Committee for Risk Assessment (RAC)

Opinion

on an Annex XV dossier proposing restrictions on

DecaBDE

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

Adopted

2 June 2015

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Opinion of the Committee for Risk Assessment

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

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation on the proposal for restriction of

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

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

PROCESS FOR ADOPTION OF THE OPINION

ECHA at the request of 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.

OPINION

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]

JUSTIFICATION FOR THE OPINION OF RAC

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.**

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)	Share	(t/year)
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 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.

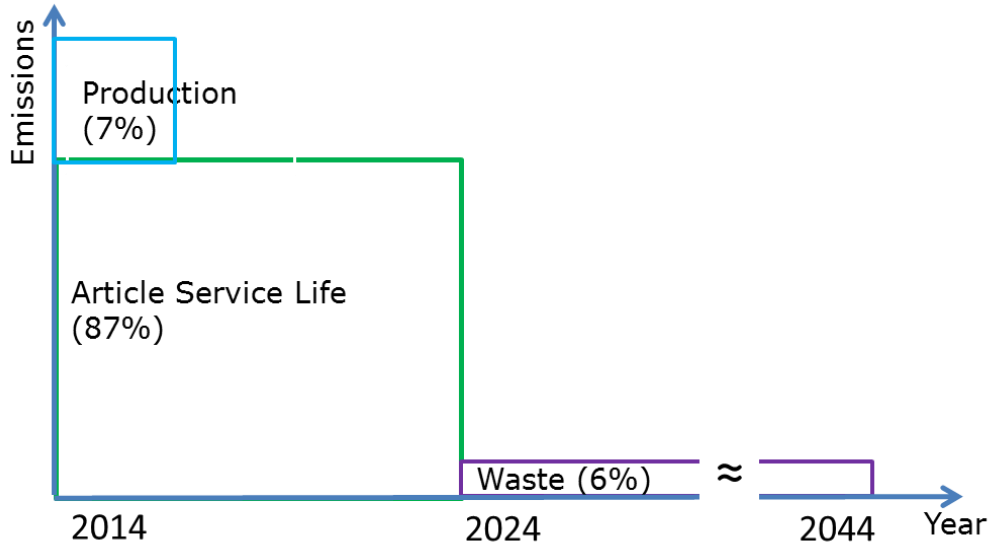
Conclusion 7: **RAC agrees that the proposed restriction is the most appropriate measure to reduce the emissions and thereby risks.**

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.**

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)[1] 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 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.**

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

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.