Specific references to Deca-BDE in the explanatory memorandum of the EU RoHS Directive proposal and Corresponding conclusions from Deca-BDE EU Risk Assessment

Explanatory Memorandum

The purpose of this document is to compare the concerns that motivated the inclusion of Deca-BDE and other PBDEs at the time the EU Restriction of Hazardous Substances (RoHS) Directive proposal was drafted, with the results of the EU Scientific Risk Assessment for Deca-BDE.

The table overleaf lists all the references to Deca-BDE or other PBDEs in the explanatory memorandum (Annex IV) of the Directive proposal. In the specific context of Deca-BDE, for each of the issues raised, relevant paragraphs have been extracted from the EU Risk Assessment and the Update Risk Assessments for the Environment and Human health.

It is apparent from the table that the EU Risk Assessment has found that none of the human health issues raised by the RoHS proposal explanatory memorandum are of concern. In relation to the environmental issues raised by the explanatory memorandum, specifically that PBDEs may be persistent, bioaccumulative and toxic, the Risk Assessment has concluded that Deca-BDE is probably persistent, but it is not bioaccumulative and it is not toxic.

Overall, it is apparent that the issues motivating the inclusion of Deca-BDE in the draft EU RoHS proposal have been addressed by the EU Risk Assessment process and that they do not support the case for restricting the use of Deca-BDE in electrical equipment plastics.

The Institute of Occupational Medicine

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Table entries are comprised of direct quotes from the explanatory memorandum Annex IV, the Risk Assessment and the Update Risk Assessment with the exception of words and phrases in italics that have been added by way of explanation or summary by the Institute of Occupational Medicine (IOM).

Specific References to Deca-BDE and PBDEs in Annex IV of the RoHS Directive proposal (Annex IV: Memorandum on scientific evaluation regarding the substitution requirement set out in Article 4 of the Proposal for a European Parliament and Council Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment)	**Pages**	**Corresponding conclusions (specific to Deca-BDE) from Deca-BDE EU Risk Assessment (RA) And update Risk Assessments: Health – February 2004 (URA-H) and Environment - November 2003 (URA-E)**	**Pages**
1. HAZARD IDENTIFICATION PBB, penta-, octa- and Deca-BDE are not classified under council Directive 67/48/EEC on the classification and labelling of dangerous substances	42	No classification proposed	11 RA
2. DOSE (CONCENTRATION) - RESPONSE (EFFECT) ASSESSMENT **2.1 Adverse effects on human health** **PBB and PBDE** The lower brominated technical PBDE compounds show effects above all on the liver but also on thyroid hormone and affect the behaviour of experimental animals. They occur widely in the environment, in human blood and in mother's milk. The highly brominated compounds included in technical octaBDE and Deca-BDE are persistent, have effects on reproduction and can cause tumour formation in the liver. There are scientific data which support the assumption that these compounds can be transformed into lower-brominated compounds.	43	***Liver***: in B6C3F1 mice, hepatocellular adenomas or carcinomas (combined) occurred from 25,000 ppm without a dose-effect relationship and were considered as equivocal evidence of carcinogenicity. This effect was not confirmed in Fischer 344/N rats since no malignant tumours have been observed. But in rats, dose-related increases in liver tumours (neoplastic nodules) were observed in both sexes that allows some evidence of carcinogenicity. The well documented existence of strong interspecies and interstrains differences in liver tumours susceptibility should be kept in mind, B6C3F1 mouse being characterized by a high liver tumour background incidence….. Therefore, based on these results and the argumentation mentioned above, a classification for carcinogenicity is not proposed. But following a cautious approach, a LOAEL for carcinogenicity of 1,120 mg/k/day is stated based on the increased incidence of liver neoplastic nodules from	148 RA 148 RA 149 RA

… text referring to PBB... It has been demonstrated that PBDEs may also act as endocrine disrupters. In the case of pentaBDE and octaBDE, the highest exposure in animal experiments which has not given rise to harmful effects (NOAEL) is, for rats and rabbits, 1-2 mg/kg per day.	44 44	the lowest tested dose (1,120 mg/kg/day) and considered for the risk characterisation. ***Thyroid/ endocrine disruption****:* ..given that extremely large dose of DBDPO (>94% purity) were tested for either 13 weeks and over a lifetime, that no effects were found in either sex of two species after 13 weeks treatment and that only mild effects (follicular cell hyperplasia and marginally increased incidence of thyroid follicular cell adenomas or carcinomas) were found in one species after a lifetime exposure. Additional testing for this end-point was not judged necessary. Conclusion (ii) is drawn for this end-point ***Human blood****: the risk assessment and the update risk assessment do not comment on the significance of the reported detection of Deca-BDE in blood. With respect to its detection in adipose tissue, it is noted that a low bioaccumulation potential might be anticipated.* ***Breast milk****:* …Moreover since DBDPO presents a low systemic toxicity even at high dose level in mice or rats the rapporteur might assume a low concern for this end point… ***Effects on reproduction:*** In this recent prenatal developmental toxicity study (BRIP, 2000), no maternal or developmental toxicity was observed up to the highest dose tested of 1,000 mg/kg/day. …. The recent well conduced, prenatal developmental toxicity study (BRIP), carried out with a composite of commercial DBDPO of greater purity (97.4%) was judged preferable to assess the developmental toxicity.. Thus based on this recent prenatal developmental toxicity, no concern for adverse effects on development may be assumed. ***Potential to cause tumours***: *see liver above* ***NOAEL:*** a NOAEL of 1,120 mg/kg bw/day was identified in an oral chronic toxicity study in rats.	 RA 157 156 RA 151 RA 152 RA 1 URA-H

2.2 Adverse effects on the environment **Brominated Flame retardants** The lower brominated technical PBDE compounds, containing mostly pentaBDE, are persistent, bio-accumulative and toxic in the aquatic environment. PentaBDE are persistent, both microbially and abiotically in water and air. Tetra- and pentaPBDEs in particular have a high potential for bio-accumulation, with a bio concentration factor of between 5,000 and 35,000. No significant bio-accumulation has been demonstrated regarding octaBDE and Deca-BDE. Octa- and Deca-BDE are persistent, both microbially and abiotically in water and air. Successive debromination in UV light and sunlight has, however, been demonstrated for Deca-BDE	44	***Persistence*** The rate of degradation of decabromodiphenyl ether under aerobic and anaerobic conditions appears to be very low Decabromodiphenyl ether is not readily biodegradable. It is not expected to degrade biotically at a significant rate under aerobic conditions and no degradation was seen in an anaerobic sediment over a 32 week period. Therefore decabromodiphenyl ether is considered to meet the very persistent (vP) criterion.	 56 RA 80 URA-E
		Bioaccumulation Overall, it can be can be concluded that, although there is some experimental evidence that decabromodiphenyl ether can be taken up by aquatic organisms via food, only a very small proportion of the total dose was taken up (0.02-0.13% over 120 days) and so the substance can be considered to have a low bioaccumulation potential. Further evidence for this comes from the fact that there are very few reported occurrences of decabromodiphenyl ether in biota samples taken from the environment. Decabromodiphenyl ether does not meet either the bioaccumulative (B) of very bioaccumulative (vB) criterion described in the Technical Guidance Document.	 62 RA 80 URA-E

		Toxicity The following conclusions apply to the aquatic compartment. Result Conclusion (ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already. This applies to the assessment for surface water, sediment and wastewater treatment plants from local and regional sources of decabromodiphenyl ether. The available aquatic toxicity data for decabromodiphenyl ether show no effects at the limit of water solubility of the substance. In addition no effects were also seen in studies with the sediment species *Lumbriculus variegatus*. Therefore it is considered that decabromodiphenyl ether does not meet the T criterion.	106 RA 81 URA-E
		Summary of PBT assessment For the PBT assessment decabromodiphenyl ether can be considered to be very persistent (vP) but not bioaccumulative or toxic	81 URA-E

		Formation of lower brominated diphenyl ethers There is currently no evidence that significant degradation to lower brominated diphenyl ether congeners is actually occurring in the environment. Overall, although it can be concluded that formation of lower brominated diphenyl ethers and brominated dibenzofurans can occur from the photolysis of decabromodiphenyl ether in the environment, the actual significance of the process is likely to be limited owing to the lack of exposure to light of the bulk of decabromodiphenyl ether in the environment. It is considered unlikely that such photolysis reactions of decabromodiphenyl ether could explain the widespread occurrence of tetra-, penta- and hexabromodiphenyl ether congeners in the environment; it is considered much more likely that the levels of these congeners found are a result mainly of the emissions of the commercial pentabromodiphenyl ether and octabromodiphenyl ether flame retardants. However any photolysis of decabromodiphenyl ether that does occur in the environment could make a (probably small) contribution to the levels of the lower brominated congeners present in the environment In summary, any photolysis of decabromodiphenyl ether that does take place in the environment could make a contribution to the levels of more accumulative and toxic substances. It is impossible to quantify this based on current knowledge. A major research programme could be requested in an attempt to resolve this issue, but the rapporteur considers that on the balance of evidence, the overall significance of this process is likely to be small.	 109 RA 28 URA-E 84 URA-E
3. EXPOSURE ASSESSMENT It should be underlined that scientific data on exposure is not always available for all of the Community. However, there is no indication of significant differences of exposure to human health and the environment. **PBDE**	46	***Sections in the RA and URA linking exposure to risks to health*** **Consumers** Due to the lack of detailed information about consumer exposure to DBDPO, it is not possible to conduct a sound risk assessment for the consumer. However, based on scattered pieces of evidence, and in agreement with	 159 RA

PentaBDE occur widely in environmental samples from sediment and biota. Monitoring data from the Baltic and elsewhere suggest higher concentrations of lower-brominated PBDEs higher up in the food chains. Generally, humans are most probably exposed to PBDEs through similar exposure routes as many neutral lipophilic organohalogen compounds (…) with food as the major source. Inhalation of particulate bound PBDEs in certain occupational settings may, however, also contribute to human exposure, whereas gaseous phase exposure to PBDEs probably is of minor importance because of the low vapour pressures of these compounds. There are indications that diet is another exposure source for PBDEs…”		the previous risk assessment conducted under the auspices of IPCS (WHO, 1994), it is felt that consumer exposure to DBDPO is likely to be negligible, with no resulting risk for consumers.	
		Conclusion (ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already.	159-60 RA
		Humans exposed via the environment	
		The estimated maximum human intake from environmental sources is estimated to be in the range 8-12 ug/kg bw/day from local and regional sources…. A NOAEL of 1,120 mg/kg bw/day was identified in an oral chronic toxicity study in rats. As the exposure via the environment is mainly through root crops, this value will be used directly. With a maximum intake of 12 ug/kg/ bw/day, a MOS of 93,933 can be derived. This value does not lead to concern. Conclusion (ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already. A revised uptake of environmental exposure is given in the URA	160 RA
		The estimated maximum human intake from environmental sources is estimated to be in the range 0.07-5 ug/kg bw/day from local and regional sources…. A NOAEL of 1,120 mg/kg bw/day was identified in an oral chronic toxicity study in rats. As the exposure via the environment is mainly through root crops, this value will be used directly. With a maximum intake of 5 ug/kg/ bw/day, a MOS of 224000 can be derived. This value does not lead to concern.	12 URA-H
		…Reproduction Based on a one generation study, a NOEAL >100 mg/kg bw/day was	12 URA-H

		derived and could be used directly. With a maximum intake of 5 ug/kg bw/day, a MOS > 20,000 can be derived. This value does not lead to concern. Neurotoxicity In a study of behavioural disturbances in neonatal mice…..the toxicological significance of these findings is unclear. On the assumption that the Viberg study is nevertheless taken into account, a NOAEL = 2.2 mg/kg bw/day could be used directly. With a maximum intake of 5 ug/kg bw/day, a MOS of 440 is calculated. The use of this result in the risk characterisation for Man via the environment would represent a worst case situation. **Combined exposure** Combined environmental and occupational exposure will not influence the characterization of the risks which are outlined in Sections 4.1.3.2 and 4.1.3.4. *(for which Conclusion (ii)-There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already – was drawn*	13 URA-H RA 160
4. RISKS CHARACTERIZATION **PBB and PBDE** High concentrations of tetra- and pentaBDEs have been observed in freshwater fish, such as pike, perch and eel. In Swedish mother's milk the concentration has been rising exponentially since the 1970s. OctaBDE have been measured in indoor air on premises containing flame-retarded electronic apparatus such as computers and television receivers. Elevated blood concentrations of OctaBDE have been shown in occupational categories of		**Concentrations in wildlife**: overall the available results indicate that decabromodiphenyl ether may be present in certain organisms in the environment, particularly marine mammals and predatory birds' eggs, but only a relatively low concentrations. **Concentrations in breastmilk**: the rapporteur might anticipate a rather low excretion of this compound in breastmilk **Concentrations in indoor air:** quantitative measurements of PBDPOs in the air at ordinary offices show concentrations of DBDPA of at most 0.08 ngm^{-3}………In conclusion, exposure to DBDPO during subsequent	90 RA 156 RA 117 RA

people handling computers. In the case of pentaBDE and octaBDE, the highest exposure in animal experiments which has not give rise to harmful effects (NOAEL) is, for rats and rabbits, 1-2 mg/kg per day. It has to be noted, however, that these experimental animal data are not based on lifetime exposure, which would be a more realistic scenario to take into account for comparison with human exposure. (note absence of reference to Deca-BDE in this section)		use of flame retarded equipment is likely to be negligible. **Occupational exposure:** There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already **NOAEL**: 1120 mg/kg bw/day see above	 162 RA
5. CONTRIBUTION OF WEEE TO THE GENERAL RISKS **5.1 Current use in EEE of the substances under examination** **PBDE and PBB** Brominated fire retardants are today regularly designed into electronic products as a means for ensuring flammability protection, which constitutes the main use of these substances. Polybrominated biphenyls (PBBs) and polybrominated diphenyl ethers (PBDEs) account for approximately 1% and 9% respectively. The three groups of PBDEs, which are commercially available are penta-, octa- and decabromodiphenylether. The use is mainly in four applications: in printed circuit boards, in components such as connectors, in plastic covers and cables. According to a Danish estimation, WEEE represents about 78% of the total content of brominated flame retardants in waste.			

5.2 Problems associated with current management of WEEE **Incineration of WEEE** **Brominated Flame Retardants** There is a large body of literature that shows that polybrominated dibenzofurans and dibenzop-dioxins can be formed from PBDEs and PBBs under certain combustion/pyrolysis conditions. At temperatures of about 300°C the dioxin formation is maximal. However, data from municipal waste incinerators in the Netherlands did not show any significant relationship between dioxin formation and the bromine content of the waste. However, further research is necessary in order to assess this issue. In particular, further assessment should be carried out in order to assess the threshold above which the content of halogenated substances would influence the formation of dioxins. In addition, the issue of dioxins formation during the recycling of brominated flame retardants is described later in this document…”	p.49 / 50	**Incineration** ….. it was concluded that the formation of halogenated dibenzo-p-dioxins and furans was dependent on the products of incomplete combustion and if the burnout of the reactor is optimised, the amounts of halogen present in the fuel had no significant influence on the amounts of halogenated dibenzo-p-dioxins or furans formed. …..Proper incinerator design should also reduce the potential for release to the environment from the brominated dibenzo-p-dioxins and furans. Hamm et al. (2001) have investigated the potential for formation of polybrominated dibenzofurans and dibenzo-p-dioxins from the repeated reprocessing of samples of high impact polystyrene containing decabromodiphenyl ether. The decabromodiphenyl ether (along with antimony trioxide) was incorporated into the plastic by extrusion. The plastic was then further processed by injection moulding and the amounts of polybrominated dibenzofurans and dibenzo-p-dioxins in the sample were determined. Subsequently the sample was ground and injection moulded four times and the amounts of brominated dibenzofurans and dibenzo-p-dioxins were re-determined. In all cases the levels found were at least one order of magnitude below the regulated limit in the German Chemicals Banning Ordinance…”	199 RA 13 URA-E
Landfilling of WEEE When brominated flame retarded plastic (…) are landfilled, (…) polybrominated diphenylethers (PBDEs)… may leach into the soil and groundwater. **Brominated Flame Retardants** Although leaching of the compounds from plastics on a short-term scale is small, the compounds will sooner or later be released from the plastic, at least at the rate the plastic is degraded. The time scale of the exposure scenario can therefore reach hundreds of year. In the context of this long-term exposure scenario, the key question is whether the compounds are degraded before they will	p.52	**Losses from landfill and incineration** When decabromodiphenyl ether in plastics is disposed of to landfill, in theory it could leach out of the plastic and intro groundwater or volatilise to the atmosphere. However several experiments have shown that leaching of decabromodiphenyl ether from polymers is minimal (..) and it would not be expected to leach to a significant extent from polymers in land fill, unless the polymer itself undergoes some form of degradation, thus releasing the decabromodiphenyl ether. Any released decabromodiphenyl ether is likely to adsorb strongly onto soil, thus minimising the possibility of reaching groundwater..	26-27 RA

end up in the leachate. As some of the compounds are persistent in the environment long term diffuse emissions from landfills are likely. It is important to note that PBBs have been found to be 200 times more soluble in a landfill leachate than in distilled water; this may result in a wider release into the environment.			
Recycling of WEEE **Brominated flame retardants** Both dioxins and furans are generated as a consequence of recycling the metal content of WEEE, which also contain halogenated plastics. Halogenated substances contained in WEEE, in particular brominated flame retardants, are also of concern during the extrusion of plastics, which is part of the plastic recycling. This is due to the fact that during recycling of plastics containing brominated flame retardants, brominated dibenzofurans and brominated dibenzo-p-dioxins may be formed. Various studies suggest that the risk of generation of dioxins is a reason for the complete lack of recycling of plastics containing brominated flame retardants…”	52	The information available on the levels of polybrominated dibenzofurans and dibenzo-p-dioxins in plastics during recycling indicate that that levels present do not increase during recycling….a..recent study, using a composite sample of decabromodiphenyl ether from the three major suppliers in the EU, indicated that the levels were well below those prescribed in the German Dioxin Regulations, even after repeated recycling. Hamm et al. (2001) have investigated the potential for formation of polybrominated dibenzofurans and dibenzo-p-dioxins from the repeated reprocessing of samples of high impact polystyrene containing decabromodiphenyl ether. The decabromodiphenyl ether (along with antimony trioxide) was incorporated into the plastic by extrusion. The plastic was then further processed by injection moulding and the amounts of polybrominated dibenzofurans and dibenzo-p-dioxins in the sample were determined. Subsequently the sample was ground and injection moulded four times and the amounts of brominated dibenzofurans and dibenzo-p-dioxins were re-determined. In all cases the levels found were at least one order of magnitude below the regulated limit in the German Chemicals Banning Ordinance…”	201 RA 13 URA-E
It has been demonstrated that personnel at an electronics-dismantling plant showed significantly higher levels of all PBDE congeners in their serum compared to a control group. The results of a Swedish study showed that Deca-BDE is bioavailable and that occupational exposure to high levels of PBDEs occurs at the electronics-dismantling plant. It could be argued that special protective measures could be implemented in order to address these occupational health problems. It is unlikely, however, that such measures sufficiently eliminate the exposure of workers. In addition, the coherent enforcement of such measures in all parts of the Community cannot be ensured.	52	**Workers** Consequently, the likelihood that an adverse effect occurs by skin or inhalation exposure is very low, there is at present no need for further actions: conclusion (ii) for all scenarios. Jakobsson et al. (2003) has recently published a summary and analysis of their work of levels of decabromodiphenyl ether in blood serum.. The half-life of decabromodiphenyl ether in blood serum was estimated to be around 14 days based on samples from four employees at an electronics recycling plant and four employees at a rubber mixing plant taken both before and at various times during 4-5 week vacation.	 157-8 RA 65 URA-E

6. RISK REDUCTION BY SUBSTUTION **Alternatives to the substitution** In addition, even if WEEE were collected separately and submitted to recycling processes, their content of heavy metals, PBB and PBDE poses risks to the health or the environment			
It has been suggested by producers of brominated flame retardants that the health risks related to the extrusion of plastics containing PBB and PBDE could be avoided by strengthened worker protection measures in the recycling installations. As an example it was recommended that these workers carry protection masks. While these kind of measures should be supported in any case, there are experiences which show that such measures cannot be strictly applied throughout the recycling installations in the European Union and that these measures could no substantially reduce or eliminate the possible adverse effects related to brominated flame retardants. Clearly, the substitution of the concerned substances would provide the best protection of the concerned workers.		*As described in sections of the RA and URA documents quoted above, the risk assessment process has concluded that current levels of exposure to Deca-BDE in the workplace are much lower than those associated with toxicity in animal experiments.* Additionally the results of the risk assessment process do not suggest that additional protective measures are required.	See 160 RA And 12-13 URA-H 13 URA-H

References:

- Proposal for a Directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) COM(2000) 347 final - Annex IV: Memorandum on scientific evaluation regarding the substitution requirement set out in Article 4 of the Proposal for a European Parliament and Council Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment – p. 41

- Deca-BDE Risk Assessment Report – Human health Final Report, 2002

- Update risk assessment of Bis(pentabromophenyl) ether (decabromodiphenyl ether) – Environmental Draft of 7 November 2003, which was approved at the 2 December Technical Meeting at the European Chemicals Bureau

- Update risk assessment of Bis(pentabromophenyl) ether (decabromodiphenyl ether) – Human Health Draft of February 2004

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