

EEB response to Stakeholder consultation on adaptation to scientific and technical progress under directive 2002/95/EC (ROHS directive) for possible amendment of the Annex

5 July 2004

The EEB appreciates due notification of this technical adaptation consultation. However, given the scientific and political context of certain elements within the consultation the EEB would like to request that the consultation be reformulated for re-consultation, for the following reasons:

1) In general, the questions that are being asked are not in line with the provisions of the directive (Article 5.1 (b) and (c)).

The requirements in the directive are whether elimination or substitution via design changes or materials and components (which do not require any of the materials or substances referred to therein) is technically or scientifically either impracticable or possible. Or whether the negative environmental, health and/or consumer safety impacts caused by substitution are likely to outweigh the environmental, health and/or consumer safety benefits thereof or not.

This is different to asking about the existence of feasible substitutes in an industrial and/or commercial scale, whether restrictions apply to such substitutes, and what the costs and benefits and advantages and disadvantages of such substitutes would be.

2) The questions that are being asked are always the same, although the approach should be different, depending on whether they concern the request for a new exemption (Article 5.1 (b), or whether they concern the deletion of an existing exemption (Article 5.1 (c)).

The substances and applications addressed in Q1 and Q4-Q13 concern potential new exemptions, while Q2 and Q3 concern the potential deletion or time-limitation of current exemptions. As far as additional exemptions are concerned, the burden of proof should be on the proponents of these exemptions. Firstly, proponents should justify their requests for exemptions from the provisions of Article 4.1 according to the provisions of Article 5.1(b). These requests should be made available to stakeholders for comment. However, the Commission has taken the opposite approach. The requests for exemptions have not been made public, a valid reason for request for exemption is presupposed, and the burden of proof was put on the regulator and other stakeholders to show the availability and cost and benefits and advantages and disadvantages of substitutes.

As far as the deletion of exemptions is concerned, the burden of proof should be on the proponents of these deletions, to be justified according to the provisions of Article 5.2 (c).

3) No evidence has been given about scientific and technical progress to justify an adaptation.

Article 5.1 only foresees amendments that are necessary in order to adapt the Annex to scientific and technical progress. As confirmed by the judgement of the European Court of Justice in Case

C-314/99¹, scientific and technical progress needs to be shown to be able to resort to adaptation. Therefore, adaptation of the Annex to Directive 2002/95 is only justified when scientific and technical progress has been shown to have occurred. There is no evidence to this regard in the consultation.

4) It is not appropriate that the article 4 (1) ban of Deca-BDE (Q1 of the consultation document) be addressed in this consultation procedure (detailed reasons given below)

The EEB asks therefore that Q1 be withdrawn from consultation, and that Qs 2-13 be reformulated for re-consultation in line with the provisions of Article 5.1(b) and (c) as explained in point 1 and 2 above, provided that point 3) can be shown to be fulfilled.

Reasons why it is inappropriate and inadmissible that Deca BDE be addressed in this consultation process.

a) Procedural - Risk assessment and risk reduction process still ongoing

The question posed in the technical adaptation consultation process, on the feasibility of substitutes and the costs and benefits and advantages and disadvantages of such substitutes would seem to imply that it is the Commissions intention to consider revising the current ban on Deca BDE on the basis on availability or non-availability of substitutes. Apart from the general concerns raised in points 1 and 2, it is difficult to understand why this issue is being raised now.

Deca BDE was inserted into the annex (by the Council) to be 'subject to a review in the light of the risk assessment' (reconfirmed recently in a letter from Mrs Wallstrom to the European Parliament – 29 March 2004).

This presupposes that;

- 1- the complete risk assessment has been finalised
- 2- agreement on risk reduction measures has been finalised, in case such measures have been called for
- 3- the analysis of the advantages and drawbacks of the substance and the availability of replacement substances has been performed (according to Article 10 (3) of Regulation (EEC) No 793/93) as part of the risk reduction strategy

None of this is currently the case.

While the environmental part of the risk assessment is considered finalised, the health part is still missing.

While the environmental part has been finalised with a conclusion (i) [*meaning there is a need for further information and/or testing*] as well as conclusion (ii) [*meaning 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 process to agree on risk reduction measures is nevertheless ongoing.**

¹ Netherlands against the European Commission on Cadmium in Fertilisers and adaptation of directive 769

In fact, Council and Parliament agreed on the following with regard to Deca-BDE in the conciliation on Directive 2003/11/EC², recital (6): "*The risk assessment on decaBDE was concluded in August 2002 and has revealed a number of uncertainties concerning possible effects on the environment of this substance. Risk reduction measures should be taken by the Community without delay and a risk reduction strategy has therefore to be established immediately. The Commission expects the results of the risk reduction strategy not later than 30 June 2003. It should then immediately assess these results and propose appropriate and strict measures to address risks identified. The European Parliament and the Council should consider this proposal without delay. **Restrictions approved by the Community on the marketing and use of decaBDE are to enter into force without further delay, unless the further testing provided for in the above risk assessment resolves the current uncertainties by concluding that deca BDE gives no cause for concern.***"

Accordingly, a risk reduction strategy should be undergoing development by the UK Competent Authority since 2002. According to Article 10 (3) of Regulation (EEC) No 793/93, a risk reduction strategy should contain an analysis of the advantages and drawbacks of the substance and the availability of replacement substances, which would be of relevance for the assessment of specific requests for derogations. Moreover, the Competent Authority meeting in Dublin at the end of May 2004 agreed to discuss risk reduction measures to be taken (beyond those suggested by the industry) at a meeting in October/November 2004.

PROCEDURALLY, IT IS CLEARLY INAPPROPRIATE TO CONSIDER POTENTIAL EXEMPTIONS OR CONSULT ON SUBSTITUTES FOR DECA RIGHT NOW, WHEN THE SAME QUESTIONS ARE BEING ADDRESSED IN A FORMAL PROCESS PURSUANT TO 793/93

b)The latest conclusions of the risk assessment process have clearly illustrated that the current risk assessment procedure is not able to cope with situations requiring a precautionary approach

Lack of Conclusion (iii) in the current risk assessment of Deca BDE is highly questionable given the growing scientific evidence for concern and recognition that the risk assessment methodology is not adequate for the main concern – the potential or known PBT properties of Deca BDE

Growing scientific evidence:

The Competent Authorities already agreed in 2002 that risk reduction measures should be taken immediately for Deca BDE (see risk assessment of July 2002 and recital 6 in Directive 2003/11/EC), and the concern has grown since on bioaccumulation and neurotoxic effects (see extract of WWF paper on growing scientific evidence in Annex).

Methodology not adequate on PBT:

The Risk Assessment (RA) states the following in the summary:

² DIRECTIVE 2003/11/EC amending for the 24th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (pentabromodiphenyl ether, octabromo diphenyl ether).

"Decabromodiphenyl ether is likely to be very persistent (vP), but not bioaccumulative nor toxic in the marine environment according to the criteria presented in the Technical Guidance Document. However, the PBT assessment is complicated by data available on the:

** widespread occurrence of the substance in top predators (e.g. birds and mammals, including terrestrial species) and the Arctic;*

** neurotoxic effects and uptake of the substance by mammals in laboratory studies; and*

** possible formation of more toxic and accumulative products such as lower brominated diphenyl ether congeners and brominated dibenzofurans in the environment.*

This means that the available assessment methodology might not be applicable to this substance.

Conclusion (i)³ as well as conclusion (ii)⁴ in the RA, clearly illustrate the inability of the current RA process to deal with a situation that requires precautionary action. In particular if there is growing but un-explained evidence of presence/accumulation of the substance in food chains and the necessity for specific methodology adequate to the behaviour of the substance in question. We lack altogether the conclusion type iv [for e.g.: *there is a need for further information and testing or different methodologies of assessment, in the meantime precautionary risk reduction measures should be applied*].

THE CONFLICTING CONCLUSIONS OF THE RA PROCESS CLEARLY ILLUSTRATE THE INABILITY OF THE CURRENT RA PROCESS TO DEAL WITH SITUATIONS THAT REQUIRE PRECAUTIONARY ACTION OR FOR WHICH CURRENT METHODOLOGY IS NOT SUFFICIENT.

c) Disregard of the Commission's own justifications for banning all PBDEs including Deca BDE

It was the Commission's original intention, supported by the European Parliament and the Council, to ban all PBDEs, including Deca BDE (Commission proposal for a directive on ROHS June 2000). The Commission's proposal for this was based on a wide range of arguments, ranging from releases during use and disposal, dioxin formation in incineration or landfill fires, problems with recycling, evidence about debromination of Deca BDE to more toxic and bioaccumulative substances, evidence about bioaccumulation of Deca BDE as such, and the availability and proportionality of substitutes (see attachment - *Excerpts on PBDEs in COM proposal RoHS June 2000*).

In the meantime, key concerns have been confirmed (*possible formation of more toxic and accumulative products such as lower brominated diphenyl ether congeners and brominated dibenzofurans in the environment*), and new ones have been added (*neurotoxic effects, widespread occurrence of the substance in top predators*), given the following findings in the risk assessment:

³ [there is a need for further information and/or testing]

⁴ [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 CLEAR POLITICAL PRECAUTIONARY DECISION WAS MADE IN 2000 BY THE COMMISSION AND SINCE THEN EVIDENCE FOR CONCERN HAS INCREASED NOT DECREASED, THEREFORE THERE IS NO REASON TO QUESTION THE EXISTING BAN ON DECA BDE

d) Voluntary industry initiatives are completely insufficient

Existing industry codes of conduct only concern production and processing. This excludes import products. It also disregards releases to the environment, which occur during use and disposal, which represent the biggest share of total releases.

The following information is given in the risk assessment -

Imported goods:

1300 tonnes of deca that are imported in goods. . This equals 14% of the total (8300 tonnes are imported as such and used in the EU). These are not addressed by the code of conduct.

Releases during production, processing, use and disposal (see table 4 on page 21 of the risk assessment):

Polymers (70% of the use of deca)

- releases during production: roughly 10 kg/year (regional model) or 80 kg/year (continental model)
- releases during use and disposal: roughly 15 kg/year (regional model) or 130 kg/year (continental model)

In other words, according to the RA, releases during use and disposal account for ca. 60%.

Textiles (30% of the use of deca)

- releases during production: roughly 17 kg/year (regional model) or 150 kg/year (continental model)
- releases during use and disposal: roughly 12.500 kg/year (regional model) or 37.500 kg/year (continental model)

In other words, according to the RA, releases during use and disposal account for more than 99,5%.

DECA BDE IMPORTED IN FINISHED ARTICLES IS NOT ACCOUNTED FOR BY LIKELY FUTURE INDUSTRY VOLUNTARY INITIATIVES (14% OF TOTAL), NOR ARE RELEASES OF DECA TO THE ENVIRONMENT DURING USE AND DISPOSAL (BETWEEN 60 AND 99,5% OF THE RELEASES)

e) Availability of substitutes

Apart from the evidence given in the Commission's original proposal for this Directive, significant work has gone into studying alternatives to the very closely related substance Octa BDE with a largely similar use pattern to Deca BDE.

Octa BDE, which is to be phased out in general, is used almost exclusively in polymers. Deca BDE is used primarily in polymers (70%) and secondly in textiles (30%).

For Octa BDE, detailed information is available about the substitutes (in the risk reduction strategies), which added to the justification for a phase out. This information should also be valid for the polymer uses of Deca BDE.

As far as textiles are concerned, around half of the use of Deca BDE occurs in the UK. According to the risk assessment, "the reason for this is that the only EU countries that currently have regulations specifying a level of flame retardancy for domestic upholstery fabrics are the United Kingdom and Eire". We however question the need to use DecaBDE in textiles altogether as no other country has seen the need to specify similar regulations.

GIVEN THE LARGELY SIMILAR USE OF DECA BDE COMPARED TO OCTA THE DETAILED INFORMATION ABOUT SUBSTITUTES FOR OCTA BDE FROM THE RISK REDUCTION STRATEGY SHOULD BE SIMILARLY VALID TO CONTRIBUTE TO MAINTAINING THE BAN OF DECA BDE.
THE USE OF DECA BDE IN TEXTILES SHOULD BE MADE OBSOLETE BY REVIEWING THE REGULATIONS ON FLAME RETARDANCY FOR DOMESTIC UPHOLSTERY IN THE UK AND IRELAND.

ANNEX

Extract from *WWF's submission on deca brominated diphenyl ether (Deca-BDE) for a meeting of the Competent Authorities of the Member States held under the Irish Presidency, 26th May 2004.*

The justification for precautionary action

WWF believes that the Competent Authorities of the Member States have delayed long enough in trying to gather information in order to bring more certainty to the risk assessment of deca-BDE, but this is still elusive. However, during the last 2 years WWF considers that the concerns have grown, and outlined below are some of the reasons for this added concern.

- Two years ago, there was doubt about the validity of the levels reported in Peregrine Falcon from Sweden, such that re-analysis of samples from Sweden was undertaken in addition to further monitoring of tissue samples from birds of prey from the UK. The contamination of the Swedish birds was confirmed and moreover, in the UK study the following birds were found to be contaminated with deca: Peregrine Falcon; Sparrowhawk; Common Kestrel; Barn Owl; Red Kite; Montagu's Harrier; Merlin; Great Crested Grebe; Heron; and White Tailed Eagle; - with terrestrial species showing greater contamination than aquatic species. Analysis of tissues taken at different times does not give a clear indication of whether the levels are increasing with time, but does indicate that the extent of the contamination is more widespread in recent years, with more samples showing contamination than previously (see EU environmental risk assessment report, 2004).
- Studies of gulls in polar regions have shown extensive contamination of liver, plasma and eggs (with 17 out of 20 samples of birds liver showing deca contamination), with one bird with 10ug/kg liver wet weight.
- A WWF study clearly indicates that deca-BDE is now found in the blood of a significant proportion of people in the UK and other EU countries. Data obtained during a 2004 WWF biomonitoring survey can be found at the end of this submission. The study demonstrated that the contamination is not simply a matter of occupational exposure that can be addressed by industrial hygiene measures. It showed that members of the public can be exposed to levels ten times higher than occupationally exposed individuals. Another study has indicated that deca is the flame retardant occurring most frequently and at the highest levels in the dust of people's homes in Britain and Europeⁱ.
- Deca has also been found in the blood of citizens from the USA, and recent studies conducted in Japanⁱⁱ and the USA have revealed breast milk contamination. For example, 7 out of 23 women from Dallas had levels ranging between 0.48-8.24 µg/kg lipid.ⁱⁱⁱ Another US study has confirmed widespread contamination of breast milk. Out of 20 mothers from fourteen states, 80% were contaminated at a concentration of 0.08-1.23 µg/kg lipid.^{iv} Given that deca has been found in the blood of EU citizens, it stands to reason that it will also be found in some EU mothers' breast milk.
- There are also concerns about potential de-bromination in the environment and in fish. A recent study in fish, published in 2004, illustrates that lower brominated congeners, including penta, may be formed as a result of deca metabolism.^v

- Widespread exposure from a chemical used in textiles and polymers might be considered to be surprising, especially since industry formerly argued that it was unlikely to accumulate in animal tissues because of deca's molecular size and low water solubility. Deca has now clearly been shown to be taken up by organisms, such that it is time to act on this chemical.

No threshold for observed neurodevelopmental effects

The concerns about the developmental neurotoxicity of PBDE 209, a major constituent of the commercial deca-BDE formulation, still remain. In EU technical group discussions, many experts of the Member States have concluded that the concerns raised by the Viberg study^{vi} about the potential developmental neurotoxicity, cannot be dismissed. It is particularly worrying that a single dose of PBDE-209 (which is contained in the commercial deca formulation) appears to accumulate in the brains of mice while their brain is undergoing development, and cause persistent effects on behaviour. In WWF's view, a No Observed Adverse Effect Level (NOAEL) cannot be derived from the Viberg study, because animals dosed on their third day of life with the lowest dose tested (2.22mg /kg bw/day) exhibited some statistically significant effects on behaviour, and it is not clear that there is a threshold for this effect.

Implications for humans

WWF considers that there are a number of reasons why it is impossible to make any firm predictions about what the reported effects in rodents mean for the health of humans and other long-lived species with more complex brains. This is not least because diseases or disorders characterised by language - or social - impairment are hard to demonstrate in rodents. Therefore, whilst tests on rodents enable developmental neurotoxicants to be identified, they may be less useful for deriving reliable safe levels in humans. There are indications that for some other developmental neurotoxicants, the threshold for effects in humans is far lower than at first believed. We would like to remind the CAs that PCBs are already considered to have taken a toll on the brain development of children in the EU. We do not want to see this situation repeated and we therefore urge the CAs to consider a precautionary phase out of deca-BDE.

Similarities with the other PBDEs

In noting the growing concerns about deca, WWF suggests that this chemical has many similarities with octa-BDE and penta-BDE. The CA's will be aware that both octa and penta are slated to be banned in the EU in August 2004. Furthermore, it should be recalled that the ban on penta was not imposed because of a known and quantifiable risk. The decision to ban this chemical was a precautionary measure because of concerns about it being found as a widespread contaminant of breast milk and the unacceptable time it would take to gather the information needed to enable an adequate scientific evaluation. WWF considers that it is now time to reach a similar conclusion for deca-BDE. In light of the properties of deca-BDE and the available information, and in the absence of adequate scientific knowledge, coupled with the time it would take to gather the information needed to enable an adequate scientific evaluation, the risk should be considered unacceptable. Thus, it is time for a political decision to take precautionary action on deca-BDE. A conclusion (iii) should be agreed which would mean that there is a need for limiting the risks.^{vii}

WWF does not think it is appropriate to repeat the study showing developmental neurotoxicity, at this late stage. This would result in an unacceptable further delay, and moreover, would not

negate the concerns that the substance may have effects in birds, and the concerns related to the fact that deca is now found as a widespread environmental and human contaminant, and is passed on to offspring at an early stage of development.

We note that the UK authorities have begun to draft a risk reduction strategy for deca, as was previously agreed at a CA meeting. WWF maintains that marketing and use restrictions on all uses would be the only way to ensure adequate control of deca-BDE. We believe that it is important that a phase-out date be set as soon as possible, in order to enable industry to more clearly plan to move away from the use of this substance, and to allow economic and legislative pressure to stimulate the innovation of safer alternatives, or the use of fabrics for which alternative flame retardants are known to be suitable.

It would be imprudent to delay, because the EU market for deca in the 15 original countries where data was gathered, is believed to be slowly increasing and is currently estimated to be in excess of 8000 tonnes per year.^{viii}

In conclusion, unless urgent action is taken to phase out this chemical, many birds of prey will be subject to on-going exposure and potential effects. Similarly, generations of children may be exposed to a developmental neurotoxicant during the period of brain development.

WWF believes that in the interests of a sustainable environment, no chemical that is found to accumulate in wildlife, or in the blood and/or breast milk in the general public, should be in widespread use.

WWF's study on human contamination with deca-BDE

In November 2003 WWF conducted a survey of levels of synthetic contaminants in the blood serum of 47 volunteers from some EU nations. Deca was detected in 16, i.e. 34% of the 47 self-selecting male and female volunteers, including samples from Austria, Belgium, The Netherlands, UK, Denmark, France, Germany, Italy, Ireland, Spain and Sweden. The results were as follows, in nanogram (ng) deca per gram of blood lipid. The methodology has been described in documents presented to the technical experts of the Member States.

	BDE209 (ng/g blood lipid)
1	27.77
2	33.27
3	34.75
4	38.25
5	38.36
6	40.03
7	40.47
8	45.44
9	67.48
10	76.38
11	77.22
12	97.17
13	123.61
14	239.76
15	1223.29

16	2357.85
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Max	Min	Median
2357.85	27.77	56.46

WWF considers that the findings of deca-BDE in the blood of over 33% of our sample of European volunteers, with levels in some individuals being up to 10 times higher than the levels found previously in occupationally exposed individuals, highlights that deca exposure is widespread in the general population, not just occupationally exposed workers.

ⁱ Greenpeace (2003). Consuming Chemicals: Hazardous chemicals in house dust as an indicator of chemical exposure in the home.

ⁱⁱ Hori S., Akutsu K., Oda H., Nakazawa H., Matsuki Y. and Makino T. (2002). Development of an analysis method for polybrominated diphenyl ethers and their levels in Japanese human mother's milk. *Organohalogen Compounds*, **58**, 245-248.

ⁱⁱⁱ Schecter A., Pavuk M., Pöpke O., Ryan J. J., Birnbaum L. and Rosen R. (2003). Polybrominated diphenyl ethers (PBDEs) in U.S. mothers' milk. *Environ. Health Perspectives*, **111**, 1723-1729.

^{iv} Lunder S. and Sharp R. (2003). Mothers' Milk. Record levels of toxic fire retardants found in American mothers' breast milk. Environmental Working Group. Available from: <http://www.ewg.org/reports/mothersmilk/es.php>.

^v Stapleton H M, Alaee M, Letcher R J, and Baker J E (2004). Debromination of the flame retardant Decabromodiphenyl ether by juvenile carp (*cyprinus carpio*) following dietary exposure. *Environm Sci Technol*, **38**, p112-119.

^{vi} Viberg H., Fredriksson A., Jakobsson E., Örn U. and Eriksson P. (2003). Neurobehavioural derangements in adult mice receiving decabrominated diphenyl ether (PBDE 209) during a defined period of neonatal brain development. *Toxicol. Sci. Nov*;76(1):112-20.

^{vii} A conclusion (iii) means that there is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

^{viii} It has been estimated that 30% of this use is in the textile industry and the rest in plastics, with the latter use perhaps decreasing as compared to that in textiles (see draft risk reduction report, RPA, Nov 2003).

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