

EXECUTIVE SUMMARY

On 31 March 2008, UBA published a very critical paper about brominated flame retardants (BFRs). Their approach is not new. Only UBA expresses this view in this manner and has been doing so for several years. It is part of a politically motivated anti-bromine policy, which is not supported by the existing extensive scientific studies and therefore not justified. At times it even seems to have missionary characteristics. While we have vitiated several of the criticised points in the past, we have again taken the time to re-examine each point in this paper and responded with the detailed and comprehensive rebuttal attached.

The members of EBFRIIP are committed to developing and marketing products with the best qualities in every sense. Ensuring fire safety, protecting the environment and human health are all equally key criteria for us. Our substances have been thoroughly tried, tested and evaluated in EU Risk Assessments and we are committed to the strict rules set up by the EU legislator. Furthermore we are committed to product stewardship and make considerable efforts to reduce emissions of chemicals to the environment even if there is currently no risk identified. In this context, it is sad to see that, like in the past, UBA seems to apply their own set of rules, with an eclectic approach as to which of the numerous existing studies to base their assessments on rather than accepting the results of the comprehensive procedures under the Risk Assessment procedure with its strict standards and soon REACH. With that, UBA tolerates and even triggers unjustified and arbitrary market inventions.

Not only does the UBA paper contain, as did preceding UBA papers on this issue, a number of visible mistakes, it also displays a list of misunderstandings and generalisations with misleading conclusions about substances that have actually been tested much more comprehensively in the EU Risk Assessments or are still in this process.

As an example, UBA suggests that any persistent substance cannot be handled in everyday applications and should therefore be banned. This approach is strongly overstressing the precautionary principle and lacks any scientific justification, as the Risk Assessments take the risks from such qualities into account but frequently come to different conclusions on the need for restrictions. The approach also lacks a comprehension of its practical consequences as it would e.g. ban even many applications of metals.

Any chemical, even table salt, arguably poses risks depending on its use and the volume. We call on UBA to accept the conclusions of the comprehensive EU Risk Assessments, saying that the use of the major brominated flame retardants poses no risk to human health or the environment and they should therefore not be restricted. The industry in general, both producing but also using flame retardants, needs a reliable framework to operate in. Demanding bans even for Risk Assessed, or soon REACH assessed substances is an attack on all approved chemicals, including flame retardants, and raises questions as to how UBA thinks the fire safety standards that consumers need can be met.

GENERAL REMARKS			
<p>Generalisation. In the summary it is correctly mentioned that not all brominated flame retardants (BFRs) have equally harmful effects on the environment and human health. However, in the last paragraph of the summary and in many other parts of the paper, no further differentiation is made and only general concerns are raised that do not take into consideration different properties of substances.</p> <p>Monitoring data. These reflect emissions from the past, due to the persistency of some BFRs and the fact that, in the past, these substances were not as well controlled by users and producers as nowadays. Still, on the premise of the TBBPA and Deca BDE levels reflected by these given monitoring data, the EU risk assessment came to no health or environmental risk conclusion. The introduction of environmental quality programs have led to a considerable reduction of local entries into the environment, which are the most prominent sources of emissions. The industry engages in further monitoring activities, the results of which will soon become available. Early data suggests that BRF levels in the environment are declining.</p> <p>Dioxins and furans. It is stated in several parts of the paper that BFRs contribute to the formation of dioxins and furans in the case of a fire. Aside from the fact that this would be equally be valid for any halogenated substance including table salt, such statements need to be put into perspective, as for example stated in the EU risk assessment of TBBPA: <i>“In the case of accidental fires, given the large amounts of toxic products known to be formed, notably chlorinated dibenzo-p-dioxins and dibenzofurans, but also non-halogenated products such as polycyclic aromatic compounds, <u>the presence of tetrabromobisphenol-A is unlikely to significantly affect the total release of toxic products from fires as, in most cases, tetrabromobisphenol-A will only constitute a small proportion of the total halogenated material present in a fire.</u>”</i> What is said about TBBPA here applies to other BFRs just as well. Moreover, BFRs reduce the overall amount of fires. This leads to less overall emissions of dioxins/furans and PAHs to the environment since there are less fires producing toxic combustion products (SP LCA study¹).</p> <p>Overstraining the precautionary principle. The postulations made in the paper go far beyond the REACH requirements. In section 4 of its paper, UBA promotes the prevention of any emissions of persistent or bioaccumulative substances. This absolute request is put forward whilst appealing to the precautionary principle, but goes without any scientific justification and without a critical review of its practical consequences. For example, such extreme prevention puts an end to many metal applications. It is disappointing to see that an institution that is relied upon to give scientifically founded views is making such extreme recommendations that are neither supported by an in-depth analysis of the scientific information available nor accompanied by a balanced risk benefit analysis of their consequences.</p>			
Chap	Page	Text	Comment
1.		<p>Summary</p> <p>What are flame-retardants and what purpose do</p>	

¹ M. Simonson & H. Stripple, LCA study of Flame Retardants in TV Enclosures, *Flame retardants 2000*, Interscience Communications, 2000, 159-169

	<p>they serve?</p> <p>Flame-retardants serve to delay the ignition of inflammable materials such as plastics, textiles or timber, and to slow down the spread of fire. In this way, fires can be either prevented altogether, or the time available to make an escape is extended. As a rule, even flame-retardant items will burn once a fire has taken hold. Many different chemical compounds are used as flame-retardants.</p>	
	<p>What are the properties that are specific to bromine-based flame-retardants?</p> <p>Bromine-based flame-retardants can readily be combined with a wide range of plastics and are relatively cost-effective. Some compounds of this group of substances are persistent and as such are not readily degradable in the environment, and accumulate in living organisms, i.e. are bio-accumulative. In case of fire, or if disposed of without due care, they may form highly toxic dioxins and furans.* However: not all bromine-based flame-retardants have the same effects on the environment and on health. Flame-retardants of differing chemical compositions, such as chlorinated paraffin and certain halogen phosphorous compounds, can have damaging effects on the environment.</p>	<p>*BFRs reduce the overall amount of fires. This leads to less overall emissions of dioxins/furans and PAHs into the environment, since there are less fires producing toxic combustion products (SP LCA study¹⁾). In case of fire, dioxins and furans will always be formed, due to the presence of chlorine, which weighs much more than BFRs.</p>
	<p>Which are principal bromine-based flame-retardants?</p> <p>Bromine-based flame-retardants widely produced around the world are decabromine diphenylethers (DecaBDE), tetrabromine bisphenol A (TBBPA) and hexabromine cyclododecan (HBCD). DecaBDE is used mainly for resistance to fire in plastic housings in electrical and electronic appliances and textiles. TBBPA is used predominantly in printed circuits, also at low volumes in plastic housings. The principal area of the use of HBCD is in insulating materials (expanded and extruded polystyrene) and textiles; rarely in housing plastics.</p>	
	<p>In what way do bromine-based flame-retardants harm the environment?</p> <p>The differing contributions of the various ways of reaching the environment have not been adequately clarified thus far. Emissions when processing flame-retardants in plastics and products – known as point sources – are however quite significant. Environmental discharges caused by fumes or washouts during cleaning of products and disposal – known as diffuse sources – are also important. Owing to their persistence and bio-accumulation potential, bromine-based flame-</p>	<p>This paragraph does not answer the question as to how BFRs do actually harm the environment. The presence of some BFRs at trace levels in the environment is not desirable but the current levels pose no harm to the environment. Just 10 years ago most of the values found today would have been below the detection limit. The issue of</p>

¹⁾ See above.

	retardants can be traced in sediments and dusts, also in numerous species of animal, for example, raptors, polar bears, seals and foxes. They can reach remote areas such as polar regions through global air-streams.	point sources is addressed through VECAP and SECURE.
	<p>In what way do bromine-based flame-retardants harm humans?</p> <p>DecaBDE, TBPPA and HBCD can be found in maternal milk and human blood at low concentrations. At such concentrations, there are no immediate risks, according to the European Union's (EU's) risk-assessments. Nonetheless, on precautionary grounds mother's milk should not contain such substances (for a justification of the precautionary principle, see chapter 4). Food constitutes the principal method of intake. In addition to this, household dust plays some part. In view of its accumulation through the food-chain, it is essential to exclude long-term indirect risks as a consequence of the accumulated (intensified effect) of low concentrations of individual substances.</p>	<p>This paragraph does not deliver any evidence for actual harm to humans. Deca-BDE is almost never found in maternal milk and human blood or at very low concentrations. Also TBBPA is almost never found in maternal milk and human blood. It cannot be postulated that all BFRs will accumulate in the food-chain. Please be specific in the statement.</p>
	<p>What risks were identified by the EU risk-assessment?</p> <p>The assessment of chemicals within the EU is currently undergoing radical change. The EU Old Substance Directive, aimed primarily at controlling immediate risks, was replaced on 1 June 2007 by the new Chemicals Directive REACH, which seeks also to minimise long-term risks on a precautionary basis (see chapter 4 on the Minimisation Order under REACH). Substances that persist, are bio-accumulative or toxic (PBT substances) may be used under REACH with an authorisation that is subject to specified conditions. EU experts arrived at the following results for individual flame-retardants:</p>	<p>The PBT criteria under REACH have yet to be approved by the authorities but even under the current regulation, a substance has to fulfil the three criteria, persistency, bioaccumulation and toxicity, to be considered as a PBT.</p>
	<p>- Decabromine diphenylether (DecaBDE) is highly persistent and accumulates in living organisms. It has not hitherto been classified as a hazardous substance. It is suspected of having long-term neurotoxic effects and of breaking down slowly into highly-toxic bromine-containing compounds. DecaBDE does not exceed harmful concentration thresholds in the environment. However, the EU's competent expert committee is considering its classification as a PBT substance in view of its particular properties.</p>	<p>The EU RA did not identify any risk from the use of DecaBDE. It identified some <i>uncertainties</i>, which are currently being addressed by a large scale study programme under the supervision of the EU and its results should not be pre-empted.</p> <p>In May 2007, the PBT WG reviewed the PBT classification of DecaBDE and agreed that it is not a PBT. According to the latest update of the EU risk assessment of 2007 the data available do not allow a general conclusion about a potential</p>

			<p>bioaccumulation in the food chain. According to the EU risk assessment the findings in biota need to be viewed in context. The monitoring program for DecaBDE is comprehensive in particular when compared to other substances. The levels occurring at all levels of the food chain are typically in the region of several parts per billion on a wet weight basis. This only indicates that low amounts of the substance can be taken up, but there is no evidence for enrichment, accumulation or increasing levels. Contrary to the UBA statement there is up to now no firm evidence of increasing levels in the environment or biota.</p> <p>Regarding degradation to lower brominated congeners with higher toxicity, the latest update of the EU risk assessment of 2007 states that the most reliable results from the monitoring studies did not find any evidence for such a degradation of Deca-BDE in the environment.</p>
		<p>- Tetrabromine bisphenol A (TBBPA) is also highly persistent and accumulates in living organisms. It is toxic to aquatic organisms but not to humans. Local risks do exist with TBBPA, as concentrations in the environment do not exceed the threshold levels for potential environmental damage at individual production sites.</p>	<p>UBA claims that TBBPA is bioaccumulative. Standard studies on bioaccumulation demonstrate that this is not the case. The bioaccumulation is well below the threshold value of the EU for accumulative substances that is already conservative. The available monitoring data indicate some exposure, but are in no way indicative of an accumulation or biomagnification. At <u>one</u> single plant in Europe, a low risk was identified, which is now managed under VECAP.</p>
		<p>- Hexabromine cyclododecan (HBCD) is persistent, highly bio-accumulative (and thus builds up vigorously in</p>	<p>The RA report concluded that "HBCD doesn't unequivocally</p>

	<p>living organisms) and is poisonous to aquatic organisms. Furthermore, there is a danger of long-term damage to human health and ecosystems, owing to its pronounced tendency to accumulate. HBCD presents both local risks at individual production sites and indirect risks in view of its possible uptake through the food-chain.* The competent EU expert committee has assessed HBCD as being a PBT substance.</p>	<p>fulfil the Persistency criterion". Nevertheless, HBCD was considered as a PBT substance based on traces found in wildlife distant from its actual use and trends of increasing concentrations. It should be noted that the monitoring data on which this conclusion was reached were collected before 2003, i.e. before the emission reduction programs were initiated.</p>
	<p>What decisions are made at EU level? Over the coming months, decisions will be made within the EU concerning risk-reduction measures for HBCD, under which significant restrictions on use are expected. Furthermore, in 2008 there will be a ruling by the European Court of Justice on complaints made by Denmark and the European Parliament against the European Commission. Denmark and the EU Parliament are demanding that DecaBDE be banned in electrical and electronic appliances as part of the European RoHS guidelineⁱⁱⁱ, since sufficient alternatives are available that are more environmentally-acceptable. Recently, in 2008, the EU Commission has presented a proposal to revise the RoHS guideline, which could include restrictions on extra harmful substances in electrical appliances, such as HBCD or unbound TBBPA* (used as additive).** Decisions on the authorisation of HBCD and DecaBDE*** will be made from 2009 under REACH.</p>	<p>* It is inappropriate for a Member State Regulator to speculate on the outcome of a EU consultation process (RoHS) or to use unscientific terms such as "extra harmful". **Saying that RoHS could include restrictions on HBCD or unbound TBBPA means pre-empting any discussions or decisions at EU level and is in contradiction with the TBBPA RA. ***As DecaBDE has not been classified as a PBT substance, why allege that under REACH, a decision on its authorisation will have to be made?</p>
	<p>What are industrial organisations that produce or process bromine-based flame-retardants to do? Manufacturers and processors of bromine-based flame-retardants have initiated the "VECAP" and "SECURE" programmes, with the aim of controlling and reducing emissions of bromine-based flame-retardants in production or processing^{iv}. Thus, we are dealing with technical measures to reduced emissions. On the strength of substance audits and personal advice by the manufacturer of the flame-retardant, each firm that processes flame-retardants will identify potential sources of uncontrolled emissions and undertake technical and organisational measures to diminish such emissions.</p>	
	<p>What is the Federal Environmental Agency advocating?</p>	<p>UBA is not right when alleging that all BFRs accumulate in</p>

iii Guideline 2002/95/EG on restricting the use of certain hazardous substances in electrical/electronic appliances.

iv VECAP: Voluntary Emission Control Action Plan. SECURE: Self-Enforced Control of Use to Reduce Emissions.

	<p>Applying the precautionary principle, the Federal Environmental Agency is advocating the avoidance of any discharges into the environment of non- or poorly-degradable (i.e. persistent) substances and/or substances that bio-accumulate in living organisms. This applies equally where there are (as yet) no known toxic effects associated with discharges into the environment because such chemicals can be retrieved neither from the environment, nor from the human body.</p> <p>The Federal Environmental Agency considers it essential on precautionary grounds to minimise discharges into the environment of DecaBDE, HBCD and TBBPA, as all three flame-retardants are non- or poorly degradable and accumulate in living organisms. Furthermore, they are in some degree toxic, and potentially harmful in the long term to humans and to the environment. The damaging effects can be prevented when suitable but less problematic substitutes and products are used instead, or if emissions are significantly reduced through technical measures. In the eyes of the Federal Environmental Agency, substitution takes priority, since total replacement alone will ensure a clear-cut reduction in discharges into the environment (see chapter 6 for the properties required of substitute substances). Where companies continue to use these flame-retardants, thoroughgoing technical measures to reduce emissions during production and processing are sensible and necessary.</p>	<p>organisms.</p> <p>In order to fulfil its function, a flame retardant preferentially is persistent, meaning that alternatives to BFRs are likely to be persistent as well. However, thanks to the comprehensive risk assessments, much more is known about BFRs than any other flame retardant.</p> <p>Emissions of BFRs have been significantly reduced through VECAP. Since the introduction of this program, which is applied to DecaBDE, TBBPA and HBCD, probably BFRs belong to the most controlled chemicals that are being used currently. Thoroughgoing technical measures to reduce emissions should be put in place for the production and processing of all chemicals, not just BFRs.</p> <p>There are currently no technically feasible alternative to HBCD in EPS/XPS application.</p> <p>Emissions from BFRs are subject to emissions control:</p> <ul style="list-style-type: none"> • Since 2006, HBCD producers and EPS/XPS manufacturers have been implementing "SECURE", a product stewardship programme designed to control emissions in the EPS/XPS manufacturing process. • Deca-BDE and HBCD emissions from the Textiles industry are covered by the VECAP product stewardship programme. <p>Moreover, in order to assess the effectiveness of the programme, Industry has launched an extensive 10-year monitoring project. It aims at collecting reliable data on</p>
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			trends of HBCD concentrations in key environmental compartments, including sediment and biota.
		Substitutes with fewer harmful effects on humans and the environment are available in varying degrees, and the three flame-retardants are more-or-less bonded to the plastic. Hence, a differentiated, temporally-staged procedure for individual uses of flame-retardants makes sense:	A serious problem with so called substitutes is that – in many cases – they have not been assessed as well as BFRs!
		- For DecaBDE, TBBPA and HBCD in housing plastics of electrical and electronic appliances, less problematic substitutes are available. Total replacement is therefore both possible and desirable. Many companies are already using these alternatives, which are generally halogen-free, phosphorous organic flame-retardants.	Again, for many so called alternatives, no RA is available and there are no programs in place for their proper management, as is the case for BFRs. As pointed out above, alternatives are very likely to be persistent substances as well.
		- For the use of DecaBDE and HBCD in textiles such as curtains and soft furnishings, again there are less problematic alternatives available. Fibreglass or fire-resistant types of plastics such as fibres with firmly-bonded fire-retardants are suitable. Here, too, total abandonment of use is both possible and desirable.	For HBCD there are no feasible substitutions for specific applications, e.g. for transparent coating, light-weight fabrics and fabrics with a very open weave structure used for roller blind materials, filter clothes, lamellas, cinema canvas and awnings for use in public buildings (cinemas, hospitals, prisons etc.), cars and aeroplanes. These applications need a defined decomposition temperature which only HBCD can provide.
		- For the use of HBCD in insulating materials made of polystyrene there has hitherto been no known alternative flame-retardant; however, for most types of application, other insulating materials can fulfil the same function*. In view of the good environmental impact of heat insulation, continued limited use of HBCD as flame-retardant is tolerable, providing there are strict emission controls during production, processing and disposal.	* For any suggested alternative insulation material, a risk assessment should be performed for human health and environment. In addition, a full life cycle assessment is essential in order to ensure that the proposed alternative is indeed superior.
2.		Context Bromine-based flame-retardants have been released into the environment for many years past. In the 1990s, most attention was paid to polybromine-based biphenyls	

	<p>PBBs) and polybromine-based diphenylethers (PBDEs). The context was the structural similarity of these substances to the polychlorinated biphenyls (PCBs) and highly toxic, persistent dioxins and furans.</p>	
	<p>The last-named appeared in flame-retardants as impurities, and was emitted during combustion. Since that time, the burning of waste has improved so greatly in Europe from the technical point of view that emissions of dioxins and furans are now very low during controlled disposal.</p>	<p>This is not correct. There has been an issue with DecaBDE in lesser purity, containing lower PBDEs. These form dioxins and furans much more easily. This is however not the case for any other BFRs. Besides, a voluntary industry program was initiated with the OECD, where manufacturers proposed to put a very pure DecaBDE (>97%) on the market.</p>
	<p>In case of fire or uncontrolled disposal, things are of course quite different. PBBs have now disappeared off the market owing to their harmful properties. Since 2004, the introduction of penta- and octabromine diphenylether has been banned within the EU. Decabromine diphenylethers are still being produced on a large scale by various manufacturers though with greatly improved purity.</p>	<p>As pointed out, BFRs reduce the amount of fires, curbing overall emissions of dioxins and furans. In case of uncontrolled disposal, as long as there's no fire, no dioxins and furans can be formed.</p>
	<p>At the present time, tetrabromine bisphenol A (TBBPA), decabromine diphenylether (DecaBDE) and hexabromine cyclododecan (HBCD) are the most widely used bromine-based flame-retardants worldwide. They are a focus of scientific and political debate, since concentrations of these substances are increasing worldwide in sediments, dust particulates and in many species of animal, such as raptors (and their eggs), crustaceans, fish, polar bears, seals and foxes.</p> <p>It is possible for residues to arrive in the human food-chain that could potentially have effects at critical stages of embryo development or early childhood.</p>	<p>It is not correct that concentrations of BFRs are increasing. The industry has seen a certain increase in some places for DecaBDE, and taken immediate steps to manage this through VECAP. Overall, no increasing trend was found. TBBPA is hardly ever found and if so, it's at very low concentrations. For HBCD, recent information shows that concentrations are going down.</p> <p>Please provide references for the statement that it is possible for residues to arrive in the human food-chain that could potentially have effects at critical stages of embryo development or early childhood.</p> <p>Note that recently, an extended 2-generation study conducted by the Japanese Ministry of</p>

			<p>Health, Labour and Welfare has been publishedⁱ, which did not identify any “effects at critical stages of embryo development or early childhood” upon treatment with HBCD. This extensive guideline study did not confirm the reports of Eriksson et al.ⁱⁱ on developmental effects, who used non-validated experimental procedures and inadequate statistics. Furthermore, an OECD 414 teratogenicity study was without findings. The “effects at critical stages of embryo development or early childhood” proposed by the UBA report do therefore lack a scientific basis.</p>
		<p>In recent years, results have been published of much research into the health and environmental effects of these three bromine-based flame-retardants and their dispersal in the environment. Risk-assessments under European old-substance procedures are available for DecaBDE, TBBPA and HBCD in initial draft form. All three substances can be assessed only inadequately using standard risk-assessment tests, since the poor water-solubility and size of the flame-retardant molecules partially produce testing problems.*</p> <p>The high persistence and accumulation in organisms do however give rise to concerns about the long-term risk potential of these substances.** The EU Commission has therefore ordered further research to clarify their behaviour in the environment. Among other things, the EU’s “FIRE”^v programme will serve to elucidate the potential effect on the hormonal system in mammals.</p>	<p>*Please correct. The risk assessments for DecaBDE & TBBPA have been finalised. The risk assessment of HBCD is in <u>final</u> draft form. We are surprised by the statement that the assessment could be only inadequately performed since this was not the conclusion in any of the risk assessments conducted for these BFRs, including HBCD. The risk assessment on HBCD was based on a very large number of valid and well conducted tests and the methodology was not questioned by any member state. The risk assessment for DecaBDE & TBBPA has been finalised without any question around applicability of the methodology for these substances.</p> <p>** It is not correct that all BFRs have “high accumulation”. DecaBDE & TBBPA are not classified as very bioaccumulative.</p>

v FIRE: Flame-Retardants Integrated Risk-Assessment for endocrine Effects.

	<p>HBCD meets the criteria for persistent, bio-accumulating and toxic substances (PBT substances) of the new European chemicals directive REACH.* In the case of DecaBDE, there remains scientific uncertainty as to the long-term harmful effects and possible toxic breakdown products, hence the expert community considers fulfilment of PBT criteria as controversial.**</p> <p>From the viewpoint of the Federal Environmental Agency, there are sufficient indicators available of harmful effects to require that DecaBDE be classified as a PBT substance.*** PBT substances may be used only under very specific and stringent conditions, and only where there are no suitable substitute materials or products available. Use of DecaBDE in electrical or electronic appliances, which was initially banned under the RoHS guideline but then allowed once again, is being legally challenged. At the present time, the case is with the European Court of Justice for a ruling.</p>	<p>*The PBT criteria under REACH are not finalised and have yet to be approved by the authorities</p> <p>** See previous remark on degradation. According to the latest update of the EU RA of 2007, the most reliable results from the monitoring studies did not find any evidence for such a degradation of Deca-BDE in the environment. Other studies have many confounding factors like the presence of some lower congeners in some historical commercial products or analytical difficulties. *** Please provide information on these indicators.</p>
	<p>The European Association for Bromine-based Flame-Retardants (EBFRIP) and its scientific offshoot BSEF^{vi}, also some associations of the textiles and plastics industry, have very recently responded to the voluntary emissions reduction programmes "VECAP"^{vii} and "SECURE"^{viii}. By so doing, participating manufacturers and users in the EU are expected to reduce considerably their emission discharges of DecaBDE, TBBPA and HBCD during the production and processing of flame-retardants. Developments in Germany have gone rather differently: as early as 1986, the Association of Plastic-producing Industries (VKE) and Association of Textile Additive Manufacturers (TEGEWA)^{ix} have voluntarily abandoned all polybromine-based diphenylethers. However, this does not prevent other firms that do not</p>	<p>Germany is one of the biggest</p>

vi BSEF: Bromine Science and Environmental Forum.

vii VECAP: Voluntary Emission-Control Action Plan.

viii SECURE: Self-Enforced Control of Use to Reduce Emissions.

ix TEGEWA: Association of the manufacturers of textiles, paper, leather and fur additives, tensides, complex formers, antimicrobials, flocculants, raw materials for cosmetics and pharmaceutical excipients and related products.

		belong to either industrial association from continuing to use DecaBDE. While the TEGEWA association has now terminated its commitment on DecaBDE in order to join VECAP, the VKE is adhering to its own original commitment of 1986.	users of DecaBDE.
		The Federal Environmental Agency is continuing to support the risk-assessment of bromine-based flame-retardants* and favours the use of more environmentally-acceptable alternatives. With regard to a possible authorisation requirement for HBCD and DecaBDE** under the REACH Directive and the legal proceedings over DecaBDE in electrical and electronic appliances, under the RoHS guideline, the question of suitable substitute substances assumes great urgency. The Federal Environmental Agency recommends, going beyond the legal requirements, that as few flame-retardants as possible that are harmful to the environment and health should be used, or that the use of flame-retardants with different product designs should be avoided. On the strength of scientific knowledge, the Federal Environmental Agency is therefore elaborating recommendations that will influence the criteria for allocating environmental markers (for details see section 6).	*If UBA doesn't acknowledge the risk assessment's outcome, and not even its underlying methodology, then its support seems questionable. **Again, there is no reason to imply that DecaBDE should be classified as a PBT, nor CMR nor vPvB substance under REACH.
3		Use of flame-retardants Flame-retardants serve to delay the ignition of inflammable materials such as plastics, textiles and timber and to slow down the spread of fire. In this way, fire can be either prevented altogether or, if not prevented, there will be more time to allow humans to escape or be saved. However, in a full-blown fire, fire-retardant items will generally burn. Apart from fitting inflammable items with flame-retardants, there are also other approaches to fire-prevention, such as the use of non- or poorly-inflammable materials, such as glass, metal or fire-resistant types of plastics – or safety-oriented product design with integral sealant coatings or sufficiently wide safety gaps. Moreover, organisational or structural measures are vital components of fire-prevention measures.	
		Chemically very diverse substances are used as flame-retardants; they are intended to prevent the spread of any incident of fire through various mechanisms. To do this, the use of a flame-retardant may be either reactive, i.e. with a firm chemical bond to the material to be protected, or additive, i.e. used in addition but without any firm chemical bond. European use of flame-retardants was some 463,800 tonnes in 2005, of which	

		50,000 (11%) were bromine-based flame-retardants (EFRA 2006). Fig. 1 shows the proportions of various flame-retardant materials in overall use.	
		<p>Use of flame-retardants in Europe (2005)</p> <p>Bromine-based compounds 11% Melamine 3% Antimontrioxide 3% Chlorinated paraffin 7% Chlorinated phosphorous compounds 9% Borate and stannate 3% Magnesium dihydroxide 4% Non-halogenous phosphorous compounds 10% Aluminium trihydroxide 50%</p> <p>Fig. 1: Use of flame-retardants in Europe, 2005: proportions of the various types of flame-retardants by weight (source: EFRA 2006)</p>	
		The principal uses of flame-retardants are in electrical and electronic appliances, vehicles (rail, air sea), building products, also furniture and textiles. Each case has its own regulations relating fire-prevention requirements and testing standards.	
		Bromine-based flame-retardants are found mainly in electrical and electronic appliances, but also in building materials and textiles. The flame-retardants used in vehicles, on the other hand, are largely halogen-free ^x , as no corrosive fumes may be emitted in the event of fire. Bromine-based flame-retardants can be combined with many different plastics and cost relatively little. They act at the gaseous phase of the fire. By heating, the bromine-based flame-retardants separate out bromine hydrogen (hydrobromic) and loose bromine, which chemically disrupt the normal chain-reaction of combustion. The individual substances with the largest proportions of overall use of bromine-based flame-retardants are TBBPA, DecaBDE and HBCD.	
4		<p>Assessing the risks of substances</p> <p>In order to assess the health and environmental effects of chemicals and any potential risks, there are agreements; these are standardised throughout the EU. Flame-retardants are industrial chemicals. The legal basis for their evaluation is currently being transferred from the EU Old-substance directive (EG/793/93) over to the Chemicals Directive (EG/1907/2006), which came</p>	

x And are thus free of the chemical elements designated as halogens; bromine, chlorine and fluorine.

	into force on 1 June 2007. The directives, including their technical implementation support contain, apart from testing procedures to determine hazardous properties of chemicals, also standardised methods for the quantitative assessment of risks to humans and environment of chemical origin, from manufacture through to disposal.	
	A risk within the meaning of the EU Old-substance Directive can be quantified on the basis of specific substances and situations. It relies on transparent cause-and-effect relations that can be replicated in the laboratory. With these prerequisites, the procedure is suitable primarily for assessing direct risks through spatially- and temporally-delimitable substance discharges. An immediate risk exists if the previously-expected concentration of chemical (PEC ^{xi}) is above the threshold for a harmful effect (PNEC ^{xii}). If no risk is found in the risk-assessment, it does not follow that the substance is intrinsically without any effect, but merely that its current uses do not bring about any concentrations that are environmentally harmful.	
	Indirect or systemic risks are to be distinguished from direct risks. In these instances, damage does not occur as a consequence of direct contact with the chemical, for example by inhaling, but indirectly through interactions in ecological systems (for example by accumulating in the food-chain). It is characteristic of this type of risk that it is not possible to obtain a minimum threshold level for harm (PNEC), and hence no harmless concentration of the substance (PEC) either. Quite the contrary: there is much scientific uncertainty as to the long-term effects, even at low concentrations in the environment. Owing to their great chemical stability, bromine-based flame-retardants and accumulation within organisms are a cause for concern in that they may cause indirect risks.	Via higher tier testing and the determination of critical body burden (CBB) a PNEC can also be established for e.g. PBT substances (see also ECETOC TR 98).
	Scientific uncertainty over effects on the environment, also on the assessment and control of risks, arise typically in substances with quite specific properties. Under the new Chemicals Directive REACH, therefore, the following substances are regarded as giving cause for particular concern:	
	- PBT substances: persistent, bio-accumulating <u>and</u> toxic substances. Persistence (not readily degradable in the environment), bio-accumulation	

xi PEC: Predicted Environmental Concentration. The concentration expected in the environment on the basis of calculations or measurements.

xii PNEC: Predicted No Effect Concentration. The concentration level above which harmful environmental effects cannot be ruled out.

		(accumulates inside organisms) and toxicity (poisonous effects on humans, ecosystems or organisms) must thereby occur in combination.	
		- vPvB substances: extremely persistent and highly bio-accumulating substances. ^{xiii} Where there is very high persistence and bio-accumulation, then, there is no requirement for evidence of toxicity. Taken together with results of laboratory studies, indications of persistence and bio-accumulation provide evidence of geographically wide distribution of a chemical, even in organisms that live in unpopulated areas, such as the Arctic.	
		- CMR substances: carcinogenic, mutagenic or reproductively-toxic substances, i.e. substances that trigger cancers (are carcinogenic), hereditary damage (are mutagenic) or congenital/reproductive harm (are reproductively toxic) in mammals.	
		- Substances with similarly concerning properties.	
		On precautionary grounds, the new REACH Chemicals Directive prohibits the manufacture, marketing and use of substances with these particularly worrisome properties. Exceptions apply in the case of uses where no substitute is available, and where the socio-economic benefits outweigh the risks. For uses of this type, the EU will issue an authorisation upon application by the manufacturer or user of the substance. To obtain the authorisation, the applicant must demonstrate that discharges into the environment are kept to the lowest level that is technically and practically feasible (the Minimisation Order).	
		The Federal Environment Agency sets criteria for a sustainable and precautionary policy on substances that will extend in part beyond legally-binding EU precepts. On precautionary grounds, the Federal Environment Agency advocates the avoidance of discharges of persistent and/or bio-accumulative substances into the environment, even where no toxic effects are known thus far. In the view of the UBA, persistent and accumulating chemicals have no place in the human body – nor in that of the polar bear. The following box summarises the Federal Environment Agency's action targets for a precautionary and sustainable policy on substances:	The postulations made here go far beyond the REACH regulation. UBA is recommending the prevention of any entries of persistent or bioaccumulative substances into the environment. This absolute request is formulated quoting the precautionary principle, but without any scientific justification and without a critical review of its practical consequences. It is disappointing to see that an institution that is supposed to

^{xiii} vPvB: very persistent, very bio-accumulative.

			have a scientifically founded view is making far reaching recommendations that are neither supported by an in depth analysis of the scientific information available to date nor accompanied by a balanced risk benefit analysis of its consequences.
		<p>The Federal Environment Agency's five action targets for a precautionary and sustainable substance policy^{xiv}:</p> <ol style="list-style-type: none"> 1. No irreversible discharges of persistent and/or bio-accumulative foreign matter into the environment, irrespective of its toxicity. 2. No discharges of carcinogenic, mutagenic or reproductively-toxic foreign matter into the environment. 3. No release of natural substances with the properties mentioned in 1. and 2. by humans, where this will lead to an increase in the natural background level. 4. Reduction in discharges of other toxic or ecotoxic substances to the technically-irreducible level. 5. Minimisation of the discharge of substances with unknown effects where these cannot be retrieved from the environment. 	
5		<p>Assessments of substances by DecaBDE, TBBPA and HBCD</p> <p>The flame-retardants decabromine diphenylether (DecaBDE), tetrabromine bisphenol (TBBPA) and hexabromine cyclododecan (HBCD*) are widely scattered in the environment** and can be found at the top of the food-chain and in the polar regions***. These findings demonstrate the substance's propensity to persist and to bio-accumulate. The Federal Environment Agency therefore considers either a total abandonment, or at least minimisation of discharges into the environment of these three bromine-based flame-retardants, to be essential. As well as their common aspects, these flame-retardants also display differences in the properties of their constituents, their toxic effects and chemical discharges following a fire. The areas in which the three substances are used vary in some respects. In other cases, only one of the three is used.</p>	<p>* On HBCD, please note that new scientific information on environmental monitoring became available after the last draft risk assessment was issued. These data have been submitted to SCHER. We expect that this could affect the PBT assessment.</p> <p>** It is not correct to generalise that BFRs are widely scattered in the environment – e.g. TBBPA has hardly been found.</p> <p>*** Neither is it correct to generalise that BRFs can be found at the top of the food-chain and in the polar regions either: It is not legitimate to extrapolate that because one</p>

xiv Federal Environment Agency (1999): Areas for action and criteria for a precautionary and sustainable substance policy on the example of PVCs. Erich Schmidt Verlag.

		<p>Their uses, also their toxicology profiles, results of European risk-assessments and existing measures, yield the following picture:</p>	<p>substance has been found once or twice, all BFRs are being found all the time. Such statements need to be put into perspective.</p>
5.1		<p>Decabromine diphenylether</p> <p>Use: In the case of DecaBDE we are concerned with the bromine-based flame-retardant with the world's second-largest production output at approx. 56,4000 tonnes a year; the volume processed in Europe is some 8,300 tonnes a year. DecaBDE is used predominantly as a flame-retardant in electrical and electronic appliances, where it is used primarily to protect plastic housings. Its second-largest application is in textiles.</p>	
		<p>Environmental stress and toxicity: DecaBDE is highly persistent, accumulates and shows great mobility. DecaBDE is found in both concentrations in sediments in the vicinity of individual production sites, at the top of food-chains and in remote areas. DecaBDE has been found in foxes, seals, falcons' eggs and in mothers' milk. Certainly DecaBDE is not classified as being toxic to humans or ecologically toxic; however, there remain doubts over its potential toxic effects at low doses (neurotoxicity and endocrine effects). Thus, there are indications that DecaBDE breaks down slowly into low bromine, highly toxic and highly bio-accumulating compounds such as PentaBDE and OctaBDE. Even now, Penta- and OctaBDE may be neither sold nor used in Europe; nor may it be contained in products. Rising concentrations in the environment and the harm caused to humans by fatty foods and through products in their local habitat are therefore cause for concern. However, there are still no complete details on the extent and significance of the various methods of discharge and distribution of DecaBDE in the environment. In the event of fire or uncontrolled disposal, DecaBDE contributes to the formation of highly toxic dioxins and furans.</p>	<p>According to the latest update of the EU risk assessment of 2007 the data available to date do not allow a general conclusion about a potential bioaccumulation in the food chain. According to the EU risk assessment the findings in biota need to be viewed in context and the monitoring activity for this substance is intense in particular when compared to other substances. The levels occurring at all levels of the food chain are typically in the region of several parts per billion on a wet weight basis. This only indicates that low amounts of the substance can be taken up, but there is no evidence for enrichment, accumulation or increasing levels. Industry is proactively working on reducing the entries in the environment through the VECAP and SECURE programs. These have been launched not only in Europe, but also in other regions of the world. At the same time industry is engaging in monitoring activities to follow time trends in environmental concentrations and biota. Contrary to the UBA statement there is no firm evidence of</p>

			<p>increasing levels in the environment or biota so far.</p> <p>The conclusion of UBA that the substance undergoes long-range transport has similarly to be treated with caution. In the EU risk assessment this is put into perspective as it concludes that the presence of Deca-BDE in animal species in the Arctic is not in itself indicative of long-range transport via the air. For example migratory species exposed in industrial areas may themselves act as sources of transport to remote regions.</p> <p>The UBA review states that Deca-BDE is suspected to have long-term neurotoxic properties. In fact the risk assessment has reviewed publications claiming a developmental neurotoxicity under certain conditions in mice and found that those publications did not contain sufficient information for such a conclusion. In fact industry is performing a study according to internationally accepted guidelines and a protocol agreed by the EU authorities at the moment and results should be awaited before drawing any conclusions for this effect.</p>												
		<p>Table 1: Evidence of decabromine diphenylether in the European environment (the figures are taken from the update of the EU risk-assessment of August 2007)</p> <p>Evidence of decabromine diphenylether (DecaBDE) in the European environment</p>													
		<p>Evidence in environmental media ^a</p> <table border="0"> <tr> <td>Surface water (fresh water)</td> <td></td> <td>µg / l</td> </tr> <tr> <td>Sediments (fresh water)</td> <td><0.25 – 1.293 (174,000)</td> <td>µg / kg TG</td> </tr> <tr> <td>Ground</td> <td><0.02 – 330 (2,200)</td> <td>µg / kg TG</td> </tr> <tr> <td>Sewage sludge</td> <td><0.1 – 7.963 (18,039)</td> <td>µg / kg TG</td> </tr> </table>	Surface water (fresh water)		µg / l	Sediments (fresh water)	<0.25 – 1.293 (174,000)	µg / kg TG	Ground	<0.02 – 330 (2,200)	µg / kg TG	Sewage sludge	<0.1 – 7.963 (18,039)	µg / kg TG	
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	<p>Fish, Scheldt estuary, mud-flats (including eel, plaice, sole, herring) 1.9 – 17 µg / kg fat</p> <p>Prawns, Scheldt estuary 269 – 600 µg / kg fat</p> <p>Blue mussels, Norway 0.04 – 0.46 µg / kg FG</p> <p>Cod, liver, Norway 0.4 – 3.0 µg / kg FG</p> <p>Seals, Norway 0.02 µg / kg fat</p> <p>Polar bears, fatty tissue, Norway 0.09 µg / kg fat</p> <p>Fox, liver, Belgium <9.1 – 760 µg / kg fat</p> <p>Raptors, blood, Belgium <2- 58 µg / kg fat</p> <p>Evidence in humans</p> <p>Blood <1 - 273 (2,400) µg / kg fat</p> <p>Mothers' milk <0.1 – 6.8 µg / kg fat</p> <p>TG: dry weight. FG: moist weight. () : extreme high individual weight a: the highest concentrations came from the immediate vicinity of industrial plant. b: concentrations in fat are greater than in the overall fresh weight since DecaBDE accumulates in fat.* In view of the differing proportions of fat in organs and organisms, there is no universal conversion factor available.</p>	
	<p>Results of the EU risk-assessment: The 2005 risk-assessment produced no immediate need to undertake legal risk-reduction measures for DecaBDE. In order to clarify major unresolved issues, the EU Commission is requiring industry to conduct further studies by 2014. A programme to monitor the environment (2004 to 2010) and humans (2004 to 2014) will help fill in gaps in our knowledge of bio-accumulation and breaking down of the substance into compounds with low-bromine, -toxicity and -persistence characteristics. At the present time, a committee of experts at the European Chemicals Bureau (ECB)^{xv} is discussing whether DecaBDE should be treated as a PBT substance in view of its potential long-term toxicity. As a PBT substance, DecaBDE would fulfil the REACH criteria for compulsory authorisation.</p>	<p>* The RA shows that DecaBDE does not accumulate in fat.</p> <p>This has been discussed at the PBT WG in May 2007 and at that meeting, DecaBDE has not been classified as a PBT substance. To our knowledge no further discussions are currently ongoing.</p>
	<p>Further measures: Sweden has already issued a national ban on the use of DecaBDE*; a similar ban comes in to force in Norway on 1 April 2008.** According to the international convention on protection of the North and Baltic Seas, OSPAR and the Helsinki Agreement, DecaBDE discharges should be reduced in the medium term to zero. Furthermore, the EU Parliament and Denmark on the one hand, and the EU Commission on the other, are in dispute at the European Court of Justice (EuGH) over the ban on the use of DecaBDE in electrical and electronic appliances. The RoHS guideline originally provided for a ban on the use of DecaBDE in such appliances. Exemptions would be</p>	<p>* Sweden has not issued a national but a partial ban, as automotive and E&E are exempt. ** As all transport areas are exempt, also for Norway, there is only a partial ban.</p>

xv The European Chemicals Bureau co-ordinates all work on European assessment of chemicals for the EU Commission. A committee made up of industry and official experts is currently discussing over 100 known doubtful substances and is examining whether they are candidates for authorisation. The committee is simultaneously examining whether existing authorisation criteria for PBT and vPvB substances are fit for purpose (Appendix XIII, REACH).

	<p>allowed only where no suitable alternative was available. Notwithstanding the availability of substitutes, the EU Commission lifted the ban on use of DecaBDE proposed under the RoHS guideline. In order to control the further use of this substance, in 2004 manufacturers and processors initiated the so-called "VECAP" project in Europe for voluntary emission-reductions, which makes reference to the use of DecaBDE in plastics and textiles. In Germany there has been a voluntary abandonment of the use of DecaBDE in plastics since 1986 by the Association of plastic-producing industries (now known as Plastics Europe Deutschland).***</p>	<p>*** Germany remains one of the largest users of DecaBDE.</p>
	<p>The position of the Federal Environment Agency: DecaBDE is a flame-retardant used as additive for which more environmentally-acceptable* alternatives are available in the case of both plastics and textiles. The Federal Environment Agency therefore considers total abandonment of its use both feasible and desirable. The manufacturers and processors of bromine-based flame-retardants are opposing voluntary measures to reduce emissions within the EU. With these measures, discharges of DecaBDE into the environment during production and processing can be reduced at sites in the EU. Discharges into the environment during use, and uncontrolled disposal, also discharges into the environment from production and processing that takes place outside the EU, can however be prevented only through a substitute for DecaBDE.** In the absence of any reliable knowledge on the main discharge pathways, measures that are confined to production and processing will not suffice.***</p>	<p>* Please provide the scientific data & risk assessment data for these environmentally acceptable alternatives as well as the chemicals management programs that are put in place to manage these alternatives through the supply chain. ** Please provide information on how substitute discharges will be prevented? *** This applies to so called alternatives rather than to BFRs (see above).</p>
5.2	<p>Tetrabromine bisphenol A</p> <p>Use: TBBPA is the bromine-based flame-retardant with the world's largest production volume at approx. 145,000 tonnes per year; consumption within the EU is approx. 7,000 tonnes per year. It is used at about 90% as a reactive flame-retardant in electronic circuit-boards. It is also used to a lesser extent as an additive flame-retardant in phenol resins and ABS plastics^{xvi}, the latter used primarily for housings of electrical and electronic appliances.</p>	
	<p>Environmental harm and toxicity: TBBPA is not classed as toxic to humans, but is in the case of aquatic organisms. Moreover, this substance is highly persistent in the environment and is found at low concentrations at the top of the food-chain.* In Europe, for example, it can be traced in falcon tissues and in the eggs of birds</p>	<p>* If TBBPA is found, it will be in few instances only and in very low concentrations (the figures below are extremely low). ** See above. TBBPA reduces the overall amount of fires.</p>

Kommentar [MR1]: Übersetzungsfehler

xvi ABS: Acrylonitrile butadiene styrene plastics

	<p>of prey (raptors) from Greenland, also in human mothers' milk. In the case of TBBPA, too, the bromine content with support from catalytically-acting copper from printed circuits, may contribute to the formation of dioxins and furans in the event of fire or uncontrolled disposal**, though not to the same extent as DecaBDE.***</p>	<p>Especially printed circuit boards will not often lead to uncontrolled disposal, as they are valuable waste and metal smelters will pay to recover the waste printed circuit boards. *** Standard studies on bioaccumulation demonstrate that TBBPA is not bioaccumulative. The bioaccumulation is well below the threshold value of the EU for accumulative substances that is already conservative. The available monitoring data indicate some exposure, but are in no way indicative of an accumulation or biomagnification.</p>																											
	<p>Table 2: Evidence of tetrabromine bisphenol A in the European environment (figures taken from draft EU risk-assessment of June 2007)</p>																												
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			properties, which is not correct.
		<p>Results of the European risk-assessment: As with DecaBDE, in the case of TBBPA the European risk-assessment reveals major gaps in our knowledge and hence much uncertainty over existing exposure (environmental concentration)*. Nonetheless, it identifies both risks to water, ground and sediments in the immediate vicinity of production sites (point sources)**, as well as systemic risks. The indirect long-term risks*** can be attributed to diffuse discharges of TBBPA into the ground and the possible breakdown into bisphenol A and tetrabromine bisphenol A bis (methyl ether): the last-named is a candidate for classification as a PBT substance4*. Consequently, in November 2007 the EU recommended measures to restrict emissions and regulations under the European industrial plant and water law (IVU guideline^{xvii} and Water framework guideline^{xviii} in order to reduce risks from point sources.5* TBBPA does not fulfil current PBT criteria according to REACH, as its bio-concentration factor and toxicity lie below the critical threshold level.</p>	<p>*Please be precise on the gaps and the uncertainties that are meant here. ** For only one single production site, a very low risk has been identified. With the help of VECAP, risks to water and soil have been reduced to a level, below which no risk is identified. *** Please be precise on "indirect long-term risks", as these have not been identified by the RA. 4* Within the RA of bisphenol A (update ECB 2008), the risks of bisphenol A resulting from TBBA degradation in soil have been evaluated and no risks for this scenario have been identified. The other possible metabolite mentioned is if at all occurring very minor. Therefore, the RA does not call for further investigations at this point in time. 5* This is not correct. The only measure agreed upon is the IPPC Directive, through permitting requirements.</p>
		<p>Further measures: The international convention on the protection of the North and Baltic Seas – the OSPAR and Helsinki agreement provide that discharges of TBBPA should be reduced in the medium term to zero. At EU level, the European Parliament proposed TBPPA as a priority substance for the Water framework guideline.* At the present time, producers and processors of bromine-based flame-retardants have voluntarily adopted the emission reductions of the VECAP programme and are collecting more accurate data on emissions from the use of this substance. Whether this initiative will suffice to control the identified potential risk cannot be foreseen at the present time.**</p>	<p>* This is only a proposal, and by no means a regulation. ** VECAP has already done so: The risk to water & soil has been reduced to a level, below which no risk is identified. The only remaining, low risk is to sediment at only ONE site in Europe. Besides, the IPPC Directive has been recommended as measure to control risks in the future through permitting requirements.</p>

xvii Guideline 96/61/EG of the Council of 24 September 1996 on integrated prevention and reduction of pollution and contamination of the environment.

xviii Guideline 2000/60/EG of the European Parliament and Council of 23 October 2000 on the creation of a structuring framework for community measures in the domain of water policy (Water framework guideline WRRL).

	<p>The position of the Federal Environment Agency: Since TBBPA is indisputably persistent and is widely dispersed in the environment*, prevention has to be of capital importance in selective measures to limit emissions. There are adequate alternative** substances available for additive uses of TBBPA that can be used in the short term (see chapter 6). For reactive use in printed circuits with epoxy resin as the carrier material, too, the manufacturers of printed circuits have developed alternatives in recent years, whose market share remains small.*** In the medium term, replacement by more environmentally-acceptable alternatives should be sought for this use, if the manufacturer is unable to produce evidence of effective prevention of emissions at all phases of a product's life.4*</p>	<p>* Again, looking at the monitoring data, "dispersed" in the environment is not really the case, as it's hardly ever found & if found, it's at very low concentrations. ** Please provide scientific studies & risk assessments for these alternatives. *** TBBPA is used as a monomer in printed circuit boards, & hence is part of the final plastic. Is this the case for the alternatives? 4* How about for the alternatives, are there any effective prevention of emissions? Are they subject to chemicals management program such as VECAP for TBBPA?</p>
<p>5.3</p>	<p>Hexabromine cyclododecan</p> <p>Use: approx. 22,000 tonnes HBCD are used annually worldwide, hence HBCD is the bromine-based flame-retardant with the third-highest usage. Consumption within the EU is some 9,600 tonnes a year. It is used predominantly as a flame-retardant in insulator materials made of polystyrene, also in textiles and components for electrical and electronic appliances.</p>	
	<p>Environmental harm and toxicity: HBCD is toxic to aquatic organisms. It can be detected in numerous marine organisms and in human mothers' milk. The hazard to humans through transmission in mothers' milk, potential reproductive damage effects or neurotoxic developmental disturbance have not as yet been scientifically elucidated. HBCD is persistent* in the environment and shows a strong tendency towards bio-accumulation. It can be found at the top of the marine (raptors, seals, polar bears) and terrestrial (raptors) food-chains. It occurs in both inhabited and uninhabited areas, such as polar regions. Environmental stress** is clearly increasing over time. Where burning methods are unsuitable, or in uncontrolled fires, polybromine dioxins and furans will form from HBCD***; though not to the same degree as with DecaBDE.</p>	<p>A differentiation should be made between hot spots (where HBCD is / has been produced or where HBCD is used) and pristine locations with much lower concentrations in e.g. sediments.</p> <p>*HBCD is not persistent.</p> <p>**The term "environmental stress" suggests proven adverse effects for which there is no evidence. ***This could be said of many materials, products and not just flame retardants. In any case HBCD is added to prevent fires since it is a flame retardant. HBCD has been tested to</p>

			<p>ensure that it does not generate dioxins and furans sufficient to meet the German Dioxin Verordnung. In addition Industry data indicate that since HBCD is not aromatic, its likelihood of forming dioxins and furans is low. Incineration experiments under optimum and low oxygen conditions ("Schwelbrand") resulted in no differences of the brominated dioxin and furan spectrum between HBCD containing EPS and EPS without HBCD under both incineration conditions. The detection level was that low that even ubiquitous chlorinated dioxin could be found without any added source of chlorine. That supports the knowledge that HBCD under ignition temperatures produces quantitatively HBr which is the reason for the high efficiency of HBCD as FR.</p> <p>Please note that new scientific information on environmental monitoring became available after the last draft risk assessment was issued. These data have been submitted to SCHER. We expect that this could affect the PBT assessment.</p> <p>Please note that recently, an extended 2-generation study conducted by the Japanese Ministry of Health, Labour and Welfare has been publishedⁱⁱⁱ, which did not identify any "effects at critical stages of embryo development or early childhood" upon treatment with HBCD. This extensive guideline study did not confirm the reports of Eriksson et al. on developmental effects, who used non-validated experimental procedures and inadequate statistics.</p>
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			Furthermore, an OECD 414 teratogenicity study was without findings. The sentence <i>"The hazard to humans through transmission in mothers' milk, potential reproductive damage effects or neurotoxic developmental disturbance have not as yet been scientifically elucidated."</i> is therefore inadequate.
		Table 3: Evidence of hexabromine cyclododecan in the European environment (figures are taken from the draft EU risk-assessment for the environment of October 2006). In the case of humans, they are taken from Covaci et al (2006), since this part of the risk-assessment is not yet to hand.	We strongly suggest using the latest version of October 2007 instead of 2006.
		Evidence of hexabromine cyclododecan (HBCD) in the European environment Evidence in environmental media ^a Surface water (fresh water) <0.02 – 1.5 µg / l Sediments (fresh water) <0.1 – 11,000 µg / kg TG Ground 0.14 – 90 µg / kg TG Sewage sludge <0.3 – 9,120 µg / kg TG	
		Evidence in organisms (selection) ^b Fresh-water fish (incl. perch, eel, trout) <0.03 – 9,432 (27,705) µg / kg FG (fat) Moss, Norway <1.5 – 11,114 µg / kg FG Peregrine, eggs (incl. Greenland, Sweden) <0.002 – 160 (590) µg / kg FG (fat) Crustaceans (incl. mussels, shrimps) <0.5 - 329 (17,337) µg / kg FG (fat) Marine fish, muscle (incl. perch, eel, grudgeon) <0.001 – 49 (113) µg / kg FG (fat) Marine fish, liver (incl. cod, sole) <0.3 – 89 µg / kg FG Marine mammals (seal, porpoise, dolphin) 0.5 – 6,400 (21,345) µg / kg FG (fat) Polar bears 5 – 45 µg / kg FG Sea-birds 0.5 – 100 µg / kg FG	
		Evidence in humans Blood, Netherlands <80 – 360 µg / kg fat Mothers' milk, Sweden <0.2 – 2.4 µg / kg fat TG: dry weight. FG: moist weight. () : extreme high individual weight a: the highest concentrations came from the immediate vicinity of industrial plant. b: concentrations in fat are greater than in the overall fresh weight since DecaBDE* accumulates in fat. In view of the differing proportions of fat in organs and organisms, there is no universal conversion factor available.**	*As above! This table is supposed to be on HBCD. Obviously, UBA simply copied statements from the DecaBDE to the HBCD section. Again, this confirms that they do not look at the substances individually but assume that all substances have the same properties, which is not correct

	<p>Results of the EU risk-assessment: The risk-assessment yielded direct risks and a systemic risk potential. The processing of HBCD brings about considerable local risks to humans and environment alike (water, sediments)*. Critical point sources are plants for the formulating of expanded and extruded polystyrenes (EPS, XPS) and for textile coatings. The exposure scenarios used in the risk-assessment provide evidence of workplace health hazards as a consequence of inhaling HBCD in the form of fine powder. Heavy bio-accumulation also creates indirect risks in all food-chains, and especially to marine mammals. Those risks can be traced to all the main areas of use. Just as in the cases of the other two flame-retardants, there are also serious doubts and uncertainties in the case of HBCD, notably over quantifying the discharge pathways**; hence the authors of the risk-assessment recommend improvements to the standard of data through further tests and data from field observations in the environment. However, since there is an overall need for serious action, the risk-assessment provided by EU member state Sweden in September 2007, which is competent for HBCD, included risk-reduction proposals.*** These provide for a ban on virtually all uses. There is an exemption for its use in heat insulators, for which Sweden proposes a transitional period. In addition, HBCD fulfils the criteria for compulsory authorisation under REACH. If HBCD becomes a substance requiring authorisation under REACH, its use – if at all – would take place only for a limited period and under strict conditions.</p>	<p>Please note that the environmental risk assessment of HBCD is not finalised and has to be reviewed by the SCHER experts.</p> <p>* If the environmental risk assessment is not yet to hand (cfr Table 3), how does UBA know that there are “considerable” risks? ** It is not correct to speak of doubts & uncertainties. *** Risk reduction proposals are not incorporated into a risk assessment. A risk reduction strategy is ongoing for HBCD, & the outcome should be awaited before taking any action.</p>
	<p>Further measures: As well as the expected wide-ranging risk-reduction measures, Sweden proposed that HBCD should be subject to further regulation. The international Convention on the protection of the North and Baltic Seas provides for a medium-term reduction in HBCD discharges to zero. Industrial firms that produce or process HBCD are currently bringing the flame-retardant within the ambit of the VECAP* emission-reduction project. Moreover, in 2007 the manufacturers' association EBFRIP** began an HBCD environment-monitoring programme at EU level (SECURE), to raise data on current damage*** and future trends.</p>	<p>* There are two emissions reduction programs, VECAP for textile use and SECURE for the EPS and XPS application.</p> <p>** The environmental monitoring program is a joint manufacturers and users program. SECURE is the emission reduction program.</p> <p>*** The aim of the environmental monitoring program is incorrectly stated. The aim is to assess the effectiveness of the emission reduction programs.</p>
	<p>The position of the Federal Environment Agency: HBCD is a flame-retardant used as an additive; it has a</p>	<p>* Studies have shown that</p>

	<p>very strong tendency to bio-accumulate, and whose long-term toxicity to humans has not yet been fully elucidated. Moreover, it is persistent* and is toxic to aquatic organisms.** Prevention of this substance in the environment must therefore take high priority in selective emission-reduction measures. There are satisfactory more environmentally-acceptable alternatives to HBCD available for uses in textile back coatings and plastic housings, hence these uses can be ended in the near future (see chapter 6). For insulators made of polystyrene, on the other hand, in the short term there is as yet no known satisfactory flame-retardant. Research is required here to seek out and test a suitable flame-retardant. While producers of polystyrene insulators continue to use HBCD, measures to ensure effective prevention of emissions are required at all phases of production in the short term. Furthermore, the Federal Environment Agency advocates using other environmentally-acceptable*** insulation materials for heat insulation wherever technically feasible, until an alternative flame-retardant for polystyrene is found.</p>	<p>HBCD can degrade to cyclododecatriene which further mineralise.</p> <p>** Please note that new scientific information on environmental monitoring became available after the last draft risk assessment was issued. These data have been submitted to SCHER. We expect that this could affect the PBT assessment.</p> <p>*** The only technically available alternative to HBCD in textile backcoating is DecaBDE. Scientific risk assessments for the alternatives insulation material should be provided.</p>																				
<p>5.4</p>	<p>Substance assessments in overview</p> <p>Table 4 shows the hazardous features and the assessment of potential direct and indirect risks of the three bromine-based flame-retardants, decabromine diphenylether (DecaBDE), tetrabromine bisphenol A (TBBPA) and hexabromine cyclododecan (HBCD) in summary.</p>																					
	<p>Table 4: Summary of hazardous properties and risk characteristics of the three flame-retardants examined</p> <table border="1" data-bbox="300 1294 865 1718"> <thead> <tr> <th>Flame-retardant</th> <th>DecaBDE</th> <th>TBBPA</th> <th>HBCD</th> </tr> </thead> <tbody> <tr> <td>Hazardous feature (classification and identifier)</td> <td>-</td> <td>R 50/53</td> <td>R50/53, R33, R64 (proposals) *</td> </tr> <tr> <td>Direct risks (PEC / PNEC assessment)</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Local environmental risks at point sources (water, ground, sewage sludge, sediment)</td> <td>no</td> <td>Yes*</td> <td>yes</td> </tr> <tr> <td>Health risks (protection for work, product use)</td> <td>?*</td> <td>no</td> <td>yes (protection for work)</td> </tr> </tbody> </table>	Flame-retardant	DecaBDE	TBBPA	HBCD	Hazardous feature (classification and identifier)	-	R 50/53	R50/53, R33, R64 (proposals) *	Direct risks (PEC / PNEC assessment)				Local environmental risks at point sources (water, ground, sewage sludge, sediment)	no	Yes*	yes	Health risks (protection for work, product use)	?*	no	yes (protection for work)	<p><u>Table</u></p> <p>* this doesn't necessarily mean it is prone to long distance travelling)</p> <p>** Criterion of NOEC < 10ug/l)</p> <p><u>DecaBDE</u></p> <p>* No health risks according to the RA</p> <p>** No Bio-accumulation according to the RA</p> <p>*** No. Found in some raptors, but that doesn't mean it bioaccumulates in the food chain.</p> <p>4* It has not been proven that DecaBDE does degrade. Besides, according to UBA it is very persistent?</p>
Flame-retardant	DecaBDE	TBBPA	HBCD																			
Hazardous feature (classification and identifier)	-	R 50/53	R50/53, R33, R64 (proposals) *																			
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Local environmental risks at point sources (water, ground, sewage sludge, sediment)	no	Yes*	yes																			
Health risks (protection for work, product use)	?*	no	yes (protection for work)																			

		<p>Indirect risks (PBT assessment)</p> <table border="1"> <tr> <td>Persistence Half-life > 60 days water</td> <td>yes (highly persistent)</td> <td>yes (highly persistent)</td> <td>yes (persistent) **</td> </tr> <tr> <td>Half-life > 120 days lime sediment/ground</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Bio-accumulation BCF > 2000</td> <td>? (test problem)*</td> <td>yes (below threshold) **</td> <td>yes (highly bio-accumulative)</td> </tr> <tr> <td>Accumulation in the food-chain (findings of monitoring)</td> <td>Yes***</td> <td>Yes***</td> <td>yes</td> </tr> <tr> <td>Evidence in polar regions (potential to travel long distances)*</td> <td>yes</td> <td>Yes</td> <td>yes</td> </tr> <tr> <td>Long-term toxic properties (CMR effects, neurotoxicity)</td> <td>? (endocrine effects, neurotoxicity)</td> <td>no</td> <td>?</td> </tr> <tr> <td>Long-term ecotoxic properties (0.1** mg/l in chronic test for aquatic organisms)</td> <td>?</td> <td>yes (below threshold)</td> <td>yes</td> </tr> <tr> <td>Toxic and/or persistent products of breakdown</td> <td>Yes4*</td> <td>Yes4*</td> <td>Yes***</td> </tr> </table> <p>BCF: Bioconcentration factor. PEC: Predicted Environmental Concentration. PNEC: Predicted No Effect Concentration. PBT: persistent, bio-accumulating and toxic. CMR: carcinogenic, mutagenic or reproductively toxic, R50/53: highly toxic to aquatic organisms; may have long-term harmful effects in water. R33: risk of cumulative effects. R64: may harm infants via mother's milk.</p>	Persistence Half-life > 60 days water	yes (highly persistent)	yes (highly persistent)	yes (persistent) **	Half-life > 120 days lime sediment/ground				Bio-accumulation BCF > 2000	? (test problem)*	yes (below threshold) **	yes (highly bio-accumulative)	Accumulation in the food-chain (findings of monitoring)	Yes***	Yes***	yes	Evidence in polar regions (potential to travel long distances)*	yes	Yes	yes	Long-term toxic properties (CMR effects, neurotoxicity)	? (endocrine effects, neurotoxicity)	no	?	Long-term ecotoxic properties (0.1** mg/l in chronic test for aquatic organisms)	?	yes (below threshold)	yes	Toxic and/or persistent products of breakdown	Yes4*	Yes4*	Yes***		<p>TBBPA * At one single plant in Europe ** No (below threshold) *** No. Found in some raptors & in very low concentration, but that doesn't mean it bioaccumulates in the food chain 4* TBBPA is very persistent according to UBA? It can degrade under one condition to BPA for which a RA is ongoing. To our understanding BPA can also degrade.</p> <p>HBCD * R33 and R64 were removed in the last risk assessment version – please remove from the table. ** The draft HBCD risk assessment states that HBCD does not unequivocally fulfil the Persistency criterion. *** The degradation product of HBCD is cyclododecatriene. This substance is not a PBT substance as agreed by the PBT working group.</p>
Persistence Half-life > 60 days water	yes (highly persistent)	yes (highly persistent)	yes (persistent) **																																	
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6		<p>Reducing discharges of bromine-based flame-retardants into the environment</p>																																		
6.1		<p>Emission controls and substitution as reduction strategies</p> <p>Discharges of bromine-based flame-retardants into the environment can in principle be reduced in two ways: firstly through technical emission-controlling measures and secondly by substitution with less troublesome flame-retardants in the various applications or with completely different materials, as well as methods of fire-prevention. Technical measures facilitate control primarily of point sources during production or through targeted waste treatment, whereas diffuse sources in use, or uncontrolled disposal, can as a rule be</p>		<p>* See above. Please explain how to deal with diffuse source emissions from substitutes.</p>																																

	eliminated only by substituting with an alternative flame-retardant. In the case of bromine-based flame-retardants, all routes of discharges into the environment play a role.*	
	When making a choice of risk-reduction measures, the REACH assessment of a substance will be decisive in future.* In principle, users of flame-retardants are free to elect either substitution of less problematic substances or emission-control measures. Where we are concerned with PBT substance according to REACH criteria, and hence with a persistent, bio-accumulative and toxic substance, its use would be permissible only for a transitional period, after which it would in principle be banned entirely on precautionary grounds. Further use would be authorised only upon application if there were no less harmful substitute substance available, the socio-economic consequences of an outright ban would be unacceptable, and emissions of that substance could be kept under sufficient control throughout its life-cycle. The European Chemicals Bureau proposes HBCD as a flame-retardant; DecaBDE** is also on the agenda. In the event of both substances being classified as PBT substances, available substitutes and options for effective emission controls (i.e. minimisation) will be authoritative in any subsequent decision on an application for authorisation.	* Hence REACH should be awaited because at least that will give a level playing field. While a lot is now known about some of the BFRs, not much is known about the alternatives including potential emission sources & chemicals management programs. ** This is not correct.
	The Federal Environment Agency considers stringent emission-control measures and/or substitution to be essential for all three bromine-based flame-retardants in any case, even if they are not classified as PBT substances by REACH criteria.* Even if the flame-retardant does not completely fulfil all three PBT criteria, some threshold values may be just missed, or suggestive indicators of harmful effects may not be sufficiently weakened (see table 4). In addition, up till now the PBT criteria in Appendix XIII to REACH fail to display sufficient robustness to allow of the confident identification of known problem substances. Accordingly, the legislator is setting a deadline of 1 December 2008 for the revision of Appendix XIII. The three bromine-based flame-retardants DecaBDE, HBCD and TBBPA fulfil the UBA criteria justifying precautionary measures (see info box, section 4). Environmental findings from around the world and at the top of food-chains confirm their persistence, great mobility and tendency to accumulate.	It is disturbing that UBA is proposing precautionary principle for substances that have undergone a full risk assessment & that have been the subject to decision at EU level, while they would allow substances that have not undergone any risk assessment at all, & for which scientific data is much less abundant, & finally, which are not subject to any chemicals management program. It is also striking that UBA asks to ignore REACH if the REACH results would contradict their own view, although REACH is legally binding.
	Manufacturers of bromine-based flame-retardants are making voluntary commitments to control emissions under the VECAP and SECURE programmes.* The programmes are aimed at both subsidiary organisations	See above

	<p>and directly at all purchasers of bromine-based flame-retardants. On the strength of substance appraisals and personal advice by the suppliers of substances, each firm identifies the possible sources of uncontrolled emissions and then attempts to eliminate them. Estimates made by DecaBDE producers show that emissions can be reduced at many production and processing sites. This is a good first step. However, it is not in itself sufficient to reduce damage significantly, particularly in the marine environment.</p>	
	<p>In order to reduce discharges from both products and from harmful by-products in cases of fire or during uncontrolled disposal, the Federal Environment Agency considers it essential to seek substitutes for the three bromine-based flame-retardants as widely as possible. From the resulting use of replacement substances or products there will follow the reduction of discharges of bromine-based flame-retardants into the environment, also among those companies in the EU that do not themselves participate in the emission-reduction programmes, and at production sites outside Europe.</p>	See above
	<p>Table 5 shows the Federal Environment Agency's general existing ecological priorities on the use of various flame-retardants in products. The Federal Environment Agency considers that the use of halogen-free reactive bonded flame-retardants or the use of alternative materials and appliance designs is generally ecologically beneficial by comparison with halogenous flame-retardants^{xix}. In addition, reactively-fixed flame-retardants have less tendency to migrate or flush out of products as an additive flame-retardant*, and as such are to be preferred. A requirement for the use of all flame-retardants (both halogenous and non-halogenous) is that their environmental and health effects have been properly investigated and that no risks to health or to the environment arise during manufacture or disposal. In individual cases, technical operating and usage measures may result in the resetting of priorities. The Federal Environment Agency recommends that product manufacturers should abandon the use of flame-retardants that fail to display the properties shown in table 5.</p>	<p>* This is the case for TBBPA, so why ask for substitution in the first place?</p>
	<p>Table 5: Ecological priorities when including flame-retardants in products</p>	<p>* Red phosphorous is classified as very toxic to the</p>

^{xix} Virtually all flame-retardants identified as being particularly troublesome come from the group of halogenous flame-retardants. In particular, many bromine-based compounds display a tendency towards persistence and bio-accumulation. Thus, bromine compounds whose structure is modified only slightly do not represent a satisfactory substitute. However, halogenous phosphorous compounds have undesirable ecological characteristics; moreover, in all strongly halogenous compounds there is an increased potential for the formation of corrosive fumes, together with dioxins and furans, in the event of fire.

	<p>Ecological priorities when including flame-retardants in products</p> <ol style="list-style-type: none"> 1. Constructive measures to reduce the use of flame-retardants (use of fire-resistant materials, inclusion of sealant coatings, adjusting the use of flame-retardants as appropriate for the voltage of the appliance, etc). 2. Inorganic flame-retardants (aluminium hydroxide, magnesium hydroxide, red phosphorous* (micro-encapsulated), ammonium polyphosphate) 3. Reactively-fixed halogen-free organic nitrogen and phosphorous compounds** 4. Additively-used halogen-free organic nitrogen and phosphorous compounds that are not persistent, bio-accumulative, nor have long-term toxicity to humans or ecological toxicity.*** 5. Reactively-fixed halogenous flame-retardants 6. Additively-used halogenous flame-retardants that are not persistent, bio-accumulative nor toxic to humans or ecologically toxic. 	<p>environment, and it leads to highly toxic decomposition products. Unlike TBBPA, it's not a reactive. No RA has been done on red P. ** these do not have risk assessments, scientific data, chemical management programs, understanding of findings in the environment, monitoring programs *** See above</p>
<p>6.2</p>	<p>Substitution of DecaBDE, TBBPA and HBCD</p> <p>The development and assessment of options for substitution for the three bromine-based flame-retardants is at varying stages. The current position of potentially suitable halogen-free substitutes for the various types of use is summarised in this section; however this does constitute a fully-detailed evaluation of the health and environmental effects of these substitutes.*</p>	<p>* Again, no risk assessments, no scientific data, no chemicals management program, no knowledge of whether they are found in the environment, no understanding of where the substances end up, no monitoring programs are available.</p>
	<p>Replacement of DecaBDE, TBBPA and HBCD in plastics for electrical and electronic appliances:</p> <p>There are numerous studies and examples of practice for the substitution of bromine-based flame-retardants in plastic housings and small components of these appliances. For housing plastics, halogen-free, organic phosphorous compounds are generally used instead of bromine-based flame-retardants. This requires simultaneously exchanging the useful amount of plastic ABS (acrylonitrile butadiene styrene) and HIPS (high impact polystyrene, impact polystyrene) for rather more expensive but less inflammable blends of those plastics with PC (polycarbonate) or PPE (polyphenylether). For small components made of polyester plastics (PBT, PET) or polyamide (PA), substitute substances such as magnesium hydroxide, micro-encapsulated red phosphorous, melamine or organic phosphinates are suitable. In the case of low-voltage appliances, the</p>	

	<p>amount of flame-retardant used can often be reduced, since they are often designed more robustly than is actually required to fulfil fire-prevention regulations. Also, the increasing fire-protection of electrical and electronic appliances against external sources of ignition, which results in increased use of flame-retardants, calls for a wider debate among experts and in society at large in order to weigh up the advantages and drawbacks. This debate has hitherto taken place exclusively in committees concerned with flame-retardants at the technical level.</p>	
	<p>Replacement of DecaBDE and HBCD in textiles: There are many ways of replacing bromine-based flame-retardants in textiles: these are the permanent inclusion of cellulose fibres with reactive phosphorous-based flame-retardants or inherently flame-proof polyester fibres with integrated flame-retardant molecules that likewise contain phosphorous. Fabrics made from fire-resistant fibre materials such as polyaramides, or from non-inflammable fibreglass, are also tried-and-tested. Another possibility is further development of intumescence systems that will expand in the event of fire, thereby forming a sealing coat. The structure and density of the fabric or upholstery also have a crucial effect on behaviour in fire.</p>	
	<p>Replacement of TBBPA in printed circuits: There have been many technical advances in bromine-free printed circuits in recent years. Some manufacturers have products ready for market. Here, too, substitutes containing phosphorous, such as DOPO (dihydroxaphospha-phenanthren), polymer phosphonates and metallic phosphinates come widely into use, sometimes in combination with inorganic compounds, such as aluminium hydroxide or silicon dioxide. The usual carrier polymer remains epoxy resin, as in conventional printed circuits. The findings of recent research also show a possible inclination towards thermo-plastic printed circuits made of fire-resistant carrier polymers such as PEI (polyetherimide) and PES (polyethersulphone).</p>	
	<p>Replacement of HBCD in insulators: Thus far there is no known flame-retardant for insulators made of polystyrene that would be suitable as a substitute for HBCD. In principle, mineral wool is suitable as a substitute material for fire-protected polystyrene insulators – with the exception of heat insulators for earthed components (perimeter insulation). The health effects of mineral wool when using buildings are nowadays quite innocuous. However,</p>	<p>It seems there is more emphasis in this section in substitution products for the insulation. Before suggesting competing products, insulation products should be evaluated on their ability to serve the purpose in all respects. Otherwise a misleading</p>

	<p>usual workplace protection practices need to be observed whilst fitting. It is clearly necessary on climate-change grounds to improve the standard of heat-insulation in buildings compared with the current position. EU member state Sweden, which is the competent state for elaborating risk-reduction measures, therefore recommends “considering whether there should be a time-limited exemption from a total ban on use in the case of insulators made of polystyrene”, in order to allow the continuation of heat insulation using flame-retardant polystyrene insulators.</p>	<p>conclusion can be reached. For instance, mineral fibre is not a direct replacement for XPS in load bearing applications. Mineralwool is not an appropriate substitute of styrenic foams in their specific applications (apart from perimeter e.g. Facades). They are much heavier causing static problems and installation with much higher costs. In addition, for applications outside a building the high permeability for water leads quickly to a drastic loss of insulation due to the high humidity inside. Together with high energy per insulation for production this results in a very low ecoefficiency. The high costs for installation causes high entrance barrier for insulation especially of the vast majority of existing buildings. Polystyrene insulation foams represent a third of the insulation material market in Europe. These products are critical to meet the European Union targets for energy efficiency requirements. Making polystyrene foams unavailable to the construction sector would jeopardize CO2 reduction objectives.</p>
	<p>Table 6 summarises the essential technically-suitable halogen-free substitution options for the various types of use. A detailed assessment of the health and environmental characteristics of the substitute materials is not made; however, as a minimum they fulfil all the requirements shown in Table 5.</p>	
	<p>Table 6: Summary of options for halogen-free substitution of bromine-based flame-retardants DecaBDE, TBBPA and HBCD (examples) *</p>	<p>*See above (comments on substitutes). Please provide the data available & to a similar degree as the data we have for DecaBDE, TBBPA & HBCD. If data are not available, they should first of all be generated (monitoring data, neurotoxicity</p>

Domain of use	Bromine-based flame-retardant (plastic/fibre)	Technically suitable options for substitution (examples) Replacement substance and /or material	data etc.)
Housing plastics for electrical and electronic appliances	DecaBDE (ABS, HIPS) HBCD (HIPS) TBBA additive (ABS)	Flame-retardants containing phosphorous; halogen-free: RDP, BDP, (PC/ABS, PPE/HIPS)	
Small components for electrical and electronic appliances	DecaBDE (PBT, PET, PA)	Red phosphorous (micro-encapsulated), magnesium hydroxide, melamine, metallic phosphinate (PA) Metallic phosphinate (PBT, PET)	
Printed circuits	TBBPA reactive (epoxy resin) TBBA additive (phenol resin)	Flame-retardants containing phosphorous; halogen-free: DOPO / aluminium hydroxide (epoxy resin) Metallic phosphinate/ DOPO/ silicon dioxide (epoxy resin) Polymer phosphonate (epoxy resin) Fire-resistant duro-plastics Fire-resistant thermo-plastics (under development)	
Textile backcoatings **	DecaBDE (various fibres) HBCD (various fibres)	Intrinsically fire-retardant man-made fibres with interwoven FSM (PP, PE)*** Fire-resistant man-made fibres (polyaramide)4*; fibreglass Permanent inclusion of phosphonium 5* compounds (cellulose) Intumescence systems6* (various	<p>**Bromine is the most effective FR as it works in the gas phase, thus being capable of working from the back coating without affecting the front side of the fabric.</p> <p>*** Some applications need a defined decomposition temperature which only HBCD can provide: Transparent coating, light- weight fabrics and fabrics with a very open weave structure used for roller blind materials, filter clothes, lamellas, cinema canvas and awnings for use in public buildings (cinemas, hospitals, prisons etc.), cars and aeroplanes. 4* way too expensive for use 5* Effective but a very "dirty" process. What is known about THPC in view to HSE?</p>

			fibres)	
		Insulators made of polystyrene	HBCD (EPS, XPS)	Mineral wool (except for perimeter insulation)7*
		With: ABS: Acrylonitrile butadiene styrene		
		PC: Polycarbonate		
		BDP: Bisphenol A-bis (diphenyl phosphate)		
		PET: Polyethylene terephthalate		
		DOPO: Dihydroxaphospha-phenanthren		
		PP: Polypropylene		
		EPS: Expanded polystyrene		
		PPE: Polyphenylether		
		FSM: Flame-retardant		
		RDP: Resorcinol-B (diphenyl phosphate)		
		HIPS: High-Impact Polystyrene		
		XPS: Extruded polystyrene		
7.		Need for wide-ranging action and research		
		In the view of the Federal Environment Agency, the following overriding points require further action and research:		
		The current REACH criteria for PBT substances are not sufficiently flexible to capture those chemicals that environmentally-relevant with confidence. The existing criteria rely primarily on laboratory tests, which are unsuited to many chemicals that are relevant for the environment. Thus, the EU should take greater account of the results of investigations involving the monitoring of chemical residues in the environment when identifying PBT substances.		
		The inadequate classification and identification of persistent, bio-accumulative substances renders it difficult for non-experts to identify the need for precautionary technical measures. A more robust requirement for classification and identification would provide strong support to the developing of more environmentally-acceptable and healthy products, since product-developers would then be able more easily to identify such doubtful substances and replace them with less troublesome ones.		
		The assessment of substitute substances is of capital importance, for both the assessing of		

6* High levels of addition needed – easily can turn a textile material into a hard board.
7* Please provide information on whether mineral wool was risk assessed and whether its risks to human health are inferior to HBCD risks?

		<p>authorisation applications under REACH and for voluntary substitution measures. Since we are seeing continuous technical advances, a regular, possibly institutionalised assessment of replacement substances and products is needed in order to be able to issue recommendations with a sufficient degree of confidence.</p>	
		<p>It is essential to turn our attention not only to the three bromine-based flame-retardants described in this paper. Research work needs to examine the occurrence of other bromine- or non-bromine-based flame-retardants in the environment, wherever there are indications of potentially worrisome properties.</p>	

ⁱ Ema M, Fujii S, Hirata-Koizumi M, Matsumoto M. Two-generation reproductive toxicity study of the flame retardant hexabromocyclododecane in rats. *Reprod Toxicol.* 2007 Dec 28, in press.

ⁱⁱ Eriksson et al. Impaired behaviour, learning and memory, in adult mice neonatally exposed to hexabromocyclododecane (HBCDD.)*Environmental Toxicology and Pharmacology* 21 (2006) 317–322.

ⁱⁱⁱ Ema M, Fujii S, Hirata-Koizumi M, Matsumoto M. Two-generation reproductive toxicity study of the flame retardant hexabromocyclododecane in rats. *Reprod Toxicol.* 2007 Dec 28, in press.