Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restriction on

Bis(pentabromophenyl) ether (DecaBDE)

ECHA/RAC/RES-O-0000006155-77-01/D
ECHA/SEAC/RES-O-0000006155-77-03/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 2 June 2015) and SEAC's opinion (adopted 10 September 2015)

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2 June 2015

ECHA/RAC/RES-O-0000006155-77-01/D

10 September 2015

ECHA/SEAC/RES-O-0000006155-77-03/F

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

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

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

Chemical name(s):	**Bis(pentabromophenyl) ether (DecaBDE)**
EC No.:	**214-604-9**
CAS No.:	**1163-19-5**

This document presents the opinions adopted by RAC and SEAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed grounds for the opinions.

PROCESS FOR ADOPTION OF THE OPINIONS

ECHA on a request from the Commission 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 17 September 2014. Interested parties were invited to submit comments and contributions by **17 March 2015**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: *Frank JENSEN*

Co-rapporteur, appointed by RAC: *Steve DUNGEY*

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment has been reached in accordance with Article 70 of the REACH Regulation on ***2 June 2015***.

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

The RAC opinion was adopted ***by consensus*** of all members having the right to vote.

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

Rapporteur, appointed by SEAC: *Karen Thiele*

Co-rapporteur, appointed by SEAC: *Endre Schuhtar*

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on ***10 June 2015.***

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://www.echa.europa.eu/web/guest/restrictions-under-consideration/-/substance-rev/1897/term** on ***17 June 2015***. Interested parties were invited to submit comments on the draft opinion by ***17 August 2015***.

The opinion of SEAC

The opinion of SEAC on the suggested restriction was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **10 September 2015**.

The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation.

The opinion of SEAC was adopted ***by consensus*** of all members having the right to vote.

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 ***decaBDE*** 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 substance, of the group of substances or of the mixture	Conditions of the restriction
Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE) CAS No 1163-19-5 EC No 214-604-9	1. Shall not be manufactured, used or placed on the market: ○ as a substance, ○ as a constituent of other substances, or in mixtures after [date of entry into force], if the concentration is equal or greater than 0.1 % by weight. 2. Articles or any parts thereof containing decaBDE in concentrations equal to or greater than 0.1 % by weight shall not be placed on the market after [date of entry into force]. 3. By way of derogation, paragraph 2 shall not apply: ○ to articles placed on the market for the first time before [date of entry into force] ○ to electrical and electronic equipment within the scope of Directive 2011/65/EU 4. By way of derogation, paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market for the production, maintenance, repair or modification of any aircraft or article eligible for installation on an aircraft: ○ produced in accordance with a type certificate or restricted type certificate, issued under Regulation (EU)216/2008, provided the application for such certificate was done before [date of entry into force], or ○ produced in accordance with a design approval issued under the national

Designation of the substance, of the group of substances or of the mixture	Conditions of the restriction
	regulations of an ICAO contracting State, provided the application for such approval was done before [date of entry into force], or for which an ICAO contracting State has issued a Certificate of Airworthiness under the provisions of Annex 8 of the Chicago Convention, provided that such State issued the first Certificate of Airworthiness for an aircraft of the same aircraft type before [date of entry into force]

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 ***Bis(pentabromophenyl) ether (DecaBDE)*** 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 scope and/or conditions are modified.

The conditions of the restriction proposed by SEAC are:

Designation of the substance, of the group of substances or of the mixture	**Conditions of the restriction**

Designation of the substance, of the group of substances or of the mixture	Conditions of the restriction
Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE) CAS No 1163-19-5 EC No 214-604-9	1. Shall not be manufactured, used or placed on the market: ○ as a substance, ○ as a constituent of other substances, or in mixtures after [date of entry into force], if the concentration is equal to or greater than 0.1 % by weight. 2. Articles or any parts thereof containing decaBDE in concentrations equal to or greater than 0.1 % by weight shall not be placed on the market after [date of entry into force]. 3. By way of derogation, paragraph 2 shall not apply: ○ to articles placed on the market for the first time before [date of entry into force] ○ to electrical and electronic equipment within the scope of Directive 2011/65/EU 4. By way of derogation, paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market for the production, maintenance, repair or modification of any aircraft or article eligible for installation on an aircraft: ○ produced in accordance with a type certificate or restricted type certificate, issued under Regulation (EU)216/2008, provided the application for such certificate was done before [date of entry into force], or ○ produced in accordance with a design approval issued under the national regulations of an ICAO contracting State, provided the application for such approval was done before [date of entry into force], or ○ for which an ICAO contracting State has issued a Certificate of Airworthiness under the provisions of Annex 8 of the Chicago Convention, provided that such State issued the first Certificate of Airworthiness for an aircraft of the same aircraft type before [date of entry into force]. ○ produced in accordance with specifications of a military procurement or development contract signed before the [date of entry into force] 5. By way of derogation, paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market: ○ for the production, maintenance, repair or modification of road vehicles produced in accordance with Directive 2007/46/EC before July 1st, 2018, ○ for spare parts for vehicles referred to in the above sub-paragraph. 6. By way of derogation, paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market for spare parts, for machinery produced before July 1st 2018, within the scope of Directive 2006/42/EC.

Designation of the substance, of the group of substances or of the mixture	Conditions of the restriction
	7. By way of derogation, paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market for spare parts, for agricultural and forestry vehicles produced before July 1st 2018, within the scope of Regulation EU 167/2013.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD AND RISK

Justification for the opinion of RAC

Description of and justification for targeting of the information on hazard and exposure

The restriction proposed by the Dossier Submitter is based on the following assumptions/premises:

- Bis(pentabromophenyl)ether (decaBDE) was identified as a PBT and vPvB substance according to the REACH Regulation and included in the Candidate List on 19 December 2012. The proposal is underpinned by the conclusions on the intrinsic hazard (i.e. PBT/vPvB properties) of decaBDE (SVHC support document (SD), 2012), but also takes account of additional information that has been published since 2011 (in particular data on neurotoxicity).

- Experience with PBT/vPvB substances has shown that they give rise to specific concerns based on their potential to persist and accumulate in the environment leading to widespread distribution and with potential to cause effects that are unpredictable in the long-term and are difficult to reverse (even when emissions cease). Therefore, the risk from PBT/vPvB substances cannot be adequately addressed in a quantitative way, e.g. by derivation of PNECs and a qualitative risk assessment has therefore been carried out (see also Annex I/6.5 of the REACH Regulation). Emissions and subsequent exposure, in the case of a PBT/vPvB substance, can be usefully considered as a proxy for unacceptable risk.

- DecaBDE is widely used as an additive flame retardant with applications in many different sectors. It is mainly used in plastics and textiles but uses in adhesives, sealants, coatings and inks have been reported previously. Based on EU emission estimates for the plastics and textile industries (including the Industry's Voluntary Emissions Control Action Programme (VECAP)), the Dossier Submitter proposes a general restriction on all uses of the substance, with the exception of articles that were in use prior to the entry into force of the restriction, certain types of electrical equipment (to avoid double regulation) and the aviation sector (where product certification requirements apply). The proposal aims to reduce emissions of decaBDE as much as possible in the medium/long term.

Description of the risk to be addressed by the proposed restriction

Information on hazard(s)

DecaBDE environmental hazards

PBT assessment

According to the ECHA Member State Committee (Agreement adopted 29 November 2012), decaBDE fulfils the criteria of Articles 57(d) [PBT] and (e) [vPvB] of the REACH Regulation on the basis that *"there is a high probability that it is transformed in the environment to form substances which themselves have PBT/vPvB properties, or act as precursors to such substances, in individual amounts greater than 0.1% w/w over the timescale of a year"*. On the basis of available information the MSC could not conclude that decaBDE itself fulfilled the criteria of Articles 57(d) and (e).

The REACH Regulation does not distinguish between different PBT or vPvB substances once they are identified. However, the rate and extent of transformation of substances to and from PBT or vPvB substances under different environmental conditions are relevant considerations during risk assessment, at least on a scientific basis, and subsequently for assessing the proportionality of the risk reduction that would be achieved by any risk management.

Few studies provide reliable information on the transformation of decaBDE in air, sediments, agricultural soils and biota (e.g. fish, birds, mammals) under environmentally relevant conditions. NonaBDE congeners are the PBDE transformation products formed in the highest amounts, and the SVHC dossier indicated that these do not have intrinsic PBT/vPvB properties, although they are precursors for substances that do (SVHC support document (SD), 2012). The high level of concern for decaBDE has recently been confirmed at the 10th meeting of the Persistent Organic Pollutant Review Committee of the UNEP Stockholm Convention in October 2014, which decided that its main constituent *"is likely as a result of its long range environmental transport to lead to significant adverse human health and environmental effects such that global action is warranted*".

The BD suggests that the rate at which decaBDE may form lower molecular weight PBDEs of concern in sediments/soils is between 0.1 and 10 % w/w per year, although there are several uncertainties and limitations in the underlying laboratory and field studies that lead to this estimate. Whilst the overall rate of environmental transformation may be quite low, this does not necessarily reflect the transformation rate within organisms since some studies suggest that the rate/extent of transformation could be higher in some species of fish and rodents than that observed in sediments/soils. It should be noted that the amounts of decaBDE present in biota are much smaller relative to those in sediments and soils, so the overall level of environmental transformation is likely to be limited. Nevertheless, once decaBDE has been taken up into an organism, there is potential for exposure to its more hazardous transformation products.

As well as PBDEs formed through debromination in the environment, other transformation products can include hydroxylated and methoxy-PBDEs (as products of metabolism) and polybromodibenzodioxins and furans (e.g. during exposure to elevated temperatures) (such products are not always fully identified or quantified in published studies). Some of these other transformation products give cause for concern as potential PBT/vPvB substances, but none have been formally identified as meeting the REACH Annex XIII criteria.

RAC accepts that insufficient information is available to provide reliable estimates of the amounts of relevant decaBDE transformation products that will be produced in different matrices over any particular length of time and, with the exception of lower molecular

weight PBDEs, the hazards, risks and impacts of these transformation products cannot be confirmed. Given the high persistence of decaBDE, it seems reasonable to conclude that an annual emission of 1 kg of decaBDE does not automatically equate to an emission of 1 kg of PBT/vPvB substances over the same period.

The Dossier Submitter concludes that the rate at which decaBDE transformation products are formed in the environment cannot be reliably incorporated into the emission/exposure assessment on a quantitative basis. Should transformation occur only slowly the cost-effectiveness of any restriction based on total emissions of decaBDE (per year) would be reduced. However, this should be balanced against the potential for decaBDE to act as a long-term source of PBT/vPvB substances and the potential hazardous properties of decaBDE itself (see next section).

DecaBDE human health hazards

Developmental neurotoxicity

There are many academic studies and one GLP-compliant OECD TG 426 study (Biesemeier et al., 2011) on the developmental neurotoxicity of decaBDE in rodents. Most academic studies are positive, but the different designs (e.g. different activity periods) and conduct make direct comparison of the findings difficult. Whilst the Viberg group's original studies were criticized in the EU RAR (2007a) under the Existing Substances Regulation, the RAC notes that the findings have since been repeated by the same group (Buratovic et al., 2014) addressing most of the points raised, e.g. with the litter as the statistical unit, and more dose levels. In contrast, the OECD TG 426 study is negative, but it has also been criticised by Health Canada (2012) who suggested a NOAEL of 10 rather than 1,000 mg/kg/day as suggested by the authors. Furthermore, the US EPA has found the academic study of Viberg et al. (2003) to be sufficiently reliable for setting their reference dose (RfD). The Viberg study is supported by further studies (e.g. Viberg et al., 2007; Rice et al., 2007; Rice et al., 2009; and Buratovic et al., 2014). EFSA has also evaluated the developmental neurotoxicity of the PBDEs (including decaBDE), and concluded that all tested PBDEs induced long-lasting behavioural alterations, particularly in the motor and cognitive domain. Accordingly, EFSA based their risk assessment of the PBDEs on the endpoint developmental neurotoxicity (EFSA, 2011). Based on a cumulative risk assessment for the PBDEs, Kortenkamp et al. (2014) expressed concern for developmental neurotoxicity in young children.

Based on consideration of animal data, *in vitro* mechanistic studies, epidemiological studies and evaluations of other scientific bodies, the RAC concludes that decaBDE can cause, or contribute to, developmental neurotoxicity.

RAC notes, that the potential of tetra- to heptaBDE congeners to cause effects such as neurotoxicity is implicitly taken into account by their PBT/vPvB designation (based on the classification of commercial penta- and octaBDE products under Regulation (EC) No. 1272/2008 as "specific target organ toxicity after repeated dose, Category 2 (H373 - May cause damage to organs through prolonged or repeated exposure) and Lact. (H362 - May cause harm to breast-fed children)" and "toxic to reproduction Category 1B (H360DF - May damage the unborn child. Suspected of damaging fertility", respectively, the tetra- to heptaBDE congeners already fulfil the T criterion based on human health hazard properties).

Conclusion 1: **The widespread distribution of decaBDE in the environment, biota and humans creates a high potential for long-term (lifetime) exposure to decaBDE and a variety of hazardous transformation products including lower molecular weight PBDEs, which are known to be toxic and may also have the potential for combined toxicity. It is not possible to reliably estimate the amounts of hazardous transformation products that will be produced in different matrices over any particular length of time. Therefore, the assumption that the release of a fixed amount of decaBDE is equivalent to an identical amount of PBT/vPvB substances**

is not justified based on the available evidence. However, this should be balanced against the potential for decaBDE to act as a long-term source of PBT/vPvB substances due to its high persistence in the environment and accumulation in biota. Since it is not possible to take this information into account in a quantitative way, RAC recognises this as an uncertainty, but considers that the emissions of decaBDE itself are a suitable proxy for emissions of hazardous transformation products in the absence of more reliable information. Therefore, RAC believes, despite the remaining uncertainties, that there is an environmental risk that needs to be addressed, based on the PBT/vPvB hazards without an identified threshold.

RAC further acknowledges that there is an additional concern for developmental neurotoxicity, as discussed by the Dossier Submitter. RAC acknowledges that DecaBDE has the capacity to cause (or contribute to) developmental neurotoxicity in mammals (and potentially other taxonomic groups). However, RAC was not able to perform any quantification of potential human health risks as relevant exposure data were not available in the restriction dossier. Consequently, developmental neurotoxicity has to be dealt with in a qualitative way in the socio-economic analysis.

Environmental and human health hazards of alternatives for DecaBDE

The Dossier Submitter has identified thirteen potential alternative substances, although other substances might also be suitable, as has been proposed during the public consultation (e.g. Paxymer®). Some are subject to Substance Evaluation under REACH and no definitive conclusion on their hazard profile can be reached before this is completed. Definitive hazard property information is also missing for others. RAC has not looked at the hazard properties of Paxymer® in detail, partly because of confidentiality issues.

As might be expected, only brominated flame retardants appear to be able to act as 'drop-in' replacements for decaBDE in a wide range of applications, and one of these (ethane-1,2-bis(pentabromophenyl), also known as EBP) is widely regarded to be the most feasible replacement from both a technical and an economic perspective. Concerns for this substance are related to potential PBT/vPvB properties similar to decaBDE (i.e. due to transformation) combined with evidence of long-range atmospheric transport. RAC supports that further exploration is made of this and other alternatives as regards their risk.

RAC recognises that it is very difficult to compare substances when the nature of the hazards is different. For example, some of the alternatives have human health classifications or concerns, but do not appear to have PBT/vPvB properties. For the purposes of the proposal, the Dossier Submitter has assumed that the identified alternatives are less hazardous than decaBDE based on the available data. This conclusion is subject to revision should additional reliable information become available on their hazardous properties.

Conclusion 2: **The analysis of alternative substances is hampered by lack of comparable hazard and risk data and/or ongoing evaluations that prevent definitive hazard conclusions from being drawn at this stage. RAC has concerns that some 'drop-in' alternatives could pose similar hazards to decaBDE, and that others have human health or different types of environmental hazards. However, some are likely to be less hazardous overall, at least in a PBT context.**

Information on emissions and exposures

Emissions

The emissions of decaBDE were estimated in previous EU RARs (2002, 2004 and 2007). As the RoHS Directive came into force after the publication of the previous RARs these emissions estimates were not considered fit for purpose for this restriction proposal. The Dossier Submitter has therefore developed new "high" and "low" scenarios taking into account the uncertainties in getting information. The different scenarios are described in detail in Section B.8.2 of the BD. The "high" scenario can be seen as a worst case estimate and the "low" scenario is based on the few actual measurements carried out and new information from industry's VECAP (2013) (for the production life cycle step). The Dossier Submitter has used OECD Emission Scenario Documents as the basis for most of the calculations concerning emissions from article service life and also the EU RAR as a basis for other calculations taking into account information provided by Industry and others. The "central" scenario is calculated as the average of emission factors from the low and high scenarios.

The total emissions and emission factors under the central scenario are presented in Table 6 in the BD (with information on the other scenarios presented in Annex B8.2). It is clear that the dominant emissions are associated with the service-life of articles whilst production and waste life-cycle stages are associated with lower emissions. In the BD, an emission factor of 0.11% was used in the calculations.

Calculations are only done as total EU emissions due to the lack of need for continental, regional and local scale emissions since decaBDE is treated as a PBT/vPvB substance (and therefore quantitative risk characterisation (leading to RCRs) is not needed) and the sources are assumed to be diffuse sources. RAC supports this approach.

Table 6 from BD: Summary of estimated emissions of decaBDE in the EU in 2014 – central scenario (supplemented by data from Annex B.8.2.6)

	Central scenario		Potential range (low-high scenario) (t/year)
	(t/year)	Share	
Production	0.31	7%	0.06 – 0.56
Article Service Life	4.15	87%	2.07 – 6.23
Waste	0.28	6%	0.04 – 0.52
Total	4.74	100%	2.17 – 7.32
Emission Factor	0.11%		

There are many uncertainties associated with these calculations and they have been thoroughly described by the Dossier Submitter in Section 8.2. One important uncertainty is the assumption that imported articles containing decaBDE contribute 10% of the imported tonnage of the substance itself. However, the Dossier Submitter has shown that although emissions would be higher, the cost effectiveness figures do not change significantly even if it is assumed that the percentage is 20%. A further important uncertainty is the lack of knowledge about the exact number of sites using decaBDE in the EU (estimated in the SVHC document to be more than 100) and to which degree any individual site is following the guidelines provided by VECAP.

Table 7 in the BD shows the estimated distribution of releases to the different environmental compartments. Although the initial modelling assumptions specify the releases to air, water and soil by the corresponding emission factors, the final fate of decaBDE is defined ultimately by its physicochemical properties. So, even if initially released to air or water, decaBDE is prone to finally partition to soil and sediment.

Table 7 from BD: Distribution of releases of decaBDE to the different environmental compartments in the EU in 2014 – central scenario

	(t/year)	share
Air	1.46	31%
Water	2.32	49%
Soil	0.96	20%
Total	4.74	100%

To evaluate the validity of the Annex XV report emission estimates, a complementary assessment has been performed by the Dossier Submitter and included in the BD. The assessment is made by using observed concentrations of decaBDE in sewage sludge. These observed concentrations are then back-calculated to a total EU tonnage of decaBDE emitted to water based on the amount of sludge produced annually in the EU. The results of the two analyses are then compared. Since decaBDE nearly completely partitions to sludge during wastewater treatment, emissions of decaBDE to the environment via WWTP effluent are not considered in the model. Both deterministic and probabilistic assessments were performed. The deterministic model assessment resulted in a water emission of 2.76 t/year compared to the predicted amount of 2.32 t/year (range from 1.04-3.61 t/year). The probabilistic model assessment (10^{th} and 90^{th} percentile) was 2.67 and 11.72 t/year, where the most sensitive factor was the uncertainty in the dry weight conversion factor. It has to be mentioned that the sludge data were collected in 2005-2008, when the consumption of decaBDE was expected to be much higher than 2014. All in all the Dossier Submitter concludes that the emission figures presented in the dossier could be considered as reliable. Based on the numbers and calculations presented the RAC can support this conclusion.

Automotive vehicles

During public consultation there was a request from the automotive industry to exempt the use of decaBDE in automotive vehicles currently in production and in spare parts (for suede effect leather, electrical applications, powertrain applications and fuel systems). RAC notes that the justification provided for this derogation relates entirely to technical and economic issues (i.e. testing and certification costs for articles produced using alternatives). RAC considers that the tonnage for which the derogation is sought is high relative to the overall use of decaBDE (a total of approximately 1000 tonnes from 2017 to 2035, out of which approximately 60 tonnes are for spare parts), but also notes that the use is expected to occur predominantly in the early years after the entry into force and decline progressively to < 1 tonne per year from 2030 as vehicles which are currently in production are replaced with new models that will not contain decaBDE. However, no information was provided in the public consultation about the emissions that could result from this use, or the life-cycle stages that these would occur from (production, service-life and waste). RAC therefore considers that emissions could occur during production and service life. In addition, whilst RAC acknowledges that the ELV directive is relevant to the waste life cycle stage for this sector it does not consider that it will explicitly control emissions of decaBDE. RAC therefore concludes that this derogation is not supported. For comparison, according to information from the public consultation, the use of decaBDE in the aviation sector, in the EU, is estimated at significantly less than 10 tonnes per year. There is no information about the potential for emission during the life cycle for this application either (and therefore risks

cannot be excluded). RAC notes that the justification provided for this derogation relates entirely to technical and economic issues (i.e. testing and certification costs for articles produced using alternatives).

Articles made from recycled materials

Articles made from recycled materials containing decaBDE will generally have the same risk profile as articles made from virgin materials that are intentionally treated with decaBDE, in terms of their potential for decaBDE emission. The information received during public consultation has not indicated that there is an issue related to recycling and the proposed concentration limit for decaBDE.

Potential minor uses

The Annex XV dossier mentions that there could be minor uses of decaBDE in applications such as adhesives and/or coatings. No specific information on such uses was provided during the public consultation even though this was specifically requested; one comment mentioned that "small amounts" of decaBDE are used in adhesives. On this basis, RAC concludes that there is no significant use of decaBDE in these applications and therefore there is no need for considering emissions or derogations for them.

Conclusion 3: **The calculations seem well documented and the uncertainties - although fairly large - are well described. The contributions from article service life are expected to dominate and the distribution between the different compartments show that water/sediment is the biggest recipient but also air and soil are important. The emission figures seem justified and supported by a validity check performed by the Dossier Submitter. The total release of 4.74 tonnes/year will be used for further calculations. RAC has not identified the need for derogating any other uses (including recycling) that were not already derogated in the original proposal.**

DecaBDE exposure assessment

It should be noted that REACH registration dossiers for decaBDE do not contain information on the environmental exposure of decaBDE, either on a per use, or on an aggregated basis. This is because the current registrations are based on the information requirements prior to the decision to identify decaBDE as a PBT/vPvB substance (in December 2012), i.e. as decaBDE was not classified as hazardous by the registrants, exposure assessment (including exposure scenario development) and risk characterisation were not required. As a consequence of the identification of decaBDE as a PBT/vPvB updates to the registration dossiers of decaBDE are now pending, but have not been received by the Agency at the time of publication of the opinion. RAC notes that this legal update of the registration dossiers would have helped the evaluation.

The estimated emissions do not incorporate the subsequent likely fate of decaBDE in the environment (e.g. emissions to water are likely to selectively partition to sediments and emissions to air are likely to accumulate in soils) and an estimate of bioaccumulation of decaBDE in aquatic or terrestrial biota has thus not been undertaken. Therefore, updated PECs for decaBDE (compared to RAR estimates) based on contemporary information on tonnages and emissions have not been estimated.

The exposure assessment for decaBDE comprises instead a summary of relevant biomonitoring and environmental monitoring data collated from various regulatory and literature sources, including the EU RAR (2002) and updates. These monitoring and biomonitoring data may incorporate exposure to decaBDE emitted from additional, historic,

uses (including any contribution from long-range transport).

Where possible, information on human exposure is presented according to the relevant life-cycle stage, i.e. occupational exposure (including during the waste stage) or consumer exposure during article service-life (e.g. exposure via house dust). Disaggregation of the source contribution of different life-cycle stages to concentrations observed in the environment or wildlife has not been possible. The data are presented in detail in Section B.9.3 of the BD.

In older studies decaBDE was initially detected infrequently in aquatic species (i.e. fish, invertebrates and marine mammals) sampled within the EU. These results were associated with issues surrounding analytical sensitivity and, in some instances, reproducibility of measurements. However, over the past 10 years, improved analytical methods have been developed to measure decaBDE with good accuracy and precision. With the use of these methods, reliable data on the presence and concentration of decaBDE in the environment and wildlife have been generated. It can be concluded that decaBDE is present almost ubiquitously in the European environment and in European wildlife, albeit in relatively low concentrations in some species (e.g. marine mammals) when compared with historic persistent organic pollutants (such as PCBs and DDT).

Monitoring data from a large number of reliable studies strongly suggests that decaBDE is present almost universally in the aquatic and terrestrial environment of the EU as well as within wildlife species, notably accumulated within the tissues and eggs of predatory and other bird species. Its presence in the tissues of so many species is a cause for concern.

Although there are few data on mammalian wildlife, bird tissues seem to have been sampled more often and have a large proportion of positive detects. DecaBDE has been found over a wide scale at low (parts per billion) levels in a variety of predatory and other bird species, including their eggs, across Europe and elsewhere (i.e. Arctic regions). Given these findings, it can be anticipated that other bird species would also accumulate decaBDE, and this is confirmed by detection of decaBDE in samples of Glaucous Gull from polar regions. Especially bird-eating raptors appear to have the highest levels in relative terms compared to species from aquatic food webs, i.e. Eurasian Sparrowhawk and Peregrine Falcon.

The exact route of decaBDE exposure to these organisms is not clear, but could occur via diet, water and air as well as through ingestion of contaminated dust, sediment or soil that is present in or on food items or adhered to body surfaces (e.g. during preening).

Interim results (2005-2010) from a ten-year monitoring programme (known as the conclusion (i) monitoring programme, or DECAMONITOR) commissioned to investigate the long-term trends of decaBDE concentrations in the EU confirm that decaBDE is widely distributed in the environment and biota and no trend (either increasing or decreasing) in concentrations is apparent.

The Dossier Submitter concludes that:

- DecaBDE can be found widely in sediments and sewage sludge, where it is frequently the dominant PBDE congener present. Based on the available data, decaBDE should be considered as ubiquitous in these environments in some parts of Europe.
- Sewage sludge is a potentially major source of decaBDE to agricultural land because of sludge spreading. The levels of decaBDE found in sludge in the EU in recent studies are generally around 0.1 mg/kg dry weight up to a few mg/kg dry weight. It is expected that decaBDE will be persistent in agricultural soils once applied, and indeed Sellstrøm et al. (2005) detected levels of a few mg/kg dry weight in a farm soil in Sweden that had last received an input from sludge around 20 years before.

- DecaBDE can be detected in a wide variety of biota, including aquatic organisms. It is frequently detected in invertebrates, fish, predatory birds and some mammals. There is some indication that levels in terrestrial species might be higher than those in the aquatic organisms. Its presence in the tissues of so many species is a cause for concern.

RAC has the following observations on the Dossier Submitter's conclusions:
The conclusions presented by the Dossier Submitter seem justified. DecaBDE can be found in almost all compartments in different concentrations and the data suggest big variations also within the various compartments and within species thus suggesting local or regional influences. The findings in remote areas underline the possibility for long range transport and thereby an impact that is not just localised to the actual emission point.

Conclusion 4: **RAC agrees with the conclusion by the Dossier Submitter that decaBDE can be found widely in sediments, sewage sludge as well as aquatic and terrestrial biota; sewage sludge is a potentially major source of decaBDE to agricultural land because of sludge spreading. In particular, its presence in the tissues of so many species is a cause for concern.**

○ Characterisation of risk(s)

In general, due to the high uncertainties regarding long-term exposure and effects, the risks of PBT/vPvB substances, such as decaBDE transformation products, to the environment or to humans via the environment cannot be adequately addressed in a traditional quantitative assessment, e.g. by derivation of PNECs (or DNELs). Exposure, in the case of a PBT/vPvB, can therefore be usefully considered as a proxy for risk, i.e. during consideration of the proportionality of the proposed restriction by SEAC.

As a consequence, the Dossier Submitter refers to the emissions and subsequent exposure when characterising the risks. RAC has already noted that the lack of quantification of the amounts of transformation products formed in different matrices is an uncertainty, but that the widespread and long-term exposure of wildlife and humans justifies the assumption that decaBDE exposure itself is a suitable proxy for risks of hazardous transformation products in the absence of more reliable information.

Conclusion 5: **RAC accepts the conclusions by the Dossier Submitter that decaBDE emissions are a suitable proxy for assessing environmental risks.**

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

Justification for the opinion of RAC

DecaBDE is identified as an SVHC on the basis of its transformation in the environment to substances which themselves have PBT/vPvB properties. DecaBDE is widely dispersed in the environment and is found in remote regions. Humans are also exposed to decaBDE. It is used in a wide range of applications and there is a potential for release during the production of articles treated with decaBDE, and during the service life and disposal of such articles. Articles produced or imported in one Member State may be transported to and used in other Member States as the articles are traded freely and may be used in all Member States.

Thus, RAC considers that the primary reason to act on a Union-wide basis is to effectively reduce the environmental exposure to decaBDE in the EU. Action on a Union-wide basis

would also limit the potential for trans-boundary exposure to decaBDE from EU sources.

Conclusion 6: **RAC agrees that action to reduce the risks arising from decaBDE needs to be taken on an EU-wide basis.**

Justification for the opinion of SEAC

The restriction proposal is based on the concern that decaBDE is transformed to lower molecular weight polybromodiphenyl ethers (PBDEs), which have PBT/vPvB properties. Hence, it is not possible to establish a safe level of exposure for decaBDE meaning that emissions of decaBDE are to be minimised (REACH recital 70/ Annex I, para 6.5). DecaBDE is released to the environment during the production, disposal and in particular during the service life of articles containing decaBDE. These articles are placed on the market and used across all EU Member States. Furthermore, decaBDE has a potential for long-range transport once it has entered the environment. Hence, emissions of decaBDE contribute to transboundary pollution reflected by widespread environmental occurrence of this substance in the EU.

With regard to the functioning of the internal market, the dossier highlights that action on an EU-wide basis would avoid the potentially distorting effects of national regulation of decaBDE. Articles treated with decaBDE as a flame retardant (textiles, plastics) are traded across EU Member States and are also imported from outside the EU. Therefore, action is required on an EU wide basis to maintain the free circulation of goods on the internal market as well as a level playing field for industry within the EU as well as between EU and non-EU companies. This conclusion is supported by the fact that the use of decaBDE in electrical and electronic equipment already has been regulated on an EU wide basis, i.e. in the RoHS directive.

SEAC supports the conclusion of the Dossier Submitter that action is required on an EU wide basis.

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

Justification for the opinion of RAC

The Dossier Submitter has assessed several restriction options based on their contribution to total emissions reduction (as well as their cost-effectiveness) in section E.1.2 and Annex E.

Based on the analysis it was concluded that a general restriction (combining all the sub-options) is the most appropriate restriction option. This option was further assessed as to its effectiveness, practicality and monitorability and was found to satisfy these criteria. Aside from restriction proposals, a risk management option based on waste management was also described by the Dossier Submitter, without further assessing this option in detail. Finally, considerations related to manufacture, recycling, the second hand market, aviation sector and the RoHS Directive are presented. The conclusions reached are reflected in the proposed restriction.

The conclusion reached by the Dossier Submitter is that a restriction is considered the most appropriate risk management option to manage exposure and risks from the use of decaBDE in the EU.

Conclusion 7: **RAC agrees that the proposed restriction is the most appropriate measure to reduce the emissions and thereby risks.**

Justification for the opinion of SEAC

DecaBDE is used as an additive flame retardant in plastic and textile articles, which are used in transport, building/construction and mining applications. To reduce the emissions of decaBDE as far as possible the **proposed restriction** covers the manufacture, use and placing on the market of decaBDE as a substance, in articles and mixtures. The Dossier Submitter originally proposed exemptions for second hand articles, articles covered by the RoHS directive and for the aviation sector (manufacture, maintenance and repair of aircraft in accordance with an existing type approval certificate). The broad scope of the proposal will remove all significant emission sources of decaBDE (apart from those originating from the existing stock and from the derogated uses). In the dossier, it is estimated that the proposed restriction will result in a reduction of 4.74 t of emissions per year with a cost-effectiveness of 464 € per kg of emissions reduced. A transition period of 18 months is proposed to allow industry to clear their stocks before the restriction will enter into force.

In addition to the proposed restriction, the Dossier Submitter also screened a set of other more targeted restriction options in terms of their potential to reduce emissions (effectiveness) and their costs to achieve this emission reduction (cost-effectiveness). The options for restriction are based on the main uses of decaBDE in textiles and plastics as well as on information on emissions during the different life-cycle stages (i.e. production, service-life, waste). The following more targeted **restriction options** were considered in the dossier (see BD Annex E.1.1):

- Restriction on **plastics** used **indoors** (Option 1, emissions reduced: 1.37 t/y, 29 % of emission reduction of the proposed restriction, cost-effectiveness: 773 €/kg)
- Restriction on **plastics** used **outdoors** (Option 2, emissions reduced: 0.04 t/y, 0.08 % of emission reduction of the proposed restriction, cost-effectiveness: 30 €/kg)
- Restriction on **textiles** used **indoors** (Option 3, emissions reduced: 1.44 t/y, 30 % of emission reduction of the proposed restriction, cost-effectiveness: 756 €/kg)
- Restriction on **textiles** used **outdoors** (Option 4, emissions reduced: 1.9 t/y, 40 % of emission reduction of the proposed restriction, cost-effectiveness: 30 €/kg)

In addition to these options, the Dossier Submitter also considered the restriction of the use of decaBDE in the EU (production and placing on the market of articles containing decaBDE, Option 5 in BD) and the restriction of placing on the market of articles containing decaBDE (i.e. production for export would still be possible, Option 6 in BD).

The dossier concludes that a targeted restriction would not be effective, because it would not reduce emissions of decaBDE as much as practically possible (either not all uses or no imported/exported articles are covered). It is also argued that the gain in cost-effectiveness (= lower cost per kg reduced) of any of the different targeted restriction options would not justify the loss in overall effectiveness (= emission reduction) compared to the proposed restriction. In addition, a targeted restriction could be difficult to enforce (e.g. identification of articles intended for outdoor vs indoor use).

SEAC notes that a targeted restriction of the most cost-effective options (30 €/kg for outdoor uses of plastics and textiles) will only cover about 40 % of total emissions. To abate the remaining 60 % of decaBDE emissions (indoor uses of textiles and plastics) the cost per kg emissions is much higher (756 to 773 €/kg). However, despite these greater costs, SEAC considers that it is still cost-effective to include indoor uses in the restriction (see discussion on cost-effectiveness of the proposed restriction later). Therefore, SEAC accepts the

conclusion of the Dossier Submitter that the proposed restriction is the most appropriate EU-wide measure to reduce emissions of decaBDE.

Furthermore, **other EU-wide risk management options** are considered in the dossier but are discarded for the following reasons (BD E.1.3.1):

- **Authorisation**: Authorisation would not lead to a sufficient risk reduction, because emissions from imported articles would not be covered, which contain decaBDE in relevant amounts (the related volume is estimated to account for about 10 % of volumes used in the EU). Furthermore, the potential regulation of decaBDE under the Stockholm Convention (see below) would exclude authorisation as a possible RMO for the use of decaBDE.

- **Waste management**: Mandatory incineration of articles containing decaBDE would only cover emissions from the waste phase (6% of total emissions). Also, such a scheme would be difficult to implement and enforce across all EU Member States. There are at present no established effective screening and separation techniques at industrial scale to distinguish PBDE containing waste streams from waste streams that contain other brominated flame retardants which are not restricted. Implementation is furthermore difficult as there is a shortage of incineration capacity in some EU Member States, but there are overcapacities in some other Member States.

- **POP regulation**: DecaBDE has been proposed by Norway as a POP to be included in the Stockholm Convention. This proposal is still under consideration in the appropriate body of the Stockholm Convention. Presuming the proposal is accepted by this body, the earliest opportunity for the Parties to the Stockholm Convention to consider the inclusion of decaBDE will be in 2017. When included, the EU POP Regulation should be amended accordingly. As a consequence decaBDE will then be taken out of Annex XVII of REACH. The REACH restriction process will be finalised already in 2015 and information gained in this process can be fed into the process under the Stockholm Convention.

SEAC concurs with the arguments given by the Dossier Submitter that the proposed broad restriction is the most effective measure to reduce emissions of decaBDE compared to other possible RMO such as a targeted restriction or measures other than restriction (e.g. authorisation or waste management conditions).

SEAC has assessed the **derogations** that have been proposed by the Dossier Submitter or that have been requested during the public consultation of the Annex XV report and the SEAC draft opinion.

As regards the derogation for the **aviation industry**, SEAC notes that the replacement of decaBDE would be difficult for aircraft currently in service (i.e. in spare parts), or that will be manufactured in the future based on an existing type certificate, due to both the high costs and time needed to switch to alternatives (because of stringent certification requirements in the aviation industry) and also because of the high complexity of the aviation supply chain. Information provided by industry confirms that it will be feasible to completely replace decaBDE in aircraft with a type approval issued after 2017. Accordingly, the derogation is only proposed for aircraft type approvals issued before the entry into force of the restriction. Due to the low tonnage used (< 10 t/y), the derogation will represent only a small fraction of total emissions by the foreseen date of entry into force of the restriction. This fraction is expected to drop even further as old aircraft are replaced by new ones. As there is no figure for the exact costs to the aviation sector available, SEAC cannot assess the cost-effectiveness of this derogation in order to conclude on its proportionality. However, SEAC considers that the information provided is sufficient to conclude that it is

likely that the derogation will improve the cost-effectiveness of the restriction, especially when considering the low tonnage of decaBDE used. The derogation originally proposed by the Dossier Submitter and SEAC in its draft opinion only covered the use of decaBDE in aircraft used in civil aviation highlighting that military applications could be derogated under Article 2(3) of the REACH regulation, which gives Member States the possibility to allow for exemptions in the interest of defence. The public consultation on the SEAC draft opinion included comments from the aerospace industry detailing concerns that the use of Article 2(3) would lead to additional administrative costs to industry and authorities, because the exemption will have to be approved by each Member State. Furthermore, exemptions for defence applications may differ between Member States, which may result in market distortion and hamper the functioning of the internal market for military aircraft applications. The European Defence Agency (EDA) also responded to the public consultation on the SEAC draft opinion highlighting that Article 2(3) of the REACH regulation should not be considered the only option for dealing with defence related issues under REACH. SEAC agrees with the arguments provided in the public consultation to include a derogation for aircraft used for military applications in the restriction proposal.

Overall, SEAC supports that the derogations proposed by the Dossier Submitter will improve the proportionality of the restriction by facilitating efficient use of resources, preventing costs for articles that would need to be replaced prematurely, i.e. prior to the end of their service live (second hand articles), by avoiding double regulation (articles covered by RoHS directive) and by reducing potentially high cost to industry for additional testing and difficulties to switch to alternatives in time for the entry into force of the proposed restriction (aviation industry). In addition to the derogations proposed by the Dossier Submitter, there has been a request in the public consultation by the **automotive industry** for a derogation for the automotive sector for the **manufacture of vehicles** based on a type approval certificate issued before 2020, spare parts for these vehicles and legacy **spare parts** (meaning vehicles covered by type approval certificates issued in 2020 and beyond would not be covered by the proposed derogation). In its draft opinion, SEAC considered that sufficient evidence had not been provided to justify the derogation requested by the automotive sector, also taking the relatively high tonnage of decaBDE used in the automotive sector into account. In the public consultation of the SEAC draft opinion, the request was modified, indicating that the substitution of decaBDE in the manufacture of new vehicles is feasible sooner than originally anticipated, but not before July 1st, 2018. Hence, if the restriction will enter into force before July 1st 2018 a slightly extended transitional period would be needed. Industry could not provide an estimate of the additional volumes of decaBDE that will be used resulting from this extended transitional period. With regard to the use of decaBDE in spare parts for cars, trucks and buses, industry estimated an annual tonnage of between 0.5 to 5 t. Should a derogation for spare parts not be included in the restriction the stakeholders state in the public consultation that vehicle manufacturers would face additional costs for material testing to the amount of between 20,000 to 150,000 € per tested material (excluding vehicle validation costs). Based on the information received, SEAC concludes that it is likely that the derogation on the whole will improve the cost-effectiveness of the restriction, taking into account the data on the additional cost for testing, and that the overall tonnage covered is likely to be moderate. SEAC also notes that the volume of decaBDE required for spare parts in the automotive sector will progressively decline to zero over time as legacy vehicles are replaced and decaBDE containing parts are no longer required.

In the public consultation of the SEAC draft opinion, an additional request for a derogation for **other vehicles and machinery** (e.g. for agricultural and heavy duty commercial purposes) has been received including a longer transition period (up to 10 years) for the use of decaBDE in new vehicles as well as a derogation for the use in spare parts. By analogy to the proposed derogations for the aviation and automotive industry, SEAC considers the benefits of a derogation for the use of decaBDE in spare parts to be plausible. However, SEAC concludes that the need for a longer transition period has not been sufficiently justified by the information provided to the public consultation.

SEAC notes that the original dossier did not consider a possible exemption for **recycling**. Although the Public Consultation of the Annex XV report did not indicate that a specific exemption for the recycling sector was needed, this issue was intensively discussed in SEAC. The mere fact that there was no information in the dossier nor from the public consultation indicating the need of an exemption for recycled materials could not be interpreted as evidence that decaBDE was not recycled. In the consultation of the SEAC draft opinion the recycling sector was actively approached to comment on the proposal and to indicate the need for an exemption. A number of comments were received, elaborating the practices of recycling and proposals for concentration limits. As a result, there has been a request from the recycling industry for a higher concentration limit for recycled materials[1].

SEAC accepts that the proposed restriction could have potential negative impacts on the recycling of plastic and textile waste. These negative impacts may result from additional costs to detect and separate materials containing decaBDE from waste streams and an increase in the volume of waste that will have to be disposed of (landfill or incineration) rather than recycled. SEAC underlines the social benefits of recycling in terms of resource efficiency and its special importance for sustainable development. In this context, SEAC notes that the proposed restriction could impede the goals of Circular Economy and the achievement of recycling targets. Furthermore, waste incineration capacities differ between EU Member States and there could be a lack in capacity in several Member States. If the proposed restriction would result in a significant increase in waste that will be going to incineration, it would contribute to this general problem.

However, SEAC observes that there is insufficient evidence to conclude that the proposed restriction will actually trigger these potential negative impacts. Available data on the concentration of decaBDE in recycled plastics placed on the market (after waste processing) does not indicate that the proposed concentration limit of 0.1 % would be exceeded. On the other hand, recent data on shredder fractions of plastic waste in the Netherlands show that decaBDE concentrations in waste of electronic and electrical equipment (WEEE) can exceed 0.1 % in some cases (IVM, 2013). On the whole, available measurement data imply that it seems to be a small fraction of waste, mainly from WEEE, that is highly contaminated with decaBDE. In the contributions of the recycling sector in the public consultation of the SEAC draft opinion, industry indicated that high concentrations of elemental bromine are found in waste from WEEE and end-of-life vehicles (ELV) and that the proposed restriction (additional to RoHS and EU POP regulation) may counteract achieving ELV recycling targets. In contrast, information provided by the automotive industry indicates that waste fractions containing decaBDE from ELV will comply with a concentration limit of 0.1 % (based on the total non-metal fraction of a vehicle). Consequently, stakeholders from the automotive sector confirmed that the proposed restriction will not hamper to achieve the recycling targets set by the ELV directive. However, available data is limited and do not to cover all waste streams. These data therefore have limitations when assessing the feasibility of a concentration limit of 0.1%. Overall, the available data on decaBDE concentrations in plastic waste is not considered sufficient to make a robust estimate of the overall share of plastic waste that contains decaBDE in concentrations above 0.1 %. There is even less data available on the concentrations of decaBDE in textile waste. Moreover, based on the evidence available SEAC is not able to assess, if and to what extent concentrations of decaBDE above 0.1 % in waste streams will lead to concentrations above 0.1 % in the recycled materials placed on the market. In this respect it is important to note that according to industry only a minor part (30 % of WEEE plastics) of materials does contain flame retardants at all.

It is also questionable, if the proposed restriction would actually lead to additional efforts for the separation of waste containing decaBDE. According to industry, it is standard practice to screen waste streams based on their elemental bromine content in order to separate fractions for their suitability for further processing (termed de-pollution). According to the

[1] 0.3 % of decaBDE (for 15 years) or 3000 ppm of elemental Bromine for recycled materials

EU CENELEC technical specification for de-pollution (EC 50625-3), a concentration of 2000 ppm elemental bromine is used to separate wastes that are likely to contain currently restricted brominated flame retardants above established concentration limits (i.e. for those restricted under RoHS and the EU POPS regulation) from those that are not. SEAC was informed about the technical infeasibility to take out decaBDE from potential waste streams and concludes that there are at present no effective screening and separation techniques at industrial scale to separate decaBDE in waste streams from other waste streams that contain allowed brominated flame retardants, which complicates the phasing out of decaBDE from the recycling of waste[2]. Based on information from industry, compliance with legal standards for PBDEs, which are already established by the RoHS directive (0.1 % for all PBDEs) and by the EU POP regulation (0.1 % for tetra- to heptaBDE for recycled materials or materials from waste prepared for re-use) is only assessed once the waste material has been recycled into a product to be placed on the market. At this stage compliance with the proposed restriction will also have to be determined by recycling companies. SEAC discussed the different interpretations regarding the status of the waste streams and noted that Member States have different interpretations if waste is still waste or meets the end-of-waste criteria and could be considered a product. SEAC notes that these different interpretations could be an obstacle for a level playing field for recycling within the EU and make it more difficult to assess the impacts of a restriction on the recycling sector across EU Member States.

As such, SEAC considers it to be unlikely that the proposed concentration limit will result in significantly greater costs to the recycling industry for compliance testing. Nevertheless, SEAC acknowledges that the proposed concentration limit for decaBDE, if used alongside the existing CENELEC screening standard of 2000 ppm bromine, could possibly result in some material that could previously have been marketed as compliant with POPS regulation[3] limits (but not RoHS) as no longer suitable for use in recycled plastics, and which would have to be disposed of. However, SEAC has no information to conclude if this would be the case and what the importance of this fraction to the recycling industry in terms of revenues or volumes would be, because this information was not provided by industry in their public consultation response. Still, SEAC notes that the proposals of the recycling industry for a higher limit value (and their backgrounds) indicate that more evidence is needed to come to a better justified proposal for a limit value. Further information and assessment is needed to come to a better picture of the technical and economic impact on recycling of decaBDE containing plastic wastes. SEAC realises that such an investigation is outside the context of this restriction proposal. Finding a balance however between chemicals and waste policies is also an issue in the context of Circular Economy.

Overall, SEAC concludes that the available evidence seems to suggest that the proposed restriction will not have an additional negative impact on the recycling of materials than that which is already imposed by existing legislation. This conclusion is based on indications that only a small fraction of waste streams would contain decaBDE above the concentration limit proposed of 0.1 % and that the existing practice in the recycling sector is to separate wastes containing brominated flame retardants, regardless of the proposed restriction. However, SEAC highlights that this conclusion is not substantiated by sufficient data and that the proposed restriction still could have a negative impact on the recycling of different waste streams. Therefore, SEAC recommends to undertake further monitoring to come to a better picture of the actual decaBDE concentrations in recycled materials and the potential technical and economic impact of the proposed restriction for recycling once the restriction has entered into force.

[2] For example ELV have a number of plastics components that might contain decaBDE and which are not known to the dismantler or the shredding facility. As the specific removal of decaBDE plastics from a car before shredding is not economically and technically feasible, it could also have an impact on recycling targets for this sector.

[3] concentrations of tetra- to heptaBDE were each < 0.1 %, but total PBDE congener concentration >0.1%

In case a derogation for the recycling of materials would be required, i.e. by setting a higher concentration limit than 0.1 %, SEAC notes that this could lead to a lower emission reduction of decaBDE. It is not possible to assess the size and significance of the emissions from the recycling of waste containing more than 0.1 % decaBDE. SEAC also notes that a derogation of the recycling of materials could complicate the enforcement of the proposed restriction.

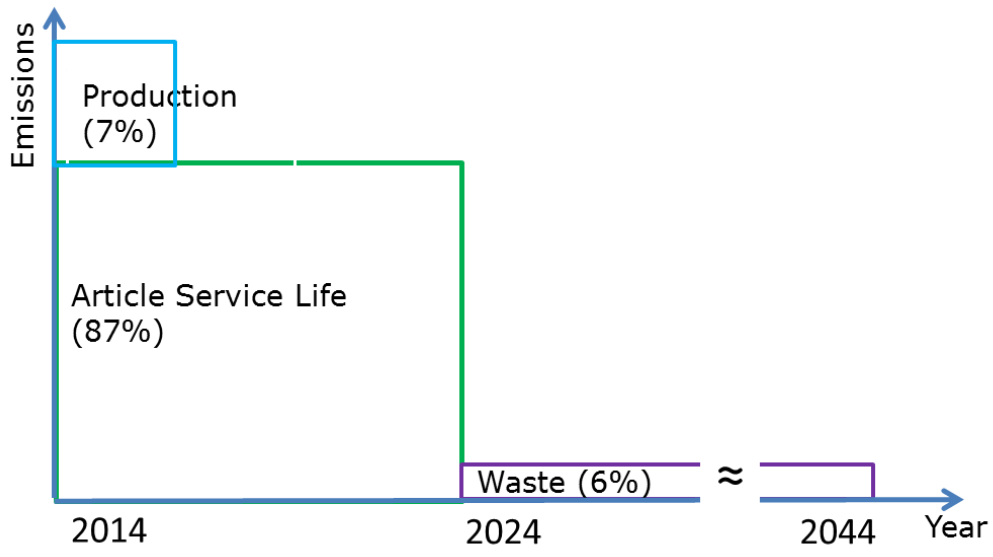
SEAC notes that no comments on the **transition period** were received during the public consultation (apart from the comments received from the automotive industry). This lack of response suggests that 18 months seem to be sufficient for industry to substitute and clear their stocks of articles containing decaBDE, as suggested by the Dossier Submitter.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

The Dossier Submitter explains that the emission estimate of 4.74 t/year of decaBDE (see conclusion 3 above) includes emissions from the production and subsequent service life and waste lifecycle steps of articles that are placed on the market in a given year (i.e. articles placed on the market in 2014 in the above calculations). Emissions from article production occur during the same year of the production. Emissions from article service life is set to occur over 10 years. Finally, emissions from waste in landfills occur for 30 years from the assumed end of the service life. The figure below gives a schematic representation of the occurrence of the decaBDE emissions in time. However, emissions from incineration and recycling operations occur shortly after the articles have reached their end of service life (this is not pictured in the figure). In addition, recycling might lead to the incorporation of decaBDE in new articles, which will continue to emit for a second service life (these emissions are not included in the calculations).

Emissions from the service life and the waste stage of legacy articles (i.e. those placed on the market prior to any restriction) will continue after the entry into force of the proposed restriction. These emissions were not quantified in this restriction proposal, since they are not impacted by the proposed restriction. These emissions are considerable since imports of decaBDE were approximately two times higher than current imports.



RAC has the following observations on the Dossier Submitters explanation:
It is clear that emissions of decaBDE will take place decades after a ban has been

implemented due to emissions from the service life of treated articles and from waste handling. This will of course reduce the effectiveness of the proposal, but on the other hand it demonstrates the need for action within a short time period to minimise exposure (and risk) as far as practically possible.

Conclusion 8: **Due to the very large stock of decaBDE in the technosphere (and already in environmental sinks such as sediment), the environment will remain at (unquantified) risk from this substance for decades to come. The restriction is the only option that can prevent additional emissions (and therefore risks) and thereby minimise exposure as far as practically possible.**

Proportionality to the risks

Justification for the opinion of SEAC

As the proposed restriction is based on the PBT/vPvB concern related to decaBDE the quantification of the benefits (in terms of damage) is not possible in order to assess the proportionality of the proposal. Hence, the Dossier Submitter has carried out an analysis of the cost-effectiveness of the proposed restriction complemented by qualitative information and arguments on the concerns related to decaBDE to facilitate the proportionality assessment.

SEAC concludes that the approach taken by the Dossier Submitter is in line with the approach to evaluate PBT/vPvB substances in SEAC (see SEAC/24/2014/04) .

Cost assessment

In the dossier compliance costs are assessed based on the estimation of substitution costs to producers/importers to replace decaBDE. Although SEAC agrees with the Dossier Submitter that substitution costs are likely to be the main cost triggered by the proposed restriction, SEAC considers that information on other relevant cost elements such as enforcement costs or compliance control costs would have been helpful to get a more complete picture of the economic impact of the proposal. However, as no information on other relevant cost elements has been received in the public consultation SEAC considers that this lack of comments indicates that other costs are less relevant compared to substitution costs.

The calculation of substitution costs is based on the following assumptions (for details please see Table 97 in BD):

- EBP will be used to replace decaBDE in all applications (textiles + plastics)
- EBP is a 'drop in' alternative, i.e. there will be no/minimal investment costs to switch to EBP
- EBP is slightly more expensive (i.e. 12%, 0.5 €/kg) than decaBDE
- the loading of EBP is the same as for decaBDE

On this basis, the **annual compliance costs** are estimated to be **2.2 million €**.

Even though EBP is a 'drop in' alternative and already widely used to replace decaBDE, the Dossier Submitter highlights that there are indications that the market will not completely switch to the use of EBP, but that other, also non-brominated, substances as well as non-chemical alternatives may be applied (especially in plastics), which usually are much more expensive than EBP. SEAC notes that in case other alternatives than EBP are used there

must be some additional benefits to industry (e. g. a gain in reputation by green marketing) compared to using EBP of decaBDE, because EBP is technically feasible to replace decaBDE in all uses considered by the Dossier Submitter at the lowest additional cost. However, these additional benefits cannot be quantified based on the information available. As the prices of potential alternatives vary significantly, the alternative to be used to substitute decaBDE will have a major influence on the size of the overall compliance cost of the proposed restriction. To reflect the uncertainties related to the responses of industry to the proposed restriction and the possibility that other alternatives than EBP may be used, the Dossier Submitter has developed a second scenario assuming that users of decaBDE in plastics would switch to a variety of alternatives (see BD Annex F.2.1). The magnitude of costs for R&D and other investment needed to implement other alternatives than EBP are still not considered in this scenario due to lack of available information. This scenario would result in considerably higher compliance cost (9.6 million € per year) representing these additional benefits.

There are several factors in the analysis that are beset with uncertainties (information on price difference of the alternative and decaBDE, loadings). These are of varying importance for the overall order in magnitude of the cost estimates. Accordingly, the main driver of the analysis is the choice of the alternative used by industry (as explained earlier). No trend in the prices and in the amounts of the alternatives and decaBDE is considered in the cost calculations carried out by the Dossier Submitter due to the lack of information on price development. As a consequence, compliance costs are considered to be representative for all years after the restriction will enter into force. SEAC accepts this approach.

The Dossier Submitter has reflected the effect of these uncertainties on the overall results by using sensitivity analysis of the price difference of the alternative and decaBDE (see Table 14 in BD). SEAC considers this approach appropriate, because the choice of the alternative (representing the price difference to decaBDE) seems to be the most important driver of substitution costs (in the absence of quantitative information on other cost elements such as R&D and reformulation costs). Accordingly, substitution costs range between 0.5 and 12 Mio. €/y.

SEAC supports the overall approach of the Dossier Submitter to estimate substitution costs to assess the compliance costs of the proposed restriction. However, SEAC notes that there is a lack of information on important drivers of the costs (i.e. alternative used by industry, price development). SEAC considers the sensitivity analysis included in the dossier as a useful tool to reflect the uncertainty arising from this lack of information.

Benefit assessment

The restriction proposal is based on the concern that decaBDE is transformed to substances with PBT/vPvB-properties (lower brominated congeners) in the environment and biota. As the risk/impacts of PBT/vPvB substances cannot be quantified with sufficient reliability, **abated emissions are used as a proxy to describe the benefits** of the proposed restriction. RAC considers that some alternatives could pose hazards similar to decaBDE. However, the 'drop-in' alternative EBP has not been identified as a PBT/vPvB substance so far and there are some alternatives that are likely to be less hazardous overall, at least in a PBT context. **SEAC bases its benefit assessment on the abated emissions of decaBDE as a PBT/vPvB substance.**

The emissions were estimated based on:

- the volumes of decaBDE used in the EU (4000 t/y) as well as in imported articles (400 t/y)
- different emission factors for all life-cycle stages (production, service-life, waste) of

the uses of decaBDE (textiles and plastics)

Accordingly, **total emissions are estimated to be 4.74 t per year**, with the major amount of emissions (87%) occurring during the service-life of articles containing decaBDE.

To reflect uncertainties of the emission factors used, the Dossier Submitter has included sensitivity values to assess the potential effect on cost-effectiveness estimates (see discussion on proportionality).

When considering the overall benefits of the proposed restriction SEAC notes that the impact on emission sources outside the EU is uncertain, although some reduction in use is likely because the restriction will apply to articles imported to the EU. As decaBDE is a transboundary pollutant with the potential for long-range environmental transport any emissions occurring outside the EU can contribute to decaBDE exposure within the EU. In this respect, global action (the Stockholm Convention) would be more effective to eliminate decaBDE in the long-run. However, the potential for long-range transport does not adversely affect the benefits of the proposed restriction because, as decaBDE is a PBT-substance, any reduction in emissions has to be considered as a benefit, even though other emission sources may remain (see also RAC opinion, conclusion 8). Equally, as this long-range transport potential is acknowledged to be limited, the proposed restriction will effectively reduce European exposure to decaBDE irrespective of uses outside of the EU.

In addition to the emission estimates, the Dossier Submitter has included qualitative information on the **specific factors of decaBDE that contribute to the overall concern related to decaBDE** (in addition to the general PBT-concern). This information contributes to get a better picture of the benefits of the proposed restriction such as:

- **Extent and trend of environmental exposure and distribution**
    - Long range transport potential of decaBDE and findings in remote areas. Apart from its PBT/vPvB properties the reason decaBDE has been proposed as a POP to be included in the Stockholm Convention.
    - DecaBDE mainly affects sediments and soils at concentrations up to several milligrams per kilogram (parts per million, on a dry weight basis). Overall, decaBDE is the most abundant PBDE congener in sediments, sewage sludge, soil, dust and air (See section B.9 of BD).
    - DecaBDE is also present in many types of aquatic and terrestrial wildlife species (including the eggs of predatory birds) at numerous geographical locations.
- **Human exposure and hazards**
    - DecaBDE is frequently detected in human matrices, demonstrating that humans are extensively exposed to decaBDE.
    - DecaBDE can cause developmental neuroxicity and breaks down to substances with neurotoxic properties.
- **Stock of decaBDE in society and the environment as well as timescale of emissions' occurrence**
    - Monitoring data show no clear decreasing environmental trend in concentration levels over the last decade, despite the risk management measures already introduced (industry voluntary emission reduction programme (since 2004) and the restrictions in RoHS on decaBDE in EEE (since 2008)). Some studies

indicate that the levels of decaBDE in the Arctic atmosphere are increasing.

- The stock of decaBDE is considerable and present in a large variety of articles, with a potential to accumulate in society depending on the service life of the article. Consumption of decaBDE is estimated at 150 K tonnes in the EU in the period 1991-2010 (Earnshaw et al., 2013).

- The timescale of emissions' occurrence is differing between the life-cycle steps (production, service life, waste) of articles that are placed on the market. Emissions from article production occur immediately, whereas emissions from article service life and from waste in landfills occur over much longer time periods (estimated in the BD to 10 to 40 years).

- **Transformation of decaBDE to lower molecular weight PBDEs (PBT/vPvB substances)**

  - It is well demonstrated that emissions of decaBDE will lead to exposure to the environment and humans to lower molecular weight PBDEs. Furthermore, there is evidence that decaBDE also breaks down to other substances with potential PBT/vPvB properties in the environment or biota. However, according to RAC's assessment the transformation rate of decaBDE is uncertain and cannot be quantified with sufficient reliability to use it for a quantitative analysis of the contribution of decaBDE to the formation of PBT/vPvB substances. As the transformation rate is considered to have a significant influence on the overall impact of decaBDE in the environment, SEAC recognises that it may also affect the cost-effectiveness of the proposed restriction. However, taking into account that this effect cannot be quantified and that RAC considers the emissions of decaBDE as a suitable proxy for the risk of hazardous transformation products, because of the potential for decaBDE to act as a long-term source of PBT/vPvB transformation products, SEAC supports to use the total reduction in the emissions of decaBDE as a basis for the cost-effectiveness analysis.

With regards to the valuation/monetisation of the benefits of reducing the emissions of decaBDE, it is pointed out in the dossier that there has been recent research on this issue. The results of a recent study looking at the valuation of precautionary control of decaBDE provide some indications regarding the proportionality of the proposed restriction (along with the other evidence provided in the section). Although the results of the study are not directly applicable to the proposed restriction, the study indicates a clear and potentially substantial willingness-to-pay amongst the general public for precautionary reductions in environmental accumulation and human health concerns for decaBDE (see BD, Annex F 1.2). Therefore, SEAC considers that the results of this study further corroborate the proportionality of the proposed restriction.

SEAC agrees with the approach taken by the Dossier Submitter to assess the benefits of the proposed restriction. It is in line with the current framework of SEAC to evaluate PBT/vPvB substances.

Proportionality

The proportionality assessment includes as part of the evaluation cost-effectiveness analysis as recommended by SEAC (see SEAC/24/2014/04).

Based on the substitution cost estimates (see above under 'cost assessment') and the emission estimates (see above under 'benefits assessment') the Dossier Submitter has calculated the cost of one kg of decaBDE emissions avoided (= cost-effectiveness) by the proposed restriction and also other restriction options (see above). Accordingly, the central estimate of the **cost-effectiveness of the proposed restriction is 464 € per kg**

emission avoided.

SEAC notes that there are considerable uncertainties related to the underlying assumptions of the cost-effectiveness analysis (see cost and benefits assessment). These may have a significant impact on the cost-effectiveness estimates. The Dossier Submitter has described these uncertainties in the dossier (F.7) and has reflected the potential effect of these uncertainties by using sensitivity analysis combining a low emission factor with a high cost estimate and vice versa (Table 14 of BD). Accordingly, the cost-effectiveness of the proposed restriction ranges between 125 and 4000 € per kg decaBDE emitted. SEAC considers this approach as appropriate to assess the probable range of cost-effectiveness scenarios. The analysis indicates that the selection of the alternative used by industry as well as the emission factor do have a major influence on the cost-effectiveness of the proposed restriction. The difference of the sensitivity values of the cost-effectiveness was up to one order in magnitude.

SEAC highlights that the cost-effectiveness estimates *per se* do not give any indication on the proportionality of the proposed restriction. In order to conclude on proportionality, the cost-effectiveness has to be considered in relation to the benefits of the proposed restriction. So far, SEAC has not been able to establish a benchmark (range) of proportionate costs to reduce emissions of PBT/vPvB substances.

In the original dossier, the conclusion on proportionality is mainly based on the argument that the cost-effectiveness of the proposed restriction is in the same order of magnitude as the cost-effectiveness of recent restrictions of PBT-like substances (Hg, Phenyl-Hg) under REACH. SEAC agrees that data on the cost-effectiveness of former measures to reduce emissions of PBT/vPvB substances is of relevance to assess the proportionality of the proposed restriction.

However, SEAC highlights that the usefulness of this kind of data to conclude on the proportionality of the propsed restriction of decaBDE is limited due to, among other factors

- differences in the reference mass applied (volumes emitted vs volumes used)
- differences in the kind of costs incurred by a certain risk management measure (e.g. substitution vs clean up costs)
- difficulties to quantitatively compare the 'welfare consequences' (damage potential) of decaBDE and other PBT/vPvB substances in a meaningful and consistent way

Therefore, in addition to information on the cost-effectiveness of former regulation on PBT/vPvB substances SEAC proposes to base the proportionality assessment of the proposed restriction also on qualitative information and arguments more specifically describing the concern related to decaBDE and the benefits of the proposed restriction in a weight-of-evidence approach. Accordingly, the following **additional arguments** should be taken into account in addition to cost-effectiveness data when assessing the proportionality of the proposed restriction:

- the specific factors of decaBDE that contribute to the **overall concern related to decaBDE in the environment and humans** (see above 'benefits assessment')
- based on the comparison with other risk management options presented in the dossier the proposed restriction seems to be the **only effective measure to reduce emissions of decaBDE E. g.** voluntary risk management measures by industry (i.e. VECAP initiative) was not sufficient to minimise the emissions.
- DecaBDE has already been **phased out in the US** by the end of 2013 based on a voluntary agreement with industry.

- the **overall substitution costs** are **moderate and society is expected to put a significant value on reducing decaBDE emissions** (in relation with the recent study indicating a clear and potentially substantial willingness-to-pay amongst the general public) .

Taking into account the cost-effectiveness of the proposed restriction and the qualitative arguments presented, SEAC concludes that the proposed restriction is a proportionate measure to reduce emissions of decaBDE.

Practicality, incl. enforceability and monitorability

Justification for the opinion of RAC

Implementability and manageability

The Dossier Submitter has demonstrated that an important portion of the market has already phased out decaBDE. In addition, alternative substances are available for all uses, whilst noting that there are certification issues for the aviation sector where some types of articles are proposed to be exempted for specific reasons. The implementation of the proposed restriction (by switching to alternative substances or techniques) is clear and understandable to all actors involved. In consequence, RAC agrees this restriction is implementable and manageable.

Enforceability and monitorability

The Dossier Submitter states that enforcement activities should cover the import of decaBDE as such, in mixtures and in articles, and the production of articles in the EU. However, production of articles for the aviation sector, whose use is proposed for derogation, should continue. Therefore, import of decaBDE as such, in mixtures, in articles or the production of articles in the EU (and subsequent placing on the market) should be permitted only if the final article is used according to the terms of the derogation proposed for the aviation sector.

For other articles placed on the market (i.e. except for derogated articles) enforcement authorities could check documentation from the supply chain confirming that the articles do not contain decaBDE. In addition, it can be envisaged to verify if the articles contain decaBDE by testing. Currently, 0.1% w/w is the limit that triggers the notification requirement under article 7(2)[4] of REACH and the information requirement under article 33 of REACH. This limit also applies to recycled articles. According to article 33.2 the supplier already has an obligation within 45 days to inform the consumer (if asked) if the article contains decaBDE. Finally, the same limit of 0.1% w/w is applied for PBDEs, including decaBDE, under the RoHS Directive (see Table 8). To enhance the enforceability of the restriction the same concentration limit of 0.1% w/w is proposed. This is also the case for the use in mixtures.

The proposed limit will according to the Dossier Submitter ensure that decaBDE is not intentionally added to products since concentrations below this limit will not ensure flame retardancy. This is because decaBDE is used in much higher quantities to be effective. The range of reported concentrations is between 7.5 and 20% depending on the application. Finally, there is no information on any products that would contain decaBDE as impurity in

[4] An additional requirement is that the substance is present in the articles in quantities totalling over 1 tonne per producer or importer per year.

concentrations higher than 0.1%, meaning that the restriction will not inadvertently affect any products into which decaBDE is not intentionally added.

Analytical methods to verify the concentrations exist and are well established according to the Dossier Submitter.

The monitoring of the restriction will be done through enforcement. No additional monitoring is envisaged according to the Dossier Submitter.

The FORUM has examined the proposal with regards to enforceability and it concludes in its draft advice that the proposed text of the proposal is generally fit for purpose with some minor adjustments.

The FORUM also noted that enforcing the restriction will require new ways of working that could be complicated and it is preferable to have systems/contact points in place at relevant authorities to check that exemptions are applicable to particular aircraft/articles. Enforceability, practicability and monitorability is dependent upon the recommendation of suitable sampling, preparation and analysis methods – standard methods may be preferable to ensure affordability and reliable results. Enforcing Authorities will be required to undertake sampling of non-derogated articles and check compliance by analysis – there is no information about alternative (less expensive or burdensome) ways to enforce and monitor, such as documents that could demonstrate compliance with the restriction or exemption.

RAC has the following observations:
From a risk management point of view the proposed restriction seems implementable and manageable as the scope is clear. RAC notices the point raised by FORUM regarding the derogation related to production of articles for the aviation sector and has taken this into account regarding rewording of the scope.

Conclusion 9: **The restriction proposal is very clear, and will impose a restriction with a limit value of 0.1% in both chemical mixtures and articles. This is considered to be both implementable and manageable. From a risk assessment point of view the monitorability is also clear.**

Justification for the opinion of RAC

In the dossier, it is concluded that the proposed restriction is implementable and practicable, because alternatives are available and technically and economically feasible for all uses of decaBDE covered by the proposal. This conclusion is supported by the fact that a significant part of the market has already phased out decaBDE.

In the following, the practicality of the proposal is assessed in more detail.

Clarity of the scope of the proposed restriction

The Forum highlights in their draft advice that the wording originally proposed in the dossier does not clearly reflect the intention of the Dossier Submitter to exempt the production, placing on the market and use of aircraft components containing decaBDE. The exemption as it has been phrased in the dossier will not allow these articles to be produced using decaBDE within the EU, only their import and placing on the market from outside the EU. The Dossier Submitter has revised the proposed wording based on the draft Forum's advice.

SEAC concurs that the new wording improves the clarity of the proposed restriction.

Enforceability

In the dossier several analytical test methods are given that could be used to enforce the proposed restriction.

The limit of detection of different **analytical methods** (with varying complexity to use) is suitable to use these methods for enforcement activities. In addition, sampling and preparation methods to facilitate enforcement are available. Some information on testing costs has also been collected (from a Danish laboratory). However, these data are not sufficient to assess the magnitude of enforcement costs (see below). The **derogations** proposed for the use of decaBDE in aircraft as well as second hand articles requires enforcement authorities to identify these articles. The Dossier Submitter has proposed a way to enforce the derogation on the basis of type certificates. SEAC considers this approach to be feasible, however it may lead to difficulties in the practices of enforcement authorities (as pointed out by Forum in its draft advice). Hence, the enforcement practices for aircraft component should be clarified as much possible to ensure the effective enforcement of the proposal. The same applies to the additional derogations proposed by SEAC.

SEAC notes that **enforcement costs** have not been quantified in the dossier. Also, no information on enforcement costs has been received during the public consultation. Hence, SEAC cannot evaluate their relevance (compared to substitution costs).

Monitorability

The dossier concludes that there are suitable analytical methods to monitor the effectiveness of the proposed restriction through enforcement activities. This conclusion is confirmed by the Forum in its draft advice. SEAC expects that the **cost of monitoring** will be mainly incurred by enforcement authorities. However, it is not clear to what extent industry will undertake monitoring activities. Also, the overall size of monitoring costs is uncertain (see text on enforceability above).

BASIS FOR THE OPINION

The Background Document, provided as a supportive document, gives the detailed grounds for the opinions.

Basis for the opinion of RAC

The main changes introduced in the restriction as suggested in this opinion compared to the restriction proposed in the Annex XV restriction dossier submitted by ECHA are a minor change to the derogation related to aircraft and a clarification that articles placed on the market for the first time before the date of entry into force are exempted. These changes are introduced based on submissions during the public consultation and advice from the FORUM.

Basis for the opinion of SEAC

The main changes introduced in the restriction as suggested in this opinion compared to the restriction proposed in the Annex XV restriction dossier submitted by ECHA on a request from the Commission are changes to the derogation related to aviation, as well as additional derogations for road vehicles and spare parts for machinery, and agricultural and forestry vehicles. Furthermore, a clarification that articles placed on the market for the first time before the date of entry into force are exempted was included. These changes are

introduced based on submissions during the public consultations and the advice from the FORUM.