General Comments and answers to specific information requests

## Specific information requests:

1. Do you have information on uses of decaBDE in adhesives, sealants, coatings and inks? Based on the stakeholder consultation it is assumed in the restriction report that these uses are negligible and that restricting them will not have any significant effect on the marketing and use of adhesives, sealants, coatings and inks (these uses are identified in registration dossiers for decaBDE but limited information was provided during the stakeholder consultation). i) is decaBDE currently used in the applications described above and in what amounts? ii) if yes, what function does it provide and do you have information on the releases of decaBDE from the production or use of adhesives, sealants, coatings and inks iii) do you have any information on alternative substances and techniques for the above uses, including availability, technical feasibility and substitution costs?
2. Do you have information on how recyclers (especially of plastic materials, potentially also of textiles) could be affected by the proposed restriction? The proposed restriction includes a concentration limit of 0.1% w/w for recycled articles (for enforcement purposes). This is in line with previous restrictions on brominated flame retardants (RoHS Directive, REACH Annex XVII). i) do you know if recycling of plastics (or potentially of textiles) could result in concentrations of decaBDE in the final article of greater than the proposed restriction limit of 0.1% w/w? ii) if yes, could you tell us more about the concentrations of decaBDE in recycled materials (and articles produced from recycled materials) and the implications of the adoption of the proposed limit of 0.1% w/w?
3. The costs of the proposed restriction to society were estimated as the costs of substituting decaBDE with a drop-in alternative (ethane-1,2-bis(pentabromophenyl) (EBP)). Do you have information on any additional costs of the restriction, which might not be included in this calculation? Examples of such costs are e.g. costs of chemical analysis of recycled plastics to ensure that the concentration limit is respected, enforcement costs etc. Please quantify your reply, if possible.

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| **Ref.** | **Date/type/Org./** | **Comments** |
| **1165** | **Date:** 2014/11/03 11:57  **Type:** MemberState  **MS name:** Germany  **Related to:** (A) (F)  **Company name confidential:** **No** | **Comment:**  The German CA supports the proposal to restrict DecaBDE.  **Specific comment:**  In the decaBDE Dossier the cost effectiveness (cost of reducing 1 kg of decaBDE emission) is estimated to be 464 €/kg. This value is compared to the cost effectiveness in previous restrictions under REACH, i.e. in the restrictions on mercury, because mercury has some environmental properties similar to decaBDE. As the calculated values for the cost effec-tiveness in both cases are in the same order of magnitude, it is concluded that the additional costs, due to the proposed restriction on decaBDE, are proportionate to the risk reduction.  We think this approach of using previous restrictions as a benchmark for assessing proportionality should be handled with caution. The decision on mercury was a precedent, but was not meant to be used as a bench-mark for all subsequent restrictions on PBT/vPvB substances. This is in-deed also acknowledged by the authors of the decaBDE restriction dossier who mention that their approach should not exclude the possibility that even higher cost-effectiveness estimates could be considered proportionate. On the latter we would like to place emphasis with this comment. We would like to propose that reference to the mercury restrictions is deleted in chapter A of the decaBDE restriction dossier in order not to attach too much importance to this kind of approach. |
| **Dossier submitter response:**  Thank you for your support and comments. We agree that the cost-effectiveness figures calculated in the Hg in measuring devices restriction report cannot be directly used as a benchmark for all subsequent restrictions. We have now modified the text in section A.3.3 “Justification that the proposed restriction is the most appropriate Union-wide measure/Proportionality to the risks”, of the Background Document, as follows:  “The cost-effectiveness of the proposed restriction for decaBDE is in the same order of magnitude (or lower) as previous restrictions under REACH on mercury and its compounds (i.e. phenylmercury), which has some similar environmental properties. However, the comparision of cost-effectiveness between decaBDE and mercury compounds is not straightforward as their individual circumstances (i.e. hazard potential / exposure in the environment), are not directly comparable. This precludes the use of the cost-effectiveness of previous restrictions as a benchmark of acceptable cost-effectiveness. However, this information remains relevant to a discussion on proportionality and is included as supporting information.”  Similar modifications were made to section E.2.1.1.3 “Proportionality”. |
| **RAC Rapporteurs comments:**  This is a SEAC issue. |
| **SEAC Rapporteurs comments:**  We would also like to thank for your comments. We agree with the Dossier Submitter about using the cost-effectiveness of the previous restrictions under REACH on mercury and its compounds as supporting information in the proportionality assessment, however not as a benchmark to conclude on proportionality of the proposal. |
| **1170** | **Date:** 2014/11/14 12:42  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Paxymer AB  **Org. country:** Sweden  **Company name confidential:** **No**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** The reason for requesting information to be held confidential is due to the competitive situation on the market. This information is only available to the market under secrecy agreement with specific customers in development projects. Know how is an important part of the development project and including the amendments under V would put the submitting organisation at a competitive disadvantage. The submitting organisation is a new innovative alternative on the market with its own proprietary technology that has significant potential. Leaking of the confidential information can cause the company significant economical damage. | **Comment:**  Deca-BDE has long since been one of the main “workhorses” of flame retardants. It works in a wide range of applications and is combined with the synergist of Antimony trioxide to be efficient as a flame retardant. The following comments are from a company which has developed a proprietary solution with similar efficiency for polyolefin plastics especially thick walled plastics which maintains mechanical and processing properties of the material and provides an improved fire safety with regard to heat release rate, smoke toxicity and dripping behaviour compared a polyolefin protected with Deca-BDE. The alternative is altogether non-persistent and contains no EDC or PBT classified substances. It is available on the market under the name Paxymer®  **Specific comment:**  We will provide comments on Paxymers alternative in comparison with Deca-BDE.  Burning behaviour  Comparing the burning behaviour of these solutions is not simple. The industry standard has been a test called the UL94-V0 – this is a test that measures self-extinguishing behaviour with a small flame. It has very little implication for any real fire scenario and a material that extinguishes within 10 seconds after 2 ignitions is passed without regard to smoke amount, smoke toxicity or burning behaviour during the application of the flame.  Standards on the market are however growing more sophisticated with measurement of heat release rate of the material, smoke toxicity and smoke density as well as dripping behaviour. All of which measured at longer times and higher energy added to the material (See EN5660 - cone calorimetric standard and EN13501 – building materials).  Comparing fire behaviour in this way one will find that non-halogenated fire performance in polyolefins is improved compared to halogenated alternatives on the following accounts:  - reduced peak heat release rate  - slower flame propagation  - reduced smoke toxicity and elimination of corrosive smoke  - reduced smoke density  - improved dripping behaviour  Please find a summary of specific testing results compared to publicly available results from brominated solutions in the confidential appendix.  Usability/Material performance  One of the main determinants of overall material performance is the concentration of additive necessary to achieve sufficient fire performance. A common critique is that halogen free flame retardants are inefficient. The current solution described is active to fulfil fire standards with between 15-30% of dosage of the master batch depending on fire classification. A brominated solution containing Deca-BDE will normally fulfil the same burning behaviour with between 5-15% of Deca-BDE and an addition of 15-25% of antimony trioxide as a synergist – the total addition of flame retardant and synergist is similar in both cases.  New generations of halogen-free flame retardants free from persistent chemicals are improved both in dispersion and compatibility. Paxymer®’s proprietary solution incorporates functional polymers that improves mechanical and processing performance by enhancing the compatibility with the carrier polyolefin material.  Price impact  Price impact differs between applications and is also skewed by the volumes sold on the market where economies of scale are significant. However as quantities stand today the halogen-free alternative have no price impact in some cases to about twenty percent premium compared on a kg/kg basis. Impact depends on application, fire classification, supplier.  If one includes waste handling cost, cost for handling hazardous materials/protective equipment in the production etc. halogen free alternatives give a cheaper total cost of good sold with about five to fifteen percent compared to existing Deca-BDE alternatives. In addition price volatility is high for the antimony trioxide synergist  The indicative price level at larger quantities of the Paxymer® can be found in the confidential attachments.  Other restrictions/investments/implementation costs  There are no additional investment required in equipment, tooling or auxiliaries. Materials are expected to be able to reach same or better performance with regard to mechanical properties, UV-stability and aging properties. The substitution projects where Paxymer has been involved and successful have stretched form six months and up. If the customer is motivated projects can be conducted quickly without risk of deteriorating material performance or introducing uncertainty regarding the new alternatives..  Current projects where Paxymer® is involved  Paxymer® is currently in a handful of applications and the company is involved in about 40 test processes for different applications.  The company has exchanged or been evaluated against Deca-BDE alternatives in:  - injection moulded and extruded electrical boxes and conduits  - blow moulded white goods application  - extruded sheet that is vacuum moulded in wind turbines  - injection moulded building platforms produced with aluminium reinforcements  - injection moulded and extruded applications in the automotive industry  - injection moulded and extruded applications in the building industry  - injection moulded and extruded applications in the electrical and electronic industry  - flame retardant synthetic fibres or monofilament and multifilament yarns in polypropylene  - development project for polyolefin film  - various project with composite materials such as wooden polymer composite (WPC) materials  The product is adapted for polypropylene (PP), polyethylene (PE) and EVA mainly. We are also involved in projects for TPE and rubber applications.  As mentioned above there is not one solution that works across the line as Deca-BDE did but in the polyolefin application the proprietary solution Paxymer® is competitive both with regard to price and functionality – especially in the context of evaluation in accordance with the more sophisticated fire standards. |
| **Answer to specific info request 1:**  No further info. |
| **Answer to specific info request 2:**  Threshold values can prevent substitution and encourage unintended misuse of the threshold values.  The company has faced significant problems to differentiate a completely halogen free pipe on the market from the LS0H (low smoke zero halogen) pipes sold according to standard. The standard stipulates that <1500 ppm halogen content is to be considered halogen-free and requires no disclosure by the producer of any halogen content. Combined with an imprecise evaluation standard of halogen content this allows a relatively high halogen content in reality. The threshold is not encouraging use of recycled materials as intended but rather halogen addition as flame retardant creating cheaper compound costs and unfairly competing with fully halogen-free solutions. The end customer are weighing one halogen free solution against another and cannot understand the concept of the threshold value and therefore choses the cheaper material containing halogens.  The company suggest that a threshold value can be set in place but limited for use only with applications using recycled plastics where contamination is possible – not virgin materials. In addition full disclosure of the elemental composition of the compound to detection level is essential regardless of threshold values. |
| **Answer to specific info request 3:**  No further info. |
| **Dossier submitter response:**  Thank you for this information which supports the overall conclusion that technically and economically feasible alternatives to decaBDE are available on the market.  Reply to Answer 2:a threshold value is necessary to make the restriction enforceable, for both virgin and recycled materials. In addition, the level of the threshold value was set to 0.1% taking into account the following considerations:   * 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. * Ensure that any products that might contain decaBDE as an impurity are not inadvertently affected. * Ensure that recycling activities are not negatively affected. |
| **RAC Rapporteurs comments:**  We agree with the Dossier Submitter, and have made some reflections on the alternative in the opinion, respecting the confidentiality claims and so not being able to go into details. |
| **SEAC Rapporteurs comments:**  We appreciate your information and answer to specific info request 2. We agree with the response of the Dossier Submitter. |
| **1172** | **Date:** 2014/11/25 03:16  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Belgium  **Company name confidential:** **Yes** | **Comment:**  **<removed>** acting as the LR for : Bis(pentabromophenyl) ether (Deca-BDE) would like to provide some first preliminary comments and observations to the Annex XV restriction report. These comments only concern parts of the report. Further, more detailed comments will be provided at a later stage.  Our present comments concentrate on the conclusions, but also apply to the same conclusions repeated throughout the dossier. The comments relate to the conclusions on Deca-BDE as well as one of the alternatives mentioned in the document.  For better readability the comments are also attached as a pdf file.  **Specific comment:**  Deca-BDE PROPOSAL FOR RESTRICTION (page 9)  It is important to state the reasons for the decision on the PBT/vPvB listing of Deca-BDE in the EU, as it is not based on the properties of the substance itself, but on the conclusion of the MSC, “ that there is a high probability that deca-BDE is transformed in soil and sediments to form substances which either have PBT/vPvB properties, or act as precursors to substances with PBT/vPvB properties, in individual amounts greater than 0.1% over timescales  of a year.”  While deca-BDE can be regarded as persistent, the substance itself does not meet the B-criterion. An in depth analysis of the available data provided in the industry comments to the UN POP discussions in 2014, confirmed this conclusion. Those comments represented a comprehensive assessment of the literature with respect to calculated accumulation factors. Those comments also calculated accumulation factors, many for the first time, from laboratory studies. , , ,  The regulatory decision of the EU to identify deca-BDE as bioaccumulative based on probability considerations on transformation products, still warrants a scientific debate on the environmental relevance of a limited transformation under certain conditions of an otherwise very persistent substance. Details on the evidence and levels of transformation products reported in the literature have also been discussed in the above mentioned comments.2,3,4,5  A.3. Summary of the justification (p. 11)  A.3.1 Identified hazard and risk  • See also comments to page 9 above. It is important to state the reasons for the decision on the PBT/vPvB listing of Deca-BDE in the EU, as it is not based on the properties of the substance itself, but on the conclusion of the MSC “that there is a high probability that deca-BDE is transformed in soil and sediments to form substances which either have PBT/vPvB properties, or act as precursors to substances with PBT/vPvB properties, in individual amounts greater than 0.1% over timescales of a year.”1  • Concerns for neurotoxicity are mainly based on a study whose experimental design was found not useful for risk assessment by the EU . A robust definitive rat developmental neurotoxicity study on Deca-BDE , which was conducted following Commission Regulation (EC) No. 2592 (2001) and that has been peer-reviewed and published, establishes a NOAEL of 1000 mg/kg/d. If metabolism occurs as postulated by other authors, symptoms of neurotoxicity related to those metabolites would have been identified as well. Assuming a 3.2% biotransformation as indicated in Riu et.al., 2008 , the dose of putative metabolites to which rats were exposed in the guideline developmental neurotoxicity study was above doses claimed to induce effects in other publications. However, neurotoxic effects were not observed in the in vivo study, indicating that neither DecaBDE nor possible metabolites were neurotoxic in this guideline conform neurotoxicity study.  • Widespread exposure is not equivalent to or evidence of adverse effects. A well-known toxicology quote states “The dose makes the poison”. The best estimate of human blood levels is in the low ng/g lw plasma range, and is exceptionally low. Plasma levels associated with the 1000 mg/kg/d NOAEL in the rat developmental neurotoxicity study were ~1000 ng/ml.  • Due to the persistency of Deca-BDE, it cannot be expected to see rapid decreases in the quantities of environmental levels observed. The fact that no increase is observed shows that the voluntary risk management initiatives, like VECAP, taken by the industry, are efficient as Deca-BDE is still used, yet to a lesser extent 10 years after the start of VECAP.  • Lifetime studies in rats and mice have been conducted on Deca-BDE. NOAELs of at least 1000 mg/kg over a lifetime were determined. A human oral Reference Dose (RfD) of 4 mg/kg/d was derived. The RfD is that dose to which humans, including the most sensitive populations may be exposed for a lifetime with the expectation of no adverse effects. Human exposures are far below this value.    A.3.3 Justification that the proposed restriction is the most appropriate, Union-wide measure, p.13 Analogy to mercury:  We do not think that the analogy, in particular with regard to the claim of similar environmental properties, is justified. Mercury is much more volatile and the atmospheric distribution is completely different to that of Deca-BDE. As a small molecule, elemental mercury is readily absorbed by the inhalation route and distributed in organisms. The neurotoxic effects are obvious and very well established. The analogy is not justifiable.  C.2.12 Alternative 12: Ethane-1,2- bis(pentabromophenyl) (EBP) (p.307 f)  Human health information C.2.12.1  C.2.12.1.1.1 Information from government and other regulatory authority  We note that this section does not include the UK Environment Agency’s 2007 “Environmental risk evaluation report: 1,1’-(Ethane-1,2-diyl)bis[penta-bromobenzene”. This report reviewed both environmental and human health data, and concluded, “Overall, the risks arising from direct toxic effects of EBP are low, especially in the UK content.” The human health data are reviewed on pages 59-71 of that report. The human health risks are considered on pages 81-82, with the conclusion “Overall, no hazards have been identified in relation to acute toxicity, irritation, mutagenicity, carcinogenicity or reproductive toxicity. No definitive conclusions can be drawn in relation to skin sensitisation due to limitations in the database, and the only key health effect identified concerns repeated dose toxicity. The NOAEL of 1,000 mg/kg/d identified in a rat 90-day study will be used in the risk characterization.” A conclusion of no concern for local or regional exposures of repeated exposures was reached.  References quoted:  ECHA, 2012: MEMBER STATE COMMITTEE SUPPORT DOCUMENT FOR IDENTIFICATION OF  BIS(PENTABROMOPHENYL) ETHER, AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS  PBT/vPvB PROPERTIES Adopted on 29 November 2012  Bromine Science and Environmental Forum, Comments on the draft risk profile for decabromodiphenyl ether, 5/19/2014 available at: http://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC9/POPRC9Followup/CommentondecaBDE/tabid/3700/Default.aspx  Bromine Science and Environmental Forum, Environmental assessment of accumulation, magnification and trophic transfer, 5/19/2014 available at: http://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC9/POPRC9Followup/CommentondecaBDE/tabid/3700/Default.aspx  Bromine Science and Environmental Forum, Summary: BSEF position on second draft Risk Profile for decabromodiphenyl ether, 5/19/2014 available at: http://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC9/POPRC9Followup/CommentondecaBDE/tabid/3700/Default.aspx  Bromine Science and Environmental Forum, Detailed comments on the draft Risk Profile for decabromodiphenyl ether, 5/19/2014 available at: http://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC9/POPRC9Followup/CommentondecaBDE/tabid/3700/Default.aspx  Viberg et al. 2003. Neurobehavioral derangements in adult mice receiving decabromoinaded diphenyl ether (PBDE 209) during a defined period of neonatal brain development. Toxicol Sci 76:112-120.  European Union, 2002 Risk Assessment ReportBIS(PENTABROMOPHENYL) ETHER, CAS No: 1163-19-5, EINECS No: 214-604-9  Biesemeier et al. 2011. 2011 An oral developmental neurotoxicity study of decabromodiphenyl ether (DecaBDE) in rats. Birth Defects Res Part B 92:17-35. Plus 60 pages SI.  EC (2001) Commission Regulation (EC) No 2592/2001 of 28 December 2001 imposing further information and testing requirements on the manufacturers or importers of certain priority substances in accordance with Council Regulation (EEC) No 793/93 on the evaluation and control of the risk of existing substances, available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001R2592&qid=1402412431638&from=EN  Riu, A., Cravedi, J.-p., Debrauwer, L., Garcia, A., Canlet, C., Jouanin, I., & Zalko, D. (2008) Disposition and metabolic profiling of [14C]-decabromodiphenyl ether in pregnant Wistar rats. Environment international, 34, 318-329.  Hardy et al. 2009. Toxicology and human health assessment of decabromodiphenyl oxide. Critical Reviews in Toxicology. 39(S3): 1-44.  Dungey and Akintoye. 2007. 2007. Environmental risk evaluation report: 1,1’-(Ethane-1,2-diyl)bis[penta-bromobenzene]. CAS: 84852-53-9. SCHO0507BMOR-E-P. U.K. Environment Agency. Bristol, UK. |
| **Dossier submitter response:**  Thank you for these comments, please find replies to each specific sub-item commented below.  Deca-BDE PROPOSAL FOR RESTRICTION (page 9):  Please note that the conclusion of the MSC (Member State Committee) that you mention is included in section B.8.1 of the Annex XV restriction report. In addition, a new section (B.9.4 “Degradation and transformation”) has been added in the Background Document to place additional emphasis on these issues. This new section highlights the following points:   * there is uncertainty on the exact transformation rate of decaBDE to lower PBDEs in sediments and soils (% w/w per year). * transformation rates in other environmental matrices, including biota, are also important to consider. Despite the uncertainties, there is evidence of higher transformation rates (than in sediments/soils) in these matrices. * decaBDE is also known to degrade to other substances with hazard profiles of concern such as hydroxylated and methoxy-PBDEs as well as PBDFS (Polybrominated dibenzofurans). * degradation over the short-term (i.e. over a period of a year) should be balanced against the potential for decaBDE to act as a long-term source of PBT/vPvB substances to the environment and humans. * given the above, the rate at which breakdown products of decaBDE are formed in the environment cannot be reliably incorporated into the emissions / exposure assessment on a quantitative basis. * and finally, the REACH regulation does not distinguish between different PBT or vPvB substances once they are identified. The obligations to minimise emissions and exposures throughout the lifecycle of the substances from manufacture or identified use are the same irrespective of the basis upon which a PBT or vPvB substance is identified.   Any discussion on the PBT properties of decaBDE is out of the scope of this restriction proposal as this relates to a regulatory decision that has already been taken. Nonetheless please find below a recent international development on the status of decaBDE, provided here only for information: The Persistent Organic Pollutants Review Committee (POPRC) “completed an evaluation of the proposal by Norway to list decabromodiphenyl ether (commercial mixture, c-decaBDE) in Annexes A, B and/or C to the Stockholm Convention and having decided at its ninth meeting, in its decision POPRC-9/4, that the proposal meets the criteria set out in Annex D to the Convention” and has further adopted the Risk Profile at the POPRC meeting in 27-30 October 2014.  A.3. Summary of the justification (p. 11) and A.3.1 Identified hazard and risk:  On the transformation and degradation aspects, see reply above.  On the neurotoxicity aspects, please see below:  As noted in the Annex XV restriction report the Biesemeier study has been critically evaluated by several authors; Shibutani et al. (2011) noted the omission of measurement of thyroid-related effects, histopathological parameters on neuronal migration, oligodendroglial development, neglection of the significant decreases in the hemisphere height and decrease in the pons and cortex vertical thicknesses. The Biesemeier study has also been discussed in the Health Canada (2012) report and Fowles and Morgott (2013). The limitations listed were that the numbers of pups found dead were higher in the 100 and 1000 mg/kg bw/day groups than in the control group, and several other treatment-related effects were observed at 1000 mg/kg bw/day (number of missing pups was increased, some of the motor activity parameters showed significant differences at 6 months in both sexes and a few of the brain morphometric analyses were significantly different at PND 21 in males and females and at PND 72 in males). Although Biesemeier et al. (2011) claimed that these effects were within historical control values and an increased number of deaths at 100 and 1000 mg/kg bw/day were not related to treatment, several different parameters were affected, historical control data were not provided in the supplementary data and significant differences in a number of motor activity parameters all occurred at the same time point (PND 180). Additionally, Biesemeier et al. (2011) did not provide an explanation for the increased number of missing pups at 1000 mg/kg bw/day. A LOAEL (100 mg/kg bw) and NOAEL (10 mg/kg bw) value were suggested based on this study in the Health Canada (2012) report, compared to the NOAEL value of 1000 mg/kg bw concluded in Biesemeier et al. (2011).  Also, as described in the Annex XV restriction report, several studies (e.g. Viberg et al., 2003; Viberg et al., 2007; Johansson et al., 2008; Rice et al., 2009; Fujimoto et al., 2011; Heredia et al. 2012; Reverte et al. 2013) show that decaBDE affects early foetal and neonatal development, and epidemiological studies support that exposure to decaBDE and other PBDEs may result in human neurodevelopmental toxicity (Gascon et al., 2012; Chao et al., 2011). Several epidemiological studies (Harley et al., 2010, 2011; Hoffman et al., 2012; Herbstman et al., 2008; Chevrier et al. 2010, 2011; Gascon et al., 2011; Roze et al., 2009; Eskenazi et al., 2013; Schreiber et al., 2010) support the notion that exposure to PBDEs may result in human neurodevelopmental toxicity. In these studies individual PBDEs may act alone or in combination to exert the reported effects.  Furthermore, two recent studies published after the Annex XV restriction report was submitted support that decaBDE results in neurodevelopmental effects (*Mariani A, Fanelli R, Re Depaolini A, De Paola M (2014). Decabrominated diphenyl ether and methylmercury impair fetal nervous system development in mice at documented human exposure levels. Dev Neurobiol. doi: 10.1002/dneu.22208; Buratovic S, Viberg H, Fredriksson A, Eriksson P. (2014). Developmental exposure to the polybrominated diphenyl ether PBDE 209: Neurobehavioural and neuroprotein analysis in adult male and female mice. Environ Toxicol Pharmacol. 38(2): 570-85. doi: 10.1016/j.etap.2014.08.010).* In toviovic et al. 2014,the behavioral data were analyzed for different individuals from each litter, and litter was the experimental unit, and there was a higher response at higher BDE209 levels for the behavioral tests, and the results were similar at 2 and 4 months of age. In Mariani et al. 2014, prenatal exposure to realistic concentrations (relevant for human exposure) of decaBDE induced impairment of fetal CNS development in mice, suggesting a potential risk of fetotoxicity in humans. According to the authors, such decaBDE levels have been reported for fetuses in USA and could, therefore, represent a possible environmental risk that might assume clinical and social relevance. If compared to the fetal exposure estimated for European children, the effective dose of decaBDE in the experimental mouse model was reported by the authors to be tenfold higher (Mariani et al 2014).  Widespread exposure, and levels of decaBDE in humans and derivation of threshold values:  We agree that “Widespread exposure is not equivalent to, or evidence of, adverse effects”. Our approach consists in presenting information on widespread exposure and assess it in combination with evidence of adverse effects.  As described in the Annex XV restriction report, the available evidence suggests widespread exposure of decaBDE to humans (of all ages). A large number of studies have shown decaBDE to be frequently detected in human blood and breast milk. We do not agree that the plasma level of decaBDE is “exceptionally low”; in many of the studies, decaBDE was in fact the PBDE congener present in highest amounts, particularly in breast milk.  As pointed out DecaBDE meets the definition of a PBT/vPvB substance in accordance with Annex XIII of the REACH Regulation. As described in the Annex XV restriction report (A.2 Targeting page 13), no PNECs or DNELs have been derived, as the risks of PBT/vPvB substances cannot, in general, be assessed quantitatively.  In the case of decaBDE it would however be unjustified to not also present the additional concern that exposure to decaBDE and the lower brominated transformation products (as documented to be formed both through processes in soil and sediments as well as in biota/organisms) may result in neurotoxicity in mammals, including humans.  The Biesemeier study is not appropriate for the purpose of deriving a risk level due to the arguments given in response to comments A.3.1, bullet point two, above. Other RfDs has been derived, e.g. in USEPA (2008) an oral RfD of 0,007 mg/kg bw/d is reported (based on Viberg et al 2003). The doses reported to provide developmental neurotoxicity in the study by Johansson et al. (2008) and Viberg et al.(2003) are comparable to the doses used in the recent Buratovic et al 2014 study where litters were used as the statistical unit. In the recent Mariani et al 2014 study (referred above, not included in the Annex XV restriction report), the authors report that prenatal exposure to realistic concentrations (relevant for human exposure) of decaBDE induced impairment of fetal CNS development in mice, suggesting a potential risk of fetotoxicity in humans. According to the authors, such decaBDE levels have been reported for fetuses in USA and could, therefore, represent a risk of concern that might assume clinical and social relevance. If compared to the fetal exposure estimated for European children, the effective dose of decaBDE in the experimental mouse model was reported by the authors to be tenfold higher (Mariani et al 2014).  Moreover, the widespread distribution of decaBDE in the environment, in biota and in humans creates a high potential for long-term (lifetime) exposure to decaBDE and the lower brominated PBDE transformation products. On the basis of common modes of action and common adverse outcomes, it has been suggested that PBDEs may produce combined developmental neurotoxicity in humans (Kortenkamp et al., 2014). Since decaBDE is a source of toxic, lower brominated PBDEs which also have the capacity to work together with decaBDE to produce combined toxicity, an evaluation of decaBDE in isolation, without taking account of such combination effects, would significantly underestimate the risk of decaBDE.  Absence of decrease in the quantities of environmental levels – link with VECAP:  We do not agree that the fact that no increase is observed in the quantities of the environmental levels is a proof of the efficiency of the VECAP scheme. You also state that decaBDE is used to a lesser extent today than 10 years ago. The incidence in environmental levels observed can be a result of both a decrease in use (which is independent of the efficiency of any emission control system) and the emission reductions due to emission control (by VECAP). Please also note that the emissions calculations included in the Annex XV restriction report estimate the following average contributions to emissions per lifecycle step: production (7%), article service life (87%) and waste (6%). The VECAP scheme does not affect the article service life and waste steps, which added together correspond to an average of 93% of decaBDE emissions. Finally please note that despite low emissions attributed to the waste stage, the long-term emissions potential of decaBDE in landfills is poorly understood, as pointed out in the Annex XV restriction report.  A.3.3 Justification that the proposed restriction is the most appropriate, Union-wide measure, Analogy to mercury:  The comparison with mercury was essentially made in terms of the cost-effectiveness of the proposed restriction when comparing with previous restrictions under REACH (Hg in measuring devices and phenyl-Hg compounds). We have modified the relevant sections in the Background Document to clarify that the cost-effectivness of previous restrictions cannot be used as a benchmark of acceptable cost-effectiveness. Please see reply to comment 1165 above.  C.2.12 Alternative 12: Ethane-1,2- bis(pentabromophenyl) (EBP) Human health information C.2.12.1.1.1 Information from government and other regulatory authority:  The study that you mention (UK Environment Agency’s 2007 “Environmental risk evaluation report: 1,1’-(Ethane-1,2-diyl)bis[penta-bromobenzene”) was reviewed, and is referenced in RPA (2014). |
| **RAC Rapporteurs comments:**  We agree with the comprehensive response by the Dossier Submitter, especially highlighting the absence of decrease in environmental levels. |
| **SEAC Rapporteurs comments:**  We agree with the response of the Dossier Submitter with regard to the use of cost-effectiveness data on mercury in the proportionality assessment of the restriction proposal. Please see also our response to comment 1165. |
| **1199** | **Date:** 2015/01/12 13:30  **Type:** MemberState  **MS name:**  Sweden  **Company name confidential:** **No** | **Comment:**  SE welcomes the proposal for a restriction of deca-BDE and would like to thank ECHA and Norway for their excellent work. The dossier is well-written and easy to follow. However, we have a couple of comments.  Regarding the assessment of alternatives, the alternatives listed in the dossier all have undesirable properties. It is stated in the dossier that only alternatives that are registered under Reach are considered available on the market. The assessment would benefit from the inclusion of alternatives under development and low volume alternatives. If such do not exist, this too would be valuable information. An assessment of alternative techniques would also be desirable.  In context of trying to make the restriction process more efficient (as discussed in RETF), we would like to raise the issue of the size of the dossier. Considering that deca-BDE has been identified as an SVHC and is included in the Candidate List, the comprehensive assessment of PBT/vPvB-properties seems redundant. Would it not be sufficient to refer to the existing SVHC-dossier? |
| **Dossier submitter response:**  Thank you for your comments and support. Please find replies to your comments below.  Assessment of alternatives: the identification of alternative substances included several screening steps. A first screening, using information from the literature and consultation, resulted in the identification of approximately 200 substances. Given the high number of possible alternatives it was necessary to apply further screening criteria in order to reduce their number and more importantly, identify those which are more likely to be used by industry. The following further screening steps were the following: technical feasibility, economic feasibility, hazards and market availability (for details see Annex C.1.2.1 of the Annex XV report and RPA, 2014). Twelve substances were prioritised for further assessment and one extra substance was added to the list based on information received from industry. As reported in the Annex XV report, the shortlisted alternative flame retardants represent a small proportion of all potential alternatives for decaBDE. Finally, it is planned to report in the Background Document, information on alternatives received during the public consultation (see comment no 1170).  For some alternatives, hazard property data are incomplete or uncertain and others are subject to ongoing regulatory scrutiny with regards to their hazardous properties. For the purposes of the Annex XV report, alternatives that appear to be less hazardous than decaBDE based on the available data, but with limited or incomplete hazard information or subject to ongoing regulatory scrutiny, were considered to offer a net reduction in risk relative to the use of decaBDE (see also section C.2.4 of the Annex XV report).  As mentioned in the Annex XV report (see section C.1 of the Annex XV report), the assessment was limited to alternative substances, as this was identified during stakeholder consultation as the most likely industry response, should the use of decaBDE be restricted. Because of that, alternative techniques have limited relevance for the socio-economic analysis, although the possibility that some companies may move to non-chemical alternatives if decaBDE is restricted cannot be excluded (see also Annex C.1.1). Nevertheless, several alternative techniques were briefly described in Annex C.1.1 of the Annex XV report.  Reference to SVHC dossier and assessment of PBT/vPvB properties: the approach followed in the annex XV restriction report was not to re-assess the PBT/vPvB properties but to report new information, generated after the inclusion of decaBDE in the Candidate List. The information identified supports the conclusions reached when decaBDE was identified as SVHC. It would be equally important to report, if the case presented itself, any information that would contradict, or challenge, these conclusions. |
| **RAC Rapporteurs comments:**  We refer to the comments from the Dossier Submitter which gives the reasons for addressing the alternatives in the way the Dossier Submitter has chosen. The opinion is based on the dossier (with the relevant modifications given in the final Background Document). |
| **SEAC Rapporteurs comments:**  We would like to thank SE for the comments. For the benefits of the proposed restriction it would be of high importance that DecaBDE is not replaced by other environmentally harmful substances. We refer to the Dossier Submitter’s and RAC’s assessment in this respect. |
| **1238** | **Date:** 2015/03/10 11:08  **Type:** BehalfOfAnOrganisation  **Org. type:** Trade union  **Org. name:**  European Trade Union Confederation  **Org. country:** Belgium  **Company name confidential:** **No** | **Comment:**  ETUC supports the proposed restriction on DecaBDE. This substance degrades in PBT susbatnces and is also a neurotoxicant. As textile and plastic articles containing DecaBDE are used and imported in all EU countries, action is needed at EU-level.  ETUC is also of the opinion that the proportionality assessment of the proposd restriction should include both environmental and human health benefit aspects.  The proposed restriction should also make sure that recycling of existing articles containing DecaBDE is adressed to miniize this source of DecaBDE entry on the EU market. |
| **Dossier submitter response:**  Thank you for the support. As decaBDE is a PBT/vPvB substance, the proposed restriction is focused on the environmental concern, however human health aspects are also included (qualitative assessment of neurotoxicity) as supplemental information. |
| **RAC Rapporteurs comments:**  Seen from a risk assessment point of view (taking into account the PBT properties) it makes no difference whether or not the substance is used in virgin or recycled materials/articles and this is addressed in the opinion. |
| **SEAC Rapporteurs comments:**  We agree with your comments and the response by the Dossier Submitter. Based on RAC’s view, SEAC has assessed human health aspects of the proposal in a qualitative way. The proposed limit value of 0.1 % does also apply to recycled materials placed on the market. |
| **1241** | **Date:** 2015/03/13 12:08  **Type:** BehalfOfAnOrganisation  **MS name:**  **Org. type:** Industry or trade association  **Org. name:**  **<removed>**  **Org. country:** Belgium  **Company name confidential:** **Yes** | **Comment:**  **<removed>** notes that use of deca-BDE in safety related Aerospace applications is low and in continued decline; estimated to be significantly less than 10 tonnes pa in Europe. However, substitution in all existing applications would be disproportionately difficult.    **<removed>** wishes to question the wording of paragraph 3 of the Conditions relating to the proposed Restriction. This does not allow use in the EU (such as incorporation into new articles) since the derogation applies to paragraph 2 but not paragraph 1. Manufacture of Articles outside the EU, and use of imported articles within the EU are not so affected. **<removed>** therefore requests that Paragraph 3 should refer to both paragraphs 1 and 2.    **<removed>** also requests that Paragraph 3 also has a 4th sub-paragraph to cover defence aerospace applications not covered by civil aviation design approval. It is suggested that the 4th sub-paragraph read “for a military aircraft of a design contracted before [date of entry into force]”. |
| **Answer to specific info request 1:**  NONE |
| **Answer to specific info request 2:**  NONE |
| **Answer to specific info request 3:**  NONE |
| **Dossier submitter response:**  Thank you for your comment. Please find some replies below:  Wording of paragraph 3 of the proposed restriction: this issue was identified in the advice provided to ECHA by the Forum for Enforcement. Following the advice, it is now suggested that the derogation for aviation should include paragraphs 1 and 2 of the proposed restriction.  Defence aerospace applications: Article 2(3) of the REACH regulation states that “Member States may allow for exemptions from this Regulation in specific cases for certain substances, on their own, in a mixture or in an article, where necessary in the interests of defence”. A specific derogation for defence aerospace applications would thus be redundant since such cases are already foreseen by a provision of REACH.  NOTE: similar replies were provided to comment 1245 which referred to the same issues. |
| **RAC Rapporteurs comments:**  We agree with the response made by the Dossier Submitter. |
| **SEAC Rapporteurs comments:**  We agree with the Dossier Submitter and consider the above mentioned derogations will ensure the substitution of decaBDE in the requested aerospace applications without disproportionate costs to industry and undermining the objective of the proposed restriction. |
| **1242** | **Date:** 2015/03/13 13:33  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:**  ACEA - European Automobile Manufacturers Association  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No** | **Comment:**  Manufacturers of service parts for past models require an unlimited exemption on the use of DecaBDE in legacy spare parts. Due to the potentially long service life of these vehicles and the need to ensure that their fire-safety is not compromised. This exemption is also essential to ensuring that industry warranty obligations and legal type approval requirements are fulfilled. The risk of using DecaBDE in legacy spare parts in already low and will further decrease over time due to the low volumes of spare parts manufactured and diminishing demand.  To meet these objections we would propose adding the following derogation to the REACH restriction:  By way of derogation, paragraph 2 shall not apply:  to recycled materials  to automotive vehicles that were Type Approved before Jan 1st, 2020 and spare / replacement parts for these vehicles |
| **Answer to specific info request 1:**  Information provided by our supply base indicate that small amounts of DecaBDE are used in adhesives.  It cannot be verified whether these uses are coming from outside of the EU. |
| **Answer to specific info request 2:**  The recycling of textiles would be negatively impacted by a restriction, as these could contain DecaBDE in concentrations exceeding 0.1%, particularly in automotive NVH applications, where they are not diluted too much with virgin material. |
| **Answer to specific info request 3:**  Substantial costs are not factored in to the current proposals, these include, but are not limited to:  Scrapping of parts on stock. The automotive industry has parts on shelf that contain this substance. Under the current proposals these would need to be scrapped (which makes no sense economically or sustainably).  We are unable to comply with the current proposals. The industry does not have the chemical information for all parts on stock, particularly for parts produced longer than 10 years ago. These parts potentially would need to be scrapped also, as we cannot guarantee compliance, resulting in more ELV's as vehicles will not be able to be maintained / kept running.  The costs of substitution with EBP does not address our industries concern with the current CoRAP process, which could identify EBP to being subject to future authorisations / restrictions, meaning the substitution process would need to be repeated for the substitute. |
| **Dossier submitter response:**  Thank you for your comment, please find some replies below.  General comment: the available information from the transport sector, including the automotive sector, has been assessed during the drafting of the Annex XV report. Although some information gaps were identified, the results indicated the absence of a problem for the automotive sector (see RPA, 2014, section 3.3.8: <http://echa.europa.eu/documents/10162/13641/annex_xvi_consultant_report_decabde_en.pdf>).  Your comments contain two requests for derogation from the proposed restriction. However, the information provided is not sufficient to meaningfully judge the impact of the proposed restriction on the automotive sector and the need for a specific derogation. The DS has contacted the European Automobile Manufacturers Association to obtain clarifications on the information contained in the comment. These clarifications will be reflected in the Background Document.  Derogation for automotive vehicles that were Type Approved before Jan 1st, 2020 and spare / replacement parts for these vehicles: to be able to better understand the consequences of any potential derogation for your sector it is very important to have an idea of the amount of decaBDE that would be derogated, per year, for use in the automobile sector. In addition, the proposed derogation is suggested to last until 2020, which is after the date of the anticipated entry into force of the proposed restriction.  Recycled materials: the proposed restriction limit is considered appropriate to ensure that recycling activities are not negatively affected and at the same time articles and mixtures with high concentrations of decaBDE are not placed on the market. In order to meaningfully assess a need to derogate articles and/or mixtures for recycling, quantitative information is necessary on why the 0.1% limit is not appropriate. |
| **RAC Rapporteurs comments:**  Articles made from recycled materials containing decaBDE 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 . This is addressed in the opinion.  We are surprised to see that alternatives are not available for the use in cars; we consider this to be a technical and economic issue due to the type approval system, but this is not an issue for RAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We consider that sufficient evidence has not been provided to justify the derogation requested by the automotive sector. The justification for this derogation will be re-assessed in the light of any new information to be provided by stakeholders in the Public Consultation on the SEAC draft opinion. |
| **1243** | **Date:** 2015/03/16 13:52  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:**  Allgemeine Unfallversicherungsanstalt  **Org. country:** Austria  **Company name confidential:** **No** | **Comment:**  The US industry was fading out more than one year ago: “Following negotiations with the Environmental Protection Agency, three companies have agreed to phase out production and sale of the brominated flame retardant decabromodiphenyl ether (decaBDE) for most uses within three years.  Albemarle and Chemtura, which produce decaBDE in the U.S., and Israel's ICL Industrial Products (IP), the largest U.S. importer of the chemical, say they will end sales for all remaining "essential uses" by the end of 2013.” (Chemical and Engineering News, Web Date: December 18, 2009)  http://cen.acs.org/articles/87/web/2009/12/Industry-Phase-decaBDE.html  There are a lot of alternatives available on the market as can be demonstrated by the US ban of decaBDE. Thus we strongly support the restriction of this substance. |
| **Dossier submitter response:**  Thank you for your comment and support. The US and Canadian phase out has been reported in the Annex XV restriction proposal (in sections B.2.1, E.1.1 and Annex B.2.1). We agree with the observation that this strongly indicates that alternatives are available for the uses of decaBDE. |
| **RAC Rapporteurs comments:**  We agree with the comments made by the Dossier Submitter. |
| **SEAC Rapporteurs comments:**  We would also like to thank for your comments and the information on alternatives. |
| **1244** | **Date:** 2015/03/16 17:32  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Italy  **Company name confidential:** **Yes**  **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** Protection of commercial interests. | **Comment:**  The main uses of Deca-BDE are in plastics and textiles. In plastics, it is used for electrical and electronic equipment such as personal computers and television sets; in the construction and building sector, it is used in cables, pipes and carpets; and in the transport sector, in automobiles and aircraft.  ABS and HIPS plastics are the two main polymer resins which are used for electric and electronic uses. Deca-BDE is also used in electronic devices such as connectors, plugs and switches.  In textiles, Deca-BDE is used in various types of furniture in order to comply with fire safety standards in public places and with ever more stringent fire safety requirements for the home.  Deca-BDE was added to the candidate list because it is a very persistent substance (Annex XIII criteria), as demonstrated by field studies that show primary degradation half-life in sediments and soils. Furthermore, Deca-BDE is widely detected in many environmental compartments. In conclusion, there is a high probability that Deca-BDE is transformed in the environment to form substances which themselves have PBT/vPvB properties.  Deca-BDE is therefore considered as meeting the definition of a PTB/vPvB-forming substance, in accordance with Annex XIII of the REACH, and thereby article 57(d) and (e).  Imports of Deca-BDE in the EU were estimated in 2012 at 4,133 tonnes, while exports were estimated at 482 tonnes, thus assuming a consumption of 3651 tonnes (source: Eurostat) with main uses in electronic and PS.  If our EU customers are no longer allowed to use Deca-BDE, they will cease to be able to compete in manufacturing outside the EU.  At this time, we are nowhere near an alternative, yet to be developed through research and development, for a feasible and economic substitute to Deca-BDE, without major and expensive changes in the production processes at literally thousands of companies which are currently using Deca-BDE.  The majority of substances which are proposed as substitutes to Deca-BDE in the Annex XV Dossier are quite short of toxicity studies. No animal cancer studies are available and no information on potential human exposure is given.  Furthermore, the substances which are proposed do not appear to meet environmental criteria for persistence and bioaccumulation, as data on toxicity is limited.  Based on the above, there does not appear to be any obvious alternatives to Deca-BDE that are less toxic, persistent and bioaccumulative, and have enough data available for making a robust assessment.  The main alternative proposed in the “Annex XV proposal for a restriction” is Ethane-1,2-bis(pentabromophenyl) (EBP). Although this substance is used in the same material range and at a “similar” price (though 15% higher), Deca-BDE and EBP have very different technical characteristics. For example, they have a different melting point. Furthermore, Deca-BDE and EBP have a very different TGA (Thermogravimetric analysis). Indeed, Deca-BDE loses 10 % (mass) at 349 °C (515 °K) while EBP loses 10 % (mass) at 370 °C (643 °K) with a difference of 21 °C. |
| **Dossier submitter response:**  Thank you for your comment. Please find some clarifications/replies to your comment below.  Uses of decaBDE: please note that decaBDE is included in the restricted substances list of the RoHS Directive, and is not allowed in quantities higher than 0.1 % w/w (see section B.9.1.1 of the Annex XV report). Some of the uses indicated in your comment (for example computers and television sets) seem to fall within the scope of the RoHS Directive.  Eurostat data: data from Eurostat have been reported in RPA (2014). However, these data do not refer specifically to decaBDE, but rather on “brominated derivatives of aromatic ethers”, see also Footnote 4 in section B.2.1 of the Annex XV report. As explained in the Annex XV restriction report, registrations are considered as the most reliable source; however Eurostat data cover a larger time-span and were used to indicate trends. Information on exports is considered as highly uncertain. In the Annex XV report it was mentioned that no re-export of decaBDE from the EU is considered likely to occur in either finished articles, mixtures or the substance (see section B.2.1).  Alternatives: the Annex XV report contains detailed information on a small sub-set of potential alternatives that were identified as the most likely to be used by industry, after a screening exercise (for details on the screening criteria see section C.1 and Annex C.1.2.1). It is correct that information gaps exist for some of the alternatives, and these are clearly highlighted in the Annex XV report, see section C.2.4). Information on an additional alternative was provided during this public consultation (see comment number 1170). Information from the stakeholder consultation carried out during the drafting of the restriction proposal (RPA, 2014) indicates that some actors have already switched to alternatives. US and Canada industries have voluntary phased out decaBDE (see also comment 1243 above). These considerations have led to the following conclusion (please see section A.3.3):  “Alternatives to decaBDE are available on the EU market for all uses. Many are technically and economically feasible and are considered less hazardous than decaBDE, although (for some alternatives) their properties are less well understood than decaBDE.”  Finally, with the exception of the aviation and automotive sectors (see comments 1241, 1242 and 1245) no information on specific uses for which no technically and economically available exist has been submitted in the public consultation, so that they can be assessed for an eventual derogation from the proposed restriction.  Technical characteristics of EBP: our information suggests that EBP is a drop-in alternative to decaBDE (see section C.2.4 and Annex C.2.12.3 of the Annex XV report). It is unclear from your comment how the mentioned differences in technical characteristics affect the technical and economic feasibility of substitution, and for which specific applications this would be relevant. |
| **RAC Rapporteurs comments:**  We agree with the comments made by the Dossier Submitter, and notice that you have mentioned that a number of several thousands of companies will be affected by this restriction which seems rather high as the uses are limited (e.g. no use allowed for articles that fall under the RoHS Directive). |
| **SEAC Rapporteurs comments:**  Thank you for your comment. We agree with the response of the Dossier Submitter. |
| **1245** | **Date:** 2015/03/17 10:33  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  Boeing  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No**    **Attachment confidential:** **Yes**  **<removed>**  **Privacy comment:** Protection of commercial interests would be undermined | **Comment:** |
| **Dossier submitter response:**  Thank you for your comment. Please find some replies below.  1) Use in the EU: this issue was identified in the advice provided to ECHA by the Forum for Enforcement. Following the advice, it is now suggested that the derogation for aviation should include paragraphs 1 and 2 of the proposed restriction.  2) Imported aircraft: according to article 3(12) of the REACH regulation “Import shall be deemed to be placing on the market”.  3) Military and defence aircraft: Article 2(3) of the REACH regulation states that “Member States may allow for exemptions from this Regulation in specific cases for certain substances, on their own, in a mixture or in an article, where necessary in the interests of defence”. A specific derogation for defence aerospace applications would thus be redundant since such cases are already foreseen by a provision of REACH.  NOTE: similar replies on items 1) and 2) above were provided to comment 1241 which referred to the same issues. |
| **RAC Rapporteurs comments:**  We agree with the comments made by the Dossier Submitter. |
| **SEAC Rapporteurs comments:**  We agree with the Dossier Submitter. Please, see also our response to comment 1241. |
| **1246** | **Date:** 2015/03/17 16:48  **Type:** BehalfOfAnOrganisation  **Org. type:** Regional or local authority  **Org. name:**  Flemish Environmental Agency  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment**  **confidential:** **No** | **Comment:**  1. The Flemish region fully supports the proposed restrictions in substances and products for decaBDE. Still, we have some remaining concerns about the current, high concentrations of decaBDE in the sediments in the Flemish region. Flanders always had an intensive textile industry and that is why concentrations in the Flemish fluvial sediments are consistently higher than elsewhere (see included data: measurements of BDE209 in Flanders). When those sediments are used for landfilling, they are currently classified as ‘non hazardous’ and no special protection measures are taken to the environment. Yet, the ECHA states that there can be risks to soil and terrestrial biota. The report also states that the main uptake route of decaBDE is via suspended solid matter , i.e. sediment particles, which can give a risk to humans when sediments are manipulated for landfilling.  For the moment, the European Landfill Directive & the Council Decision 2003/33/EC foresees no technical requirements and procedures for BDE209. Since the pollutant is classified as vPvB, it could be useful to include some supplementary measures for decaBDE in the appropriate legislation. We invite the RAC to emit an opinion on the need for supplementary measures for landfilling with BDE209 containing sediments.    2. In the proposal, an exemption is foreseen for the production, the maintenance and the repair or modification of aircrafts. We have the experience that it is difficult to find Best Available Techniques to remove BDE209 from the waste water. Biological purification is not an efficient treatment and tertiary treatment is a proven but not yet a standard technique in the metal sector. Therefore, we ask the RAC to recommend to Commission to define Best Available Techniques and BAT-AEL’s on an European level for the aviation sector.    3. In the proposal, the concentration of decaBDE in mixtures is limited to 0,1% w/w. In the past, a similar restriction was made for nonylphenol (ethoxylates). In the case of NPE, we saw that this restriction to 0,1% w/w still could lead to 5-10 mg of NPE per litre of released waste water in textiles (see calculation below). This concentration was in some cases not sufficient to attend the very stringent environmental quality standard of 0,3 µg/l in surface water. Could the RAC indicate its opinion specifically on the expected fate of decaBDE from textile (based on the proposed limit) to the Environment. |
| **Dossier submitter response:**  Thank you for your comments and support, please find some replies to each specific comment below.  1. Thank you for providing extensive measurements of decaBDE in fluvial sediments in the Flemish region. Although the highest concentrations seem to have been reported back in 2006, there are high concentrations (of the order of 10 mg/kg dry solid) reported recently (2012). The presence of decaBDE in many environmental compartments has been reported in the Annex XV restriction proposal and these measurements can be used to complement the existing information. Nevertheless, although the proposed restriction aims to control the risks from decaBDE during production, article service life and waste, it does not have the potential to remediate or control risks associated with decaBDE which is already present in the environment. This seems to be the case with decaBDE present in fluvial sediments, which is subsequently removed by canal dredging operations and directed to landfill. It is beyond the scope of this restriction proposal to impose an EU-wide measure for the management of sediment (or other environmental compartments) contaminated with decaBDE. On the other hand, it is expected that if the proposed restriction is implemented and enforced, the measured concentrations in the environment will decrease overtime. It is also beyond the scope of this restriction proposal to recommend alternative disposal operations for decaBDE already present in the environment. Having said that, you may consider alternative ways of waste management, by analogy to the PBDEs currently listed as POPs in the Stockholm Convention (see for example the following publication where advice on the disposal of POP-PBDE-containing materials to landfills is given:  <http://chm.pops.int/Implementation/NIPs/Guidance/GuidancefortheinventoryofPBDEs/tabid/3171/Default.aspx>)  2. It is correct that if the proposed derogation for the aviation sector is implemented, this could lead to emissions from the production of articles (plastics and textiles) to be used in aircrafts, if these articles are produced in the EU. These emissions would occur during the production of these articles from manufacturers (downstream users of decaBDE) that supply the aviation sector. According to the information included in the restriction proposal, the majority of decaBDE emissions are associated with the article service life; it is thus considered that emissions during the production of derogated articles will be very limited. In addition, the derogated uses would fall within the scope of uses identified in registrations. Since decaBDE is identified as a PBT/vPvB, registrants (manufacturers or importers of decaBDE) have already the obligation to apply risk management measures which minimise exposures and emissions. Defining BATs and BAT-AELs could be considered as a means to minimize emissions; however this would necessitate a specific assessment which is out of the scope of the restriction proposal.  3. DecaBDE is expected to adsorb strongly to organic matter in suspended particles, sewage sludge, sediment and soil (SVHC Support Document, Bis(pentabromophenyl) ether, ECHA 2012). Consequently, decaBDE is expected to partition to aquatic sediment rather than surface water. The environmental fate of decaBDE is analysed in detail in the SVHC Support Document and available new information was also included in the Annex XV restriction report (see section B.4 and Annex B.4). Its solubility in water (< 0.1 μg/l, 25 °C, see decaBDE Annex XV report) is four orders of magnitude smaller than NPE (< 4.55 mg/l, 20 °C, see Background Document to the Opinion on the Annex XV dossier proposing restrictions on NONYLPHENOL and NONYLPHENOL ETHOXYLATES). There is no environmental quality standard for decaBDE. With the proposed limit (0.1 % w/w) all emissions from intentional use of decaBDE in plastic and textile articles are expected to cease (since it is not efficient as flame retardant at such low concentrations). Only emissions from derogated uses (e.g. in the aviation sector) will continue. These emissions are expected to be very low (if use in the aviation sector is about 1-10 tonnes per year, see also comment 1241 above, emissions from the whole lifecycle are estimated at 1-10 kg per year, using an overall emission factor (for all lifecycle steps) of 0.1%. Please note that these figures are provided here only to give an idea of the order of magnitude of the expected emissions from derogated uses). |
| **RAC Rapporteurs comments:**  We agree with the comments made by the Dossier Submitter, also highlighting the very high uncertainties if we were going to calculate the emissions from use of decaBDE in textiles as there are no reliable figures for this specific use. The limit value of 0.1 % will ensure that there is no further intentional use in textiles, since a much higher amount is needed for flame retardancy. Any decaBDE present in textiles following the introduction of the restriction will therefore be the result of unintentional contamination. On that basis, we consider this potential source to be insignificant. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. We have no further comment and refer to the Dossier Submitter response. |
| **1247** | **Date:** 2015/03/17 17:29  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:**  European Environmental Bureau (EEB)  **Org. country:** Belgium  **Company name confidential:** **No**  **Attachment confidential:** **No** | **Comment:**  The EEB supports the restriction of DecaBDE submitted by the European Chemicals Agency.  We would like to provide additional information on the human health adverse effects of DecaBDE. DecaBDE is an endocrine disrupter that interferes with thyroid hormone signaling and the regulation of brain cell growth and brain connectivity during foetal development. Adverse effects include neurological disorders and lower mental development scores in small children. As an endocrine disrupter DecaBDE should also be considered a non threshold substance.  The EEB would like to explain why derogation should not be granted to recycling decaBDE as well as to provide additional information on potential alternatives.  Human health adverse effects  The proposal submitted by Norway to list DecaBDE in Annexes A, B and/or C to the Stockholm Convention on Persistent Organic Pollutants includes a review of its adverse effects:  36. Adverse effects of decaBDE to mammals have largely been investigated in controlled laboratory studies with captive organisms, mainly rodents, and have been the topic of several scientific reviews and government assessments (e.g. EC 2002, EC 2008, US EPA 2008, Costa and Giordano 2011, Dingemans et al. 2011, Health Canada 2006, Health Canada 2012, EFSA 2011). Data on adverse effects resulting from decaBDE exposure in mammals is also underpinned by in vitro studies, which provides evidence that decaBDE induces similar cellular effects as other PBDEs (Health Canada 2012). Amongst others a potential to elicit neurotoxic effects, act as an endocrine disruptor of steroid and thyroid hormone regulated processes, promote cancer, induce DNA damage, and affect metabolism has been identified in vitro (Ibhazehiebo et al. 2011, Li et al. 2012, Pellacani et al. 2012, Dingemans et al. 2011, Pacyniak et al. 2007, Karpeta and Gregoraszczuk 2010).  37. Apparently, the fetal/ neonatal nervous system, the liver and the thyroid hormone axis are the primary targets for decaBDE toxicity in rodents (Costa and Giordano 2011, Dingemans et al. 2011, Health Canada 2012). Although decaBDE appears to have low acute toxicity when given by the oral, inhalation and dermal route, available mammalian toxicology data indicates that long-term exposure could result in adverse effects similar to those observed for other PBDE congeners (see e.g. Costa and Giordano 2011, Dingemans et al. 2011, Health Canada 2010). Rodent studies have for example demonstrated that decaBDE may act as an endocrine disruptor of the thyroid hormone system (see e.g. Dingemans et al.2011, Costa and Giordano 2011 for review). In rodents, decaBDE exposure can also result in decreased immune function during pregnancy and lactation (Zhou et al. 2006, Liu et al. 2012), can compromise the organisms ability to cope with infections (Watanabe et al. 2008, Watanabe et al. 2010) and negatively affect reproductive parameters such as the number of follicle- and sperm cells (Liu et al. 2012, Miyaso et al. 2012, Tseng et al. 2006).  38. The thyroid disrupting potential of decaBDE in mammals have been the subject of several reviews/ assessments (e.g. EFSA 2011, Dingemans et al. 2011, Costa and Giordano 2011), and is considered to be of concern given that decaBDE through its interaction with the thyroid hormone system can act as neurotoxicant of the developing brain (see reviews by Dingemans et al. 2011, Costa and Giordano 2011). DecaBDE may also exert a number of direct effects on brain cells that can compromise brain function and integrity (Costa and Giordano 2011, Dingemans et al. 2011). Animal studies investigating the developmental neurotoxicity of decaBDE have reported a broad spectrum of effects ranging from no observed effects to alterations in e.g. spontaneous and cognitive behaviors, learning, memory, locomotor activity, rearing activity, reflexes and habituation following decaBDE exposure (see US EPA 2008, Dingemans et al. 2011, Costa and Giordano 2011, Health Canada 2012; and references therein). In rodents neurobehavioral effects during juvenile development or adulthood have been observed after a brief postnatal exposure to decaBDE (Johansson et al. 2008, Viberg et al. 2007, Viberg et al. 2003, Rice et al. 2007). In mice, aging appears to unmask behavioural effects not evident at a younger age (see e.g. Rice et al. 2009 and reviews by Health Canada 2012 and Costa and Giordano 2011 and references therein). Although the notion that decaBDE may be a developmental neurotoxicant has been contested (e.g. Hardy et al. 2009, Goodman 2009, Williams and de Sesso 2010), the weight of evidence of available in vitro and in vivo data altogether indicates that decaBDE has the potential to induce neurotoxic effects in mammals exposed to decaBDE during early stages of development (see reviews by Dingemans et al. 2011, Costa and Giordano 2011, Health Canada 2012).  39.Worldwide, humans of all ages are daily exposed to decaBDE via environmental media and a range of food stuffs, including mother's milk (see Costa and Giordano 2011, Health Canada 2012, EFSA 2011 and references therein). In Europe decaBDE along with BDE-47 is the predominant PBDE congener in food (EFSA 2011). In adults, household dust and occupational exposure is thought to be the main sources of decaBDE exposure (Costa and Giordano 2011). Dust will also be a major source of decaBDE for toddlers which have a higher tendency to transfer house dust particles from their hand to their mouth. Further, for infants mouthing of hard plastic toys can be an additional exposure route (Health Canada 2012).  40. The observation that exposure takes place already during the early phases of human development i.e. in utero via placental transfer or postnatally via mothers’ milk (Gomara et al. 2007, Kawashiro et al. 2008, Wu et al. 2010, Miller et al. 2012), proposes that the developmental neurotoxicity observed in mammalian models could have implications also for humans (Health Canada 2012, US EPA 2008, EFSA 2011, Costa and Giordano 2011). However, although PBDEs share structural similarities with other environmental pollutants such as polychlorinated biphenyls (PCBs) and organochlorines, investigation into the toxicity and carcinogenicity of decaBDE in humans remains surprisingly limited (for overview see e.g. US EPA 2008, Health Canada 2012, Health Canada 2006). Yet, evidence is slowly emerging that BDE-209 either alone or in concert with other PBDEs could act as a developmental neurotoxicant and possibly play a role as a risk factor in human disease (e.g. Dingemans et et al. 2011, Messer et al. 2010, Kicinski et al. 2012, Costa and Giordano 2011, Health Canada 2012, Health Canada 2006, Gascon et al. 2012, Chao et al. 2011). Effects of decaBDE on thyroid hormone signaling, a major timing factor for the precise regulation of brain cell growth and brain connectivity, has for example been proposed as a factor that could contribute to human neurological disorders such as autism (Messer 2010). In a recent epidemiological study assessing the linkage between PBDE levels in breast milk and neurophysiological development in infants decaBDE was significantly correlated with lower mental development scores in children 12-18 months of age (Gascon et al. 2012). The observation of a correlation between decaBDE exposure levels and lower mental development scores found in this study are consistent with results previously reported by Chao et al. (2011). Gascon et al. (2012), but not Chao et al. (2011), also reported a negative, but non-significant correlation between the total sum of PBDEs in breast milk and mental test scores (Chao et l. 2011, Gascon et al. 2012). In this context is also worth noting that epidemiological data 10UNEP/POPS/POPRC.9/2 indicating an association between PBDE exposure at early age and neurodevelopmental toxicity have also been reported for lower brominated PBDEs (Roze et al. 2009, Herbstman et al. 2010, Gascon et al. 2011, Kicinski et al. 2012).  41. Risk characterizations of decaBDE conducted by Health Canada (2012) and US EPA (2008), have suggested that the daily intake of decaBDE in the United States and Canada at present is not likely to result in neurodevelopmental toxicity even for the potentially most highly exposed and sensitive age group, infants. A similar conclusion was reached by European Food Safety Authority Panel on Contaminants (EFSA 2011). However, neither risk assessment take into account the potential risk that PBDEs could act in concert to induce additive or synergistic effects as suggested by the available in vitro data (e.g. Pellacani et al. 2010, Tagliaferri et al. 2010, Llabjani et al. 2010, Karpeta and Gregoraszczuk 2010, Hallgren and Darnerud 2002, He et al. 2009). In this context it is worth noting that the recently published WHO/ UNEP report on endocrine disruptors concludes that endocrine disruptors can work together to produce additive effects, even when combined at low doses that individually do not produce observable effects (WHO/UNEP 2012). Moreover, as pointed out by Health Canada (2012), the assessment of human health risks is limited by a scarcity of inhalation and/or dermal exposure data as well as by insufficient data on toxicokinetics of decaBDE in humans.  Lastly additional risk factors were also not considered. Iodine deficiency, a common condition worldwide (reviewed by Walker et al. 2007), is said to increase the sensitivity to adverse effects from thyroid-disrupting chemicals such as decaBDE (Dingemans et al. 2011). Conclusion on adverse effects according to the criteria in Annex D.  42. The weight of evidence of available toxicity data shows that decaBDE alone and/ or in concert  with its debromination products have the potential to damage human health and/or the environment.  Recycling decaBDE  In our view, the proposed restriction is the most effective risk management option to control exposure to deca BDE and recycling deca BDE shall not be exempted from the proposed restriction.  The EEB supports recycling materials as long as the final product doesn’t contain substances with unwanted properties. If recycled materials contain a substance of very high concern, the problem of continued emission in the environment would be perpetuated. The goal of reducing exposure to PBT substances (which is one of the main objectives of the REACH regulation) would not be met, as well as the EU 7th Environmental Action Programme’s goal for the non toxic environment and goals for hazardous substances and waste:  (viii) fully implementing Union waste legislation. Such implementation will include applying the waste hierarchy in accordance with the Waste Framework Directive and the effective use of market-based instruments and other measures to ensure that: (1) landfilling is limited to residual (i.e. non-recyclable and non-recoverable) waste, having regard to the postponements provided for in Article 5(2) of the Landfill Directive; (2) energy recovery is limited to non-recyclable materials, having regard to Article 4(2) of the Waste Framework Directive; (3) recycled waste is used as a major, reliable source of raw material for the Union, through the development of non-toxic material cycles; (4) hazardous waste is safely managed and its generation is reduced; (5) illegal waste shipments are eradicated, with the support of stringent monitoring; and (6) food waste is reduced. Reviews of existing product and waste legislation are carried out, including a review of the main targets of the relevant waste directives, informed by the Roadmap to a Resource Efficient Europe, so as to move towards a circular economy; and internal market barriers for environmentally-sound recycling activities in the Union are removed. Public information campaigns are required to build awareness and understanding of waste policy and to stimulate a change in behaviour;  Also, Director-General of the European Commission, Mr. Karl FALKENBERG stated at the European Parliament-ENVI committee that: "The new proposal, to be tabled this year, will address the problem of toxic materials inhibiting recycling, with the goal of producing higher quality secondary raw materials. It will also seek to promote repair."  In order to develop non-toxic material cycles, toxic substances (especially substances of very high concern such as deca BDE has to be removed in production in the first place. Therefore, restriction under REACH Regulation is an important measure to take.  Moreover, the presence of SVHC substances (including deca BDE) in materials to be recycled will make responsible recycling of electronics more expensive and difficult. If deca BDE is exempted for reclycling, recyclers would face a serious problem when recycling materials that contain SVHC since they would have to test the articles as they don’t want SVHC in their final products and this is affecting their reputation and an exemption for restriction would cause a substantial economic impact that should be taken into consideration.  Finally, hazardous legacy is an obstacle to quality recycling needed for the circular economy. The EU needs to avoid re-injection in the economic cycle, even if to start with this may limit recyclability of contaminated material (that can then be burnt in specific incinerators from which heat recovery could be considered).  This is in line with prevention first (no more hazardous substances in materials), before recycling.  Potential alternatives  Paxymer® flame retardant system is a patented technology that works synergistically with existing halogen-free technologies to boost material functionality, processability and fire performance. No components of the Paxymer flame retardant system are classified as hazardous.  The technology replaces all halogenated flame retardants in polyolefin plastics (PP, PE, EVA etc). It works both synergistically with current technologies such as phosphorous/nitrogen (P/N) systems and mineral hydrate systems and as a stand-alone system formulated with P/N base and the synergistic functionality.  Paxymer® is already implemented in a number of applications for various plastic processes. Proven processes are within injection moulding, calendaring, blow moulding and extrusion. Applications of flame retardant polyolefin plastics where Deca-BDE has ben widely used are found in builing, transportation and EEE industries.  The company states:  Costs of current generation of products are <12$/kg for the masterbatch (highly concentrated product for dilution by the compounder or converter). No additional environmental or health costs since all polyolefin materials containing Paxymer as flame retardant can be used for energy recovery because combustion of the Paxymer flame retardant system does not require any flue gas purification and polyolefins in general have very high fuel values. This simplifies waste handling problems. The system is also recyclable as it is stable at processing temperatures.  Efficacy: The alternative is developed for polyolefin plastics. It has excellent, proven performance in PP and PE. Development efforts within rubber (EPDM), TPE and EVA materials are ongoing with optimistic results.  Addition levels of the stand-alone product to achieve UL94-V0 are on par with DecaBDE and antimonytrioxide (synergist used with DecaBDE) and range between 25-32%. For conduits, wood polymer composites and building products lower addition levels have shown sufficient fire performance. Depending on the fire standard, addition levels of between 15-25%. The synergistic system (especially with mineral based systems) has recommended dosage levels of 2-8% depending on the base material, (additional flame retardant systems and base material). Moreover, addition of Paxymer reduces mineral levels in the formulations to achieve the same fire properties.  Mechanical properties and processability is maintained due to the systems excellent compatibility with the base polymer. The system is proven in blow moulding, injection moulding, extrusion and calendaring. Development projects are currently undertaken on thinner goods material including film blowing and fibre spinning.  Risk: The product has been subject to two main tests for verification of non-hazardous performance: (1) Chemical screening conducted by Environment Agency of Austria in the POPs-free pilot project. Test protocol available upon request. (2) Environmetal assessment conducted by Jegrelius institute for applied chemistry with the conclusion that “Paxymer has a place in a sustainable society” [Available online through company webpage: www.paxymer.se]  Other references for risk: Environmental risk assessment of Octa- and Decaromodiphenyl ether, S. Dungey (2001) The second international workshop on Brominated flame retardants at Stockholm University.  Combustion of brominated flame retardants (2001) Söderström, G. & Marklund, S. The second international workshop on brominated flame retardants at Stockholm University. Several presentations in this proceeding deals with the risks related to the use of BFR´s, including Deca BDE, as flame retardant.  Further information can be found at: http://paxymer.se/ |
| **Answer to specific info request 2:**  In our view, the proposed restriction is the most effective risk management option to control exposure to deca BDE and recycling deca BDE shall not be exempted from the proposed restriction.  The EEB supports recycling materials as long as the final product doesn’t contain substances with unwanted properties. If recycled materials contain a substance of very high concern, the problem of continued emission in the environment would be perpetuated. The goal of reducing exposure to PBT substances (which is one of the main objectives of the REACH regulation) would not be met, as well as the EU 7th Environmental Action Programme’s goal for the non toxic environment and goals for hazardous substances and waste:  (viii) fully implementing Union waste legislation. Such implementation will include applying the waste hierarchy in accordance with the Waste Framework Directive and the effective use of market-based instruments and other measures to ensure that: (1) landfilling is limited to residual (i.e. non-recyclable and non-recoverable) waste, having regard to the postponements provided for in Article 5(2) of the Landfill Directive; (2) energy recovery is limited to non-recyclable materials, having regard to Article 4(2) of the Waste Framework Directive; (3) recycled waste is used as a major, reliable source of raw material for the Union, through the development of non-toxic material cycles; (4) hazardous waste is safely managed and its generation is reduced; (5) illegal waste shipments are eradicated, with the support of stringent monitoring; and (6) food waste is reduced. Reviews of existing product and waste legislation are carried out, including a review of the main targets of the relevant waste directives, informed by the Roadmap to a Resource Efficient Europe, so as to move towards a circular economy; and internal market barriers for environmentally-sound recycling activities in the Union are removed. Public information campaigns are required to build awareness and understanding of waste policy and to stimulate a change in behaviour;  Also, Director-General of the European Commission, Mr. Karl FALKENBERG stated at the European Parliament-ENVI committee that: "The new proposal, to be tabled this year, will address the problem of toxic materials inhibiting recycling, with the goal of producing higher quality secondary raw materials. It will also seek to promote repair."  In order to develop non-toxic material cycles, toxic substances (especially substances of very high concern such as deca BDE has to be removed in production in the first place. Therefore, restriction under REACH Regulation is an important measure to take.  Moreover, the presence of SVHC substances (including deca BDE) in materials to be recycled will make responsible recycling of electronics more expensive and difficult. If deca BDE is exempted for reclycling, recyclers would face a serious problem when recycling materials that contain SVHC since they would have to test the articles as they don’t want SVHC in their final products and this is affecting their reputation and an exemption for restriction would cause a substantial economic impact that should be taken into consideration.  Finally, hazardous legacy is an obstacle to quality recycling needed for the circular economy. The EU needs to avoid re-injection in the economic cycle, even if to start with this may limit recyclability of contaminated material (that can then be burnt in specific incinerators from which heat recovery could be considered).  This is in line with prevention first (no more hazardous substances in materials), before recycling. |
| **Dossier submitter response:**  Thank you for the support and comments. Please find some clarifications/replies to your comments below.  Endocrine disrupting effects of decaBDE: endocrine disruption is included as a potential concern in the Annex XV proposal (see Annexes B.5 and B.7.1). Please note that as decaBDE is identified as a PBT/vPvB, it is in any case considered as a non-threshold substance.  Information from the proposal by Norway to list decaBDE to the Stockholm Convention: in order to explore potential synergies between the Stockholm Convention process and the Restriction process and avoid duplication of work, ECHA has collaborated with the Norwegian Environment Agency throughout the drafting of the restriction proposal but also during the opinion making. Norway has authored the sections on human health and exposure (among others) in order to use all the experience gained and information gathered during the Stockholm Convention process. In consequence, the information generated by the Stockholm Convention process has been taken into account in the drafting of the Annex XV restriction proposal.  Potential alternatives: this information reinforces the conclusion that technically and economically feasible alternatives are available in the market. The company that produces the alternative mentioned in your comment has also submitted information in this public consultation (see comment no 1170). This information will be taken into account in the final Background Document.  Recycling: As highlighted in the Annex XV report the proposed restriction is not intended to negatively affect recycling activities (see section E.1.4.2). On the other hand, the concentration limit of 0.1 % w/w is proposed to ensure that articles (made from recyclate or not) with high concentrations of decaBDE will not be placed on the market. There was no specific derogation for recycling foreseen, as the 0.1 % w/w limit was proposed as being fit for purpose for both virgin and recycled materials (see section E.2.1.2.2). During the public consultation two companies provided comments related to recycling (see comments 1170 and 1242), however no comments from recycling companies were received. |
| **RAC Rapporteurs comments:**  We agree with the comments made by the Dossier Submitter, also recognising the comments made on the endocrine disrupting properties and the focus on the PBT/vPvB properties in this restriction proposal. |
| **SEAC Rapporteurs comments:**  We would like to thank for your comments. With regard to decaBDE in recycled materials, we agree with the response by the Dossier Submitter and consider that there will be no significant economic impact of the proposed on the recycling of materials, which would justify a derogation for recycling. |
| **1248** | **Date:** 2015/03/17 19:47  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:**  **<removed>**  **Org. country:** Belgium  **Company name confidential:** **Yes**  **Attachment confidential:** **No** | **Comment:**  Following the initial comments on the restriction dossier we would like to address some additional points of the registration Dossier. The comments are attached in a document file as references are quoted there.  They refer to the following chapters of the restriction report:  A.3. Summary of the justification (p. 12), B.4.4 Bioaccumulation and transformation  A.3.1 Identified hazard and risk  B.4.4 Bioaccumulation and transformation  B 4.4.2 p. 20 and B.5.1 Toxicokinetics p. 20-21  B 5.2.1 p. 21 Developmental toxicity  B.5.2.2 Other reproductive toxicity (p. 24)  B.8.2 Emission Characterisation  B. 11 Summary of Hazard and Risk p. 36  E.1.1 Risks to be addressed – the baseline |
| **Answer to specific info request 1:**  To the best of my knowledge these uses do not play a role. |
| **Dossier submitter response:**  Thank you for this detailed review of the Annex XV restriction report. Please find some clarifications/replies to your comments below.  A.3. Summary of the justification (p. 12)/ A.3.1 Identified hazard and risk:  The Annex XV restriction report reads (section A.3.1/ last bullet):  “The widespread distribution of decaBDE in the environment and in humans creates a high potential for long-term (lifetime) exposure to decaBDE and lower brominated PBDE (Polybrominated diphenyl ether) transformation products.”  Related to the lower brominated PBDEs, in your comment you seem to indicate that in order to justify the above conclusion, we need to observe (in the environment or biota) the same or similar trends in the concentrations of the now banned POP PBDEs, that were observed prior to the ban. This could be then interpreted as proof that decaBDE debrominates in the environment. However, this is not what is claimed in the above extract. In general, nowhere in the report is it claimed that decaBDE is assumed to debrominate in the environment and biota to such an extent so as to replace the concentrations in lower brominated congeners observed in the past in the environment and biota. In addition, please note that a new section (B.9.4 “Degradation and transformation”) has been added in the Background Document to place additional emphasis on these issues. For details, please see reply to comment 1172 above.  The decrease in environmental concentrations of the lower PBDEs as shown in a number of studies (as referred on page 1 and 2 of 9) is expected due to restrictions at EU-level and globally of the previous High Production Volume commercial penta- and octaBDE products. The current levels and continued release of lower PBDEs from products still in use (e.g. in articles) might mask low levels of formation of these congeners from decaBDE.  Environmental monitoring of "markers" for debromination (congeners not present in the commercial mixtures) is therefore a more useful tool to detect environmental debromination of DecaBDE. As part of an Industry-funded ten-year monitoring programme in response to Commission Regulation (EC) No. 565/2006 the congener,3’,4,4’,5- pentaBDE (BDE-126) was specifically chosen as a representative marker for abiotic decaBDE degradation and had not been detected in commercial PBDE products up to the point of its inclusion in the monitoring suite in 2006. (ECHA Support Document, 2012). The results of the first six sampling years has been reported (H. A. Leslie, J.L. Barber, J. de Boer, 2012). BDE 126 was detected in sediment sampling sites, but not in all sampling years and generally at low levels (above LOD but below LOQ). BDE-126 was detected in sewage sludge samples at both sampling locations at low levels in 2007 and 2009 only. BDE-47 was the most abundant congener in sewage sludge, followed by BDE-99, 100, 153, 183, 28 and 126. BDE126 was detected in both sparrowhawk eggs (in 2010) and glaucous gull eggs (in 2009, 2010).  The environmental levels are low, but if the BDE-126 is derived from decaBDE, higher molecular weight PBDE congeners would also be present as intermediate degradation products, and it is likely that other pentaBDEs would also be formed through competing reactions. (ECHA Support Document, 2012).  Another congener considered to be marker of debromination of decaBDE is BDE 202. The publication Kim et al 2013 (referred on page 2 of 9, eight paragraph) does not suggest no debromination of BDE-209, but minimal debromination. However, according to the Authors of the study: "In order to acquire more information about potential debromination during sludge treatment, BDE-202 was analyzed as well. BDE-202’s presence is an indicator of debromination because it is not present in any PBDE commercial mixtures. In our study, BDE-202 was detected in 41 of 75 sludge samples, at concentrations up to 3.3 ng/g and was also detected in four of 30 influent samples at levels of 160 63 pg/L."  Many of the publications reported in your comment, attribute the stabilising or decreasing trend of the POP PBDEs as the result of regulation and in addition provide evidence of debromination of decaBDE. For example, Gauthier et al (2008) states that there was no increasing trend in congeners derived from pentaBDE and octaBDE mixtures. It also states that “The source of the octa and nona-BDE congeners, e.g., BDE-207 and BDE-197, are the result of BDE-209 debromination, and they are either formed metabolically in Great Lakes herring gulls and/or bioaccumulated from the diet and subsequently transferred to their eggs”.  Please note that the reference number 3 provided in your comment seems to be incorrect, as the publication does not study PBDEs. The correct publication is the following one:  Robin J. Law, Colin R. Allchina, Jacob de Boerb, Adrian Covacic, Dorte Herzked, Peter Lepome, Steven Morrisa, Jacek Tronczynskif and Cynthia A. de Witg (2006), Levels and trends of brominated flame retardants in the European environment. Chemosphere 64, 2, 187 – 208  The publication reports a peak in the concentrations of one tetra- and two penta- BDEs in archived freeze-dried mussels from the Seine estuary, which occurs between 1999 and 2001, followed by a return to the levels of the years 1990 – 1995. This publication also contains a review of other publications containing information related to the debromination of decaBDE in the environment and biota.  B.4.4 Bioaccumulation and transformation  B.4.4.2 p. 20 and B.5.1 Toxicokinetics p.20-21  We do not agree with the conclusions reached in the comment regarding the bioaccumulation and transformation of decaBDE. Please find some detailed replies below:  Page 3 of 10:  A detailed description of the Letcher et al. (2014) study is given on page 156 in the Annex XV report; "The mean decaBDE level in plasma was 1474 ng/g wet weight at the end of the uptake period, and dropped by 88% after the 25 day depuration period. This results in a decaBDE half-life in plasma of approximately 14 days."  The text on page 20 could accordingly be slightly corrected to; "Letcher et al. (2014) report a half-life of decaBDE of approximately 14 days in the blood plasma of male kestrels (Falco sparverius) exposed in the laboratory to decaBDE."  Since the different congeners have different depuration rates and distribution between the different tissues (and no samples from lipid or liver tissue were taken directly after the exposure), it is not possible to draw conclusions on the actual biotransformation kinetics of decaBDE in this study. Based on the available information, however, the Authors estimated that at least 80% of the non-decaBDE concentration in the kestrel tissues and plasma originated from decaBDE debromination by the kestrels.  Page 5 of 10, bullet point 2:  Minor note: since Wang 2010 administrated 100 mg/kg bw/day of BDE-209 with ≥99% purity (see Supplementary info of that study) for 90 days, the cumulative dose of impurities could not have exceeded 90 mg/kg bw (in bullet point number 2 it is claimed that the level of impurities administered would have reached 178 mg/kg bw).  Page 5 of 10, bullet point 3:  Other studies than Biesemeier et al 2010 show no uptake saturation above 10 mg/kg bw/day. E.g. Wang 2011 repeatedly administrated BDE-209 (0, 10, 50 mg/kg bw/day) in male rats over 90 days and found that levels of BDE-209 in multiple tissues (e.g. kidney, liver and adipose) were much higher at 50 than at 10 mg/kg bw. Even higher levels were found in these tissues at 100 mg/kg bw/day (Wang 2010). Furthermore, recent studies show increased neurodevelopmental effects with increasing doses above 10 mg/kg bw (e.g. Buratovic et al 2014; 0, 1.34, 5.76, 13.4 mg/kg bw; Rice et al 2009; 0, 6, or 20 mg/kg decaBDE; Mariani et al 2014; 0.3, 3, 30 mg/kg).  Page 5 of 10, 1st paragraph after bullet point 5:  Several **rodent** studies in addition to Huwe & Smith, 2007 and Riu et al. 2008 have demonstrated metabolism of decaBDE into lower brominated congeners (F. Wang et al., 2010; Cai et al., 2012) and decaBDE is most likely biotransformed to lower brominated congeners in humans as well. However, it is still not clear by which rate decaBDE is metabolized in mammals, where the metabolism occurs and what the identity of all metabolites are.  Page 5 of 10, last bullet point:  The study on juveniles, Noyes et al, 2011, reported that ~5.8% of the BDE-209 exposure was estimated to be bioavailable to juvenile fathead minnows in this study based on the suite of metabolites identified. The potential influence of lower brominated congeners present as contaminants in food was investigated and excluded. The cumulative BDE-209 exposure over the 28-day exposure was estimated to be ~0.45 nmol per fish (or ~429 ng of BDE-209 per fish), and the summed metabolites detected at day 28 were ~0.026 nmol per fish ((0.026 nmol per fish / 0.45 nmol per fish) \* 100 = 5.8%). The value of ~0.006% stated in the comments for the metabolism of the cumulative exposure of BDE-209 by fathead minnow could only be obtained by erroneously dividing the cumulative exposure expressed in ng w/w by the summed metabolites expressed on a molar basis. The authors do not include the accumulation of BDE-209 itself in their calculations. Where molar concentrations of BDE-209 and metabolites in fish are both included in calculations the percentage of cumulative exposure of BDE-209 accumulated in fathead minnow is ~8.75%. The authors concluded that BDE-209 was readily metabolised by juvenile fathead minnow to lower PBDE congeners dominated by penta- to octaBDEs. The BDE-179, BDE-188 and BDE-202 octa-congener was detected in this study and since these congeners is normally not present in the commercial products it is usually interpreted as a specific marker for debromination. Additional calculations made by the Dossier Submitter indicate that >60 % of total PBDEs (based on molar concentrations) in fathead minnow after 28 days are present as metabolites, supporting the author’s conclusions on the extent of metabolism occurring after accumulation (see section B.9.4 Degradation and transformation and Annex B.4.4.1.2.2 Fish).  In another study (Noyes et al, 2013) higher concentrations of BDE-202 (3400 ng/g lw), BDE-188 (7400 ng/g lw), BDE-179 (5900 ng/g lw) and BDE-154 (14000 ng/g lw) than of BDE-209 (2700 ng/g lw) were measured in fish after 28 days exposure of adult Fathead Minnow to decaBDE (97% purity), 300 ng/g. The study showed increasing formation of BDE-209 debromination-products over time.  Finally, it is important to stress both the longer timescales applicable in real environmental conditions, compared to the time scale of the laboratory experiments and also the diversity concerning the ability of different species to debrominate decaBDE. "While most vertebrates appear to be able to degrade BDE-209 to lower brominated PBDEs, different species may have different ability to debrominate BDE-209, with  debromination occurring more rapidly and to a greater extent in some species than in others (McKinney, 2011)."  Page 6 of 10 and Table 1 last row:  Related to the Noyes 2011 study, your comment states that "Only 1 congener in above 0.006% listed as POP: BDE 154."  Please be aware that in the SVHC Support Document, that was the basis for the MSC decision on decaBDE, there is a sperate assessment (in Appendix 1) of the PBT profile of PBDEs other than decaBDE, which concludes that:  •TetraBDE congeners meet the PBT and vPvB criteria.  •PentaBDE congeners meet the PBT and in some cases the vPvB criteria.  •HexaBDE congeners meet the PBT and in some cases the vPvB criteria.  •HeptaBDE congeners meet the vP and T criteria. They do not appear to meet the B or vB criteria based on an estimated fish BCF, but the balance of available evidence suggests that they can be considered to be B. HeptaBDEs are therefore considered to be a PBT substance.  Consequently, the statement that "Only 1 congener in above 0.006% listed as POP: BDE 154.", is therefore not that relevant in the REACH-context, but please be also aware that according to the legal text in the SC POPs convention, it is not only the congeners listed by specific congener nomenclature that is covered by this entry, note that the convention text reads:  “Hexabromodiphenyl ether and heptabromodiphenyl ether” means 2,2’,4,4’,5,5’-hexabromodiphenyl ether (BDE-153, CAS No: 68631-49-2), 2,2’,4,4’,5,6’-hexabromodiphenyl ether (BDE-154, CAS No: 207122-15-4),2,2’,3,3’,4,5’,6-heptabromodiphenyl ether (BDE-175, CAS No: 446255- 22-7), 2,2’,3,4,4’,5’,6-heptabromodiphenyl ether (BDE-183, CAS No:207122-16-5) **and other hexa- and heptabromodiphenyl ethers present in commercial octabromodiphenyl ether"** (emphasis added).  And likewise:“Tetrabromodiphenyl ether and pentabromodiphenyl ether” means 2,2’,4,4’-tetrabromodiphenyl ether (BDE-47, CAS No: 5436-43-1) and 2,2’,4,4’,5-pentabromodiphenyl ether (BDE-99, CAS No: 60348-60-9) **and other tetra- and pentabromodiphenyl ethers present in commercial pentabromodiphenyl ether."** (emphasis added).  Page 7 of 9, table 1, Huwe and Smith 2007:  In the comments it is referred to BDE 207, 208 and 197 as the congeners that were recovered in higher amounts than the given dose, while the authors report that it was at least BDEs-197, -201, and -207 that were recovered in higher amounts than it could be accounted for by their presence in the dose.  Page 7 of 9, table 1, Riu et al., 2008:  The purity of the DecaBDE that was used is 99.8%.  B5.2.1 p 21 Developmental toxicity  page 7 and 8 of 9:  Comments to Biesemeier et al 2010 and 2011: it is correct that these studies conclude that decaBDE is not a developmental neurotoxicant up to 1000 mg/kg bw. However, as noted in the Annex XV restriction report, the Biesemeier et al 2011 study has been critically evaluated by several authors; Shibutani et al. (2011) noted the omission of measurement of thyroid-related effects, histopathological parameters on neuronal migration, oligodendroglial development, neglection of the significant decreases in the hemisphere height and decrease in the pons and cortex vertical thicknesses. The Biesemeier study has also been discussed in the Health Canada (2012) report and Fowles and Morgott (2013). The limitations listed were that the numbers of pups found dead were higher in the 100 and 1000 mg/kg bw/day groups than in the control group, and several other treatment-related effects were observed at 1000 mg/kg bw/day (number of missing pups was increased, some of the motor activity parameters showed significant differences at 6 months in both sexes and a few of the brain morphometric analyses were significantly different at PND 21 in males and females and at PND 72 in males). Although Biesemeier et al. (2011) claimed that these effects were within historical control values and an increased number of deaths at 100 and 1000 mg/kg bw/day were not related to treatment, several different parameters were affected, historical control data were not provided in the supplementary data and significant differences in a number of motor activity parameters all occurred at the same time point (PND 180). Additionally, Biesemeier et al. (2011) did not provide an explanation for the increased number of missing pups at 1000 mg/kg bw/day. A LOAEL (100 mg/kg bw) and NOAEL (10 mg/kg bw) value were suggested based on this study in the Health Canada (2012) report, compared to the NOAEL value of 1000 mg/kg bw concluded in Biesemeier et al. (2011).  Answer to section Reverte et al 2013, Costa and Giordano (2011) and first section page 8:  As described in the Annex XV restriction report, several studies (e.g. Viberg et al., 2003; Viberg et al., 2007; Johansson et al., 2008; Rice et al., 2009; Fujimoto et al., 2011; Heredia et al. 2012; Reverte et al. 2013) show that decaBDE affects early foetal and neonatal development. Although some of these studies have been criticized because of unbalanced tracing of animals to litters and cages, more recent studies (e.g. Rice et al 2009; Buratovic et al., 2014; Mariani et al. 2014) has used litter as the statistical unit and show persistent neurodevelopmental effects. Although criticised by in particular industry sponsored studies, the US EPA has nevertheless found the academic study of Viberg et al. (2003) to be sufficiently reliable for setting their RfD. 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. Epidemiological studies support that exposure to decaBDE and other PBDEs may result in human neurodevelopmental toxicity (Gascon et al., 2012; Chao et al., 2011). Several epidemiological studies (Harley et al., 2010, 2011; Hoffman et al., 2012; Herbstman et al., 2008; Chevrier et al. 2010, 2011; Gascon et al., 2011; Roze et al., 2009; Eskenazi et al., 2013; Schreiber et al., 2010) support the notion that exposure to PBDEs may result in human neurodevelopmental toxicity. In these studies individual PBDEs may act alone or in combination to exert the reported effects.  Regarding internal dose of max level at 10 mg/kg bw exposure, page 7 of 9;  Several recent studies show increased neurodevelopmental effects with increasing doses (e.g. Buratovic et al 2014; 0, 1.34, 5.76, 13.4 mg/kg bw; Rice et al 2009; 0, 6, or 20 mg/kg decaBDE; Mariani et al 2014; 0.3, 3, 30 mg/kg) showing that a sufficient internal dose of decaBDE is reached to cause toxic effects. A large number of studies have shown decaBDE to be frequently detected in human blood and breast milk. In many of the studies, decaBDE was in fact the PBDE congener present in highest amounts, particularly in breast milk.  Regarding Huang et al (2010) page 8 of 9: Although Huang et al (2010) did not report convincing apoptotic cell death/cytotoxicity in their test system, a large number of in vitro studies show toxic effects after exposure to decaBDE, also providing mechanistic support of neurotoxic property of decaBDE. DecaBDE can interfere with neuronal signalling events such as calcium, and it induces oxidative stress and apoptosis (Chen et al., 2010c; Liang et al., 2010; Al-Mousa and Michelangeli, 2012). DecaBDE is further shown to cause changes in gene expression, intracellular protein levels, and disturbance of synaptogenesis and cell differentiation (Pacyniak et al., 2007; Viberg et al., 2008; Viberg, 2009; Zhang et al., 2010; Song et al., 2013; Mariani et al 2014). DecaBDE is also shown to lead to disturbance of cellular voltage-gated sodium channel currents (Xing et al., 2010) which may lead to neurotoxicity. Effects that may lead to impairment of long-term potentiation (LTP) after exposure to decaBDE have been reported (Viberg et al., 2008; Xing et al., 2009), supporting the hypothesis that decaBDE may affect learning and memory. Furthermore, several publications indicating that also other PBDEs than decaBDE affect the cholinergic system in both mice and rats brain (Fischer et al., 2008; Viberg et al., 2003, 2007; Liang et al., 2010) further support that decaBDE may have a potential to affect the cholinergic system which could be an important mechanism for cognitive deficits in mammals. DecaBDE is shown to lead to decrease in Ach levels (Liang et al., 2010). The weight of evidence from these publications supports that decaBDE and other PBDEs may cause neurodevelopmental toxicity.  Regarding other reproductive toxicity, page 9 of 9:  In terms of reproductive toxicity parameters, the NTP report from 1986 mainly concerns analyses of tumors in the reproductive tract and was therefore not included in section "B.5.2.2 Other reproductive toxicity". The NTP report is referred to in other sections, however. The Hardy 2002 study (developmental, but not neurodevelopmental) is mentioned in Table 34 (p. 180), but could also have been mentioned in section B.5.2.2. The reference list will be updated with this study.  B.8.2 Emission Characterisation (p. 25-26):  Information from VECAP (2013) was used in the emission calculations, for the low emissions scenario and the production life-cycle step, see section B.8.2 and Annex B.8.2.6 of the Annex XV report.  B. 11 Summary of Hazard and Risk p 36, and E1.1 Risks to be addressed – the baseline  Based on animal data, in vitro and in vivo mechanistic studies, epidemiological studies and evaluations of other scientific bodies (see our answers above), it is concluded that decaBDE can cause developmental neurotoxicity in mammals including humans.  The conclusions highlighted in bullets 3 and 6 (page 36 of the Annex XV report) remain valid. |
| **RAC Rapporteurs comments:**  We agree with the comprehensive comments by the Dossier Submitter. |
| **SEAC Rapporteurs comments:**  We have no comments. |
| **END OF COMMENTS** | | |