is uncertain if D4 or D5 will be prioritised, what the level of any EQS would be, and if measures to reduce emissions would be implemented, the Dossier Submitter considers that supply controls such as the proposed restriction would be much more effective (and most probably more cost-effective) in reducing aquatic exposure than programmes of measures under the WFD. However, they consider that any requirement for monitoring introduced as a consequence of prioritisation under the WFD would be complimentary to the proposed restriction.

Voluntary agreements

In addition to legislative measures, the Background Document discusses the possibility of reducing risks using voluntary measures. A voluntary product stewardship arrangement has

[1] Presence as impurities and use as chemical intermediates are outside of the scope of REACH Authorisation.

been set up by the industry, and the D4 and D5 REACH consortia have a range of activities under assessment. However, the Dossier Submitter notes that the results of such voluntary measures are uncertain, both on the level and timing of emission reduction.

In conclusion the proposed targeted restriction was considered the most appropriate EU wide measure due to its effectiveness, proportionality and practicality, compared to the other RMOs.

SEAC view

SEAC agrees that the proposed restriction is the most appropriate EU wide measure.

Key elements underpinning the SEAC view

SEAC agrees with the line of argumentation presented by the Dossier Submitter with regards to Authorisation, POPs, WFD and voluntary agreements being less effective or more costly ways of reducing aquatic emissions from D4/D5, than a restriction.

In addition to the exposure assessment undertaken by the Dossier Submitter, RAC has developed supplementary emission scenarios for wash-off and leave-on PCPs based on upper bound and lower bound release factors. In the upper bound scenario the leave-on products contribute more to total emissions than in the lower bound scenarios. Under this scenario a broader restriction, including leave-on PCPs, may be more effective in reducing the overall risks from D4 and D5.

However, irrespective of the relative contribution to total emissions from leave-on products it remains clear that PCPs that are washed off within a few minutes of application are causing significant emissions of D4 and D5 to the aquatic environment. SEAC therefore concludes that the proposed restriction is an appropriate EU wide measure to reduce the risks from D4/D5. SEAC notes the uncertainties in the exposure assessment highlighted by RAC and considers that additional RMOs for leave-on uses of D4 and D5 in PCPs may be needed should concentrations of D4 or D5 in the environment fail to decline in response to this proposed restriction. SEAC therefore supports the Dossier Submitter's proposal to review the effectiveness of the restriction in the future.

Effectiveness in reducing the identified risks

Proportionality to the risks

1. Summary of the proposal

The Dossier Submitter has provided an extensive proportionality assessment, where several different assessment methods are presented: cost-benefit analysis, cost-effectiveness analysis, break-even analysis, qualitative information and affordability. The four methods are partially complimentary and are recommended to be assessed together. The Dossier Submitter has undertaken the assessment in relation to both a 2-year and a 5-year compliance period.

1.1 COST-BENEFIT ANALYSIS

1.1.1 Cost estimates

The costs of restricting the use of D4/D5 in wash-off PCPs consists of: raw material costs, costs of reformulation and possible additional welfare losses associated with reduced product performance. The different elements are described further below.

Depending on different assumptions the total cost estimates vary from €7.6 million per year

to €439 million per year, with a methodologically preferred interval between **€7.6 million and €106 million per year**.

I. *Raw material costs*

One of the costs incurred by manufacturers as a result of the proposed restriction would be the additional costs from purchasing alternative raw materials to replace D4/D5 in wash-off PCPs, based on differences in prices. The analysis in the dossier is based on a conservative unit price for the substitute that is 100% more expensive than D4/D5, and a use ratio of 1 (the substitute will be used in the same amount as D4/D5 in the products). The resulting total **raw material cost increase is €3.4 million per year.**

II. *Reformulation production costs*

The other main cost faced by the manufacturers is the one-time investment associated with reformulating products to replace D4/D5.

To estimate the total cost of reformulation for the PCP industry the Dossier Submitter estimates a gross reformulation cost (based on average cost per product and the total number of products facing reformulation), and subtracts "baseline reformulation costs" that are assumed to occur in the absence of the proposed restriction. The reason for subtracting these baseline costs is that manufacturers are routinely reformulating their products every few years in response to changing consumer needs, changing costs and raw material availability. The Background Document argues that rather than viewing the restriction as creating reformulation responsibilities by forcing firms to reformulate their products, it merely forces them to reformulate them sooner than they otherwise would have. Accordingly, the one-time cost to industry is the present value of bringing forward the costs that would nonetheless occur later without the proposed restriction.

The baseline costs that are subtracted from the gross cost are comprised of two basic elements:

1) Present value of the costs of reformulations that would be incurred during the compliance period (2 years or 5 years), in the absence of the restriction. It is assumed that 5% of the products undergo a major reformulation every year, and that 15% of the products undergo minor reformulations every year, implying that 20% of the products are reformulated each year. The costs of these reformulations, for a time period of 2 years and 5 years respectively, are excluded when total reformulation costs are estimated.

2) For the remaining reformulations, the present value of the deferred costs of baseline major reformulations brought forward as a consequence of the proposed restriction. The Dossier Submitter argues that with a restriction, all products would need to undergo a reformulation during the compliance period. For the share of products that were not planned for reformulation until after the compliance deadline, there will be costs connected to undertaking reformulation sooner in order to comply with the proposed restriction. The Dossier Submitter claims that these reformulation costs would also be incurred in the absence of a restriction, only with a different and deferred time profile. Thus, it is only the cost of bringing forward the reformulation that should be included when total reformulation costs are estimated. Under this assumption, the present value of the costs of routine reformulation after the compliance period in a baseline scenario is subtracted (from year 3 to year 20, and from year 6 to year 20, depending on the length of the compliance period).

Using this method the Dossier Submitter estimates the **cost of reformulation as €20 -**

€58 million per year (2 year compliance period) and €4 - €38 million (5 year compliance period).

III. Product performance reduction loss

In addition to the costs incurred by manufacturers, there may be a reduction in consumer surplus arising from any reduction in performance and quality of the reformulated products. The Dossier Submitter estimates this loss based on the results from a willingness to pay (WTP) study (for more info on this study, see section "benefits" below). In the study, respondents were asked a series of choice questions in order to ascertain the consumer loss of functionality provided by D4 and D5 in personal care products. According to this study the WTP for beneficial properties (e.g. quick dry, smooth feel, no smell, low skin irritation etc.) provided by D4/D5 was estimated at €5 per person per year.

The Dossier Submitter has no information about the actual product performance loss (= consumer surplus loss) that will occur due to the use of alternatives. In the absence of such information they include a scenario where it is assumed that reformulation will be successful in replicating the qualities of D4/D5 in only 50% of the cases, resulting in a product performance loss in 50 % of the cases associated with the proposed restriction. Aggregated to the EU population (excluding children under 14) and calculating only the share related to wash-off PCPs, the total **annual cost associated to this loss is approximately €45 million.**

IV. Total annualised costs

The total costs include raw material costs, reformulation costs and product performance loss (PPR loss). The Dossier Submitter presents the resulting annual costs under a number of different assumptions (see Table 1 below), highlighting the net costs that are annualised over a period of 20 years. Assuming that the reformulations are completely successful in replacing the wash-off PCPs containing D4/D5 (excluding PPR loss), the dossier estimates the costs to be in the order of **€7.6 - €42 million and €23 - €61 million per year under a 5- and 2-year compliance period, respectively**. In another scenario, where the reformulations are assumed to be only 50% successful (including PPR loss), the costs are estimated at **€53 - €87 million and €68 - €106 million per year under a 5- and 2-year compliance period, respectively.**

Table 1: Summary of annualised cost estimates (Table F.1 from the Background Document)[2]

Measure of annualised reformulation costs used[1]	Compliance Period	Economic Impact Component			Agg Annual Impact (excluding PPR loss) (€) (d)= (a)+(b)	Agg Annual Impact (including PPR loss) (€) (e)=(d)+(c)	Cost-effective-ness (excluding PPR loss) €/kg (f)=(d)/199600	Cost-effective-ness (including PPR loss) €/kg(g)=(e)/199600
		Raw material substitution Costs[2] (€) (a)	Reformulation Costs[3] (€) (b)	Product performance reduction loss[4] (€)(c)				
annualised net costs (20 yrs)	**2**	**3,420,000**	**19,664,952 - 58,044,340**	**45,000,000**	**23,084,953 – 61,464,340**	**68,084,953 – 106,464,340**	**115.66 – 307.94**	**341.11 – 533.39**
	5	**3,420,000**	**4,188,567 - 38,307,702**	**45,000,000**	**7,608,567 – 41,727,702**	**52,608,567 – 86,727,702**	**38.12 – 209.06**	**263.57 – 434.51**
annualised net costs (5 yrs)	2	3,420,000	60,032,299 - 177,195,193	45,000,000	63,452,299 – 180,615,193	108,452,299 – 225,615,193	317.90 – 904.89	543.35 – 1130.34
	5	3,420,000	12,786,673 - 116,944,059	45,000,000	16,206,673 – 120,364,059	61,206,673 – 165,364,059	81.20 – 603.03	306.65 – 828.48
annualised gross costs (20 yrs)	2	3,420,000	89,551,902 - 127,931,288	45,000,000	92,971,902 – 131,351,288	137,971,902 – 176,351,288	465.79 – 658.07	691.24 – 883.52
	5	3,420,000	79,611,315 - 113,730,450	45,000,000	83,031,315 – 117,150,450	128,031,315 – 162,150,450	415.99 – 586.93	641.44 – 812.38
annualised gross costs (5 yrs)	2	3,420,000	273,380,086 - 390,542,980	45,000,000	276,800,086 – 393,962,980	321,800,086 – 438,962,980	1386.77 – 1973.76	1612.22 – 2199.21
	5	3,420,000	243,033,901 - 347,191,287	45,000,000	246,453,901 – 350,611,287	291,453,901 – 395,611,287	1234.74 – 1756.57	1460.19 – 1982.02

[2] The rows with bold typeface are the estimates preferred by the Dossier Submitter. The other rows outlining the 5 year annualisation period and the gross costs are considered by the Dossier Submitter as sensitivity checks.

1.1.2 Cost savings

In addition, the proposed restriction results in benefits from indirect economic impacts that arise from the avoidance of damage from siloxanes to energy generation equipment at anaerobic digestion plants. These avoided costs are estimated by the Dossier Submitter to result in **savings in order of €17 million per year** (bound estimate €4 - €39 million per year).

1.1.3. Benefits

The environmental benefits arise from the reduction in potential risks associated with accumulation of D4/D5 in the aquatic environment. To quantify the benefits associated with the proposed restriction, the Dossier Submitter has conducted a specially commissioned stated preference valuation study.

The study used a choice experiment questionnaire survey approach to quantify individuals' willingness to pay (WTP) to avoid the potential risks of accumulation of D4 and D5 in the aquatic environment. This WTP was valued relative to the associated consumer loss in the case of a restriction, connected to the functionality provided by D4 and D5 in personal care products. Respondents were asked to make choices amongst different levels of three attributes:

- PCP quality (based on the functional properties provided by D4/D5);
- Reduction of environmental accumulation/potential risk associated with the reduced use of D4/D5 in personal care products;
- Price of personal care products.

The survey respondents consisted of an internet based representative sample of the UK population (size = 829) split in two samples, each sample being asked to consider D4 and D5 separately in order to assess the differences in PBT and vPvB status.

The results from the study estimates WTP per person per year to be €46 to reduce the risk associated with the PBT substance (D4), and €40 to reduce the risk associated with the vPvB substance (D5).

The WTP for reducing D4/D5 accumulation is then aggregated to the EU level resulting in an annual WTP of €16 billion, excluding children aged 0 – 14 years. This estimate is however based on valuation scenarios concerning all PCPs that contain D4/D5 (not only wash-off PCP that are included in the scope of the restriction). To transform the estimate to only count for the wash-off PCPs in question, the Dossier Submitter used the ratio of the volume of wash-off to total PCPs containing D4/D5 (i.e. 4%).

Based on this study, the total environmental benefits attributable to reductions in the accumulation of wash-off PCPs containing D4/D5 in the EU is estimated at **around €0.65 billion per year.**

1.2 COST-EFFECTIVENESS ANALYSIS

1.2.1 Emissions

The Dossier Submitter's approach to calculating the surface water emissions of D4 and D5 from direct and indirect uses in PCPs was based on use tonnages and release factors, combined with estimates of removal during wastewater treatment. In the absence of more reliable information on tonnages, and using emission factors of 100% for wash-off PCPs and 0.1% for leave-on PCPs, the Dossier Submitter initially estimated total combined emissions

of D4 and D5 to surface water from wash-off PCPs of ~200 tonnes/year[3] (196 tonnes/year for D5 and 4 tonnes/year for D4). This estimate included contributions from both direct and indirect (unintentional presence as an impurity in silicone polymer) uses.

During opinion development the Dossier Submitter provided six further emission scenarios that explored the consequences of selecting different emission factors for wash-off and leave-on PCPs on overall surface water emissions of D4 and D5. The results of these emission scenarios are reported in a confidential annex to section B.9.4 of the Background Document, but were not used to update the cost-effectiveness calculations.

The Dossier Submitter has calculated the cost-effectiveness as the sum of economic impacts (cost and cost savings as presented above) divided by the reduction in emissions of D4/D5 as a result of the proposed restriction. The estimate range between €38 and €533 per kg of D4/D5 emissions reduced. Using the same definition, the cost per kg reduced decaBDE in the decaBDE restriction proposal was estimated to be €464. For PFOA the estimated cost-effectiveness was < €1 649 per kg PFOA emissions reduced, and €125 - €4000 per kg emissions of PFOA-related substances reduced. Finally, for phenyl mercury the estimated cost effectiveness was €649 per kg.

1.3 BREAK-EVEN ANALYSIS

The Dossier Submitter has also conducted a break-even analysis to further argue that the restriction is proportionate. This method summarises the net costs of the restriction, to show what the environmental benefits would have to be equal to in order to outweigh the costs.

The Dossier Submitter estimated that the environmental benefits would have to be €35-€69 million per year for the restriction to break even, and that this corresponds to an increase in the retail sales price of 0.5%-1% for wash-off PCPs. The Dossier Submitter concludes that the WTP for the environmental benefits of the restriction would have to be €0.07 – €0.14 per person in the EU, to offset the costs of the restriction.

1.4 AFFORDABILITY

As a supplement to the analysis of proportionality, the Dossier Submitter also discusses the unit price increase in retail sale as a result of the proposed restriction. This is done to give an indication of the affordability of the restriction.

Looking at the percentage retail sales price increases, the effect is small, ranging from 0.11 – 0.62% and 0.34 – 0.91% for the 5- and 2- year compliance periods, respectively. Even with worst case estimates, where the "gross reformulation cost" is used, the upper bound of the price increase, for the shortest compliance period, is 5.81%.

1.5 QUALITATIVE INFORMATION

The Dossier Submitter has also provided information on various aspects of the damage potential of D4 and D5 in the environment. D4 and D5 have been detected in biota in remote regions, including in the Arctic at low concentrations. However, it is unlikely to be a result of long range transport and redeposition, since a large proportion of emitted D4 and D5 is expected to reside in the atmosphere until it is degraded and thus limiting the redeposition to surface media. It is also noted that exposure of air-breathing organisms and humans is limited because of efficient excretion in the lungs. Some fish species are more

[3] This emission tonnage was initially reported in section F.2.5 of the confidential annex to the Background Document as the use tonnages used by the Dossier Submitter were considered by industry to be confidential. This tonnage information was subsequently disseminated publicly by industry in the public consultation (comment #1452) and can therefore be reported in this non-confidential opinion.

susceptible to these substances and D5 can attain concentrations up to a few mg/kg on a wet weight basis in tissues.

It is estimated, that the D4 and D5 stock in society, including residual impurities in polymer articles, is likely to be much lower than for other persistent substances. The complete consumption of PCPs containing D4 and D5 is likely to take place within a year (12 months) of purchase in most cases.

The vast majority of emissions from wash-off PCPs would be expected to take place within 12 months. However, emissions from the waste disposal stage may occur several years after first placing on the market, and emissions from polymer waste in landfills may occur decades from the assumed end of the service life.

1.6 OVERALL CONCLUSION AND PROPORTIONALITY

The benefits of €0.65 billion per year outweigh the costs (including the cost savings) ranging from €7.6 - €439 million per year, with a more realistic interval of €7.6 - €106 million per year. The Dossier Submitter thus concludes that the proposed restriction is proportionate to the risks.

Comparing the cost-effectiveness of the proposed restriction to other restrictions under REACH, the Dossier Submitter argues that this approach supports the conclusion that the risk reduction achieved by the restriction appears to be proportionate to the costs.

The restriction is also deemed affordable in terms of price increase of the end product.

Collectively the evidence all points in the same direction and the overall conclusion by the Dossier Submitter is that the restriction is a proportionate measure.

2. SEAC view

SEAC finds the proposed restriction to be a proportionate measure to reduce emissions of D4/D5 to the aquatic environment.

3. Key elements underpinning the SEAC view

The environmental benefits of the proposed restriction arise from the reduction in potential risks associated with emissions to and accumulation of D4/D5 in the aquatic environment. Experience with PBT/vPvB substances has shown that they give rise to broad concerns based on their potential to accumulate in the environment and cause effects that are unpredictable in the long term and are difficult to reverse (even when emissions cease). RAC consider that emissions of D4/D5 can be considered as a proxy for risk.

Based on the lower and upper release factors agreed by RAC and the updated tonnage information provided by industry during the public consultation (comment #1452), the proposed restriction will prevent emissions to EU surface waters of between 97.8 and 168.3 tonnes/year for D5 (including ~0.5% from indirect uses) and between 1.9 and 3.2 tonnes/year for D4 (including ~20% from indirect uses), respectively (see Annex I of the Background Document).

3.1 COST-BENEFIT ANALYSIS

3.1.1 Cost estimates

SEAC is in general agreement with the approach taken by the Dossier Submitter. The SEAC evaluations and corresponding conclusions on the different cost elements are presented

below.

I. *Raw material costs*

For the raw material costs SEAC accepts and agrees with the assumptions, calculations and results as presented by the Dossier Submitter. SEAC recognises that a 100% price increase is high compared with the reported price difference for some alternatives. However, the information on alternatives is sparse so SEAC cannot conclude on what the most realistic price increase will be. Nevertheless, based on the presented information SEAC accepts the Dossier Submitter's choice of using 100% as the price increase between alternatives and D4/D5.

To be consistent across all cost and benefits elements, SEAC has delayed the onset of the raw material costs until after the compliance period (which slightly reduces the cost estimates), and has computed an annuity based on a 20 year analytical period.

II. *Cost of reformulations*

SEAC agrees with most of the assumptions made by the Dossier Submitter. SEAC, in collaboration with the Dossier Submitter, has chosen to perform additional calculations to relax some of the more stringent assumptions and to investigate how sensitive the estimates are to certain parameters. The full analysis is presented in Annex I in the Background Document, and a summary is presented below.

- SEAC recognises that some coordination of ongoing R&D efforts with the R&D necessary to remove D4/D5 from all formulas is likely to be possible, and comments in the public consultation (e.g. COM 1417, 1431) also indicate that coordination with ongoing R&D may lower the costs. For example, if a company has scheduled to create a new formula for a conditioner to meet the market demand of "shiny hair", they might be able to undertake the necessary R&D to remove D4/D5 at the same time, and thus reduce the cost as compared to doing the reformulations separately. However, SEAC notes that baseline reformulations would not be performed for the purpose of removing D4/D5, but rather be motivated by e.g. innovations to meet market demand, cost reductions or other R&D needs (this is also described by the Dossier Submitter, and confirmed in the public consultation (e.g. COM 1417, 1431)). Market demand and related R&D needs are not necessarily known more than 10 years into the future, so SEAC does not agree that it will be possible to coordinate all major reformulations over the next 20 years, as implicitly assumed by the Dossier Submitter[4].

  In the additional cost estimates this assumption is relaxed, and the coordination of R&D efforts to remove D4/D5 with other required reformulations are assumed to be possible for an initial 5-10 year period after the entry into force. After this period, the companies R&D efforts return back to business as usual, i.e. they reformulate at the same rate as before the restriction to meet market demand etc.

  However, some coordination of R&D efforts may also be possible after the compliance period. In such a case, the new cost estimates may be too high. The original cost estimates in the Background Document are also evaluated, but these will be given less weight as they are considered to be an underestimation of the real costs. On the opposite side, the Background Document includes gross costs, based on an assumption of no coordination being possible. SEAC will also evaluate the no coordination scenario, but this will also be given less weight due to the likely overestimation.

[4] Note that the Dossier Submitter has only made this assumption for the 'major' reformulations. For the 'minor reformulations' it is assumed immediate return to the baseline reformulation rate. SEAC agrees with this assumption.

- The Dossier Submitter assumes for the lower bound scenarios that there are no costs connected to removing D4/D5 from products, but that it can be done with no additional costs when coordinating the reformulation with an already scheduled reformulation. For the upper bound the Dossier Submitter assumes that the additional costs of removing D4/D5 will amount to €150 000 per formula when it is coordinated with another reformulation. SEAC considers the 'no additional cost'-assumption to be an underestimation, but has little to no information about the actual 'additional' costs of removing D4/D5 from a product to allow calculations to be reliably refined. Due to the lack of information about the costs of coordinating several reformulation processes, SEAC chooses to follow the Dossier Submitter's initial approach, but will be mindful about the potential for underestimation due to the 'no cost'-assumptions in the lower bound scenarios.

- For the minor reformulations, the Dossier Submitter assumes that these will not be performed (or they will be integrated into the major reformulation without additional costs) during the compliance period. Since the minor reformulations can be performed with no additional cost in the restriction scenario, the affected companies would have a cost reduction as compared to the baseline. SEAC question whether such a cost saving would actually take place, and concludes the 'no cost'-assumption will more likely lead to an underestimation. For simplicity SEAC has thus chosen to disregard these assumed cost savings, and rather assume that the minor reformulations will be unaffected by this restriction, i.e. a zero cost assumption rather than cost savings.

  The Dossier Submitter assumes that all of the reformulation costs will be expended in the last year of the compliance period. SEAC could not find any argumentation for why all of the costs would occur in the last year of the reformulation period. By placing the costs at a later point in time, the estimates are reduced, and the cost will be underestimated. To try to counterbalance this bias and in the lack of any particular timing of these reformulation costs, SEAC chose to spread the costs equally across the compliance period. The Dossier Submitter annualises the reformulation costs using two different analytical periods, 20 years and 5 years respectively. The calculations of the reformulation costs are based on a 20 year analytical period, thus annualising these over 5 years will be inconsistent. SEAC will thus only consider the estimates annualised over the 20 year period.

The number of reformulations necessary is recognised by the Dossier Submitter as highly uncertain, and probably overestimated. The Dossier Submitter has followed the assumptions presented by one large industry actor, leading to a total number of necessary reformulation of 3761. However, as described in the Background Document there are several data sources supporting the likelihood of an overestimation:

1) The EU market would under these assumptions have 23 times more products containing D5 as compared to the Canadian market, which seems unlikely. Extrapolating from Canadian data would give 160 necessary reformulations connected to the proposed restriction.

2) A 1 year sample of newly launched PCPs (March 2012 – March 2013) showed that only 0.13% of all the new PCPs were wash-off products containing D5. Extrapolating from this source would give 400 necessary reformulations connected to the proposed restriction.

3) A small sample study which tested 231 wash-off PCPs found that only 7% of the products (all conditioners) contained D4 or D5. Extrapolating from this source would give 850 - 1050 necessary reformulations connected to the proposed restriction.

4) Industry provided information in the public consultation (COM 1417) on the number of product reformulations would be necessary if both wash-off and leave-on products

were to be restricted. Extrapolating from this source gives fewer than 1500 necessary reformulations connected to the proposed restriction.

As a whole, the other available sources show that fewer than 1500 reformulations would be necessary to comply with the proposed restriction. In other words, the Dossier Submitter might have overestimated the number of necessary reformulations by between 2 to 23 times.

Overall, SEAC agrees with the Dossier Submitter's interpretation of the available data, and finds it highly likely that the number of necessary product reformulations is overestimated. To better reflect this overestimation, SEAC has included an additional cost scenario where the number of necessary reformulations is reduced by 50% (1881 necessary reformulations), which is equivalent of giving the original data source used by the Dossier Submitter 3 times as much weight as each of the other sources. A lower bound scenario is also included, where an average of the other four data sources are used (681 necessary reformulation), i.e. an 80% reduction in the number of necessary reformulations.

Table 2 below gives an overview of the different estimates evaluated by SEAC. Due to the underlying uncertainties, the estimates should only be considered as indicative. To underline this lack of precision, all of the numbers (except the original Dossier Submitter estimates) are rounded to the nearest €10 million.

Table 2: Summary of reformulations cost estimates evaluated by SEAC in Million €

Reformulation costs sensitivity - Yearly costs in Million €							
Compliance Period	**Bound**	**DS original estimates**	**5 year coordination and 80% less products**	**5 year coordination and 50% less products (Low)**	**10 year coordination (Medium)**	**5 year coordination (High)**	**No coordination**
2 years	Lower	20	10	30	50	70	90
	Upper	58	20	50	90	100	120
5 years	Lower	4	10	30	40	60	80
	Upper	38	20	50	80	90	110

SEAC concludes that the reformulation costs are likely to lie in the interval €30 million - €100 million for the 2 year compliance period, and €30 million – €90 million for the 5 year compliance period.

III. *Product performance loss*

SEAC agrees with the general approach taken by the Dossier Submitter to estimate the product performance loss. SEAC agrees that the assumption of 50% performance loss is likely to be rather high, based on the fact that there are a large number of similar products on the market today, which do not contain D4/D5. In line with the Dossier Submitter, SEAC finds it more likely that the real performance loss will lie between 0% and 50%.

SEAC has chosen to not directly use the benefits estimates from the WTP study provided by the Dossier Submitter (see sections 1.1.3 and 3.1.1 on benefits). Since the WTP for the product quality was estimated in the same regression analysis as the WTP for reducing environmental accumulation of D4/D5, the WTP for product quality will not be directly used either.

Based on information provided by the Dossier Submitter as well as information from the public consultation, SEAC concludes that there is likely to be some loss in product performance, with a corresponding consumer surplus loss. However, SEAC notes that the

industry concern for performance loss is primarily mentioned in connection with leave-on PCPs, and that the difficulties of replacing D5 in wash-off products may be less significant (COM 1431). The size of this potential loss is unknown, but SEAC notes that the exclusion of these indirect costs may lead to an underestimation of the total costs to society of the proposed restriction.

IV. Testing costs

The Dossier Submitter has provided additional information on potential testing costs (see section F.2.1. in the Background Document), based on UK data on enforcement campaign costs. However, the costs are calculated for a few specific UK campaigns, and aggregation to the EU-level is not possible.

Some industry actors have indicated in the public consultation that testing costs could be substantial, but their scale are unknown and no further justification was provided. SEAC notes that under the Cosmetics Regulation, persons responsible for placing cosmetic products on the market (usually the manufacturer or the importer) must ensure that the product in question has undergone a safety assessment and that a cosmetic product safety report is prepared. In the public consultation (COM 1417 and 1418), the costs connected to updating of the product safety assessment required by the Cosmetics Regulation was integrated into the total reformulation costs. The Dossier Submitter (and SEAC) uses the cost numbers provided by industry, so at least parts of the potential testing costs should be included in the total cost estimates. However, due to the lack of data, SEAC is not able to conclude on the likely size of any other potential testing costs, but acknowledges that to the extent that additional testing cost would be undertaken, the total cost of the restriction would be underestimated.

V. Cost savings

As recognised by the Dossier Submitter, the potential costs savings for the EU Anaerobic Digestion (AD) plants are uncertain. They might be overestimated, since all of the damage from siloxanes is attributed to D4/D5, while other siloxanes may be more or less responsible for the damage. On the other hand, the lower bound estimate is based on costs from a Canadian study, which is specifically studying costs to AD plants from D4/D5. Even though the latter is not cost estimates based on EU data and the cost level might be somewhat different than in the EU, SEAC still considers this Canadian study to be more representative since it is specifically estimating costs related to D4/D5 and are not including costs which might be caused by other siloxanes. SEAC has thus disregarded the upper bound estimates of the cost saving.

The actual calculations of the cost savings (performed by an external consultant) deviate somewhat from the description in the dossier, due to a slight difference in discount rate, different analytical period and the assumption of the onset of the cost savings. To make the estimates consistent with the other cost estimates, updated cost savings estimates has been provided (Annex I in the Background Document) using the 4% discount rate and a 20 year analytical period.

There were only minor changes compared to the estimates used by the Dossier Submitter, and SEAC concludes that the cost savings are likely to lie in the interval €4 million - € 39 million per year for a 2 year compliance period, and €3 million - €31 million for a 5 year period.

VI. Total costs

To estimate the total costs, all the different cost elements are combined in the following way:

Total costs = Raw material costs + reformulation costs + product performance loss + testing costs – cost savings

The testing costs and the product performance loss could not be quantified, so the total cost estimates will be underestimated in terms of these missing elements.

Export and import have not been evaluated, but SEAC has currently no evidence supporting any bias (e.g. export>import) due to this omission.

Table 3: Summary of the elements in the main cost scenario

Yearly costs in Million € - 20 year analytical period - 10 year coordination (Medium)							
		Cost components (annuities)					
Compliance Period	**Bound**	*Raw material substitution Costs*	*Reformulation Costs*	*Cost savings*	*Compliance testing costs*	*Product performance reduction loss (PPL)*	**Aggregate Annual Costs (excl. PPL)**
2 years	Lower	3	50	-40	N/A	N/A	**20**
	Upper	3	90	-4	N/A	N/A	**90**
5 years	Lower	2	40	-30	N/A	N/A	**20**
	Upper	2	80	-3	N/A	N/A	**80**

Table 4: Sensitivity of aggregate costs estimates for different reformulation cost assumptions, testing costs is excluded

Aggregate costs (excl. PPL) - Reformulation costs sensitivity - Yearly costs in Million €							
Compliance Period	**Bound**	**DS original reformulation costs**	**5 y coordination and 80% less products**	**5 year coordination and 50% less products (Low)**	**10 y coordination (Medium)**	**5 y coordination (High)**	**No coordination**
2 years	Lower	-20	-30	-3	20	30	50
	Upper	60	20	50	90	100	120
5 years	Lower	-24	-20	1	20	30	50
	Upper	40	20	40	80	90	110

As shown in the tables above, the cost estimates are highly sensitive to different assumptions for the reformulation costs. The scenarios considered most likely are denoted "Low", "Medium" and "High", and will be used in the proportionality assessment. SEAC concludes that the total costs (excluding testing and product performance loss) are likely to lie in the interval €3 million - €100 million per year for the 2 year compliance period, and between €1 million - €90 million for the 5 year compliance period. As a central estimate, SEAC will use the average[5] of **€50 million per year** for the 2 year compliance period, and **€45 million per year** for the 5 year period.

3.1.1 Benefits

The benefits estimates are solely based on the WTP study, which was carried out specifically to support this restriction proposal in cooperation with the Dossier Submitter[6]. SEAC appreciates the efforts that went into producing this study and the valuable contribution to the benefits assessment. In general SEAC supports the approach of trying to calculate the WTP as a measure of the societal benefits from a restriction, but also recognises that there are major challenges involved due to the complexity of the effects to be valued.

To get reliable WTP estimates, that is, estimates that actually reflect the true benefits to

[5] SEAC uses the average of the three most likely scenarios (low, medium and high).

[6] The stated preference study and corresponding analysis was carried out by a master student at LSE, with guidance from a supervisor from LSE as well as a representative from the Dossier Submitter team.

society, it is necessary that the respondents understand the attributes they are going to value. One of the problems with PBT and vPvB substances is that the risks of future effects are unknown, and often even the potential effects are unknown (even to experts). This means that the respondents must value a "black box", which may result in a large variety of responses not necessarily connected to the problem at hand. For example, a respondent may picture one particular "prototype[7]" effect and base their entire valuation on that. Alternatively, a respondent may misunderstand the scope of the problem and provide a generic WTP for a larger group of problems (part-whole bias[8]). For example, environmental problems in general or problems connected to hazardous substances in general. It should be underlined that these issues are also connected to contingent valuation (CV) studies in general, and that choice experiments (as was used in this study) are usually better at handling such scope effects. In general there are many different challenges connected to WTP estimations, but the more complex the attribute is, the more difficult will it be to get a representative estimate. It can also be questioned whether it will always be possible to estimate WTP, in particular for highly complex issues.

These challenges will often result in WTP estimates that have low scope sensitivity or are completely scope insensitive. This means that if a similar study had been performed for a different scope, one would get approximately the same results. This raises several problems, but in the case of the benefits of a restriction proposal, this would mean that the WTP estimates imply that it would be more beneficial to divide the original proposal into many small measures, even though the exact same amounts of emissions are reduced.

One particular result from the study underpins some of the concerns mentioned above. If one looks at the results from D4 (PBT and vPvB) and D5 (vPvB) separately, one finds that the individual WTP to stop environmental accumulation, i.e. reduce/remove all emissions, is €46 and €40 respectively. D4 emissions are around 1.9% of the D5 emission (See emission section below). Using the WTP as a proxy for the benefits to society of avoiding D4 and D5 emissions, this would imply that society gains 60[9] times more per unit of D4 emission avoided than per unit of D5 emission avoided. It is difficult to justify such a large difference in the gains to society for the two substances (which are described as being rather similar in the valuation study). The differing valuations are probably due to the fact that no information was provided to the respondents on the relative amounts of the two substances. If the risks, and thereby the benefits to society can be assumed to be connected to the amount of the substances emitted into the environment, at least one of the WTP estimates will not be representative for the true benefits to society.

Another interpretation, which may circumvent some of the issues described, is to connect the WTP to the hazard of the substances rather than to the potential impacts. The WTP estimates may then reflect a societal preference for precautionary actions to prevent potential, but unknown, effects related to D4/D5. With this interpretation, it is expected that the estimates should be scope insensitive, but it would still reflect the societal gain from removing substances of concern. However, it also implies that it would not matter in terms of benefits to society, if the emissions in question actually cause any impacts. This means that the benefits could be more connected to all emission (or even use) of the substances. Moreover, it would be difficult to distinguish whether the WTP would be specific for D4/D5, or if it was rather related to a general concern for all PBTs and vPvBs (or all substances of similar concern). In the latter case, the benefits attributable to D4/D5 would only be a small share of the WTP to remove all PBTs or vPvBs.

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7 Kahneman, D. 1986. Comments on the contingent valuation method. Pp. 185-194 in *Valuing environmental goods: a state of the arts assessment of the contingent valuation method,* eds. R. G. Cummings, D. S. Brookshire and W. D. Schulze. Totowa, NJ: Roweman and Allanheld.

8 Whitehead, John C., Timothy C. Haab, and Ju-Chin Huang, "Part-Whole Bias in Contingent Valuation: Will Scope Effects Be Detected with Inexpensive Survey Methods?" *Southern Economic Journal*, 65, 160-168, 1998.

9 The ratio was derived by using the following approximation: (WTP per kg D4)/(WTP per kg D5) = (€46/0.019x kg)/(€40/x kg) = (46*x)/(40*0.019x) =60.

The Dossier Submitter notes that the study is likely to be scope insensitive. It is not necessarily the case that scope insensitivity will always invalidate WTP estimates, but it means that if the estimates should be used, it is necessary to be very careful about how they are interpreted and used.

SEAC has concluded that the benefits estimates derived based on the WTP study are too uncertain to be used as direct comparators to the costs. However, it is found that the study provides evidence for a potentially large WTP for avoiding accumulation of D4/D5 in the environment. Furthermore, SEAC notes that the WTP for the environmental improvement is clearly higher than the WTP for superior PCP quality.

SEAC also notes that several of the cost estimates are negative, meaning that the cost saving incurred by the anaerobic digestion plants, are under some assumptions, enough to justify the restriction.

3.2 COST-EFFECTIVENESS ANALYSIS

Emissions, or here, accumulating emission, can be viewed as a proxy for the benefits. Accumulating emission refers to the part of the emissions that is likely to contribute to the accumulation of D4/D5 in the environment. This means that emissions to air are excluded, and only the emissions that remain after waste water treatment will be included.

RAC considers that the quality and applicability of the experimental studies used by the Dossier Submitter to select the release factors for leave on and wash-off categories of PCPs in the original Annex XV restriction proposal are limited and potentially of high uncertainty. In response, the Dossier Submitter has included in the Background Document a series of six supplementary sensitivity analyses of potential emissions, based on the use of different release factors for leave on and wash-off products to wastewater during use. In addition, these assessments are compared in a "reality check" to the available monitoring data of D4 and D5 in wastewater influents. However, the results of these sensitivity analyses were not used in the socio-economic parts of the Background Document.

Notwithstanding these additional analyses, and based on the remaining uncertainty in the available experimental studies, RAC considers that a simplified approach to exposure assessment for D4 and D5 is appropriate to the quality of the available experimental studies. The simplified RAC approach is comprised of lower and upper bound emissions factors for wash-off and leave on products. SEAC notes that RAC does not consider that either the upper or lower bound scenarios represent realistic worst case emissions. Rather, actual emissions are considered to occur somewhere between the upper and lower bound estimates.

Based on this simplified approach, RAC considers the following emission factors to be appropriate to be used as lower and upper bounds for emission of D4/D5 to waste water:

Table 5: Emissions factors (from Annex I in the Background Document)

Product	Bound	Value (%)
Wash-off	Lower	54.0
	Upper	93.0
Leave-on	Lower	0.1
	Upper	2.6

The original tonnage estimates of D4 and D5 used in wash-off and leave-on PCPs were based on industry data that only covered parts of the market. The Dossier Submitter extrapolated industry numbers to the entire market, by assuming a one-to-one relationship between tonnage used and sales revenue. In the public consultation, new data covering the entire market was received, which the Dossier Submitter found to be more reliable than the extrapolated estimates. SEAC agrees with this, and concludes that the likely tonnages are:

Table 6: Tonnages (from Annex I in the Background Document)

Tonnage uses			
Source	**D4**	**D5**	**D4+D5**
wash off	11,3	750,0	**761,3**
leave-on	213,8	14250,0	**14463,8**
other	4,0	4,0	**8,0**
Total	229,0	15004,0	**15233,0**
% wash-off of total use	4,9 %	5,0 %	**5,0 %**

Based on the updated emission factors and tonnages, RAC has provided new emission estimates, which can be found in the table below[10].

Table 7: Emission estimates (from Annex I in the Background Document)

Emission D4+D5, in tonnes per year		
Source	**low**	**high**
wash-off	98,7	169,9
leave-on	7,4	94,0
Total	106,1	263,9
% wash-off of total emission	93 %	64 %

SEAC uses the new emission estimates to calculate the average emission per year for a 20 year analytical period, when taking into account the latency of the 2 and 5 year compliance period respectively. The resulting average yearly emissions used in the cost-effectiveness calculations are as follows:

Table 8: Average yearly emissions from wash-off PCPs

Emissions annuity- 20 year analytical period		
Compliance Period	**Bound**	**Emission in kg D4/D5 per year**
2 years	Low	**89 000**
	Average	**121 000**
	High	**153 000**
5 years	Low	**74 000**
	Average	**100 500**
	High	**127 000**

[10] Assuming 80% connection rate and removal in waste water treatment plant of 95%; 40% of formulating sites are assumed to be well controlled (emission factor of 0.009%) and 60% of formulating sites are assumed to be less well controlled (0.09%).

SEAC has calculated new cost-effectiveness estimates based on the three emission scenarios (table 8) and the three most likely cost scenarios (table 4) presented in the cost-benefit analysis above. The result is a matrix of cost -effectiveness estimates (shown in the table below), which can be used to evaluate the efficiency of the restriction proposal.

Table 9: Cost effectiveness

Cost effectiveness (excl. PPL) - €/kg				
Compliance Period	Emissions Costs	Low	Average	High
2 years	Low	<0	<0	<0
	Medium	540	**400**	310
	High	1 100	830	650
5 years	Lower	10	10	8
	Medium	590	**430**	340
	Upper	1 200	900	710

As shown in the table, the cost-effectiveness ranges from below zero to 1200 €/kg D4/D5 reduced. Using the average emission reduction and the average costs, the estimates are around 400 €/kg for a 2 year compliance period and 430 €/kg for the 5 year compliance period. Keeping in mind that the costs are likely to be underestimated due to the non-quantified elements, testing cost and product performance loss, SEAC concludes that the real cost-effectiveness is still likely to be well below 1000 €/kg.

SEAC has no established benchmarks to compare these cost-effectiveness estimates with. One set of indicators can be to look at previous restriction proposals for substances with similar properties. The Dossier Submitter cites cost effectiveness for decaBDE (€464/kg), PFOA (< €1 649/kg), PFOA-related substances (€125 - €4000) and lastly phenyl mercury (€ 649/kg), which all were considered likely to be proportionate by SEAC. The cost-effectiveness estimates for the proposed restriction are in the same range as all the above mentioned estimates. Even though the other mentioned restriction proposals are not directly comparable in terms of impacts, **SEAC finds that the similarities are sufficient to conclude that the proposed restriction is likely to be proportionate from a cost-effectiveness point of view.**

3.3 BREAK-EVEN ANALYSIS

There are several ways of calculating the necessary WTP to break even with the net economic impact costs of the restriction. In general, a break-even analysis would be a back calculation of the costs in such a way that if you replace the WTP used in the benefits calculation with the necessary WTP estimated in the break even, the resulting benefits estimates should be the same. In the Background Document the Dossier Submitter discuss whether it is most reasonable to assume that the WTP estimates from the WTP study are connected to removing the use of the substance (precautionary valuation) or to removing the emissions (impact valuation). For each of these assumptions one would get a different attributable fraction of the WTP, which leads to different benefits estimates. Even though the benefits estimates are no longer used quantitatively, SEAC has chosen to use the same two assumptions in the break-even analysis.

The approach used to calculate the necessary WTP can be described as follows:

$$WTP_{tot}\ (attributable\ fraction\ ) = WTP_{ind} * const\ (compliance\ period)$$

This means that the annualised total WTP (based on either emission or use as the attributable fraction) is proportional to the individual WTP, but the constant being dependent on the chosen compliance period. The constant is calculated based on the annualised total WTP and individual WTP when using the estimates from the WTP study.

When back calculating one can then find the necessary individual WTP to pay that would yield annualised total benefits equal to the costs. To reduce the number of estimates, only the average emission reduction capacity is used. The results from these calculations are summarised in the table below:

Table 10: Break-even analysis

Break-Even - Neccessary WTP in € per person			
Compliance Period	**Costs**	**WTP connected to emission reduction**	**WTP connected to use**
2 years	Low	-0,01	-0,2
	Medium	0,2	2,7
	High	0,4	5,7
5 years	Low	0,0	0,1
	Medium	0,2	3,2
	High	0,5	6,5

The necessary WTP ranges between €0.2 and €6.5 per person[11], if the WTP is assumed connected to the use. If the WTP is connected to emissions the range is reduced to €0.01 – €0.5. In all cases, the necessary WTP is higher for the 5 year compliance period.

SEAC notes that the necessary individual WTP estimates are fairly low for all the realistic scenarios. Keeping in mind that there is some underestimation of the costs and in some cases the costs are even negative. This by itself is not enough to conclude on the proportionality of the proposed restriction.

3.4 AFFORDABILITY

Affordability in this case can be defined[12] as an actor's ability to pay, e.g. in terms of income or profits, relative to the size of the enforced costs. As long as the actors are able to pay, that is the enforced cost is not larger than the income or profit, the measure can be seen as 'affordable'. However, it should be underlined that an affordable measure is not necessarily economically feasible, and affordability does not in itself imply a measure is (net) beneficial for society.

As presented by the Dossier Submitter the price increase arising from the cost of the restriction will be small. Using the new additional estimates outlined above (and in Appendix I of the Background Document), SEAC has estimated the price increase by dividing the respective cost to industry (excluding cost saving, which is an externality for the affected companies) by the total sales revenue for wash-off PCPs containing D4 and D5. The Dossier Submitter only provided sales revenue numbers for the PCPs containing D5, but considering the low tonnages of D4 as compared to D5 (and then probably comparably low revenue numbers), SEAC finds this underestimation to be acceptable for the purpose of the affordability analysis.

Based on the additional cost estimates as well as the abovementioned sales revenues, SEAC concludes that the price increase is likely to be <1.5% for the high cost scenario and <1% for the low cost scenario. It is noted that the product performance loss should not be (and is not) included in the affordability assessment, as these costs are intangible costs, only experienced by the consumers if they experience that the product they use has lower quality. The potential industry testing costs, on the other hand, should have been included, so the costs will still be somewhat underestimated. Keeping this in mind, SEAC observes

[11] Only counting people over the age of 15, as was done by the Dossier Submitter.
[12] There is no general definition of affordability, as it is not an analytically defined concept.

that PCPs tend to vary considerably more in price between similar products than by the price increase estimated by the Dossier Submitter as a result of the proposed restriction e.g. you may find one shampoo being twice the price of another shampoo. **SEAC thus agrees with the Dossier Submitter's conclusion that even the worst case price increase will be affordable for the consumers.**

However, it is not certain that these costs would be transferred to consumers through a price increase, in particular if the products in question lose some of their superior quality due to substitution of D4 and D5. Assuming as a worst case scenario that none of the costs can be transferred to the consumers in the prices, the companies in question would have to face a loss in revenue. If the retail sector is bearing the costs, the percentage loss would be the same as for the consumer: <1.5% and <1% for the high and low cost scenarios, respectively. If instead the manufacturers will bear the costs, the loss would be <2.5% for the high cost scenario and <1% for the low cost scenario. Whether this is affordable or not will depend on the profit margins of the affected companies. The exact profit margin for the affected companies is not known, but SEAC found some weak evidence claiming that skin and haircare products typically have profit margins greater than 60%[13]. SEAC urges the affected companies to come forward with information about their actual profit margins, and whether they consider the restriction to be affordable. In the lack of evidence disputing the cited profit margins being more than 60%, **SEAC concludes that the costs are likely to be affordable for the affected companies.**

3.5 QUALITATIVE INFORMATION

SEAC recognises the qualitative information which further elaborates on the damage potential of D4/D5.

Of the evaluated elements presented in Annex F.3 in the BD, RAC has identified long range transport as a potential area of concern. The Dossier Submitter found that long range transport was less problematic in the case of D4/D5, due to the limited redeposition potential. RAC, on the other hand states that even with low deposition rates, the high volume of emission to air (not just by wash-off PCPs) may be a source of risk to remote areas.

SEAC takes note of RAC's concern, and finds that this provides an additional argument in favour of the proposed restriction, in addition to the PBT/vPvB concern.

3.6 OVERALL CONCLUSIONS AND PROPORTIONALITY

As presented above, the restriction proposal has been evaluated using several different proportionality measures. SEAC notes that the CBA and the break-even analysis are inconclusive, since the benefit estimates were deemed too uncertain to be directly compared with the costs. However, it is highlighted that there is evidence of a WTP for avoiding D4/D5 accumulation in the environment, and this WTP is substantially larger than the WTP to preserve the superior product quality. SEAC also notes that several of the cost estimates are negative, meaning that the cost saving incurred by the anaerobic digestion plants, are under some assumptions, enough to justify the restriction.

The CEA and affordability measures indicate that the restriction is likely to be proportionate. Even though each measure by itself has uncertainties connected to it, the collective evidence is very strong. **By taking into account all the available evidence, SEAC concludes that the proposed restriction is likely to be proportionate.**

[13] http://www.forbes.com/sites/ryancaldbeck/2014/02/06/why-you-should-think-about-investing-in-beauty-instead-of-bitcoin/
http://newhope360.com/product-development/5-reasons-great-investors-brands-focus-gross-margin

3.7 COMPLIANCE PERIOD

The socio economic analysis can give an indication of which of the two proposed compliance periods that would be most beneficial to society.

A quantified CBA could not be performed, due to the underlying uncertainties in the WTP study, and thereby, the benefit estimates. Hence, from a cost-benefit point of view there is no conclusive evidence pointing in the direction of any particular compliance period.

All of the cost-effectiveness estimates indicate that the 2 year compliance period would be most cost-effective. However, the estimates for the 2 year and the 5 year compliance periods are very similar under all scenarios. Taking into account the remaining uncertainties, in particular the omission of some cost elements, the evidence is not conclusive.

The break-even estimates leads to the same ambiguous conclusion as the cost-effectiveness estimates. All of the necessary WTP estimates are higher for the 5 year period, and thus favouring a 2-year compliance period. On the other hand, also here the estimates are so similar across the two compliance periods, that one cannot conclude that one of the compliance periods are considered more beneficial from a break-even point of view.

The potential increase in the consumer price of PCPs is considered affordable for the end user in all scenarios for both compliance periods. The price increase will be higher, the higher the costs are, which means that the 5 year compliance period is more affordable under all sets of assumptions. The same conclusion will be reached if affordability for industry was used as a measure, so in general the 5 year compliance period is preferable from an affordability point of view.

From the combined analytical evidence there is a slight favouring of the 2 year compliance period, but no clear conclusion can be drawn. However, it should be underlined that the analytical modelling does not take into account potential costs that may occur if it is not technically possible to reformulate and test the products during the chosen compliance period. At the same time, there might be negative long term effects for the environment, which are not captured in the current analysis.

Industry has contributed with information, both before and during the public consultation on the length of time to market reformulated products, including detailed descriptions of each of the steps in the substation process. The information provided from different respondents is claimed as confidential and varies significantly between respondents (COM 1417, 1428). SEAC notes that it has been known by industry for several years that a regulation of these substances was likely to come. It thus seems reasonable to assume that industry would have started parts of the processes already, at least the search for potential alternatives. Still, this does not undermine the fact that the suggested compliance periods may be too short to complete reformulations for all affected actors and all affected products.

Some industry actors (COM 1428) are also worried about the possible scenario of a market recall, as some of the products are claimed to have a shelf life of several years between production and purchase. A product recall is said to damage the reputation of the company at hand, as well as create unnecessary product waste. SEAC agrees that a product recall would be unfortunate, but needs more information about the average shelf lives of the affected products (in particular shampoos and conditioners, which constitutes the main part of the scope), to conclude that a 2 year compliance period is not sufficient to sell out the existing stock.

SEAC notes that the number of affected products is probably highly overestimated in the

Medium and the High cost scenarios. Looking at the new products releases between March 2012 and March 2013, the share of wash-off products containing D5 was only 0.13%. If this is somewhat representative for the coming years as well, temporarily reducing the product portfolio by 0.13% is not necessarily a large burden for consumers. Industry, on the other hand, will still be affected by the temporarily reduced profits, and this burden may be worse for SMEs than for larger actors. SEAC is still not convinced that the consequences for industry are of such proportions that a longer compliance period is warranted.

SEAC urges industry to provide more specific information about the potential consequences that a 2 year (as opposed to 5 years) compliance period will have. And furthermore, which cost elements can be reduced and by how much, if a longer compliance period is given.

If no specific information is received, the recommendation will be based on the weak conclusions from the proportionality assessment, in favour of a compliance period of 2 years.

Practicality, incl. enforceability

Summary of the proposal

There is no one-for-one drop-in alternative for D4/D5 in wash-off PCPs. However, the Dossier Submitter notes in the Background Document that around 64 % of wash-off PCPs (by sales volume) do not contain any D4 or D5. Based on this, the Dossier Submitter considers that substitution is generally technically and economically feasible for this product type, and that the proposal is considered to be implementable and manageable.

Formulators of products that currently contain D4/D5 need to reformulate their products prior to the deadline, i.e. by the end of the transitional period before the entry into force of the restriction. They may also need to seek confirmation from their supplier about the concentration of D4/D5 in the polymers they purchase. The retailers may request declaration from their suppliers that none of their products contains D4 and D5 above the proposed concentration limit of 0.1 per cent w/w. The enforcement authorities could review such agreements, along with assessment of ingredients lists on the product label (which is required by the Cosmetics Regulation) to enable sampling products more likely to be non-compliant. Subsequent sampling and analysis would then show the level of compliance.

There are no standard analytical methods to measure the content of D4/D5 in PCPs, however, suitable methods exists. Furthermore, industry has indicated in the public consultation that a standard method is being developed (COM 1419). The limit of detection is typically around 0.1 ppm, which means that the suggested concentration limit of 0.1% w/w is well above the detection limit. The restriction is therefore considered enforceable.

RAC has proposed a different wording to what was originally proposed by the Dossier Submitter. RAC has not intended to modify the intended scope of the restriction by proposing revisions to the Dossier Submitter's proposal, but to reflect advice received during opinion development.

SEAC view

SEAC concludes that the proposal is implementable, enforceable and manageable.

Key elements underpinning the SEAC view

SEAC does not have enough information to firmly conclude that there exist alternatives for all identified uses within the scope of the restriction proposal. However, since there exist so many similar products on the market without D4/D5, SEAC finds it likely that D4/D5 is replaceable and that the alternatives are likely to be both technically and economically

feasible. SEAC does not exclude the possibility that replacing D4/D5 in wash-off PCPs might result in some product performance loss. However, SEAC concludes that the restriction proposal is implementable.

The Forum states that it is not necessary to develop a standardised sampling method for this restriction, and that even though no specific analytical method exists for the analysis, there are various methods available in the literature. The Forum considers the restriction to be enforceable, and finds the enforcement of the restriction practicable. SEAC therefore concludes that the restriction is enforceable.

The Dossier Submitter lays out the necessary steps for ensuring compliance for the different actors (producers, retailers, governments), and these are considered by SEAC to be understandable and manageable for all the involved actors.

On the other hand, there is little discussion about the manageability of the transition period. Industry has indicated that it could take more than five years to reformulate and test all the products, but SEAC does not have enough detailed information about the consequences if a shorter compliance period is recommended. Based on the available evidence, SEAC cannot firmly conclude on the manageability of the proposed restriction, but it is noted that a shorter compliance period is likely to be less manageable than a longer one.

Monitorability

Summary of the proposal

The Background Document notes that existing mechanisms, such as labelling requirements of the Cosmetics Regulation, should help to identify relevant PCPs for targeted analysis, and that monitoring in general will be carried out through regular enforcement activities for PCPs.

Environmental monitoring of the receiving environment is suggested to provide further evidence about whether the restriction is reducing the identified risks.

SEAC view

SEAC agrees that the restriction is monitorable.

Key elements underpinning the SEAC view

SEAC has not identified any potential problems with regards to monitoring and accepts the Dossier Submitter’s arguments. Based on this, SEAC considers the proposed restriction to be monitorable.