DANISH MINISTRY OF THE ENVIRONMENT

Environmental Protection Agency

Inclusion of HBCDD, DEHP, BBP, DBP and additive use of TBBPA in annex IV of the Commission's recast proposal of the RoHS Directive

- Socioeconomic impacts

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Preface

In the European Union, the restriction of certain hazardous chemicals in electrical and electronic equipment is regulated in the Directive on Restriction of certain Hazardous Substances in electrical and electronic equipment[1], the so-called RoHS Directive. As parts of the current recasting of the RoHS Directive, the European Commission has evaluated a number of substances for inclusion in the list of restricted substances in accordance with Article 6 of the Directive: "***The Commission shall also study the need to adapt the list of substances of Article 4(1), on the basis of scientific facts and taking the precautionary principle into account, and present proposals to the European Parliament and Council for such adaptations, if appropriate.***"

The Commission has not proposed addition of other hazardous substances used in electrical and electronic equipment.

The Commission's proposal for a re-cast of the Directive is currently (2009) negotiated among the Member States.

In response to the Commission's proposal, Denmark finds it relevant to consider the proposal of the inclusion of the following five substances in Annex IV of the recast proposed by the Commission, rendering their respective use in electrical and electronic equipment restricted in the European Union:

- Hexabromocyclododecane (HBCDD)
- Bis (2-ethylhexyl) phthalate (DEHP; also called di(ethylhexyl) phthalate)
- Butyl benzyl phthalate (BBP)
- Dibutyl phthalate (DBP)
- Additive use of tetrabromo bisphenol A (TBBPA)

Certain aspects relevant to the inclusion in the RoHS Directive of these substances were assessed by Öko-institut e.V. for the European Commission, DG Environment (Gross ***et al.***, 2008). The study included a review of the use of the substances, relevant legislation, human health and environmental risk assessments and information on disposal and recycling.

The Danish Environmental Protection Agency has contracted with COWI A/S to supplement the existing assessment with the present assessment of socioeconomic impacts of the inclusion of these same substances under the RoHS Directive.

This present assessment is primarily based on existing reports on the relevant substances and applications. Technical reports prepared for ECHA for the evaluation of the possible inclusion of HBCDD, DEHP, BBP and DBP in Annex XIV of REACH were included in the assessment.

[1] Directive 2002/95/EC of January 2003

The study has been guided by a steering group consisting of Dorte Lerche, Lissie Jørgensen and Anette Ejersted, the Danish Environmental Protection Agency, and Carsten Lassen and Jakob Maag, COWI A/S.

This report was prepared by Jakob Maag, Ulla Kristine Brandt, Sonja Hagen Mikkelsen and Carsten Lassen (Project Manager), COWI A/S, Denmark. The study was conducted during a period from August to October 2009.

Executive Summary

In response to the European Commission's 2009 proposal for a re-cast of the RoHS Directive on restrictions of certain hazardous chemical in electrical and electronic equipment (EEE), Denmark finds it relevant to consider the proposal of the inclusion of the following five substances under the proposed Directive's Article 4 (1) and Annex IV, rendering their respective use in electrical and electronic equipment restricted in the European Union:

- Hexabromocyclododecane (HBCDD)
- Bis (2-ethylhexyl) phthalate (DEHP)
- Butyl benzyl phthalate (BBP)
- Dibutyl phthalate (DBP)
- Additive use of tetrabromo bisphenol A (TBBPA)

Certain aspects relevant to the inclusion in the RoHS Directive of these substances were assessed in a previous study by Öko-institut e.V. (Gross et al., 2008) for the European Commission, DG Environment. The report suggested all the substances for inclusion in the list of restricted substances in the RoHS Directive.

HBCDD, DEHP, BBP and DBP are (November 2009) included in the draft list of substances recommended by ECHA for inclusion in the list of substances subject to authorisation in Annex XIV of REACH. HBCDD has been proposed based on PBT properties (persistent, bioaccumulative and toxic) and the three others based on toxicity to reproduction.

The present study supplements the existing assessment with an assessment of socioeconomic impacts of the inclusion of these substances under the RoHS Directive.

An overview of possible types of socioeconomic impacts of inclusion of the substances under the RoHS Directive is given in the table 0.1 overleaf. Within the limits of this study, only selected impacts have been assessed further. Focus is on the estimation of the main net socioeconomic costs or benefit to the EU whereas the distributional effects (that some stakeholders have benefits while others have costs) are only described briefly.

Basically, the assessment compares:

- The net costs to the society - expressed in terms of increased material costs (raw material cost, research and development (R&D) and investment in new tools and techniques) and increased costs of RoHS compliance (only assessed qualitatively).

  with:

- The benefits to human health and the environment of substitution - expressed in terms of differences in key environmental and health effects of the alternatives compared to the effects of the substances.

In order to set the estimated costs in perspective it may be relevant to look up some of the estimates in the Commission's Impact Assessment for the recast of the RoHS Directive.

According to the Impact Assessment yearly administrative costs (in particular verification of compliance) make up approximately 67% of total costs, while the share of technical costs amounts to 33% (expected to drop to 12% in the future). The most important administrative cost is compliance verification, which is an ongoing expense. There are few data and many uncertainties about actual cost impact of the RoHS Directive, but the Commission estimated the total costs to be in the range of 165 to 23,000 million €/year, corresponding to 0.042 to 5% of the total turnover of EU companies affected by RoHS. Total turnover in EU companies in the EE sector is approximately 400.000 million €/year.

Estimation of benefits of reduced health and environment impacts by substituting the substances is still very immature and incomplete, and a quantitative assessment of these benefits has been beyond the limits of this study. For the comparison between the substances and alternatives, data on key effects have been summarised on the basis of existing reviews. The key effects considered are carcinogenicity, mutagenicity and toxicity to reproduction (CMR properties), as well as persistence, bioaccumulation, and toxicity (PBT properties). For most alternatives data are missing for some of the key effects, which is a common problem in socioeconomic assessment of substitution of chemicals as full data sets are normally not available for alternatives to substances considered for restriction. The question is whether the available data are considered sufficient for demonstrating that the alternatives most probably are less problematic than the substances considered for restriction.

Table 0.1
Impacts and costs elements of including the substances under the RoHS Directive

Stakeholders	Impact elements	Cost elements	Benefit elements
Manufacturers of the substance	Impact on producers of the substance	Decreased sale of the substance	
	Impact on producers of alternatives	Costs of increasing the capacity for producing the alternatives	Income from increased sale of alternatives
Polymer converters (including formulators and some EEE manufacturers)	Impacts on polymer converters	One-time costs of adjusting polymer formulation and adapting/changing the process line	
		Increased costs of polymers, flame retardants or plasticisers	
	Impacts on working environment		Reduced costs of health effects from exposure to the substance and associated risk reduction efforts
EEE manufacturers	Impacts on EEE manufacturers	Increased costs of flame retarded plastic parts	
		Administrative compliance costs of implementing RoHS	
	Impacts on working environment		Reduced costs of health effects from exposure to the substance and associated risk reduction efforts
Consumers	Health impacts from exposure to the substance		Reduced costs of health effects from exposure to the substance
	Impacts on the price of EEE	Increased costs of EEE	
Society	Impacts on public environmental enforcement	Costs for additional chemical analyses for compliance control	
	Impacts on the environment		Reduced costs of environmental and health effects from exposure to the substance

HBCDD

The main concern regarding HBCDD is its persistence and toxicity in the environment as well as possible developmental neurotoxicity effects.

As regards human toxicity the main effect of concern is developmental neurotoxicity from exposure of the newborn child (neonatal exposure). The EU Risk Assessment Report concludes that there is a need for further information. The substance is currently not included in the list of classified substances. HBCDD is persistent in the environment and bio-accumulate and meets the PBT criteria.

The main application of HBCDD in EEE is as flame retardant in HIPS plastic used for closures and structural parts of different types of EEE. The total volume used for manufacturing processes within the EU is about 1,100 tonnes; no data are available on import/export with articles. HBCDD may as well be used in foams of EPS or XPS plastics in some EEE, but no actual use in EEE has been identified. The HBCDD has traditionally been used together with antimony trioxide (ATO), which is classified carcinogenic, but some HCBDD-based flame retardants, that can be used without ATO, have been introduced.

The use of HBCDD in EEE is not deemed essential as technically suitable alternative substances and materials are available and already used extensively today. The main alternatives are either HIPS with other brominated flame retardants (BFRs) or copolymers with phosphor esters.

Costs - At EU level the total incremental costs at the production level of replacing the HBCDD in HIPS in all EEE (both within and outside the scope of the RoHS Directive) are likely in the range of 1-10 million €/year if HBCDD is replaced with other BFRs and 5-25 million €/year if the HIPS/HBCDD is replaced by copolymers with non-halogenated flame retardants. The costs may decrease over the years as result of a larger market for the alternatives.

The main extra administrative costs is deemed to be related to compliance control, where the extra costs would mainly comprise the costs of analysis, as sampling and sample preparation will be done by the control of the flame retardants already restricted in RoHS.

Benefits - The available data indicates that a number of alternatives exists which do not meet the PBT criteria, and in this respect would probably be more environmentally friendly than HBCDD. The major uncertainly relates to data on human toxicity. Many of the alternatives have some demonstrated potential health effects. For most of the substances the available data do not indicate that the alternatives should be more problematic than the HBCDD as regards human health, but data are missing for critical endpoints.

DEHP

The main concern as to DEHP is its possible effect on reproduction. According to the EU Risk Assessment Report DEHP is bioaccumulative but is not considered a PBT substance or a vPvB (very persistent and very bioaccumulative) substance. With regard to CMR effects, DEHP raises concerns based on reproduction toxicity studies showing testicular effects, effects on fertility, toxicity to kidneys, on repeated exposure and developmental toxicity. DEHP is classified toxic to reproduction.

DEHP is mainly used in EEE as a plasticiser of flexible PVC used for wires, plugs, tubes and a number of other parts. It may in principle be found in nearly any EEE in small amounts. The exact consumption for EEE is not known, but it is likely that EEE marketed in the EU contain some 5,000-20,000 t/y of DEHP.

The use of DEHP in EEE is not deemed essential as technically suitable alternatives are available and already used extensively today. The main alternatives, which in recent years have taken over the major part of the former DEHP consumption, are the phthalates DINP and DIDP. If DEHP is restricted in EEE these alternatives will most likely take over a major part of the remaining uses. A number of non-phthalate alternatives are marketed, however, the price of these alternatives are in general somewhat higher.

Costs - It is estimated that the incremental material costs (at manufacturing stage) would be 0.5-2 million €/y (European prices) if DINP is used to substitute for DEHP in all EEE. In this case the R&D costs are assumed to be relatively low. The total costs of shifting to the cheapest of the non-phthalate plasticisers is higher and would likely be in the range 1-6 million €/y. Here R&D costs are higher. The actual costs depend on the share of the total EEE within the scope. The costs may decrease over the years as result of a larger market for the alternatives.

Substitution may result in slightly raised prices for flexible PVC parts in the EEE. For most EEE, the flexible parts which may contain DEHP comprise only a minor fraction of the equipment/product and represent only a minor part of the total production price of the product. Increases in consumer prices for the individual EEE as a result of a restriction of DEHP use in EEE are therefore expected to be small, but a restriction may impact a large share of all EEE.

Extra administrative costs are estimated to be related to compliance control, where the extra costs would comprise the costs of both sample preparation and analysis. The price of analysis for DEHP, DBP and BBP is nearly the same as for analysis of DEHP only.

Benefits - Available data for the alternatives indicate that with regard to human health effects less problematic alternatives exist. This conclusion is primarily based on data for repeated dose toxicity and existing reproductive toxicity data and it should be stressed that most of these alternatives are not fully investigated with regard to reproductive toxicity and in particular with regard to carcinogenicity. The environmental assessment of non-phthalate alternatives does not lead to the same conclusion, as most of the alternatives according to a recent (not yet published) study for the Danish EPA must be considered as more problematic for the environment than DEHP.

With regard to the phthalates DINP and DIDP, both substances show reproductive toxicity but at higher doses compared to DEHP. Also from an environmental point of view the two alternatives seem to provide a choice for more environmentally friendly alternatives based on the conclusions in the EU risk assessment reports.

DBP and BBP

The main concern as to DBP and BBP is the substances' possible effect on reproduction and possible long-term adverse effects in the aquatic environment.

The substances are with regard to human health classified as toxic to reproduction. According to the EU Risk Assessments DBP and BBP are bioaccumulative and toxic to aquatic organisms, but not persistent in the environment. DBP and BBP are therefore not considered PBT substances or vPvB substances. With regard to CMR effects the Risk Assessments conclude, based on the available studies, that DBP and BBP are not considered genotoxic and are also not carcinogenic to humans.

The consumption of DBP for EEE production in the EU is likely in the range of 50-500 t/y mainly as secondary plasticiser in PVC and in adhesives and other non-polymer applications. The consumption of BBP for EEE production in the EU is likely in the range of 20-200 t/y; the BBP may be used in flexible or rigid PVC, sheets, adhesives, sealants and other non-polymer applications. The plasticisers may be present in a low percentage of products within all product categories. It has not been possible to fully confirm that DBP and BBP are currently used in the manufacture of EEE.

The use of DBP and BBP in EEE is not deemed essential as technically suitable alternatives are available and already used today for similar applications as the possible applications in EEE, however for some specific non-polymer applications substitution may be particular difficult. All available data indicate that alternatives exist, for example DGD, Benzoflex 2088 and ASE. For PVC softening, omitting the use of these secondary plasticiser may also be technically possible, although probably with increased PVC processing expenses as a consequence.

Costs - For most EEE, the parts which may contain DBP or BBP comprise only a minor fraction of the equipment/product and thus also only a minor part of the total production price of the product. Price differences between the substances and alternatives are approximately the same as for DEHP. As the consumption of the substances is only a few percent of the consumption of DEHP the increases in consumer prices for EEE, as a result of a restriction of the use of DBP and BBP use in EEE, are therefore expected to be minimal.

The main extra administrative costs are estimated to be related to compliance control, where the extra costs would comprise the costs of sample preparation and analysis. The price of analysis for DEHP, DBP and BBP is nearly the same as for analysis of DEHP. The scattered use of DBP and BBP in non-polymer applications in EEE may result in relatively high costs of compliance control, as relatively many samples have to be taken. For non-polymer applications compliance control will be particular difficult and will imply control of materials not otherwise controlled for other RoHS substances.

Benefits - Available data for the alternatives indicate that with regard to human health effects, less problematic alternatives exist. This conclusion is primarily based on data for repeated dose toxicity and existing reproductive toxicity data and it should be stressed that most of these alternatives are not fully investigated with regard to reproductive toxicity and in particular with regard to carcinogenicity.

With regard to endocrine disruptive effects DBP and BBP are on the EU list of substances with clear evidence of endocrine disrupting effects whereas none of the alternatives are on the list. Data for endocrine disrupting have not been available for evaluation in the recent Danish EPA assessment.

As for the environmental assessment of the alternatives the picture is not as clear, but three substances seem at least to be less problematic compared to DBP and BBP and these are DEGD, DINA, and GTA. The available data indicate that a number of alternatives exist which do not meet the PBT criteria, but for which more details and evaluation are necessary to conclude about their environmental effects compared to DBP. However, based on the Danish EPA assessment, DINA and GTA appear to be more environmentally friendly compared to DBP whereas the other 8 substances have positive responses for more than one of the effects: persistence, bioaccumulation and toxicity.

With regard to the overall assessment, the uncertainty concerning human health effects of alternatives, in particular reproductive toxicity and carcinogenicity, needs to be considered.

Additive use of TBBPA

The main concern regarding TBBPA is its toxicity in the aquatic environment and possible effects of breakdown products in the environment.

According to the EU Risk Assessment, TBBPA does not meet the criteria for being a CMR, a vPvB or a PBT substance. TBBPA is not on the Candidate List of SVHC substances currently proposed for inclusion in Annex XIV of

REACH. When used additively TBBPA is used in conjunction with antimony trioxide (ATO) which is classified for carcinogenicity.

The main application of TBBPA used additively in EEE is in acrylonitrile-butadiene-styrene (ABS) plastic used for closures and structural parts of different types of EEE. The total content of additively used TBBPA in EEE marketed in the EU is estimated at some 8,000 tonnes/year assuming that 20% of the 40,000 tonnes/year in marketed EEE is used additively.

The additive use of TBBPA is not deemed essential as technically suitable alternative substances and materials are available and already used extensively today. The main alternatives for ABS/TBBPA/ATO systems are ABS with other brominated flame retardants and ATO or co-polymers (e.g. PC/ABS, PS/PPE, HIPS/PPO) with phosphate esters.

Costs - The prices of alternatives are typically 10-50% higher than ABS/TBBPA/ATO systems and it is estimated that the total incremental costs at the production level of replacing additively used TBBPA in all EEE may likely be some 5-30 million €/year depending on the actual alternatives being introduced (European prices). The costs may decrease over the years as result of a larger market for the alternatives.

The main extra administrative costs is estimated to be related to compliance control, where the extra costs would mainly comprise the costs of analysis as the sampling and sample preparation would be done in any case for control of the PBDEs in the parts.

Benefits - A number of alternatives to TBBPA exist which may potentially be less problematic than TBBPA, but data on the alternatives are missing for critical endpoints (e.g. carcinogenicity). Phosphate esters have been evaluated as promising alternatives to deca-BDE, but considering that TBBPA is neither a CMR, a vPvB nor a PBT substance, it may be considered necessary to have a more robust basis for decision on its inclusion in the RoHS directive.

RoHS vs. authorisation or restriction under REACH

HBCDD, DEHP, BBP and DBP are as mentioned included in the current draft list of substances recommended by ECHA for inclusion in the list of substances subject to authorisation under REACH.

The authorisation procedures only concern placing on the market or use of substances and do not address the import of articles containing the substances. In the case authorization is not granted for the application of the substances in EEE, European manufacturers will not be allowed to use the substances for manufacturing of EEE, whereas imported articles will not be affected.

If ECHA considers that the risk from the substances in articles (e.g. EEE) is not adequately controlled, the Agency shall prepare a dossier in relation to introduction of further restrictions and inclusion of the substances in Annex XVII of REACH. The restrictions specified in the Annex XVII concern placing on the market, manufacturing and uses of the substance on its own, in a mixture or in an article. The restriction would consequently also apply to imported EEE. By the restriction procedure a consumer safety can be achieved similar to the safety that can be achieved by inclusion of the substances in the list of prohibited substances in the RoHS Directive. The time perspective for a possible restriction in REACH of the use of the substances in EEE is unknown as no experience exist, but the procedure would probably take significantly more time than inclusion of the substances in Annex IV of the recast RoHS Directive.

Abbreviations and acronyms

ABS	Acrylonitrile-butadiene-styrene
ASE	Sulfonic acids, C10 – C18-alkane, phenylesters
ATBC	Acetyl tributyl citrate
ATO	Antimony trioxide (same as diantimony trioxide)
BAPP	Bisphenol A diphosphate
BBP	Butyl benzyl phthalate
BCF	Bioconcentration factor
BFR	Brominated flame retardant
BTHC	Butyryl trihexyl citrate
CAS	Chemical Abstracts Service
CEFIC	European Chemical Industry Council
CEPE	European Council of producers and importers of paints, printing inks and artists' colours
CMR	Carcinogenic, Mutagenic, Reprotoxic
COMGHA	Mixture of 12-(Acetoxy)-stearic acid, 2,3-bis(acetoxy)propyl ester and octadecanoic acid, 2,3-(bis(acetoxy)propyl ester.
CMR	Carcinogenic, mutagenic, reprotoxic
CRT	Cathode ray tube
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
DBP	Di-n-butyl phthalate
DCP	Diphenyl cresyl phosphate
Deca-BDE	Decabrominated diphenylether
DEGD	Diethylene glycol dibenzoate
DEHA	Bis(2-ethylhexyl) adipate
DEHP	Di(2-ethylhexyl) phthalate (also designated DOP)
DEHT	Di (2-ethyl-hexyl) terephthalate (same as DOPT)
DGD	Dipropylene glycol dibenzoate
DIBP	Diisobutyl phthalate
DIDP	Diisodecyl phthalate
DINA	Diisononyl adipate
DINCH	Di-isononyl-cyclohexane-1,2dicarboxylate
DINP	Diisononyl phthalate
DOPT	Same as DEHT
EBFRIP	European Brominated Flame Retardant Industry Panel
ECHA	European Chemicals Agency
ECPI	European Council for Plasticisers and Intermediates
EE, E&E	Electrical and electronic
EEE	Electrical and electronic equipment
EPA	Environmental Protection Agency
EPS	Expanded polystyrene
EU	European Union
EuPC	The European Plastic Converters
FR	Flame retardant or flame retarded
GC-MS	Gas chromatography followed by mass spectrometry
GHS	Global harmonized system
GTA	Glycerol triacetate
HBCDD	Hexabromocyclododecane (same as HBCD)
HIPS	High impact polystyrene
HIPS/PPO	Copolymer of HIPS and PPO (same as PPE/HIPS)

NOAEL	No observed adverse effect level
Octa-BDE	Octabrominated diphenylether
OECD	Organisation for Economic Cooperation and Development
PA	Polyadipate
PBDE	Polybrominated diphenyl ethers
PBT	Persistent, bioaccumulative, toxic
PBT	Poly(butylene terephthalate)
PC	Polycarbonate
PC/ABS	Copolymer of PC and ABS
PET	Poly(ethylene terephthalate)
PPE	Polyphenylene ether
PPO	Poly(phenylene oxide)
PS	Polystyrene
PVA	Polyvinyl acetate
PVC	Polyvinyl chloride
RAR	Risk Assessment Report
RDP	Resorcinol bis (biphenyl phosphate)
REACH	Regulation concerning the Registration, Evaluation and Authorisation and Restriction of Chemicals = Regulation 1907/2006/EC
R&D	Research and Development
RoHS	Restriction of the use of certain hazardous substances [in electrical and electronic equipment] = Directive 2002/95/EC
SCENIHR	EU Scientific Committee on Emerging and Newly Identified Health Risks
SME	Small- and medium-sized enterprises
SVHC	Substances of very high concern
TBAC	Tert-butyl acetate
TBBPA	Tetrabromo bisphenol A
TGD	Triethylene glycol dibenzoate
TOTM	Trioctyl trimellitate
TPP	Triphenyl phosphate
TXIB	Trimethyl pentanyl diisobutyrate
TV	Television
UK	United Kingdom
UL 94	Tests for Flammability of Plastic Materials from Underwriters Laboratories Inc.
USA	United States of Amerika
V-0, V-2	UL 94 Vertical burn tests
VAT	Value added tax
vPvB	Very persistent and very bioaccumulative
WEEE	Waste electrical and electronic equipment
WSDH	Washington State Department of Health
XPS	Extruded polystyrene foam (more compact than EPS)
XRF	X-Ray fluorescence

1 Introduction

In this report, the main socio-economic impacts of inclusion of the substances in question under the RoHS Directive are described separately for each substance. The description is mainly qualitative or semi-quantitative.

For each substance the description commences with a characterisation of the substance, its possible application in EEE and an estimate of the total quantities used. Thereafter follows a description of the availability of alternative substances and materials. Further, the socio-economic impacts are described with focus on cost of substitution, potential impacts on the waste management system and administrative costs. Finally the potential effects on human health and the environment of the substance and its alternatives are summarised based on existing reviews.

The supply chain and the socioeconomic impact elements are quite similar for all five substances and are described for all substances in common in the following sections.

1.1 Supply chains for substances in EEE

The generalised supply chain of the substances used in EEE is shown in Figure 1.1. The substances are used in different plastics and the actual manufacturers, formulators and converters may be different for the different substances. The manufacturers and formulators (and to some degree plastic converters) are more or less the same for the three phthalates DEHP, DBP and BBP and these actors are different from the manufacturers and formulators (and to some degree plastic converters) involved in the use of the flame retardants HBCDD and TBBPA.

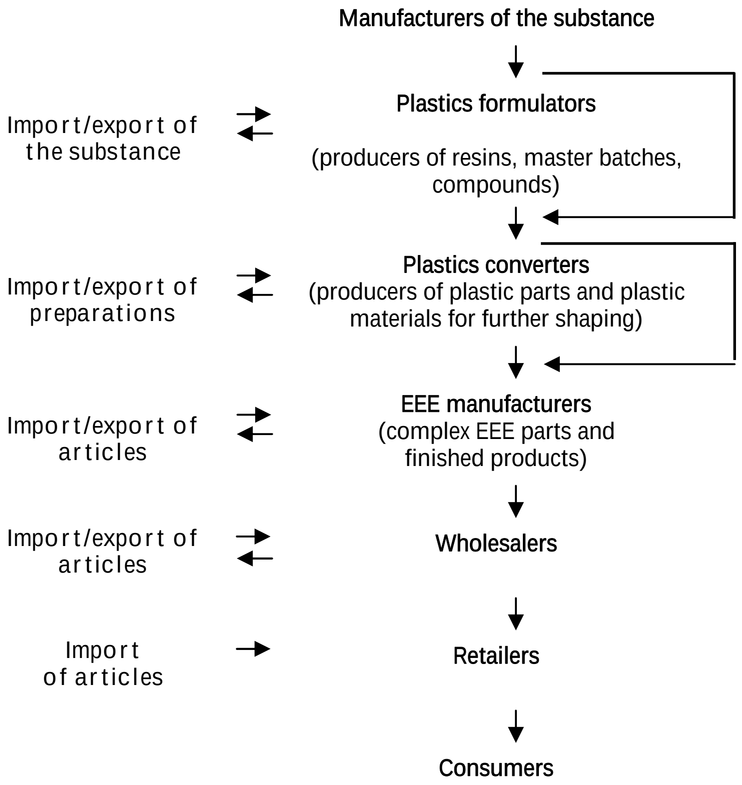


Figure 1.1
Supply chain of the substances in electrical and electronic equipment

1.2 Socioeconomic impact elements

An overview of the types of socioeconomic impacts it could have to include the substances under the RoHS Directive is given in Table 1.1. The table includes the main direct impact on each type of stakeholders including distributional effects. A distributional effect is for example that manufacturers of alternatives have benefits whereas the manufacturers of the substance have decreased sale. The socioeconomic net costs in this example concern the increased costs of the manufactured alternative if e.g. the resource consumption for manufacturing the alternative is higher than the consumption for manufacturing the substance.

Within the limits of this study, only selected impacts have been assessed further. Focus is on the estimation of the main additional socioeconomic costs to the EU, whereas the distributional effects are only described briefly.

All substitution costs are expected to ultimately be furthered to the end customers in the form of increased prices of the EEE. The substitution costs are estimated at manufacturing level, i.e. the increased costs of manufacturing the EEE parts containing the substances. The costs elements consist mainly of costs of raw materials, research and development (R&D) and investment in new tools and techniques.

In order to set the estimated costs in perspective it may be relevant to look up some of the estimates in the Commission's Impact Assessment for the recast of the RoHS Directive. According to the Impact Assessment yearly administrative costs (in particular verification of compliance) make up approximately 67% of total costs, while the share of technical costs amounts to 33% (expected to drop to 12% in the future). The most important administrative cost is compliance verification, which is an ongoing expense. There are few data and many uncertainties about actual cost impact of the RoHS Directive, but the Commission estimated the total costs to be in the range of 165 to 23,000 million €/year, corresponding to 0.042 to 5% of the total turnover of EU companies affected by RoHS. Total turnover in EU companies are approximately 400.000 million €/year.

Administrative compliance costs of implementing RoHS are in the current study addressed qualitatively and semi-quantitatively. Most manufacturers and importers of components and EEE comprising the substances are expected to have established procedures and the necessary capacity for RoHS compliance documentation. The main extra costs are estimated to be related to compliance control; both by the manufacturers (compliance control of components from sub-contractors), importers and the authorities.

Estimation of benefits of reduced health and environment impacts by substituting the substances is still very immature and incomplete, and a quantitative assessment of these benefits has been beyond the limits of this study.

The first step in the assessment of possible benefits of reduced health and environment impacts is a comparison of the inherent properties of the substances in order to evaluate whether alternatives can be expected to be more environment-friendly and ensure at least the same level of protection for consumers. For the comparison between the substances and alternatives, data on key effects have been summarised on the basis of existing reviews. The key effects considered are carcinogenicity, mutagenicity and toxicity to reproduction (CMR properties), as well as persistence, bioaccumulation, and toxicity (PBT properties).

Basically, the assessment compares:

- the benefits to human health and the environment of substitution expressed in terms of differences in key environmental and health effects of the alternatives compared to the effects of the substances

  with:

- The net costs to the society expressed in terms of increased costs at the production level and increased costs of RoHS compliance.

Table 1.1
Main Impact elements of including each of the substances under the RoHS Directive

Stakeholders	Impact elements	Cost elements	Benefit elements
Manufacturers of the substance	Impact on producers of the substance	Decreased sale of the substance	
	Impact on producers of alternatives	Costs of increasing the capacity for producing the alternatives	Income from increased sale of alternatives
Polymer converters (including formulators and some EEE manufacturers)	Impacts on polymer converters	One-time costs of adjusting polymer formulation and adapting/changing the process line	
		Increased costs of polymers, flame retardants or plasticisers	
	Impacts on working environment		Reduced costs of health effects from exposure to the substance and associated risk reduction efforts
EEE manufacturers	Impacts on EEE manufacturers	Increased costs of flame retarded plastic parts	
		Administrative compliance costs of implementing RoHS	
	Impacts on working environment		Reduced costs of health effects from exposure to the substance and associated risk reduction efforts
Consumers	Health impacts from exposure to the substance		Reduced costs of health effects from exposure to the substance
	Impacts on the price of EEE	Increased costs of EEE	
Society	Impacts on public environmental enforcement	Costs for additional chemical analyses for compliance control	
	Impacts on the environment		Reduced costs of environmental and health effects from exposure to the substance

1.3 RoHS vs. authorisation or restriction under REACH

HBCDD, DEHP, DBP and BBP are (November 2009) included in the draft list of substances recommended by ECHA for inclusion in the list of substances subject to authorisation in Annex XIV of REACH.

Authorisation for the placing on the market and use should be granted only if the risks arising from their use are adequately controlled, where this is possible, or the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable. In case the Commission assess that the use of the substances in EEE do not meet these criteria authorisation should not be granted. The authorisation procedures only concern placing on the market or use of substances and do not address the import of articles containing the substances. In the case authorization is not granted for the application of the substances in EEE, European manufacturers will not be allowed to use the substances for manufacturing of EEE, whereas imported articles will not be affected.

If ECHA considers that the risk from the substances in articles (e.g. EEE) is not adequately controlled, the Agency shall prepare a dossier in relation to introduction of further restrictions and inclusion of the substances in Annex

XVII of REACH. The restrictions specified in the Annex XVII concern placing on the market, manufacturing and uses of the substance on its own, in a mixture or in an article. The restriction would consequently also apply to imported EEE. By the restriction procedure a consumer safety can be achieved similar to the safety that can be achieved by inclusion of the substances in the list of prohibited substances in the RoHS Directive. The time perspective for a possible restriction in REACH of the use of the substances in EEE is unknown as no experience exist, but the procedure would probably take significantly more time than inclusion of the substances in Annex IV of the recast RoHS Directive.

The administrative costs for compliance control for manufacturers, importers and authorities would probably be the same if the substances are restricted via the restriction procedure under REACH or they are included in the list of prohibited substances in the RoHS Directive. If the use of the substances is restricted using the authorization procedure under REACH the total administrative costs for compliance control may be lower as the compliance control addresses the companies marketing or using the substances and not the final articles.

2 Hexabromocyclododecane (HBCDD)

2.1 Main concern

The main concern regarding HBCDD is its persistence and toxicity in the environment as well as possible development neurotoxicity effects.

HBCDD is (November 2009) included in the draft list of substances recommended by ECHA for inclusion in the list of substances subject to authorisation in Annex XIV of REACH.

The Annex XV report and the Member State Committee Support Document conclude, mainly on the basis of the EU Risk Assessment, that HBCDD is a PBT substance according to Article 57 of the REACH Regulation (ECHA, 2009). The substance fullfills the PBT criteria as the substance is persistent (P), biocaccumulative (B) and toxic to organisms in the environment (T).

Classification of HBCDD with N; R50/53 was agreed at a Technical Committee for Classification & Labelling (TC C&L)-meeting on 11-12 June, 2003 but the substance is still not included in Annex I to Regulation No 1272/2008)(ECHA, 2009). Classification for health effects has not yet been discussed (ECHA, 2009).

As consequence of its persistence and the potential for long-range environmental transport HBCDD has been proposed by Norway for inclusion as a persistent organic pollutant under the global Stockholm Convention on persistent organic pollutants (POP's).

An EU Risk Assessment has been finalised for HBCDD (ECB, 2008a). Regarding human toxicity the Risk Assessment concludes that no measures beyond those, which are being applied already, are needed for consumers and human exposure via the environment. The main effect of concern is development neurotoxicity where the Risk Assessment concludes that there is a need for further information as there are indications of developmental neurotoxicity in adult mice exposed to HBCDD as pups, but the study is not performed according to current guideline and good laboratory practice and therefore this potential developmental neurotoxicity needs to be examined further.

The review undertaken for the European Commission by Öko-institut e.V. as background for selection of candidate substances for a potential inclusion into the RoHS Directive (Gross ***et al.***, 2008) recommend HBCDD as a potential candidate.

2.2 Characterisation of the substance

Hexabromocyclododecane (HBCDD) is a brominated flame retardant (BFR) primarily used in the polystyrene foam types expanded polystyrene (EPS) and extruded polystyrene (XPS), but also to a lesser extend in high impact polystyrene (HIPS) enclosures of consumer electronics and in flame retarding back coating for certain textiles (IOM, 2009). HBCDD is the sole flame retardant used for flame retarded EPS and XPS (KemI, 2006). Flame retarded HIPS is also produced without HBCDD, yet with other flame retardants. Textiles are primarily produced without flame retarders, or with other flame retardants. The flame retarded qualities of textiles are mainly used for furniture in public places, in furniture for private homes in the UK and a few other countries, and in textiles for automobile seats.

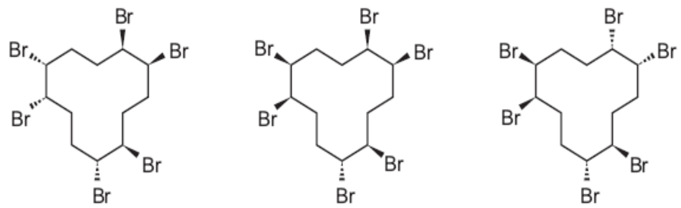
The use of flame retardants is driven by fire regulations specifying certain threshold for resistance to ignition and burning in different product types. The fire regulations vary somewhat between countries, and there are different grades of flame resistance required depending on the application and its inherent fire risks.

HBCDD is used as an additive flame retardant only i.e. the flame retardant is not bound chemically in the polymer material, and therefore continues to exist as the original substance, and has the potential for migrating or evaporating out of the polymer.

The structural formulas for HBCDD (CAS. No 25637-99-4 or 3194-55-6) are shown below. HBCDD exists in three isomers with identical composition but slightly different structure, depending on which side of the molecule's main plane the brome atoms are bonded on, so to speak. The bromine content of HBCDD is about 74%.

Different grades of the technical mixture are produced by industry, each containing different percentages of the three isomers: low melt, medium range, high melt and thermally stabilized (Greeg ***et al.***, 2004). The selection of HBCDD grade used depends on the usage of the end-product.

HBCDD



α = HBCDD   β = HBCDD   γ = HBCDD

(Diagrams from Astrup and Bergman, 2009)

According to IOM (2009), HBCDD is manufactured at one facility in the EU. Imported volumes are similar to the volume manufactured in the EU. The annual consumption in the EU in 2007 is estimated at 11,000 tonnes, of which less than 10% (less than 1,100 t/y) is used in HIPS and an estimated 2% (220 t/y) is used for back coating of flame retarded textiles. The remainder is used for EPS and XPS insulation boards primarily used in construction. The consumption has increased slightly between 2003 and 2007, but the trend is not expected to have continued.

2.3 Applications in EEE

HBCDD is used in EEE in plastics parts made of HIPS. Flame retarded HIPS is used mainly for the production of housings of equipments such as television sets, audio-videos and personal computers but it has also been mentioned as used for electrical boxes and wiring fittings, electrical appliance parts, business machines, and interior parts of refrigerators. On the European market enclosures of computer monitors seem generally not to be made of HIPS, but of acrylonitrile-butadiene-styrene (ABS) or co-polymer of polycarbonate (PC)/ABS due to their higher impacts strength and resistance to cracking (Lowell, 2005).

KemI (2006) quote the European Brominated Flame Retardants Industry panel (EBFRIP) for the information that about 5 percent of all HIPS in the EU is flame retarded with HBCDD.

HBCDD is generally used for UL 94 V-2 grade HIPS, which is the flammability grade used for housing and similar parts not in direct contact with electricity bearing parts. For V-0 grade HIPS, used for parts in closer contact with electricity bearing parts, aromatic BFRs are generally used. HBCDD is an aliphatic BFR, which is usually used together with antimony trioxide as shown in Table 2.1. As shown in the table, the aliphatic BFRs are more efficient for V-2 grade HIPS.

Slightly lower loading are indicated elsewhere e.g. for the FR-1206 with HBCDD V-2 grade is obtained by 2 to 3 % of the flame retardants and circa 1% of antimony trioxide as a synergist (ICL, 2009a).

Table 2.1
Guidance for FR HIPS class V-0 and V-2 (ICL, 2009b)

Class	Thickness mm	Bromine content, %	Antimony trioxide content, %
V-0	3.2 1.6	Aromatic Br: 8-9 Aromatic Br: 10-13	2.5-4.5 3-8
V-2	3.2/1.6	Aliphatic Br: 3-4 Aromatic Br: 6-7	1.5-2* 2-5

* Antimony trioxide free system is achievable with SaFRon-5261 (see its ADS)

HBCDD used without antimony trioxide has been introduced on the market. The flame retardant SaFRon-5261 is marketed as a heat stabilized HBCDD designed for specific and high demanding properties at high cost efficiency (less than 4% bromine is enough to reach V-2) (ICL, 2009b). The SaFRon-5261 can be used without antimony trioxide and is mentioned to have better colour thermal stability than alternatives, good corrosion resistance and high UV stability.

Refrigerators and freezers, etc., are generally insulated with polyurethane foam, which is not flame retarded, but in rare instances of non-consumer products EPS or XPS may be used (Vestfrost, 2009). EPS or XPS with HBCDD is therefore not expected to be used in EEE, but it cannot be ruled out.

HBCDD may be used in flame retarding back coating of textiles (furniture, etc. for certain markets). This application could be relevant for EEE, if furniture with EEE components, e.g. elevation chairs, is included in the scope of the RoHS Directive.

The possible applications of HBCDD in flame retarded parts of EEE are indicated in Table 2.2 below.

Table 2.2
Possible uses of HBCDD in EEE

Category	Insulation board of EPS or XPS	HIPS cabinets/ enclosures	HIPS wiring fit-tings
1. Large household appliances	?	x	?
2. Small household appliances		x	?
3. IT and telecommunications equipment		x (main)	?
4. Consumer electronics		x (main)	?
5. Lighting equipment		?	?
6. Electrical and electronic tools (except large-scale stationary industrial)		?	?
7. Toys, leisure and sports equipment		?	?
8. Medical devices		x	?
9. Monitoring and control in-struments including industrial		x	?
10. Automatic dispensers	?	?	?

2.4 Quantities of the substance used

As mentioned above, an estimated less than 1,100 t/y of HBCDD were used in 2007 for production of HIPS enclosures in the EU. A part of the HBCDD in European produced EEE will be exported with articles to countries outside the EU.

Likewise, HBCDD may be present in imported EEE and imported EEE parts

2.5 Available alternatives

HIPS
As mentioned above HBCDD is mainly used in V-2 grade flame retarded HIPS where aliphatic BFRs are more efficient than aromatic BFRs (i.e. can provide the flame retardancy at lover loadings.

A number of both aliphatic and aromatic brominated flame retardants are marketed for use in HIPS (Table 2.3). All are used in conjunction with antimony trioxide.

For the use of non-halogenated flame retardants it is necessary to replace the HIPS with copolymers like PPE/HIPS or PC/ABS.

Selected alternatives to HIPS/HBCDD systems are listed in Table 2.3.

Table 2.3
Selected alternative flame retardant systems to HBCDD in V-2 grade HIPS (based on KemI, 2006b; Lassen *et al.*,2006;ICL, 2009a)

Polymer	Flame retardants	CAS No
HIPS	Tris(tribromoneopentyl)phosphate/ATO	19186-97-1
	TetrabromobisphenolA,Bis(2,3-dibromopropyl ether) /ATO	21850-44-2
	2,4,6-Tris(2,4,6-tribromophenoxy)-1,3,5 triazine/ATO	25713-60-4
	Ethane-1,2-bis(pentabromophenyl)/ATO	84852-53-9
	Ethylenebis(tetrabromophtalimide)/AT O	32588-76-4
	Tetradecabromodiphenoxybenzene/AT O	58965-66-5
PPE/HIPS PC/ABS	Resorcinol bis (biphenyl phosphate) (RDP)	57583-54-7
	Bis phenol A bis (biphenyl phosphate)	181028-79-5
	Triphenyl phosphate (TPP)	115-86-6

Note:: /ATO: With antimony trioxide (4-6% concentration) used as synergist.

Major European manufacturers of TV sets seemed to be using copolymers like PC/ABS, PS/PPE or PPE/HIPS either without flame retardants, or with non-halogenated flame retardants (Lassen et al, 2006). Such copolymers have a higher inherent resistance to burning and spreading a fire, because they form an insulating char foam surface when heated. Further they have higher impact strength.

Flat panel TV sets are taking over from cathode ray tubes (CRT's) and for 2005, General Electric (2006) calculated the global plastic consumption for flat panel TV sets at approximately 42% PC/ABS, 33% HIPS (without flame retardants), 14% HIPS with flame retardants, 10% modified PPE and 1% other.

According to Lassen et al (2006), the PPE/HIPS copolymer blends have very similar flow properties to HIPS, meaning that the copolymer gives similar design opportunities for parts with fine structural details, and fewer changes to the expensive moulds and tooling used in the moulding process.

IOM (2009) states that: "Given that HBCDD is not widely used in HIPS, it is perhaps reasonable to assume that technically and economically feasible alternatives are already on the market".

EPS or XPS
The use of flame retarded EPS or XPS in electrical and electronic products has not been confirmed, but cannot be ruled out. Polyurethane foam seems to be the dominating insulation material for electric cooling appliances.

Only two flame retardants are currently available for use in EPS or XPS, namely HBCDD and the TBBPA-bis(allyl ether)(CAS No 25327-89-3) (KemI, 2006). According to IOM (2009), only HBCDD is used for this purpose.

IOM (2009) lists the following alternative insulation materials that may also be relevant for EEE: Polyurethane and polyisocyanurate foams.

2.6 Socioeconomic impacts

2.6.1 Substitution costs

Besides the single HBCDD producer in the EU, the substitution costs will mainly fall at the formulators and converters of HIPS (and EPS or XPS), which likely in some cases will include the EEE manufacturers, especially with regard to HIPS enclosures. The major technical costs are the costs for more expensive flame retardants, higher loadings of flame retardants and costs for new moulds. In cases where the total polymer system is changed, more process steps may need to be changed implying higher costs (but also higher impact strength as described under available alternatives). Costs for mould changes can be reduced significantly with sufficiently long transition periods, as moulds have to be replaced regularly in any case (Lassen ***et al.***, 2006).

The alternative plasticisers, polymer systems and production set-ups are already developed and on the market.

The most affected EEE manufacturers will be manufacturers of equipment in which HBCDD is present in casings and other structural part designed specifically for the equipment in question. Further, manufacturers of equipment for the low price market segment, with a strong competition on the price, may be impacted by the higher price of plastic parts with HBCDD alternatives.

Price estimates for substitution of HBCDD have not been identified, but substitution price examples for phasing out Deca-BDE in TV-sets may give an idea of the cost levels. Lassen ***et al.*** (2006) indicate the order of magnitude of price differences between compounds with Deca-BDE and alternatives on the basis of the experience of one major compounder (formulator). The extra raw material costs of replacing HIPS/Deca-BDE with the alternative materials PPE/HIPS or PC/ABS with halogen-free flame retardants would be about 5-6 € for the full enclosure of an average 27.5-inch TV-set (front and rear enclosure). The extra cost of using other BFRs would be 0.8-1.9 €, depending on the flammability grade. Note that these estimated costs are for the raw materials only. The total production cost of a 27.5-inch TV-set is roughly 300 € (Lassen ***et al.***, 2006), and the extra material cost of these alternatives can consequently be estimated at 0.5-2% of the production cost, with the higher end of that range representing the halogen-free HIPS/PPE.

In accordance with this, Lowel (2005)estimated the extra raw materials costs of replacing HIPS/deca-BDE in TV-sets, at 1.5-2.5% of the total price of the TV-set.

As shown for TV-sets above, for most EEE the parts which may contain HBCDD comprise only a minor fraction of the total production price of the product. Also, considerable fractions of the EEE parts that could be produced with HBCDD flame retarded polymers seem already to be made from other materials or with other flame retardants.

The substitution cost example above is based on HIPS/deca-BDE compound priced at 1.50-1.80 €/kg, HIPS/other BFR compound prices at 1.70-2.10 €/kg (at V1/V0), and HIPS/PPE/halogen-free flame retardants compound prices at 2.30-2.90 €/kg. As mentioned above, HBCDD and other aliphatic brominated flame retardants are more efficient in V-2 grade HIPS than the aromatic flame retardants (like deca-BDE) in V-1 grade.. There is no indication that the price of HIPS with other aliphatic brominated flame retardants should be higher than the HIPS/HBCDD whereas the price of the copolymers with non-halogenated flame retardants will likely be 0.5-0.8 €/kg higher.

Experience with substituting octa-BDE in ABS indicated that averaged over a five-years period the higher material price accounted for more than 85% of the total incremental costs while R&D and replacing moulds accounted for only 15% (Corden and Postle, 2002). Assuming that something similar would be the case for substituting HBCDD in HIPS it is roughly estimated that the incremental cost of replacing the HIPS with copolymers with halogen-free flame retardants would be in the range of 0.6-0.9 €/kg whereas the costs of replacing with other BRFs are more likely in the range of 0.1-0.3 €/kg

All substitution costs are expected to ultimately be furthered to the end customers. The total incremental costs to the consumers of replacing the HIPS/HBCDD can be roughly estimated using the following assumptions:

- Total volume of additively used TBBPA in EEE: 1,100 tonnes/year.
- Total volume of flame retardant HIPS assuming an average HBCDD load of 5% (3-4% Br): 22,000 tonnes/year.
- Total incremental costs assuming that the HBCDD is replaced by other brominated flame retardants: 2-7 million €/year.
- Total incremental costs assuming that the HIPS/HBCDD is replaced by copolymers with non-halogenated FRs: 13-20 million €/year.

Adding the additional uncertainty for the assumptions, at EU level the total incremental costs at the production level of replacing the HBCDD in HIPS are likely in the range of 1-10 million €/year if HBCDD is replaced with other brominated flame retardants and 5-25 million €/year the HIPS/HBCDD is replaced by copolymers with non-halogenated flame retardants. The costs may decrease over the years as result of a larger market for the alternatives.

2.6.2 Impacts on supply chain

SMEs

Plastic resins are produced and formulated by relatively few large companies in Europe. The resins are mixed with additives (in so-called “masterbatches”) to form compounds, which are the raw materials for further processing. Compounding may take place by the resin manufacturer, by specialised compounders or by the company manufacturing the plastic parts.

Whereas the market for compounds is dominated by relatively few large actors, the market for plastic parts is characterized by many small and medium sized enterprises (SMEs). The UK Risk Reduction Strategy and Analysis of Advantages and Drawbacks of Octa-BDE (Corden and Postle, 2002) provided details of plastics manufacturers in the UK according to a number of size categories (defined by number of employees), as well as the average turnover of the companies within those categories. Of the total 14,540 plastics manufacturers in the UK, 5,260 companies fell within the category of small companies (those with fewer than 50 employees), of which the majority (3,365) were micro-enterprises (0-9 employees). With regard to the situation for the EU as a whole, the study stated that there are 55,000 companies manufacturing rubber and plastics in the EU. Of these companies, the average enterprise size was given as 25 employees. No data have been found on how many of these actually supply EEE parts.

Previous studies have clearly indicated that SMEs are affected to a greater degree by compliance with the RoHS legislation compared to their larger competitors. The relatively larger burden for SMEs holds for total costs to comply with RoHS in general as well as more specifically the administrative burden (Bogaert ***et al.***, 2008). As most of the SMEs involved in the manufacturing of flame retarded plastics for EEE already have procedures in place for ROHS compliance, the differences between the SMEs and larger companies is probably not as large as seen by the initial implementation of the RoHS Directive. The companies offering the alternative flame retardants are large companies, and they serve as general customer advisers when it comes to adjusting polymer formulations and production setup, however, the burden of identification of suitable alternatives and R&D by introduction of new substances must still be expected to place a larger burden on SMEs than on larger companies.

EU production

Three large companies with headquarters in the USA and Israel, but production facilities in Europe (among other places), dominate bromine production globally and produce a range of brominated compounds. They also manufacture different halogen-free flame retardants like organo-phosphorous compounds and magnesium hydroxide. These three companies jointly formed the European Brominated Flame Retardant Industry Panel (EBFRIP) representing these three main members, as well as a number of major polymer producers as associate members. These companies are vulnerable to changes in the demand for BFRs (Lassen ***et al.***, 2006), however the same companies also manufacture some of the alternatives. If HBCDD in EEE is restricted the first step will likely be a shift to other brominated flame retardants and the impact on the manufacturers will be very limited.

The manufacturers of alternative flame retardants would benefit from a restriction of HBCDD in EEE, although the impact in the short term may be moderate. The phosphate esters are manufactured by the same companies that also provide the brominated flame retardants, but besides the phosphorous flame retardants are manufactured by at least two European companies (Lassen ***et al.***, 2006).

Production of EEE is substantial in the EU, however a large part of the total end-user consumption of EEE is imported as finished goods from outside the EU. This is notably the case for small household appliances, consumer electronics, IT equipment, and toys etc., but also for other EEE groups.

For EU based EEE producers, HBCDD containing parts may be produced by themselves or by subcontracting polyvinylchloride (PVC) processing or non-polymer formulator companies in the EU as well as on the world market.

Differences in restriction of the use of the substance via the RoHS Directive or via REACH are discussed in section 1.3.

2.6.3 Impacts on waste management

According to the WEEE Directive, plastics containing BFRs have to be removed from any separately collected WEEE. It is by the use of simple screening methods (e.g. X-ray fluorescence screening, XRF) not possible to distinguish plastics with HBCDD from plastics with PBDEs or PBBs already restricted by the RoHS Directive. In practice plastics with HBCDD consequently cannot be recycled, even though the use of recycled plastics with HBCDD is not restricted in the current RoHS Directive. If the HBCDD is replaced by non-BFRs, it will be possible to distinguish the flame retarded plastic parts from plastic parts with restricted BFRs by the use of XRF screening, and the plastic parts may be recycled. The enclosure parts are typically of a size that makes recycling practicable.

2.6.4 Administrative costs

Extra compliance costs related to the addition of one new substance under RoHS are expected to be minimal for companies which have already implemented RoHS, that is, most relevant companies. HBCDD is typically used in parts where deca-BDE have traditionally also been used and compliance documentation would usually be required for such parts.

The main extra costs are estimated to be related to control; both by the manufacturers, importers and the authorities. The presence of HBCDD cannot be determined by simple XRF screening (only the presence of Br), therefore sampling, extraction and laboratory analysis is required. As the parts that may contain HBCDD typically may also contain other RoHS substances the extra costs would mainly comprise the costs of analysis as the sampling and sample preparation would in any case be undertaken for control of other RoHS substances in the parts.

Brominated flame retardants and phthalates can be extracted by the same organic solvents and analysed using the same GC-MS analysis (Gas chromatography followed by mass spectroscopy), however, usually the materials containing the brominated flame retardants are different from the materials containing phthalates. The costs of an analysis of HBCDD in HIPS is in Denmark is reported to be about 250 € (excl. VAT) while the total price of analysing HBCDD, deca-BDE and TBBPA is about 310 € (excl. VAT).The extra costs of analysing for two extra flame retardants is thus about 60€ (excl. VAT). All prices are per sample when more than 20 samples are analysed.

2.7 Impacts on health and environment

2.7.1 Impact profile of substance and alternatives

Antimony trioxide
Antimony trioxide, traditionally used in conjunction with the HBCDD, is classified Carc. Cat 3; R40 (Limited evidence of carcinogenic effect).

Assessment of alternatives
Alternatives to HBCDD have recently been assessed for the European Chemicals Agency. In addition many of the alternatives to HBCDD in HIPS have been assessed in their capacity of being alternatives to the use of deca-BDE in HIPS e.g. by the Washington State Department of Health.

Unfortunately, some of the alternatives, specifically marketed as flame retardants for V-2 grade HIPS, have not been included in any of the assessments: tris(tribromoneopentyl)phosphate (TTBP) and 2,4,6-tris(2,4,6-tribromophenoxy)-1,3,5 triazine. These substances are among the substances manufacturers would most likely change to if HBCDD is prohibited for use in electrical and electronic equipment. It has been beyond the limits of this study to make a full environmental and health assessment of these substances.

Assessment of alternatives to HBCDD for the Europan Chemicals Agency (ECHA)

In a study for the European Chemicals Agency IOM (2008) assessed a number of alternatives to HBCDD. The study did not directly compare the environmental and health properties of the alternatives with the properties of HBCDD.

The summary results are shown Table 2.4. Note, that antimony trioxide is listed as an alternative, but has traditionally been used together with both HBCDD and alternative BFRs.

Regarding alternatives to HBCDD in HIPS they conclude: "***Given that HBCDD is not widely used in HIPS, it is perhaps reasonable to assume that some technically and economically feasible alternatives are already on the market, although it is uncertain whether the human health and environmental impacts of these alternatives are any less than those associated with HBCDD products.***" (IOM, 2008).

Regarding alternative insulation materials for replacement of EPS or XPS with HBCDD they conclude: "***There are however a number of alternative forms of insulation that can be used in place of XPS or EPS. These alternative insulation systems have different characteristics to XPS and EPS and may be less appropriate for some specific use scenarios or may incorporate different environmental issues such as increased energy costs during transportation.”***

Table 2.4
Summary for Human health and environmental properties of selected alternatives to HBCDD used in HIPS, EPS or XPS (based on IOM, 2008)

Use	Alternative	Human health	Environment
HIPS	Antimony trioxide (ATO)	Potential human carcinogen and reproductive toxicant	Not readily biodegradable, low to moderate bioaccumulation potential
	Decabromodiphenylether/ ATO	Neurotoxicant	Not readily biodegradable, low to moderate bioaccumulation potential
	Decabromodiphenylethane/ ATO	Limited data, but likely to be of low toxicity	Not readily biodegradable, may be persistent
	Ethylene-bis(tetrabromo phthalimide)/ATO	Low toxicity	Not biodegradable and is persistent. Non-toxic.
	Triphenyl phosphate	Chronic toxicant with effects on liver	Readily biodegradable, toxic to aquatic organisms
	Resorcinol bis (biphenyl phosphate)	Chronic toxicant with effects on liver	Inherently biodegradable, may be persistent and bioaccumulative
	Bis phenol A bis (biphenyl phosphate)	Limited data, likely to be of low toxicity	Poorly biodegradable. Non-toxic and is not bioaccumulative
	Diphenyl cresyl phosphate	Chronic toxicant with effects on liver, kidney and blood. Effects on fertility	Readily biodegradable
	Polyethylene with Magnesium Hydroxide	Insufficient data but likely to be of low toxicity	Polythene particles are highly persistent in the aquatic environment and may contribute to reduced nutritional intake by organisms; the release of large quantities of magnesium hydroxide to the environment could cause localised problems of water/soil alkalinity.
EPS /XPS	Phenolic Foam	Low toxicity in use but manufactured from materials toxic and carcinogenic	Highly persistent material, long term disposal to landfill with potential for dust emissions to air and surface water, no recycling at present
	Polyurethane and polyisocyanurate products	May emit toxic fumes if burnt, otherwise low toxicity in use, but manufacture involves the use of isocyanates – potent respiratory sensitisers	Highly persistent material, long term disposal to landfill with potential for dust emissions to air and surface water, no recycling at present
	Alternative insulation - Thermal barriers - Loose-fill insulation - Blanket insulation May incorporate glass wool, rock wool, gypsum board	Relatively minor health issues - Inhalation of low toxicity dust generated during installation and removal; no significant emissions while in use in buildings	Materials can be recycled postconsumer use

Alternatives to deca-BDE by Washington State Department of Health (2006)
Washington State Department of Health (WSDH) has as part of the development of a PBDE action plan reviewed human health and environmental data on potential alternatives to deca-BDE, among these HBCDD. The data for some of the substances relevant for the current study is shown in Table 2.5. WSDH concludes that based on the review of available information, there did not appear to be any obvious alternatives to Deca-BDE that are less toxic, persistent and bioaccumulative and have enough data available for making a robust assessment. They note that two of the alternatives with a moderate amount of data, HBCDD and TBBPA, are on the Department of Ecology's PBT list, indicating that they present a hazard to the environment and human health. HBCDD is considered to meet the PBT criteria of WSDH. Other alternatives do not appear to meet the department's PBT criteria, indicating that they are less of a concern, but WSDH states that is difficult to draw definitive conclusions based on incomplete data sets for these chemicals. The organo-phosphates RDP and BAPP (or BDP) are each described as "***one of the more promising alternatives***", but it is noted that information on toxicity is limited.

Table 2.5
Summary of persistence, bioaccumulation potential and toxicity information for HBCDD and selected potential alternatives (Based on Washington State, 2006)

Substance	Human health					A/M ecotoxic-ity. Acute or chronic	Persis-tence	Bioacc.	PBT
	Cancer hazard	Non-cancer effects	Muta-genity	Amount of tox info	Inf on poten-tial routes of expo-sure				
HBCDD	L (NI)	NI	L	L	Yes	L-H	Yes	Yes	Yes
Antimony trioxide (often used together with HBCDD)	L-M	L	M-H	M-H	Yes	L-M	NI	NI	Maybe (NI
Tetrabromobisphe-nolA,Bis(2,3-dibromopropyl ether)	M	L	H	L	NI	NI	NI	Yes	NI
Ethane-1,2-bis(pentabromophenyl)	L	L	L	L	Yes	L	NI (likely)	No	No
Ethylenebis(tetra-bromophtalimide	L	L	L	L	NI	L	NI (likely)	No	No
Resorcinol bis (diphenyl-phosphate) (RDP)	NI	L	L	L	NI	M-H	No	No	No
Bisphenol A diphosphate (BAPP, BPADP) or Bisphenol A bis(diphenyl phosphate) (BDP)	NI	L	L	L	NI	L-M	Yes	NI	NI
Diphenyl cresyl phos-phate (DCP)	NI	M	L	L-M	Yes	M-H	Yes	Yes	Maybe (NI)
Triphenyl phosphate (TPP)	L	L-M	L	L-M	Yes	M-H	No	No	No

NI : No Information/insufficient information
A/M : Aquatic and microbial
PBT: whether the alternative meets Washington State Department of Health's PBT criteria,
Ranking: H = high, M = medium, L = low concern based on available information: Ranking is based on US EPA, 2005.

Summary of the assessment of alternatives

Both assessments, referred to above, emphasise that data on alternatives are not sufficient for making a robust conclusion.

The available data indicates that a number of alternatives exists which do not meet the PBT criteria, and in this respect would be more environmentally friendly than HBCDD.

The major uncertainly related to data on human toxicity. HBCDD is not a demonstrated CMR substance although some concern on possible development neurotoxicity exists. Antimony trioxide, which traditionally has been used in conjunction with the HBCDD is classified as carcinogen.

Many of the alternatives have some demonstrated potential health effects. The available data indicate that most of the alternatives should not be more problematic than the HBCDD as regards human health, but data are missing for critical endpoints.

The overall assessment is therefore a trade off between less environmental effects vs. uncertainty about human toxicity.

2.8 Conclusions for HBCDD

The main concern regarding HBCDD is its persistence and toxicity in the environment as well as possible developmental neurotoxicity effects.

As regards human toxicity the main effect of concern is developmental neurotoxicity from exposure of the newborn child (neonatal exposure) and the EU Risk Assessment Report concludes that there is a need for further information. The substance is currently not included in the list of classified substances. HBCDD is persistent in the environment and meets the PBT criteria

The main application of HBCDD in EEE is as flame retardant in HIPS used for closures and structural parts of different types of EEE. Total volume used for manufacturing processes within the EU is about 1,100 tonnes; no data are available on import/export with articles. HBCDD may as well be used in EPS or XPS foam in some EEE, but no actual use in such equipment has been identified. The HBCDD has traditionally been used together with antimony trioxide (ATO), but some HBCDD grades have been introduced that can be used without ATO.

The use of HBCDD in EEE is not deemed essential as technically suitable alternative substances and materials are available and already used extensively today. The main alternatives are either HIPS with other brominated flame retardants or copolymers with phosphor esters. If productions of EEE with flame retarded EPS or XPS foam do occur these may need to be replaced by other insulating materials such as for example polyurethane foam. The main alternatives are either HIPS with other brominated flame retardants or copolymers with phosphor esters.

Costs - At EU level the total incremental costs at the production level of replacing the HBCDD in HIPS are likely in the range of 1-10 million €/year if HBCDD is replaced with other brominated flame retardants and 5-25 million €/year if the HIPS/HBCDD is replaced by copolymers with non-halogenated flame retardants in all EEE. The actual costs depend on the share of the total EEE which is within the scope of the Directive or exempted.

HBCDD is typically used in plastic components where other RoHS substances have traditionally been used as well (e.g. deca-BDE). The main extra administrative costs is estimated to be related to compliance control, where the extra costs would mainly comprise the costs of chemical analysis as sampling and sample preparation will be done in any case for control of deca-BDE substances in the parts.

Benefits - The available data indicates that a number of alternatives exists which do not meet the PBT criteria, and in this respect would be more environmentally friendly than HBCDD.

The major uncertainly with respect to the alternatives relates to data on human toxicity. Many of the alternatives have some demonstrated potential health effects. However, for most of the substances the available data do not indicate that the alternatives should be more problematic than the HBCDD as regards human health, but data are missing for critical endpoints.

3 Bis(2-ethylhexyl)phthalate (DEHP)

3.1 Main concern

The main concern as to DEHP is its possible effect on reproduction.

DEHP is (November 2009) included in the draft list of substances recommended by ECHA for inclusion in the list of substances subject to authorisation in Annex XIV of REACH.

DEHP is included in Annex I to Regulation No 1272/2008 (CLP) with the classification Repr. Cat.2; R61: May cause harm to the unborn child, Repr. Cat.3; R62: Possible risk of impaired fertility. DEHP is on the EU list of substances with endocrine disruption classifications, classified in CAT. 1 "Evidence for endocrine disruption in living organisms" (BKH, 2000).

Due to the possible effect on reproduction the substance shall not be used as substances or as constituents of preparations, at concentrations of greater than 0,1 % by mass of the plasticised material, in toys and childcare articles (Regulation No 552/2009). Further, it is not permitted for use in cosmetics (Directive 2004/93/EC)

An EU Risk Assessment has been finalised for DEHP (ECB, 2008b). With regard to human toxicity the risk assessment concludes that there is a need for limiting the risks for workers, consumers and humans exposed through the environment, taking the risk reduction measures already applied into consideration.

There is no classification and labelling for the environmental compartment. Measured bioconcentration factors show that DEHP can be accumulated in organisms at lower trophic levels, however, DEHP is not bio-magnified at higher trophic levels.

The review undertaken for the European Commission by Öko-institut e.V. as background for selection of candidate substances for a potential inclusion into the RoHS Directive (Gross ***et al.***, 2008) recommend DEHP as a potential candidate.

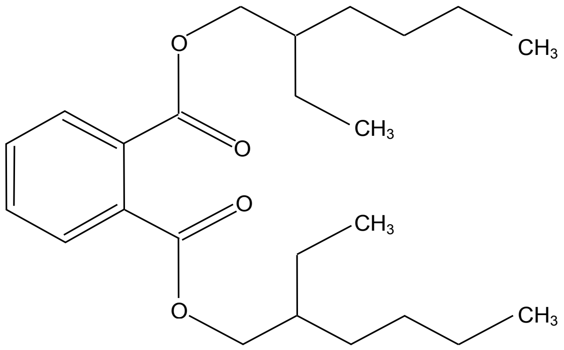
3.2 Characterisation of the substance

DEHP is a general purpose plasticiser used in flexible PVC. A few percent of the annual consumption of DEHP in the EU is used as plasticiser in other polymers and non-polymer uses such as for example in paints, adhesives, sealants, printing inks, etc. (COWI, 2009b). Phthalate plasticisers are always used as so-called external plasticisers, meaning that they are not bound chemically in the polymer matrix. They can therefore migrate out of the plasticised polymer by extraction with soapy water, oils, etc., by evaporation and by diffusion, and thereby become available for exposure to humans via inhalation, skin and diet, as well at to the environment.

The content of DEHP in flexible PVC varies but is often around 30% (w/w).

The structural formula for DEHP (CAS. No 117-81-7) is shown below.

DEHP



3.3 Applications in EEE

Possible uses of DEHP in EEE are shown in Table 3.1. The table shows the applications of flexible polymers in EEE. The polymers may be flexible PVC plasticised with DEHP, other polymers not containing DEHP, as well as PVC plasticised with other plasticisers than DEHP. It is not possible to point at exactly where the PVC plasticised with DEHP is used.

Except for a minor possible use of glues and sealants, the use of DEHP in EEE is as plasticiser in flexible PVC.

A particular use of DEHP in EEE has been the use in capacitors. According to a an assessment of DEHP use by University of Massachusetts Lowell the electrical capacitors industry sectors have largely moved away from the use of DEHP towards other chemicals (TURI, 2006.). An example of current use of DEHP capacitors are Dielektrol capacitors from the General Electric Company (GE, 2009).

Table 3.1
Potential (unconfirmed) uses of DEHP as plasticiser in EEE

Category	Cables	Plugs	"Rubber" feet	Chock absorb-ers	Handles	Anti-slip coat-ing, antislip	Keys	Tubes	Coated baskets	Sealing lists	Decoration	Straps	Glues and seal-ants	Cuffs (inflat-ables)
1. Large household appliances	x	x	x					x	x	x			x	
2. Small household appliances	x	x	x		x	x		x			x			
3. IT and telecommunications equipment	x	x	x	x	x	x	x				x			
4. Consumer electronics	x	x	x	x	x	x	x				x	x		
5. Lighting equipment	x	x	x											
6. Electrical and electronic tools (except large-scale stationary industrial)	x	x	x	x	x	x		x						
7. Toys, leisure and sports equipment	x	x	x	x	x	x	x				x	x		
8. Medical devices	x	x	x	x	x	x	x	x						x
9. Monitoring and control instruments including industrial	x	x	x	x	x	x	x	x					x	
10. Automatic dispensers	x	x	x				x	x		x			x	

3.4 Quantities of the substance used

The development in the EU use of plasticisers shows that the total consumption of DEHP deceased from 1999 to 2005 from 42% of the plasticiser market to 21% (Figure 3.1), with DINP and DIDP taking over (Cadogan, 2006).

According to resent assessments (COWI, 2009b), the total consumption of DEHP in the European Union was estimated at 291,000 t/y in 2007, of which an estimated 64,100 t/y, or 22%, was used for production (extrusion) of cable and wire. As such, production of cable is probably the largest single DEHP use in the EU. The EU production of cable and wire is estimated to be equal to the consumption, as import and export (of cable and wire) roughly equals each other (COWI, 2009b). This is assumed to be the case for cable and wire used for EEE manufacture as well. DEHP usage in cable and wire has decreased from an estimated 81,000 t/y in 1997 (ECB, 2008b). A very small part of the DEHP (7,000 t/y or 2%) is used for adhesives and sealant, but it should be noted that the total quantity used for these applications is still larger than the quantities of DBP and BBP used for adhesives and sealants.

A large share of the cable and wire produced is used for purposes outside the scope of the current RoHS Directive (in particularly in installations in buildings and industrial facilities), the exact share is however not known to us. Table 3.2 below shows the distribution (in Mio. €) of cable and wire production in the EU by applications. Based on background knowledge and global cable and wire production data (ICF, 2009), we assume that the cable used for EEE production includes less than half of the information cables (10% of the total), and 1/5 of the general wiring cable (another 10%); in total 20% of the production in the EU. Including the fact that flexible cable used in EEE is still dominated by PVC insulation and assuming that DEHP usage is equally distributed among cable types, 20% of 64,100 t/y equals some 13,000 t/y DEHP.

Table 3.2
Distribution (in Mio. €) of cable and wire production in the EU by application (from Europacable, 2009)

	Production 2004 in € Mio		Production 2003 in € Mio	
General Wiring Cables (for buildings and industry)	5,285	49%	4,880	47%
Electricity Utility Cables (large scale electricity supply)	2,108		2,119	
Information Cables (metal and optic)	2,317	20%	2,441	20%
Winding Wires (for transformers, etc.)	1,095		975	
Total	10,806	21%	10,416	23%

No detailed data were found on the consumption of other uses of DEHP in EEE. For such applications, consumption data only exist at aggregate level including al sorts of other products and items. For consumer electronics, for example, internal and external cables probably constitute at least half of the DEHP consumption based on expert judgement. The same likely applies to large household appliances, even if these include large PVC parts like PVC coated refrigerator baskets and door gaskets (which may or may not be flexible PVC). Using this approach we estimate some 10,000-20,000 t/y DEHP ending up in EEE in the EU.

Another approach is to estimate the DEHP amount on information of the consumption of PVC in EEE. Several studies on the composition of waste electrical and electronic equipment (WEEE) have tried to estimate the total PVC content of WEEE. An Irish study estimated on the basis of result of other studies that 5-10% by weight of the plastic fraction of WEEE would be PVC while Andersson (2005) quotes a study for the EU commission that 7% of the PVC was used for EEE in 1999.The total plastic consumption for EEE in 2007 in Western Europe and Central Europe is reported by PlasticsEurope to be about 2.5 million tonnes (PlasticsEurope, 2007). If 5-10% is PVC with a plasticiser content of 30% the total volume would be 37,000-73,000 t/y. If 20% of this was DEHP the total volume for DEHP in EEE would be approximately 7,000-15,000 t/year. In fact not all PVC in EEE is plasticised and the total DEHP volume would thus be lower.

Adding to this, a large part of the total end-user consumption of EEE is imported as finished goods from outside the EU This is notably the case for small household appliances, consumer electronics, IT equipment, and toys etc., but also for other EEE groups. At the same time some DEHP is exported with EEE from the EU.

On the basis of the calculations above we estimate that it is likely that EEE marketed in the EU contain some 5,000-20,000 t/y of DEHP.

3.5 Available alternatives

Today, the principle alternatives to DEHP are di-isononyl phthalate (DINP) and di-isodecyl phthalate (DIDP). These two substances are used widely in the EU as general plasticisers and have substituted for a large part of the former DEHP usage already. Also non-phthalate general purpose plasticisers exist, examples are alkylsulfonic phenylester (ASE), di-isononyl-cyclohexane-1,2dicarboxylate (DINCH) and di-ethyl-hexyl-terephthalate (DEHT). DEHT has for many years had a substantial market as general purpose plasticiser in the USA and also has a market in the EU. ASE and DINCH also have established markets, especially in sensitive applications such as toys, medical care articles and for food contact. With adjustments of the polymer/plasticiser formulations, and in some cases processing adjustments, these alternative plasticisers perform suitably as general purpose PVC plasticisers (COWI, 2009).

The evolution in the EU use of plasticisers shows that the consumption of DEHP deceased from 1999 to 2005 from 42% of the market to 21% (Figure 3.1). The DEHP was replaced by DINP/DIDP, while the non-phthalate plasticisers remained a market share of around 7-8%. The share of non-phthalate alternatives may have increased since 2005.

The use of secondary plasticisers, for example to improve plasticising performance and permanence at elevated temperatures as in electrical cables, is generally applied already, and a change of primary plasticiser is not expected to have major consequences as regards special performance requirements. Normal re-adjustment of the formulation of the system consisting of the polymer, primary plasticiser, secondary plasticisers and other additives will however likely be needed in most cases.

We cannot rule out completely that some niche productions for specialised purposes in some EEE may have difficulties in substituting DEHP, but no evidence of such niche production has been encountered in the preparation of this study.

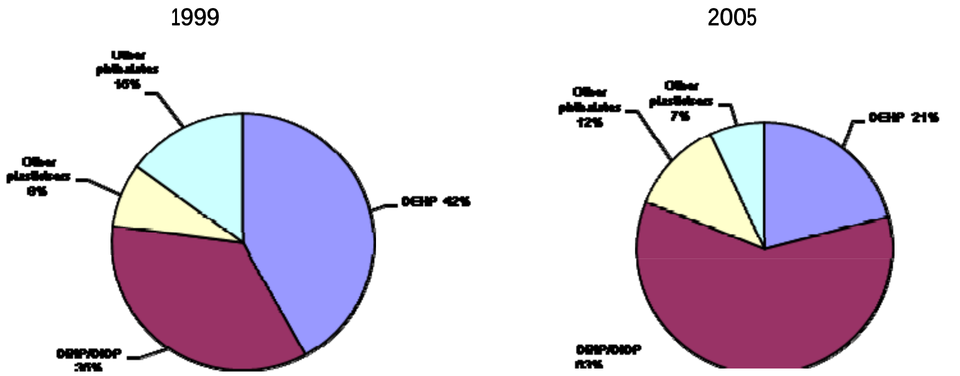


Figure 3.1
Evolution of PVC plasticisers sales between 1999 and 2005 (based on Cadogan 2006)

3.6 Socioeconomic impacts

3.6.1 Substitution costs

The substitution costs will mainly fall at the PVC processors and formulators. For coatings and other integrated composite parts, the EEE manufacturers may act as PVC processors themselves, and may need to be involved in reformulation of the PVC plastisols or compounds used. The plasticiser producers will normally be involved in the substitution, because they act as advisors for the processors and formulators in the formulation of the polymer/plasticiser system. The alternative plasticisers are already developed and marketed, but costs for increasing the production volume may be implied. Costs for research in using alternatives for new applications will be furthered to the customers.

Table 3.3 shows price examples of DEHP and selected alternatives. As shown, DINP, DIDP and DEHT had comparable or slightly higher prices than DEHP, while DINCH and ASE had somewhat higher prices. Many PVC products are sold in highly competitive markets, and PVC processing industry is sensitive to even minor price changes on raw materials (TURI, 2006). DINP and DIDP seem to have been adopted well by industry, faced with regulatory pressure on DEHP.

Table 3.3
Examples of comparative prices of DEHP and selected alternatives (from COWI, 2009)

Substance	Price,	Relative price to DEHP, %	Substitution factor	Effective relative price, %	Remarks
DEHP (2006)	0.70 USD/Lb	100%	-	-	TURI (2006)
DEHP (2006-2009)	≈0.8-1€/kg	100%	-	-	ExxonMobil (2009), Arbeitsgemeinschaft PVC (2006)
DINP (2006)	0.73 USD/Lb	104%	1.06	111%	TURI (2006)
DIDP (2006)	0.77 USD/Lb	110%	1.10	121%	TURI (2006)
ASE (2009)	1,75 €/kg	175% *1	NA	NA	Lanxess (2009)
DEHT (2006)	0.74 USD/Lb	106%	1.03	109%	TURI (2006)
DINCH (2006)	0.91 USD/Lb	130%	NA	NA	TURI (2006)

Notes: *1: DEHP price in 2006-2009 ≈0.8-1€/kg; 1€ is used for calculations. NA = Not available for this study.

Detailed data for estimation of other substitution costs than changed plasticiser prices have not been found. However, an example can be given from a large Danish toy company. When the Danish ban of six phthalates including DEHP, DINP and DIDP in toys and baby articles came into force, the production prices were initially raised by approximately 50 % because the international manufacturers had to produce special deliveries to the Danish marked without phthalates, but when the ban was implemented in the entire EU, the prices dropped again. The company estimates that the ban has resulted in a remaining price increase on the products of approximately 10-20 % for changing to non-ortho-phthalate plasticisers (COWI, 2009). This seems to be a reasonable estimate considering the price increases for the alternative plasticisers shown above.

Under the conservative assumption that production prices of plasticised PVC on average would rise corresponding to a 10% of raise in the plasticiser prise in a competitive market, the increased cost of substituting 1 tonne of DEHP by DINP would be approximately 100 €/t. With a total content of 5,000-20,000 tonnes DEHP, the total extra material costs would be 0.5-2 million €/y (European prices). The R&D costs of substituting DINP for DEHP is assumed to be relatively low. The costs of shifting to the less costly non-phthalate plasticisers may more likely be in the order of 100-300 €/t and with higher costs of R&D. If all DEHP was replaced by non-phthalate plasticiser the total costs would likely be in the range 1-6 million €/y. The costs may decrease over the years as result of a larger market for the alternatives.

For most EEE, the flexible parts which may contain DEHP comprise only a minor fraction of the equipment/product and thus also only a minor part of the total production price of the product. Further increases in consumer prices for EEE on average as a result of a restriction on DEHP use in EEE are therefore expected to be relatively small.

Note also, that considerable fractions of the flexible PVC used in EEE may already be plasticised with other primary plasticisers than DEHP; most probably with DINP or DIDP; this is however not included in the cost estimation above, which only refers to substitution of remaining DEHP consumption in EEE; i.e. change from the present situation.

3.6.2 Impacts on supply chain

SMEs

According to COWI (2009b), more than 400 manufacturers produce plasticised PVC products/parts of types, which may be of relevance for EEE. It is however not known how many of these actually produce EEE parts and how many are SMEs.

For most applications of DEHP a one-to-one replacement of DEHP with DINP will be possible and it is not expected that small and medium sized enterprises (SMEs) will be affected more than the general industry in the sectors in question with respect to the technical compliance. The plasticiser companies offering the alternatives are large companies, and they serve as general customer advisers when it comes to adjusting polymer formulations and production setup.

Previous studies have clearly indicated that SMEs are affected to a greater degree by compliance with the RoHS legislation compared to their larger competitors. The relatively larger burden for SMEs holds for total costs to comply with RoHS in general as well as more specifically the administrative burden (Bogaert ***et al.***, 2008). Some of the SMEs involved in the manufacturing of parts with DEHP (e.g. PVC tubes) may not already have procedures in place for ROHS compliance, and it must be expected that the relative cost burden will be higher for the SMEs when it comes to the administrative costs.

EU production

DEHP, DINP, DIDP, DINCH and ASE are examples of plasticisers produced by relatively large/multinational European based companies. DEHT is produced in the USA, the Middle East, Asia, and South America, but currently not in the EU.

Production of EEE is substantial in the EU, however a large part of the total end-user consumption of EEE is imported as finished goods from outside the EU. This is notably the case for small household appliances, consumer electronics, IT equipment, and toys etc., but also for other EEE groups.

For EU based EEE producers, DEHP containing parts may be produced by themselves or by subcontracting PVC processing companies in the EU as well as on the world market.

Differences in restriction of the use of the substance via the RoHS Directive or via REACH are discussed in section 1.3.

Impacts on waste management

The major part of the DEHP will by disposal of the waste EEE follow the wire fraction. Wires and cables are typically separated by chopping or stripping for recovery of the copper or aluminium parts (US EPA, 2008). The PVC may be recycled by different processes e.g. recycling into low-value PVC products or recovery of the polymer building materials (US EPA, 2008). The recycled PVC seems not to a significant extent to be recycled into new wires for EEE.

The restriction of the use of DEHP in EEE consequently will not significantly influence the management of the wires from waste EEE.

Denmark, and perhaps other EU Member States have quality criteria for the concentration of DEHP in sewage sludge disposed off as fertilizer in agriculture (Danish BEK nr 56 of 24/01/2000), and elevated DEHP concentrations can therefore dictate the need for sludge incineration with resulting costs for society. The release of DEHP from EEE to waste water is however deemed minimal due to the nature of these products and the waste management schemes in place.

3.6.3 Administrative costs

Extra compliance costs related to the addition of one new substance under RoHS are expected to be minimal for companies which have already implemented RoHS, that is, most relevant companies. DEHP is typically used in parts where lead and cadmium have traditionally also been used (e.g. in pigments, stabilisers) and compliance documentation would usually be required for such parts. This cost element is therefore not assessed further here.

The main extra costs are estimated to be related to control; both by the manufacturers, importers and the authorities. The presence of DEHP cannot be determined by simple XRF screening, therefore sampling, extraction and laboratory analysis is required. The parts that may contain DEHP (e.g. PVC sheeting of wires) typically also may contain other RoHS substances e.g. lead and cadmium, but the presence of these substances can be determined by a simple XRF screening.

The extra costs would therefore comprise the costs of sampling, sample preparation and analysis.

Brominated flame retardants (e.g. the PBDEs) and phthalates can be extracted by the same organic solvents and analysed using the same GC-MS analysis (gas chromatography followed by mass spectroscopy), however, usually the materials containing the brominated flame retardants are different from the materials containing phthalates. The price of an analysis of DEHP in a flexible PVC is in Denmark is reported to be about 160 € (excl. VAT) while the total price of analysing for DEHP, DBP and BBP is about 190 € (excl. VAT).The extra costs of analysing for DBP and BBP if analysis for DEHP is already done is thus about 30€ (excl. VAT). All prices are per sample when more than 20 samples are analysed.

3.7 Impacts on health and environment

3.7.1 Impact profile of substance and alternatives

Environmental and health properties of alternatives to DEHP, DBB and DBP have reviewed for ECHA (COWI, 2009a,b,c) as part of the evaluation of substances for inclusion of substances on the candidate list of SVHC for authorisation. These alternatives as well as other alternatives have further recently been reviewed in a study for the Danish EPA (Maag ***et al.***, 2009).

Study for the Danish EPA on environmental and health properties of alternatives to DEHP, DBP and BBP

The results of the study as regards environmental and human health properties of DEHP, DBP and BBP and alternatives are summarised in Table 3.4.

The data for DBP and BBP are further discussed in the next chapters. Reference is made to the original study for details. Data for DEHP, BBP and DBP, based on data in the Risk Assessment of each substance is summarized in the table using the same notation on the basis of data from the EU risk assessments. The table includes substances that are mainly alternatives to DBP or BBP. As the substitution is typically not a one-to-one substitution, but often is a replacement of one plasticiser system (e.g. with DEHP as primary and DBP or BBP as secondary plasticiser) with another system (with more substances together), it is convenient to keep the information on all the substances together in one table.

DINP and DIDP were not evaluated in the study, but human health properties of DINP compared with DEHP is discussed further below with reference to an evaluation made by the scientific committee SCENIHR.

The results from the EPA study indicate that a number of alternatives to DEHP exist which may potentially be less problematic than DEHP with regard to human health effects. However, for most of these substances data are missing for critical endpoints, in particular for carcinogenicity, where tests are only available for 3 out of 10 potential alternatives. Compared to DEHP and based on the available studies, the alternatives appear to be less toxic than DEHP. Like DEHP, all except GTA, have some effects on body weight, liver or kidney in repeated dose toxicity studies. With regard to reproductive toxicity, 3 of the 10 studied alternatives have some indication of developmental effects, although with considerably higher NO(A)EL values compared to DEHP. For 3 alternatives carcinogenicity is studied in combined chronic toxicity/carcinogenicity studies with negative outcome. Only one study was a guideline study.

With regard to environmental effects of the alternatives, useful fate data regarding biodegradability (in water) and bioaccumulative properties (either as bioconcentration factor(BCF) or log K_{ow}) are available for all alternatives while other fate data are quite variable and incomplete. With regard to ecotoxicological effect data, results from short-term tests with the base-set of organisms - fish, crustaceans and algae - exist for all 10 substances although the duration of some studies deviate from the current OECD standard.

None of the alternatives are considered PBT or vPvB substances. One of the 10 studied substances did not show any aquatic toxicity and is also not considered persistent or bioaccumulative whereas the other substances show positive results in one or more of these areas. From an environmental point of view only few of the substances stand out as less problematic compared to DEHP.

Table 3.4
Overview of main toxicological and ecotoxicological properties of DEHP, DBP, BBP and potential alternatives. For alternatives the summary is based on Maag *et al.*, 2009; for DEHP, BBP and DBP data has been extracted from the EU Risk Assessment reports.

Name of substance	CAS No.	Health					Environment		
		Acute, local and sens. effects (A/L/S)	Carcino-genic (C)	Muta-genic (M)	Repro-toxic (R)	Sub-chronic toxicity	Persistence *1	Bioac-cumula-tion *2	Aquatic Toxicity *3
DEHP	117-81-7	○/○/○	○	○	●	●	○	● BCF	○
DBP	84-74-2	○/○/○	○	○	●	●	○	● P_{ow}	●
BBP	85-68-7	○/○/○	○	○	●	●	○	● BCF	●
ASE	91082-17-6	○/○/○	-	○	○	●	● (not readily)	● P_{ow}	○
ATBC	77-90-7	○/(○)/○	○	○	○	[●]	○	● BCF	●
COMGHA	330198-91-9	○/○/○	-	○	-	(●)	○	● P_{ow}	●
DEGD	120-55-8	○/(○)/○	-	○	(●)	●	○	(○) BCF	●
DGD	27138-31-4	○/(○)/○	-	○	(●)	●	○	● P_{ow}	●
DEHT/DOPT	6422-86-2	○/(○)/○	○	○	○	●	● (inherently)	● P_{ow}	(●)
DINA	33703-08-1	○/○/○	-	○	-	●	○	(●) (con-flicting)	○
DINCH	166412-78-8	○/(○)/○	○	○	○	●	● (not readily)	● P_{ow}	○
GTA	102-76-1	○/○/○	-	○	○	○	○	○ BCF	○
TXIB	6846-50-0	○/(○)/○	-	○	●	●	● (inherently)	○ BCF	●

The inherent properties for the investigated substances are summarised using key parameters: acute and local effects, sensitisation, carcinogenicity(C), genetic toxicity (M), reproductive toxicity (R), subcronic toxicity, persistence, bioaccumulation and aquatic toxicity. If data are not available for all parameters or only from non standard test results a tentative assessment is given (shown in parentheses). The symbols: ● identified potential hazard, ○ no identified potential hazard, and – no data available. [] indicate the effects are considered of minor significance.

*1● Based on screening tests for ready and inherent biodegradability

*2 ● Based on BCF (fish) > 100 or Pow > 3 (BCF prevails over Pow where both values exist)

*3 Used for very toxic and toxic < 10 mg/L

SCENIHR evaluation of human health profiles of DEHP and alternatives

A number of alternative substances have been evaluated by the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR)with regard to the safety of medical devices containing plasticized PVC on neonates and other groups possibly at risk. The alternative plasticisers were evaluated for their potential toxicity and ranked according to toxicity and leaching. The results for the human toxicity part of the Danish EPA study mentioned above, is in accordance with the findings of the SCENIHR for the substances evaluated in both studies.

To compare the toxicity, a short summary of the potential genotoxicity, the carcinogenicity, repeated dose toxicity and reproductive toxicity were summarised (Table 3.5). In this table (as well as in Table 3.6) the NOAEL is shown as the lowest effects in male or female rat. Available information on the leaching behaviour of alternative plasticisers was sparse, but in general appears to be of the same order of magnitude as that of DEHP.

Table 3.5
NOAEL of DEHP compared with some alternative plasticisers. The critical endpoint is shown to indicate that for some of the chemicals it is different from reproductive effects (SCENIHR, 2008)

Plasticiser	NOAEL mg/kg bw	Reproductive Toxicity	Critical endpoint	Exposure Range (neonates) µg/kg bw/day *2
DEHP	4.8	Yes	Reproduction	42-2300
ATBC	100	No	Decreased bw	
COMGHA	5000	No data	Decreased bw	
BTHC	250	No	Liver weight	
DEHA	200	Yes	Foetotoxicity	
DINCH	107	No	Kidney *1	
DINP	15 (88)	No/Yes	Liver	
DEHT/DOTP	500-700	No	Developmental	
TOTM	100	Yes	Reproduction	

bw: body weight
*1 Kidney effects in male rats due to alpha-2-u macroglobulin, a mechanism not relevant to man.
*2 No data for exposure range for alternatives indicated by SCENIHR (2008).

According to the SCENIHR, considering similar leaching rates, the margin of safety of other plasticisers will be at least 20 times higher for most alternatives. The toxicological profile of DEHP and the alternative plasticisers with respect to repeated dose toxicity, genotoxicity, carcinogenicity and maternal toxicity is shown in Table 3.6.

Table 3.6
Comparison of the toxicological profiles of DEHP and potential alternatives to its use (SCENIHR, 2008)

Plasticiser	Repeated dose Toxicity, NOAEL mg/kg bw/day	Genotoxicity	Carcinogenicity	Maternal toxicity mg/kg bw/day
DEHP	29 (male rat)	Negative	LOAEL 320 (male rat)	LOAEL 750 (rat)
ATBC	100	Negative	Negative	NOAEL 100 (rat)
COMGHA	5000	Negative	No data	No data
BTHC	250	Negative	Negative	NOAEL
DEHA	200	Negative	NOAEL 1250	NOAEL 400 (rat)
DINCH	107	Negative	Negative	NOAEL 1000 (rat)
DINP	15 (88)	Negative	Kidney	LOAEL 750 (rat)
DEHT/DOTP	500-700	Negative	Negative	NOAEL 458 (rat)
TOTM	100	Negative	No Data	NOAEL

The SCENIHR concludes that DEHP causes the most severe effects on reproduction in animal studies evaluating toxicity. DEHA, DINP, and TOTM also caused reproductive toxicity, but in doses more than 20 times higher than that of DEHP. COMGHA and TOTM could not be evaluated for all endpoints due to lack of data.

Regarding the alternatives, for some compounds sufficient toxicological data were available to indicate a lower hazard compared to DEHP. For others, information on the toxicological profile was inadequate to identify the hazard. This limits according to SCENIHR the proper evaluation of the potential to replace DEHP by alternative plasticisers. According to SCENIHR the risks and benefits should be carefully evaluated for each individual medical device and each medical procedure in which the alternative needs to be used.

Summary of data on alternatives

Both assessments, referred to above, emphasise that data on alternatives are not sufficient for making a robust conclusion, especially with regard to human health effects.

Many of the alternatives have some demonstrated potential health effects in repeated dose toxicity studies and in relation to reproduction toxicity. The available data do however indicate that most of the alternatives are less problematic than the DEHP with regard to human health, but data are missing for critical endpoints, in particular carcinogenicity. When comparing the known toxicity of the alternatives with DEHP based on the NO(A)ELs for the most critical effect, reproductive toxicity, the alternatives in both assessments show these effects at much higher doses.

The available data indicate that a number of alternatives exist which do not meet the PBT criteria, but for which more details and evaluation is necessary to conclude about their environmental effects compared to DEHP. However, based on the Danish EPA assessment DINA and GTA appear to be more environmentally friendly compared to DEHP whereas the other 8 substances have positive responses for more than one of the effects: persistence, bioaccumulation and toxicity. One substance, DEGD, has only positive response for aquatic toxicity, but this is in general considered more serious compared to a substance which like DEHP is bioaccumulative, but not persistent. With regard to endocrine disruptive effects DEHP is as mentioned on the EU list of substances with clear evidence of endocrine disrupting effects. None of the alternatives are on the list and data for this endpoint has not been available for evaluation in the Danish EPA assessment. With regard to the overall assessment, negative environmental effects will have to be considered against less problematic human health effects.

3.8 Conclusions for DEHP

The main concern as to DEHP is its possible effect on reproduction. According to the EU Risk Assessment Report DEHP is bioaccumulative but is not considered a PBT substance or a vPvB (very persistent and very bioaccumulative) substance. With regard to CMR effects, DEHP raises concerns based on reproduction toxicity studies showing testicular effects, effects on fertility, toxicity to kidneys, on repeated exposure and developmental toxicity. DEHP is classified toxic to reproduction.

DEHP is mainly used in EEE as a plasticiser of flexible PVC used for wires, plugs, tubes and a number of other parts. It may in principle be found in nearly any EEE. The exact consumption for EEE is not known, but it is likely that EEE marketed in the EU contain some 5,000-20,000 t/y of DEHP.

The use of DEHP in EEE is not deemed essential as technically suitable alternatives are available and already used extensively today. The main alternatives that in recent years have taken over the major part of the former DEHP consumption are the phthalates DINP and DIDP. If DEHP is restricted in EEE these alternatives will most likely take over a major part of the remaining uses. A number of non-phthalate alternatives are marketed, however, the price of these alternatives are in general somewhat higher.

Costs - It is estimated that the incremental material costs (at manufacturing stage) would be 0.5-2 million €/y (European prices) if DINP is used to substitute for DEHP in all EEE (within or outside of the scope). In this case the R&D costs is assumed to be relatively low. The total costs of shifting to the cheapest of the non-phthalate plasticisers is higher and would likely be in the range 1-6 million €/y.

Substitution may result in slightly raised prices for flexible PVC parts in the EEE. For most EEE, the flexible parts which may contain DEHP comprise only a minor fraction of the equipment and represent only a minor part of the total production price of the product. Increases in consumer prices for the individual EEE as a result of a restriction of DEHP use in EEE are therefore expected to be small, but a restriction may impact a large share of all EEE.

The main extra administrative costs are estimated to be related to compliance control, where the extra costs would comprise the costs of sample preparation and analysis. DEHP is typically used in plastic components where lead and cadmium have traditionally been used as pigments and/or stabilisers; however these can be determined by a XRF screening. The phthalates are typically used in other plastic parts than the brominated flame retardants. The price of analysis for DEHP, DBP and BBP is nearly the same as for analysis of DEHP only.

Benefits - Available data for the alternatives indicate that with regard to human health effects less problematic alternatives exist. This conclusion is primarily based on data for repeated dose toxicity and existing reproductive toxicity data. However, most of the alternatives are not fully investigated with regard to reproductive toxicity and in particular with regard to carcinogenicity. The environmental assessment of the alternatives does not lead to the same conclusion as most of the alternatives investigated in the Danish EPA study must be considered as more problematic for the environment compared to DEHP.

With regard to DINP and DIDP, both substances show reproductive toxicity but at higher doses compared to DEHP. Also from an environmental point of view the two alternatives seem to provide a choice for more environmentally friendly alternatives based on the conclusions in the EU risk assessment reports.

4 Dibutylphthalate (DBP)

4.1 Main concern

The main concern as to dibutylphthalate (DBP) is its possible effect on reproduction and possible long-term adverse effects in the aquatic environment.

DBP is (November 2009) included in the draft list of substances recommended by ECHA for inclusion in the list of substances subject to authorisation in Annex XIV of REACH.

DBP is included in Annex I to Regulation No 1272/2008 (CLP) with the classification Repr. Cat.2; R61: May cause harm to the unborn child, Repr. Cat.3; R62: Possible risk of impaired fertility (Symbol: T), R50-53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment (Symbol: N). DBP is on the EU list of substances with endocrine disruption classifications, classified in CAT. 1 "Evidence for endocrine disruption in living organisms" (BKH, 2000)

Due to the possible effect on reproduction the substance shall not be used as substances or as constituents of preparations, at concentrations of greater than 0,1 % by mass of the plasticised material, in toys and childcare articles (Regulation No 552/2009). Further, it is not permitted for use in cosmetics (Directive 2004/93/EC)

An EU Risk Assessment has been finalised for DBP (ECB, 2004). The EU Risk Assessment Report (RAR) concludes that there is a need for limiting the risks for workers, taking the risk reduction measures already applied into consideration. For consumers and humans exposed through the environment the RAR concludes that there is at present no need for further information or testing or risk reduction measures beyond those which are being applied already.

DBP is considered non-genotoxic based on a variety of genotoxicity studies. No adequate long-term toxicity and/or carcinogenicity studies in animals or man are available.

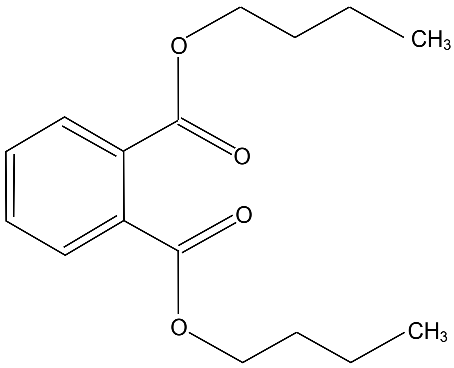
The review undertaken for the European Commission by Öko-institut e.V. as background for selection of candidate substances for a potential inclusion into the RoHS Directive (Gross ***et al.***, 2008) recommend DBP as a potential candidate.

4.2 Characterisation of the substance

DBP is a specialty plasticiser used in minor concentrations in some flexible PVC applications as well as in some non-polymer uses such as for example in paints, adhesives, sealants and printing inks (COWI, 2009c). Phthalate plasticisers are always used as so-called external plasticisers, meaning that they are not bound chemically in the polymer matrix. They can therefore migrate out of the plasticised polymer by extraction with soapy water, oils, etc., by evaporation and by diffusion, and thereby become available for exposure to humans via inhalation, skin and diet, as well at to the environment.

The structural formula for DBP (CAS. No 84-74-2) is shown below.

DBP



The following information is, if no other reference is given, extracted from an assessment of the manufacturing and use of dibutyl phthalate (DBP) recently published by European Chemicals Agency (COWI, 2009c).

The total produced tonnage in 2007 in the EU is confidential but it was less than 10,000 tonnes. A significant part of the manufactured tonnage is exported to countries outside the EU and less than 8,200 tonnes was used for formulation in the EU. DBP seems to represent less than 1% of the production of phthalates in Europe. DBP is used in relatively small concentrations in the products and may be present in significantly more than 1% of the products containing phthalates.

The major use, accounting for more than 50%, is polymer formulation and processing. DBP is a speciality fast fusing plasticiser. It is used in PVC as a gelling aid in combination with other high molecular weight plasticisers and is too volatile for PVC applications in itself. The gelling agent is the agent which reacts fastest with the PVC. Dutch surveys of phthalates and other plasticisers in toys and childcare products demonstrated that 30 % of 24 analysed products in 2004 contained DBP (FCPSA, 2008a). The share had decreased to 13% of the products in 2007 and 1% in 2008 as consequence of the regulation (FCPSA, 2008b).

The market for DBP has been decreasing over recent decades: In 1994 the production volume of DBP in the EU was 49,000 tonnes and in 1998 it was 26,000 tonnes, with an export of 8,000 tonnes.

Current uses of DBP, according to actual information obtained from industry or product registers are listed below. In general, limited information is available on the actual uses of DBP in polymers.

- Gelling aid in combination with other plasticisers in plastics (major use area). DBP is used in PVC (manufacturer information). It has not been possible to obtain very specific information on the uses, but the following applications are mentioned by different sources: floor coverings, automotive uses (manufacturer information) and garden hoses. The European Plastic Converters (EuPC), has in a survey by their members not indentified any use of DBP, and assume that DBP today is used by relatively few companies for different niche purposes. The results of the Dutch surveys show that DBP in 2004 was used at a relatively high frequency in many different types of toys (FCPSA, 2008a).

- **Rubbers** (manufacturer information). The Risk Assessment for DBP (ECB, 2004) specifies that DBP is used in some polychloroprene rubber (neoprene) and nitrile rubber, but not in all. New information on actual uses is not available.

- DBP is used in the **adhesives** industry to plasticise polyvinyl acetate (PVA) emulsions. The low viscosity and compatibility of DBP make it suited for PVA-based adhesives for bonding cellulosic materials. According to the Risk Assessment for DBP (ECB, 2004) the most important uses of the adhesives are for paper and packaging, wood building and automobile industry.

- **Epoxy resins.** Probably same application that in the Risk Assessment for DBP (ECB, 2004) is mentioned as "solvent in the production of fiber glass". More specific information on this application has not been available.

- In the coatings industry as a primary plasticiser-solvent for **nitrocellulose lacquers**.

- **Grouting agents**, used to reduce water leakages in tunnels, sewer systems, buildings etc. DBP contents as high as 30-60% were found in polyurethane foams used in grouting applications for water control in tunnels, sewer systems, buildings etc. No actual confirmation of this application has been obtained.

- **Other applications**:

- Solvent for many oil-soluble dyes, insecticides, peroxides and other organic compounds;
- Antifoam agent and as a fibre lubricant in textile manufacturing;
- Used in compounding flavours;
- Printing inks, polishing agents, corrosion inhibitor materials;
- Use in polypropylene (PP) catalytic systems;
- One application described in the confidential part of the ECHA report.

According to European Council of producers and importers of paints, printing inks and artists' colours (CEPE), DEHP, BBP and DBP are no longer used in printing inks by CEPE or European Printing Ink Association (EuPIA) members following its classification as reprotoxic category 2.

It was for the ECHA report (COWI, 2009b) not possible to obtain comprehensive quantitative updated information on the use of DBP for the different uses from manufacturers and suppliers and the available information did not allow real estimates of the distribution between the different use areas to be made.

4.3 Applications in EEE

While the use of DBP in EEE has not been identified in this study, and DBP has already been substituted in many of its former applications (consumption has decreased significantly), it cannot be ruled out that DBP may be used in EEE parts or manufacturing processes. Based on the above mentioned general knowledge of DBP applications, the possible applications areas of DBP in flexible polymers and plasticised non-polymers used in EEE are shown in Table 4.1.

The most likely applications are in PVC parts together with other plasticisers (e.g. DEHP) and in adhesives.

Table 4.1
Potential (unconfirmed) uses of DBP in EEE

Category	Cables	Plugs	"Rubber" feet	Chock absorbers	Handles	Anti-slip coating, an-	Keys	Tubes	Coated baskets	Sealing lists	Decoration, printing	Straps	Glues and sealants	Cuffs (inflatables)
1. Large household appliances	x	x	x					x	x	x			x	
2. Small household appliances	x	x	x		x	x		x			x			
3. IT and telecommunications equipment	x	x	x	x	x	x	x				x			
4. Consumer electronics	x	x	x	x	x	x	x				x	x		
5. Lighting equipment	x	x	x											
6. Electrical and electronic tools (except large-scale stationary industrial)	x	x	x	x	x	x		x						
7. Toys, leisure and sports equipment	x	x	x	x	x	x	x				x	x		
8. Medical devices	x	x	x	x	x	x	x	x						x
9. Monitoring and control instruments including industrial	x	x	x	x	x	x	x	x					x	
10. Automatic dispensers	x	x	x				x	x		x			x	

4.4 Quantities of the substance used

No estimates of DBP consumption in EEE have been found. Such estimates are hard to form due to lack of confirmation of DBP usage in EEE parts. The earlier mentioned frequencies of DBP in toys prior to the ban for this sector indicate however, that DBP usage in flexible PVC could potentially be widespread. On the other hand, European Plastic Converters (EuPC), has in a survey by their members not indentified any use of DBP, and assume that DBP today is used by relatively few companies for different niche purposes.

Less than 8,200 t/y of DBP are used for production in the EU. Of this, the majority (less than 5,900 t/y) is used as secondary plasticiser in production of polymer parts, mainly of PVC. No application in EEE is specifically mentioned by suppliers. Less than 1,890 t/y was used in PVA and other adhesives, and 160 t/y was used in paints (COWI, 2009c). Both may to some extent be used in EEE. The remaining 330 t/y are not deemed relevant for EEE applications. A minor share of the relevant consumption of DBP may be used in EEE parts; probably below 10% based on the many other potential application areas. The consumption of DBP for EEE production in the EU is therefore likely in the range of 50-500 t/y.

An additional, but unknown amount may be present in imported EEE and imported EEE parts.

4.5 Available alternatives

Much of the DBP usages have likely been substituted for by di-isobutyl phthalate (DiBP), a very similar group of substances which have similar technical performance characteristics. DiBP has however been proposed as a SVHC (substance of very high concern) due to CMR characteristics (DiBP Annex XV, 2009). Other available alternatives to DBP appear to be dibenzoates such as dipropylene glycol dibenzoate (DGD), the mixed dibenzoates product Benzoflex 2088 and dibutyl terephthalate (DBT). With adjustments of the polymer/plasticiser formulations, and in some cases processing adjustments, these alternative plasticisers are reported by producers to perform technically suitably as alternatives to DBP as specialty PVC plasticisers. There are also other alternatives to DBP, but some of these currently suffer from relatively high prices compared to DEHP and DBP (COWI, 2009).

With its faster, lower temperature, gelling characteristics compared to general plasticisers as DEHP and DINP, using alkylsulfonic phenylester (ASE) as the primary plasticiser may reduce the need for adding a gelling aid like DBP. ASE is however currently somewhat more expensive than DEHP/ DBP(COWI, 2009).

Another alternative to using DBP in PVC is to simply omit its use, and accept the potentially altered production characteristics such as slightly slower production or slightly increased energy input for gelation of the polymer.

There might be some special non-polymer applications where extensive R&D would be necessary for obtaining the desired properties of the final products with alternative plasticisers, but no specific information on such applications has been identified.

4.6 Socioeconomic impacts

4.6.1 Substitution costs

The substitution costs will mainly fall at the processors and formulators of PVC and other potentially DBP containing materials such as sealants, glues, etc. For coatings and other integrated parts, the EEE manufacturers may act as PVC processors themselves, and may need to be involved in reformulation of the PVC plastisols (suspension of PVC particles in a plasticizer) or compounds used. The plasticiser producers will normally be involved in the substitution, because they act as advisors for the processors and formulators in the formulation of the polymer/plasticiser system. The alternative plasticisers are already developed and marketed, but costs for increasing the production volume may be implied. One of the alternatives to using DBP is to simply omit its use. This may result in increased production time and thereby potentially increased production prices. All substitution costs are expected to ultimately be furthered to the end customers.

Table 4.2 shows price examples of BBP, DEHP and selected alternatives to DBP. We have not found current prices for DBP, but it has been reported to traditionally be in the same price range as DEHP. As shown, DGD and Benzoflex 2088 had comparable or slightly higher prices per weight than DEHP, while ASE had a somewhat higher price per weight. Note that alternatives may not be used in the same amount as DBP to obtain the properties of the polymer; data are not available for a closer comparison. Many PVC products are sold in highly competitive markets, and PVC processing industry is sensitive to even minor price changes on raw materials (TURI, 2006).

Table 4.2
Examples of comparative prices of DEHP, BBP and selected alternatives (from COWI, 2009)

Substance	Price,	Relative price to DEHP and BBP, %	Remarks
DEHP (2006)	0.70 USD/Lb	100%	TURI (2006)
BBP (2006)	0.70 USD/Lb	100%	TURI (2006)
Benzoflex 2088		"Slightly higher"	Genovique (2009)
DGD (2006)	0.73 USD/Lb	104%	TURI (2006)
ASE	€1,75/KG	175% *1	Lanxess (2009)

Notes: *1: DEHP € price in 2006-2009 ≈0.8-1€/kg; 1€ is used for calculations.

For most EEE, the parts which may contain DBP comprise only a minor fraction of the equipment/product and thus also only a minor part of the total production price of the product. If used at all for this equipment, DBP and alternatives are only used in small concentrations, further decreasing importance of the secondary plasticisers' price in this context. Also, considerable fractions of the flexible PVC and other materials used in EEE may already be formulated with other specialty plasticisers instead of DBP. Increases in consumer prices for EEE as a result of a restriction of DBP use in EEE are therefore expected to be minimal or even negligible.

4.6.2 Impacts on supply chain

SMEs
The considerations regarding impacts on SME are the same as for DEHP, and reference is made to section 3.3.

EU production
DBP and ASE are examples of plasticisers produced by relatively large or multinational European based companies. DGD and Benzoflex 2088 are currently produced in the USA.

Production of EEE is substantial in the EU, however a large part of the total end-user consumption of EEE is imported as finished goods from outside the EU. This is notably the case for small household appliances, consumer electronics, IT equipment, and toys etc., but also for other EEE groups.

For EU based EEE producers, DBP containing parts may be produced by themselves or by subcontracting PVC processing or non-polymer formulator companies in the EU as well as on the world market.

Differences in restriction of the use of the substance via the RoHS Directive or via REACH are discussed in section 1.3.

4.6.3 Impacts on waste management

As DBP is to a large extend used in smaller parts, their treatment when disposed off will follow the EEE products they are parts of, and a change in plasticiser will likely not in itself form the basis of changes in the solid waste handling scheme for EEE. No changes in solid waste handling costs are expected as a consequence of prohibiting the use of DBP in EEE.

4.6.4 Administrative costs

Extra compliance costs related to the addition of one new substance under RoHS are expected to be minimal for companies which have already implemented RoHS, that is, most of the relevant companies. DBP use in polymers would typically be in parts where lead and cadmium have traditionally also been used (e.g. in pigments, stabilisers) and compliance documentation would usually be required for such parts. Additional compliance documentation may be required for non-polymer applications e.g. adhesives. No data are available on how many companies could be affected by RoHS regulation because of the inclusion of DBP. This cost element is therefore not included further in the assessment made here.

The main extra costs are estimated to be related to control; both by the manufacturers, importers and the authorities. The presence of DBP cannot be determined by simple XRF screening, therefore sampling, extraction and laboratory analysis is required. The parts that may contain DBP (mainly flexible PVC parts) typically also may contain DEHP and other RoHS substances e.g. lead and cadmium, but the presence of metals can be determined by a simple XRF screening.

The extra costs would therefore comprise the costs of sampling, sample preparation and analysis.

Brominated flame retardants (e.g. the PBDEs) and phthalates can be extracted by the same organic solvents and analysed using the same GC-MS analysis (gas chromatography followed by mass spectroscopy), however, usually the materials containing the brominated flame retardants are different from the materials containing phthalates.

In PVC and other polymers DBP may be used together with DEHP which is used in much larger quantities in EEE. The price of an analysis of DEHP in a flexible PVC is in Denmark is reported to be about 160 € (excl. VAT) while the total price of analysing for DEHP, DBP and BBP is about 190 € (excl. VAT).The extra costs of analysing for DBP and BBP if analysis for DEHP is already done is thus about 30€ (excl. VAT). All prices are per sample when more than 20 samples are analysed.

For non-polymers parts like adhesives and paints, it may be necessary to take extra samples – if possible at all – in order to analyse for the presence of DBP (and eventually other regulated phthalates). There is at the moment no simple "rule-of-thump" telling where the substances could most likely be found and they are probably present at a very low frequency.

4.7 Impacts on health and environment

4.7.1 Impact profile of substance and alternatives

Environmental and health properties of alternatives to DEHP, DBB and DBP have reviewed for ECHA (COWI, 2009a,b,c) as part of the evaluation of substances for inclusion of substances on the candidate list of SVHC for authorisation. These substances and other alternatives have further recently been reviewed in a study for the Danish EPA (Maag ***et al.***, 2009).

Study for the Danish EPA on environmental and health properties of alternatives to DEHP, DBP and BBP

The results of the study as regards environmental and human health properties are summarised in Table 3.4 in section 3.7.1. Data for DEHP, BBP and DBP, based on data in the EU Risk Assessment report of each substance, is summarized in the table using the same notation. The table includes substances that are mainly alternatives to DBP or BBP, but as the substitution is typically not a one-to-one substitution, but often is a replacement of one plasticiser system (e.g. with DEHP as primary and DBP or BBP as secondary plasticiser) with another system (with more substances together), it is convenient to keep the information on all the substances together in one table.

The results from the study indicate that a number of alternatives to DBP exist which may potentially be less problematic than DBP with regard to human health effects. However, for most of these substances data are missing for critical endpoints, in particular for carcinogenicity, where tests are only available for 3 out of 10 potential alternatives. Compared to DBP and based on the available studies, the alternatives appear to be less toxic than DBP. Like DBP, all except GTA, have some effects on body weight, liver or kidney in repeated dose toxicity studies. With regard to reproductive toxicity, 3 of the 10 studied alternatives have some indication of developmental effects, although with considerably higher NO(A)EL values compared to DBP. For 3 alternatives carcinogenicity is studied in combined chronic toxicity/carcinogenicity studies with negative outcome. Only one study was a guideline study.

With regard to environmental effects of the alternatives, useful fate data regarding biodegradability (in water) and bioaccumulative properties (either as BCF or log K_{ow}) are available for all alternatives while other fate data are quite variable and incomplete. Concerning ecotoxicological effect data, results from short-term tests with the base-set of organisms - fish, crustaceans and algae - exist for all 10 substances although the duration of some studies deviate from the current OECD standard.

None of the alternatives are considered PBT or vPvB substances. One of the 10 studied substances did not show any aquatic toxicity and is also not considered persistent or bioaccumulative whereas the other substances show positive results in one or more of these areas. From an environmental point of view only few of the substances stand out as less problematic compared to DBP.

4.8 Conclusions for DBP

The main concern as to DBP is the substance's possible effect on reproduction and possible long-term adverse effects in the aquatic environment.

The substance is with regard to human health classified as toxic to reproduction. According to the EU Risk Assessments DBP is bioaccumulative and toxic to aquatic organisms, but not persistent in the environment. DBP is therefore not considered PBT substances or vPvB substances. With regard to CMR effects the Risk Assessments conclude based on the available studies that DBP is not considered genotoxic and are also not carcinogenic to humans.

It has not been possible to fully confirm that DBP is currently used in the manufacture of EEE. The consumption of DBP for EEE production in the

EU is likely in the range of 50-500 t/y mainly as secondary plasticiser in PVC and in adhesives and other non-polymer applications. The plasticiser may be present in a low percentage of products within all product categories.

The use of DBP in EEE is not deemed essential as technically suitable alternatives are available and already used today, however it cannot be ruled out for some specific non-polymer applications substitution may be particular difficult.

All available data indicate that alternatives exist, for example DGD, Benzoflex 2088 and ASE. For PVC plasticisation, omitting the use of a fast gelling secondary plasticiser as DBP may also be technically possible, although probably with increased PVC processing expenses as a consequence.

Costs - For most EEE, the parts which may contain DBP comprise only a minor fraction of the equipment/product and thus also only a minor part of the total production price of the product. Price difference between the substance and alternatives is approximately the same as for DEHP. As the consumption of the substance is only about one percent of the consumption of DEHP the increases in consumer prices for EEE, as a result of a restriction on the use of DBP in EEE, are therefore expected to be minimal.

DBP is typically used in plastic components where lead and cadmium have traditionally been used as pigments and stabilisers; however these can be determined by a XRF screening. Further, the phthalates are typically used in other plastic parts than the brominated flame retardants. The main extra administrative costs are estimated to be related to compliance control, where the extra costs would comprise both the costs of sample preparation and analysis. The price of analysis for DEHP, DBP and BBP is nearly the same as for analysis of DEHP only.

The scattered use of DBP in non-polymer applications in EEE may result in relatively high costs of compliance control as relatively many samples have to be taken. For non-polymer applications compliance control will be particular difficult and will imply control of materials not otherwise controlled for other RoHS substances.

Benefits - When comparing the known toxicity of the alternatives with DBP based on the NO(A)ELs for the most critical effect, reproductive toxicity for the three alternatives with developmental effects, the alternatives in the Danish EPA study show these effects at comparable dose levels to DBP. Substances that have been tested for reproductive toxicity with negative outcome (ASE, ATCB, DEHT, DINCH, GTA) seem to be more suitable alternatives based on health effects.

The available data indicate that a number of alternatives exist which do not meet the PBT criteria, but for which more details and evaluation is necessary to conclude about their environmental effects compared to DBP. However, based on the Danish EPA assessment DINA and GTA appear to be more environmentally friendly compared to DBP whereas the other 8 substances have positive responses for more than one of the effects: persistence, bioaccumulation and toxicity. With regard to endocrine disruptive effects DBP is on the EU list of substances with clear evidence of endocrine disrupting effects. None of the alternatives are on the list and data for this endpoint has not been available for evaluation in the Danish EPA assessment.

With regard to the overall assessment, the uncertainty concerning human health effects, in particular reproductive toxicity and carcinogenicity, needs to be considered.

5 Butylbenzylphthalate (BBP)

5.1 Main concern

The main concern as to butylbenzylphthalate (BBP) is its possible effect on reproduction and possible long-term adverse effects in the aquatic environment.

BBP is (November 2009) included in the draft list of substances recommended by ECHA for inclusion in the list of substances subject to authorisation in Annex XIV of REACH.

BBP is included in Annex I to Regulation No 1272/2008 (CLP) with the classification Repr. Cat.2; R61: May cause harm to the unborn child, Repr. Cat.3; R62: Possible risk of impaired fertility (Symbol: T), R50-53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment (Symbol: N). DBP is on the EU list of substances with endocrine disruption classifications, classified in CAT. 1 "Evidence for endocrine disruption in living organisms" (BKH, 2000).

Due to the possible effect on reproduction the substance shall not be used as substances or as constituents of preparations, at concentrations of greater than 0.1 % by mass of the plasticised material, in toys and childcare articles (Regulation No 552/2009). Further, it is not permitted for use in cosmetics (Directive 2004/93/EC).

An EU Risk Assessment has been finalised for BBP (ECB, 2007). The EU Risk Assessment Report (RAR) concludes for workers, consumers and humans exposed through the environment that there is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already. The RAR note in the summary that recent epidemiological studies support the hypothesis that prenatal phthalate exposure at environmental levels may affect male reproductive development in humans. However, due to small sample size in the studies, this issue will have to be further investigated, and new studies in the future should be taken into account in the risk assessment of BBP (ECB, 2007).

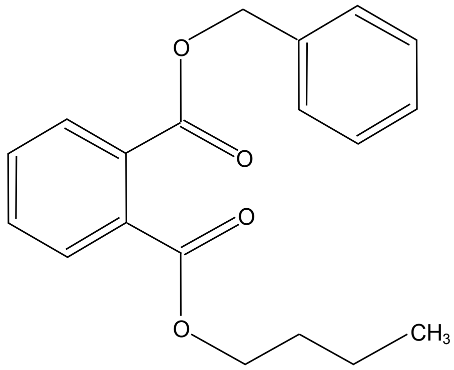
The review undertaken for the European Commission by Öko-institut e.V. as background for selection of candidate substances for a potential inclusion into the RoHS Directive (Gross ***et al.***, 2008) recommend BBP as a potential candidate.

5.2 Characterisation of the substance

BBP is a specialty plasticiser used in minor concentrations in some flexible PVC applications as well as in some non-polymer uses such as for example in paints, adhesives, sealants, printing inks, etc. (COWI, 2009a). Phthalate plasticisers are always used as so-called external plasticisers, meaning that they are not bound chemically in the polymer matrix. They can therefore migrate out of the plasticised polymer by extraction with soapy water, oils, etc., by evaporation and by diffusion, and thereby become available for exposure to humans via inhalation, skin and diet, as well at to the environment.

The structural formula for BBP (CAS. No 85-68-7) is shown below.

BBP



The following information in this section is, if nothing else is mentioned, extracted from an assessment of the manufacturing and use of butyl benzyl phthalate (BBP) recently published by European Chemicals Agency (COWI, 2009a).

The total produced tonnage of BBP in 2007 in the EU was below 18,000 t/y. A significant part of the produced tonnage is exported to countries outside the EU. The market for BBP has been decreasing over the last decade. In the period 1994-1997, the total reported Western European production of BBP was 45,000 t/y whereas for 2004 a production volume of 19,500 t/y was reported.

More than 70% of the BBP was in 2007 used as a plasticiser in polymer products, mainly PVC for flooring. BBP is typically used together with other plasticisers e.g. DEHP or DINP, in concentrations of a few percent, in order to add special performance to the polymer during processing (faster gelation of the polymer) and in the end product (hardened, stain resistant surface to vinyl flooring). BBP has been used widely by the flooring industry to speed up production and adding surface properties to flooring materials.

The end-product uses of BBP are as follows:

- Flooring (both calendered and spread coated flooring);
- Wall covering;
- Coating of leather and textiles (upholstery, shoe uppers, wallets/bags, luggage);
- Packaging films;
- Sealants (polysulphide based, polyurethane based or acrylic-based) for insulating double glazing and other applications;
- Paints for car care and construction (acrylic lacquers and other);
- Inks for paper and board;
- Adhesives (polyvinyl acetate and other);
- Miscellaneous (hard PVC, nitrile rubber and other).

The major application area flooring accounting for about 50% of the total consumption, while the second larges application area, polysulphide sealants account for about 19% of the total.

5.3 Applications in EEE

BBP usage in electrical and electronic equipment (EEE) has not been confirmed. Based on general background knowledge, BBP may however possibly be used in synthetic leather and coated textile in straps, flexible or rigid PVC sheet, sealants, printing inks and adhesives. BBP may in principle be used for these applications in products within all product types. The application of BBP in some of the other flexible polymers in EEE cannot be ruled out completely.

5.4 Quantities of the substance used

No estimates of BBP consumption in EEE have been found. Such estimates are hard to form due to lack of confirmation of BBP usage in EEE parts.

An estimated 8,000 tonnes of BBP is used annually for production in the EU, of which an estimated 3,840 t/y is used for flooring, and 560 t/ is used for calendered film. The remaining 3,600 t/y BBP is used for polysulfide and other sealants (1,520 t), imitated leather and textiles (800 t), hard PVC compounding (640 t), PVA and other adhesives (400 t), paints and inks (160 t), other uses (80) (COWI; 2009d). A minor share of this consumption may used in EEE parts; probably well below 10% considering the many other potential application areas. The consumption of BBP in EEE produced in the EU is therefore likely in the range of 20-200 t/y.

An additional, but unknown amount may be used in imported EEE and imported EEE parts.

5.5 Available alternatives

Today, the principal alternatives to BBP appear to be dibenzoates such as dipropylene glycol dibenzoate (DGD) and the mixed dibenzoates product Benzoflex 2088, which have been increasingly used in the vinyl flooring business (the main application of BBP). With adjustments of the polymer/plasticiser formulations, and in some cases processing adjustments, these alternative plasticisers are reported by producers to perform technically suitably as alternatives to BBP as specialty PVC plasticisers. Glycerol triacetate (GTA) may also be a technically suitable alternative for some (non-polymer) applications. There may also be other alternatives to BBP.

With its faster, lower temperature gelling characteristics compared to the general plasticiser DEHP, using alkylsulfonic phenylester (ASE) as primary plasticiser may reduce the need for adding a gelling aid like BBP. ASE is however currently somewhat more expensive than DEHP and DBP.

Another alternative to using BBP is to simply omit its use, and accept the potentially altered production characteristics such as slightly slower production of flexible PVC products or slightly increased energy input for gellation of the flexible polymer.

BBP is mentioned as a critical component in seals for insulating double glazing which is not relevant for EEE (BBP Information Centre, 2009), but it cannot be ruled out that there might be some particular difficulties in substituting the BBP for some niche applications of the substance in EEE.

5.6 Socioeconomic impacts

5.6.1 Substitution costs

The substitution costs will mainly fall at the processors and formulators of PVC and other potentially BBP containing materials such as sealants, glues, etc. For coatings and other integrated composite parts, the EEE manufacturers may act as PVC processors themselves, and may need to be involved in reformulation of the PVC plastisols or compounds used. The plasticiser producers will normally be involved in the substitution, because they act as advisors for the processors and formulators in the formulation of the polymer/plasticiser system. The alternative plasticisers are already developed and marketed, but costs for increasing the production volume may be implied. Costs for research in using alternatives for new applications will be furthered to the customers. One of the alternatives to using BBP is to simply omit its use. This may result in increased production time and thereby potentially increased production prices. All substitution costs are expected to ultimately be furthered to the end customers.

Table 5.1 shows price examples of BBP, DEHP and selected alternatives to BBP. As shown, DGD and Benzoflex 2088 had comparable or slightly higher prices per weight than DEHP, while GTA had a somewhat higher price per weight. Note that alternatives may not be used in the same amount as BBP to obtain the desired effect on the polymer; data are not available for a closer comparison. Many PVC products are sold in highly competitive markets, and PVC processing industry is sensitive to even minor price changes on raw materials (TURI, 2006).

Table 5.1
Examples of comparative prices of DEHP, BBP and selected alternatives (from COWI, 2009)

Substance	Price,	Relative price to DEHP and BBP, %	Remarks
DEHP (2006)	0.70 USD/Lb	100%	TURI (2006)
BBP (2006)	0.70 USD/Lb	100%	TURI (2006)
Benzoflex 2088		"Slightly higher"	Genovique (2009)
DGD (2006)	0.73 USD/Lb	104%	TURI (2006)
ASE (2009)	1,75 €/kg	175% *1	Lanxess (2009)
GTA	€1,50/KG	150% *1	Lanxess (2009)

Notes: *1: DEHP € price in 2006-2009 ≈0.8-1€/kg; 1€ is used for calculations.

For most EEE, the parts which may contain BBP comprise only a minor fraction of the equipment/product and thus also only a minor part of the total production price of the product. If used at all for this equipment, BBP and alternatives are only used in small concentrations, further decreasing importance of the secondary plasticisers' price in this context. Also, considerable fractions of the flexible PVC and other materials used in EEE may already be formulated with other specialty plasticisers instead of BBP. Increases in consumer prices for EEE as a result of a restriction of BBP use in EEE are therefore expected to be minimal or even negligible.

5.6.2 Impacts on supply chain

SMEs
The considerations regarding impacts on SMEs are the same as for DEHP, and reference is made to section 3.3.

EU production
BBP, ASE and GTA are examples of plasticisers produced by relatively large or multinational European based companies. DGD and Benzoflex 2088 are currently produced in the USA.

Production of EEE is substantial in the EU, however a large part of the total end-user consumption of EEE is imported as finished goods from outside the EU. This is notably the case for small household appliances, consumer electronics, IT equipment, and toys etc., but also for other EEE groups.

For EU based EEE producers, BBP containing parts may be produced by themselves or by subcontracting PVC processing or non-polymer formulator companies in the EU as well as on the world market.

Differences in restriction of the use of the substance via the RoHS Directive or via REACH are discussed in section 1.3.

5.6.3 Impacts on waste management

The considerations regarding waste management are the same as for DBP.

5.6.4 Administrative costs

The considerations regarding administrative are the same as for DBP.

5.7 Impacts on health and environment

5.7.1 Impact profile of substance and alternatives

Environmental and health properties of alternatives to DEHP, DBP and BBP have been reviewed for ECHA (COWI, 2009a,b,c) as part of the evaluation of substances for inclusion of substances on the candidate list of SVHC for authorisation. These substances and other alternatives have further recently been reviewed in a study for the Danish EPA (Maag ***et al.***, 2009).

Study for the Danish EPA on environmental and health properties of alternatives to DEHP, DBP and BBP
The results of the study as regards environmental and human health properties are summarised in Table 3.4 in section 3.7.1. Data for DEHP, BBP and DBP, based on data in the Risk Assessment of each substance is summarized in the table using the same notation on the basis of data from the EU risk assessments. The table includes substances that are mainly alternatives to DBP or BBP, but as the substitution is typically not a one-to-one substitution, but often is a replacement of one plasticiser system (e.g. with DEHP as primary and DBP or BBP as secondary plasticiser) with another system (with more substances together), it is convenient to keep the information on all the substances together in one table.

The results from the study indicate that a number of alternatives to BBP exist which may potentially be less problematic than BBP with regard to human health effects. However, for most of these substances data are missing for critical endpoints, in particular for carcinogenicity, where tests are only available for 3 out of 10 potential alternatives. Compared to BBP and based on the available studies, the alternatives appear to be less toxic than BBP. Like BBP, all except GTA, have some effects on body weight, liver or kidney in repeated dose toxicity studies. With regard to reproductive toxicity, 3 of the 10 studied alternatives have some indication of developmental effects at comparable levels to NOAEL for fertility for BBP. For 3 alternatives carcinogenicity is studied in combined chronic toxicity/carcinogenicity studies with negative outcome. Only one study was a guideline study.

With regard to environmental effects of the alternatives, useful fate data regarding biodegradability (in water) and bioaccumulative properties (either as BCF or log K_{ow}) are available for all alternatives while other fate data are quite variable and incomplete. With regard to ecotoxicological effect data, results from short-term tests with the base-set of organisms - fish, crustaceans and algae - exist for all 10 substances although the duration of some studies deviate from the current OECD standard.

None of the alternatives are considered PBT or vPvB substances. One of the 10 studied substances(GTA) did not show any aquatic toxicity and is also not considered persistent or bioaccumulative whereas the other substances show positive results in one or more of these areas. From an environmental point of view only few of the alternatives (DEGD, DINA, GTA) stand out as less problematic compared to BBP based on the overall assessment presented in Table 3.4.

5.8 Conclusions for BBP

The main concern as to BBP is the substance’s possible effect on reproduction and possible long-term adverse effects in the aquatic environment.

According to the EU Risk Assessment Report, BBP is bioaccumulative and toxic to aquatic organisms but not persistent in the environment. BBP is therefore not considered a PBT substance or a vPvB substance. With regard to CMR effects the RAR concludes based on the available studies that BBP is considered non-genotoxic and also non-carcinogenic. BBP raises concern because of reproductive toxicity. In conclusion, BBP is found to adversely affect the reproductive organs in experimental animal studies which may affect fertility. Furthermore the substance is found to be a developmental toxicant and to possess anti-androgen like properties in experimental animal studies.

It has not been possible to fully confirm that BBP is currently used in the manufacture of EEE. The consumption of BBP for EEE production in the EU is likely in the range of 20-200 t/y; the BBP may be used in flexible or rigid PVC, sheets, adhesives, sealants and other non-polymer applications. The plasticiser may be present in a low percentage of products within all product categories.

The possible use of BBP in EEE is not deemed essential as technically suitable alternatives are available and already used today with a reservation for some specific non-polymer applications where substitution may be particular difficult (not identified). All available data indicate that alternatives exist, for example DGD and Benzoflex 2088. For PVC plasticisation, omitting the use of a fast gelling secondary plasticiser as BBP may also be technically possible, although probably with increased PVC processing expenses as a consequence.

Costs - For most EEE, the parts which may contain BBP comprise only a minor fraction of the equipment/product and thus also only a minor part of the total production price of the product. Price difference between the substance and alternatives is approximately the same as for DEHP. As the consumption of the substance is only about one percent of the consumption of DEHP the increases in consumer prices for EEE, as a result of a restriction on the use of BBP in EEE, are therefore expected to be minimal.

BBP is typically used in plastic components where other RoHS substances have traditionally been used as well in pigments and stabilisers; however these can be determined by a XRF screening. The phthalates are typically used in other plastic parts than the brominated flame retardants. The main extra administrative costs are estimated to be related to compliance control, where the extra costs would comprise the costs of sample preparation and analysis. The price of analysis for DEHP, DBP and BBP is nearly the same as for analysis of DEHP only.

The scattered use of DBP in non-polymer applications in EEE may result in relatively high costs of compliance control as relatively many samples have to be taken. For non-polymer applications compliance control will be particular difficult and will imply control of materials not otherwise controlled for other RoHS substances.

Benefits - Available data for the alternatives indicate that with regard to human health effects less problematic alternatives exist. This conclusion is primarily based on data for repeated dose toxicity and existing reproductive toxicity data. However, most of these alternatives are not fully investigated with regard to reproductive toxicity and in particular with regard to carcinogenicity.

As for the environmental assessment of the alternatives the picture is not as clear, but three substances seem at least to be less problematic compared to BBP and these are DEGD, DINA, and GTA.

6 Additive use of tetrabromo bisphenol A (TBBPA)

6.1 Main concern

The main concern regarding additive use of TBBPA is its toxicity in the aquatic environment and possible effect of breakdown products in the environment.

TBBPA is currently (Sep 2009) not on ECHA's candidate list of substances for authorisation.

TBBPA has recently been included in Annex I to Regulation No 1272/2008 (CLP) with the classification N; R50-53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

The EU Risk Assessment Report (RAR) of TBBPA on human health concludes that no health effects of concern have been identified for TBBPA and that risks to workers, consumers and humans exposed via the environment are not expected by the use of TBBPA as additive or reactive flame retardant (ECB, 2006). The RAR concludes that there is a need for measures for reducing the emission from compounding and conversion sites where TBBPA is used as an additive flame retardants (EC, 2008a)

The risk assessment for the environment concludes that TBBPA is a vP (very persistent) substance in the marine environment. The substance cannot be considered a PBT (ECB, 2007) as it does not meet the bioaccumulation and toxicity criteria, a conclusion agreed upon by the Scientific Committee on Health and Environmental Risks (SCHER, 2008).

Regarding breakdown products the RAR mention that TBBPA has been shown to break down in estuarine sediments to another substance (bisphenol-A) that is known to be toxic and shows effects on the endocrine system. Thus this indicates that tetrabromobisphenol-A may have the potential to cause long-term adverse effects on marine ecosystems if sufficient exposure occurs, but the RAR states that it is not clear how this finding fits in with the current Marine Risk Assessment Technical Guidance. In addition, another potential metabolite/degradation product (tetrabromobisphenol-A bis(methyl ether) that may be formed by O-methylation of tetrabromobisphenol-A, can be considered to meet the screening criteria for a vPvB substance (ECB, 2007).

The review undertaken for the European Commission by Öko-institut e.V., as background for selection of candidate substances for a potential inclusion into the RoHS Directive (Gross ***et al.***, 2008), recommend TBBPA as a potential candidate. The recommendation is based on the uncertainties about breakdown products, possible formation of dioxins and furans by uncontrolled combustion processes and concerns regarding the findings of TBBPA in species at the top of the food chain with unknown long-term effects.

6.2 Characterisation of the substance

Tetrabromo bisphenol A (TBBPA) is a brominated flame retardant (BFR) widely used in electrical and electronic equipment. TBBPA is the BRF manufactured in the largest quantities (BSEF, 2009a). The substance is both used as a reactive and an additive flame retardant.

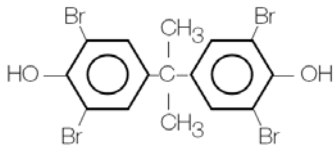
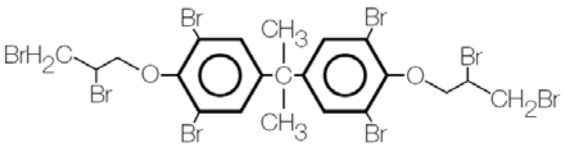
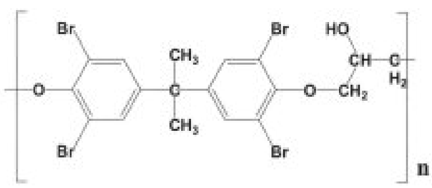
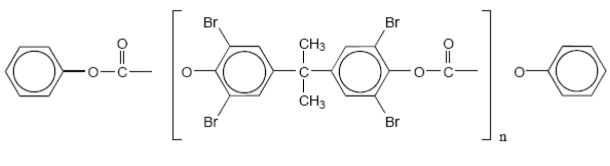
In additive usage of TBBPA, the substance is not bound chemically in the polymer material, and therefore continues to exist as the original substance, and has the potential for migrating or evaporating out of the polymer. In reactive usage of the substance, the flame retardant is bound chemically into the polymer and does not exist anymore as the monomer substance (except for possible unreacted trace concentrations).

The current description focuses on the additive use of TBBPA.

Besides the pure TBBPA, a number of derivatives of TBBPA are used as additive flame retardants. Some are used for the same applications as TBBBA whereas others are mainly used for flame retarding other polymers (see Table 6.1. The TBBPA derivatives are not included in the present assessment, but a few notes on their application are added for the framing of the description of the use of TBBPA.

TBBPA is not produced in the EU. Globally TBBPA is produced in USA, Japan, Jordan and Israel.

Table 6.1
Structural formula and TBBPA and derivatives (based on lassen *et al.*, 2006)

Chemical name	Cas No	Structural formula	Polymers the substance may be used for
TBBPA	79-94-7		ABS, HIPS, PC
TBBPA bis (2,3-dibromopropyl ether)	21850-44-2		HIPS, PP, PE, crystal PS
Brominated epoxy polymer	68928-70-1		PBT, HIPS, ABS, PC/ABS
Phenoxy-terminated carbonate oligomer of TBBPA	94334-64-2 71342-77-3		PBT/PET, PC, ABS, PC/ABS, polysulfone, SAN

6.3 Applications in EEE

The primary use of TBBPA as an additive flame retardant is in enclosures of acrylonitrile butadiene styrene (ABS) (BSEF, 2009b). ABS is widely used for enclosures and structural parts of many types of electronic and electrical equipment.

CEFIC (presentation without date on manufacturer's website) inform that ABS with TBBPA is used for personal computers, monitors, notebooks, photocopiers, scanners, cellular phones, industrial and life safety applications, battery housings, smoke alarms and safety lighting.

An American survey found that ABS with TBBPA was used in 34% of the computer monitors and in 2% of TV back casings (Kingsbury, 2002 as cited by Pure Strategies, 2005).

In flame retarded ABS for enclosures the TBBPA is typically applied in concentrations of 14-30% with about 4% antimony trioxide (ATO – CAS. No 1309-64-4) as synergist (Lassen ***et al.***, 2006). A typical loading for V0 grade ABS is 22% (Lassen ***et al.***, 2006). Traditionally octa-BDE has been the flame retardant of choice for ABS plastic, but after the phase out of octa-BDE, TBBPA has been one of the main flame retardant for this plastic type.

Some of the TBBPA derivatives may as well be used in enclosures of ABS, PP and HIPS, but besides the TBBPA derivatives are widely used in engineering plastics; first of all the thermoplastic polyesters poly(butylene terephthalate) (PBT) and poly(ethylene terephthalate) (PET). These plastics are used for more demanding applications in connectors, circuit breakers and similar parts. According to Munro ***et al.*** (2004) brominated carbonate oligomers (probably tetrabromobisphenol-A carbonate oligomer) accounted for 44% of the global flame retardant use in thermoplastic polyesters. There are currently no commercially mature non-brominated alternatives for the thermoplastic polyesters, but new alternatives have been introduced recently.

The possible applications of TBBPA in flame retarded parts of EEE are indicated in Table 6.2 below. Flame retarded ABS enclosures or structural parts may in principle be found in products within all categories, but the major part is probably used in Category 2 "IT and telecommunication equipment".

Table 6.2
Possible uses of TBBPA in EEE

Categories	ABS and HIPS enclosures and structural parts with TBBPA
1. Large household appliances	x
2. Small household appliances	x
3. IT and telecommunications equipment	x - major
4. Consumer electronics	x - major
5. Lighting equipment	x
6. Electrical and electronic tools (except large-scale stationary industrial)	x
7. Toys, leisure and sports equipment	x
8. Medical devices	x
9. Monitoring and control instruments including industrial	x
10. Automatic dispensers	x

6.4 Quantities of the substance used

The annual global production in 2004 was estimated at more than 170.000 tonnes. (Posner, 2006). About 70% of TBBPA is used as a reactive flame retardant in EEE and 20% is used as an additive to plastics (BSEF, 2009a).

The total European consumption of TBBPA from the demand for EEE is estimated by Gross ***et al.*** (2008) at around 40,000 tonnes/year (figures are based on data for 2003/2005).Thereof Gross ***et al.*** (2008) estimate that 13,800 tonnes/year were imported into the EU as the substance itself, 6,000 tonnes/year were imported in partly finished products (e.g. masterbatch, epoxy resins) and 20,200 tonnes/y were imported in finished products and components. Assuming that 20% of the 40,000 tonnes/year are used additively, the additive use of TBBPA (= total content of marketed EE products) can be estimated at 8,000 tonnes/year.

No new data on the consumption of the TBBPA derivatives have been available. The European market volume for carbonate oligomer of TBBPA in 1998 was 2,150 tonnes while the market for TBBPA bis (2,3-dibromopropyl ether) was 1,500 tonnes (IAL Market Report as cited by Lassen ***et al.*** 1999).

6.5 Available alternatives

A number of brominated flame retardants exist that can substitute for the additive use of TBBPA in ABS, but at the moment no non-brominated alternatives are available for this polymer. Manufactures of EEE, who are going for a non-brominated flame retardant, have typically changed to another polymer/flame retardant system.

Polymer/FR systems marketed for manufacturing of enclosures of EEE is shown in Table 6.3. All the BFRs are applied together with antimony trioxide (ATO) as a synergist.

Table 6.3
TBBPA and derivatives and selected alternative flame retardants for relevant V-0 grade plastics in enclosures of EEE (derived from Lassen *et al.,* 2006)

Flame retardant	CAS No	Polymer			
		HIPS	ABS	PC/ABS	PPE/HIPS
Halogen-containing FRs					
Tetrabromobisphenol-A (TBPPA)/ ATO	79-94-7	X	X		
TBBPA carbonate oligomer / ATO	94334-64-2 71342-77-3			X	X
TBBPA bis (2,3-dibromopropyl ether) / ATO	21850-44-2	X			
Brominated epoxy polymer / ATO	68928-70-1	X	X	X	
Ethane-1,2-bis(pentabromophenyl) / ATO	84852-53-9	X	X	X	X
Ethylene bis(tetrabromophthalimide) / ATO	32588-76-4	X	X	X	X
Tetradecabromodiphenoxybenzene / ATO	58965-66-5	X			
Tris(tribromophenoxy) triazine / ATO	25713-60-4	X	X		
Bis(tribromophenoxy) ethane / ATO	37853-59-1		X		
Non-halogen organo-phosphorous FRs					
Resorcinol bis(diphenylphosphate) (RDP)	57583-54-7			X	X
Bisphenol A bis(diphenylphosphate) (BDP)	5945-33-5			X	X
Triphenyl phosphates (TPP)	115-86-6			X	X

Note: ATO= Antimony trioxide added as synergist

In the USA (around 2002) the main system applied for computer monitor enclosures was PC/ABS with resorcinol bis (diphenylphosphate). Other polymers such as PC or PPO/HIPS with resorcinol bis (diphenylphosphate) took up less than 1% of the monitors market, while the US TV enclosure market was totally dominated by HIPS with deca-BDE. The European market has been quite different from the market in USA and Pure Strategies (2005) note that PPO/HIPS with resorcinol bis (diphenylphosphate) was used throughout Europe and roughly 20,000 metric tons was used in the EU TV enclosure market.

Polymers used by important European producers of TV-sets are shown in Table 6.4. Al the produces are mostly using polymer blends with –non-halogenated flame retardants, but the actual flame retardants are not reported.

Table 6.4
Polymers and flame retardants used by five important producers of TV-sets for the European market (based on Lassen *et al.,* 2006)

TV-set equipment manufacturer	Resin	Flame retardant (FR)	Flammability grade
Philips	Mostly PC/ABS	Non-halogenated FR; Partially TBBA	UL 94 V-0, V-1
Panasonic	Mostly PS/PPE	Non-halogenated FR	UL 94 V-0
Sony	HIPS/PPO, PC/ABS	Non-halogenated FR	UL 94 V-0, V-1
Loewe Opta	HIPS/PPO, PC/ABS	PBDE prohibited	Fire protection under the IEC 60065 regulation
Metz	HIPS; HIPS/PPO; PC/ABS	Non-halogenated FR	Fire protection under the IEC 60065 regulation; UL 94 HB, V-1, V-0

Much of the available information on alternatives to the additive use of TBBPA and derivatives in EEE originate from assessments of substitutes for octa-BDE and deca-BDE. In these assessments TBBPA is assessed together with other alternatives.

The polymer/flame retardant systems used in computer monitors and TV back casings are assumed to be applicable to all applications of structural parts of EEE made of flame retarded ABS or HIPS with TBBPA or derivatives.

6.6 Socioeconomic impacts

6.6.1 Substitution costs for enclosures

The cost considerations for replacing TBBPA in ABS are quite comparable to earlier considerations regarding the replacement of octa-BDE in ABS. A Risk Reduction Strategy for octa-BDE from (Corden and Postle, 2002) included a detailed assessment of the cost of substituting octa-BDE in ABS. The price of ABS with TBBPA is mentioned to be slightly lower than the price of ABS with octa-BDE. Total costs of substitution of the octa-BDE was nearly the same whether ABS with an alternative BFR, 1,2-bis(pentabromophenyl) ethane, or an alternative polymer with halogen-free flame retardant were used. The total polymer/flame retardant cost increase was estimated at 10%. Compared to an ABS/TBBPA system the price increase would be slightly higher. Furthermore, the cost estimate included an estimate for R&D by companies using octa-BDE. The total R&D costs for UK manufacturers were estimated at 0.5 m€, while the cost due to the increased price of flame retardants was estimated at 1.2 m€/year. To this was added the costs of replacing moulds.

Over a five-years period the higher material price accounted for more than 85% of the total incremental costs while R&D and replacing moulds accounted for 15%. At the time of the study (2002) the price of ABS with octa-BDE was about 1.4 €/kg and the price of alternatives about 1.6 €/kg.

The study concluded that if the increased costs were passed on to the consumer, the percentage increase in the average price of products would be between 0.19% and 0.30%, taking into account an estimated 3 million products on the market per year (Corden and Postle, 2002).

In a newer study (Lassen ***et al.*** 2006) report on the basis of information from a major market actor that the price of HIPS/PPE + halogen-free flame retardant was in the range of 2.30 – 2.90 €/kg whereas the price of PC/ABS is indicated at 2.60 – 2.80 €/kg (European prices). The prices of these co-polymer systems were about 150% the price of HIPS with other BFRs than deca-BDE. No data on ABS with TBBPA is indicated but it is certainly higher than the price of the HIPS with other BFRs.

The total price increase of changing ABS with TBBPA by copolymers with halogenfree flame retardants can based on the information above roughly be estimated at 0.3-0.7 €/kg ABS including R&D costs distributed over 5 years. The price increase is based on European prices - as much of the TBBPA is imported with EEE from Asia the actual price difference may be lower, but European prices are used here for indication of the incremental costs.

The total incremental costs to the consumers can be roughly estimated using the following assumptions:

- Total volume of additively used TBBPA in EEE: 8,000 tonnes year.

- Total volume of ABS polymer assuming an average TBBPA load of 22%: 36,000 tonnes/year.

- Total incremental costs assuming that all TBBPA is used in ABS and replaced by copolymers with non-halogenated flame retardants: 11-25 million €/year.

Considering the uncertainties related to the assumptions the total incremental costs are roughly estimated to be in the range of 5-30 million €/year. The costs may decrease over the years as result of a larger market for the alternatives.

All TBBPA is certainly not used in ABS, but the incremental costs for other additive uses of TBBPA are assumed to be close to the same range and would have a small influence on the estimated total.

6.6.2 Impacts on supply chain

SMEs

Plastic resins are produced and formulated by relatively few large companies in Europe. The resins are mixed with additives (in so-called "masterbatches") to form compounds, which are the raw materials for further processing. Compounding may take place by the resin manufacturer, by specialised compounders or by the company manufacturing the plastic parts.

Whereas the market for compounds is dominated by relatively few large actors, the market for plastic parts is characterized by many small and medium sized enterprises (SMEs). The UK Risk Reduction Strategy and Analysis of Advantages and Drawbacks of Octa-BDE (Corden and Postle, 2002) provided details of plastics manufacturers in the UK according to a number of size categories (defined by number of employees), as well as the average turnover of the companies within those categories. Of the total 14,540 plastics manufacturers in the UK, 5,260 companies fell within the category of small companies (those with fewer than 50 employees), of which the majority (3,365) were micro-enterprises (0-9 employees). With regard to the situation for the EU as a whole, the study stated that there are 55,000 companies manufacturing rubber and plastics in the EU. Of these companies, the average enterprise size was given as 25 employees. No data have been found on how many of these actually supply EEE parts.

Previous studies have clearly indicated that SMEs are affected to a greater degree by compliance with the RoHS legislation compared to their larger competitors. The relatively larger burden for SMEs holds for total costs to comply with RoHS in general as well as more specifically the administrative burden (Bogaert ***et al.***, 2008). As most of the SMEs involved in the manufacturing of flame retarded plastics for EEE already have procedures in place for ROHS compliance, the differences between the SMEs and larger companies is probably not as large as seen by the initial implementation of the RoHS Directive. The companies offering the alternative flame retardants are large companies, and they serve as general customer advisers when it comes to adjusting polymer formulations and production setup, however, the burden of identification of suitable alternatives and R&D by introduction of new substances must still be expected to place a larger burden on SMEs than on larger companies.

EU production

Three large companies with headquarters in the USA and Israel, but production facilities in Europe (among other places), dominate bromine production globally and produce a range of brominated compounds. They also manufacture different halogen-free flame retardants like organo-phosphorous compounds and magnesium hydroxide. These three companies jointly formed the European Brominated Flame Retardant Industry Panel (EBFRIP) representing these three main members, as well as a number of major polymer producers as associate members. These companies are vulnerable to changes in the demand for BFRs (Lassen ***et al.***, 2006).

The manufacturers of alternative flame retardants would benefit from a restriction of additive use of TBBPA in EEE, although the impact in the short term may be moderate. Halogen-free alternative flame retardants that may serve as alternatives to TBBPA in EEE are manufactured primarily by 6 European companies, of which 5 have headquarters within the EU (Lassen ***et al.***, 2006).

Production of EEE is substantial in the EU, however a large part of the total end-user consumption of EEE is imported as finished goods from outside the EU. This is notably the case for small household appliances, consumer electronics, IT equipment, and toys etc., but also for other EEE groups.

For EU based EEE producers, TBBPA containing parts may be produced by themselves or by subcontracting PVC processing or non-polymer formulator companies in the EU as well as on the world market.

Differences in restriction of the use of the substance via the RoHS Directive or via REACH are discussed in section 1.3.

6.6.3 Impacts on waste management

The considerations regarding waste management are identical to the considerations for HBCDD in section 2.6.3.

6.6.4 Administrative costs

Extra compliance costs related to the addition of one new substance under RoHS are expected to be minimal for companies which have already implemented RoHS, that is, most relevant companies. TBPPA is typically used additively in parts where deca-BDE or octa-BDE have traditionally also been used and compliance documentation would usually be required for such parts. This cost element is therefore not included further in the assessment made here.

The main extra costs are estimated to be related to control; both by the manufacturers, importers and the authorities. The presence of TBBPA cannot be determined by simple XRF screening (only the presence of Br and Sb), therefore sampling, extraction and laboratory analysis is required. As the parts that may contain TBBPA typically also may contain other RoHS substances (e.g. octa-BDE or deca-BDE) the extra costs would mainly comprise the costs of analysis, as the sampling and sample preparation would in any case be undertaken for control of the PBDEs in the parts.

Brominated flame retardants and phthalates can be extracted by the same organic solvents and analysed using the same GC-MS analysis (gas chromatography followed by mass spectroscopy), however, usually the materials containing the brominated flame retardants are different from the materials containing phthalates.

The extra costs of an analysis for TBBPA in ABS in Denmark, if the sample is already analysed for PBDE, is reported to be about 40€ (excl. VAT). The extra costs of analysis of TBBPA and HBCDD in HIPS, if the sample is already analysed for deca-BDE is about 60€ (excl. VAT). All prices are per sample when more than 20 samples are analysed.

6.7 Impacts on health and environment

Antimony trioxide
TBBPA used additively is in general used together with antimony trioxide, Sb_2O_3 (same as diantimony trioxide). According to the EU Risk Assessment for antimony trioxide, critical endpoints with respect to human health are skin irritation, local pulmonary toxicity and carcinogenicity. Antimony trioxide is considered to be a carcinogenic substance and is classified for carcinogenicity, Carc. 2. The risk assessment concludes that there is a need for limiting the risks to workers working with the substance e.g. in the use as flame retardant in plastics.

Assessment of alternatives
No comparative assessments focusing on alternatives to TBBPA have been identified, but a number of assessments of alternatives to octa-BDE, deca-BDE, and HBCDD have been undertaken in the recent year. TBBPA has been included in several of the assessment together with other possible alternatives, and a summary of the results of the following recent assessments is provided below:

- Assessment of alternatives to deca-BDE by Washington State Department of Health (2006)
- Assessment of alternatives to deca-BDE for the Danish EPA (2006)
- Assessment of alternatives to deca-BDE by Illinois Environmental Protection Agency (2007)
- Assessment of alternatives to HBCDD for European Chemicals Agency (2008)

Alternatives to deca-BDE by Washington State Department of Health (2006)
Washington State Department of Health (WSDH) has as part of the development of a PBDE action plan reviewed human health and environmental data on potential alternatives to deca-BDE, among these TBBPA. The data for some of the substances relevant for the current study is shown in Table 6.5. WSDH concludes that based on the review of available information, there did not appear to be any obvious alternatives to Deca-BDE that are less toxic, persistent and bioaccumulative and have enough data available for making a robust assessment. They note that two of the alternatives with a moderate amount of data, HBCDD and TBBPA, are on the Department of Ecology's PBT list, indicating that they present a hazard to the environment and human health. TBBPA is considered to meet the PBT criteria of WSDH, which is in contrast to the PBT evaluation in the EU Risk Assessment. Other alternatives do not appear to meet the department's PBT criteria, indicating that they are less of a concern, but WSDH states that is difficult to draw definitive conclu-

sions based on incomplete data sets for these chemicals. The organophosphates rescorcinol bis(biphenylphosphate (RDP) and bisphenol A diphosphate (BAPP or BDP) are each described as "one of the more promising alternatives", but it is noted that information on toxicity is limited.

Table 6.5
Summary of persistence, bioaccumulation potential and toxicity information for selected potential alternatives (Based on Washington State, 2006)

Substance	Human health					A/M ecotoxicity. Acute or chronic	Persistence	Bioacc.	PBT
	Cancer hazard	Non-cancer effects	Mutagenity	Amount of tox info	Inf on potential routes of exposure				
TBBPA	L	M	L	M	Yes	M-H	Yes	Yes	Yes
Antimony trioxide (used together with TBBPA)	L-M	L	M-H	M-H	Yes	L-M	NI	NI	Maybe (NI
Bis(tribromophenoxy)ethane	L	L	L	L	NI	L-M	Yes	Yes	Yes
1,2-bis(tetra-bromophthalimido) ethane	L	L	L	L	NI	L	NI (likely)	No	No
Resorcinol bis (diphenyl-phosphate) (RDP)	NI	L	L	L	NI	M-H	No	No	No
Bisphenol A diphosphate (BAPP, BPADP) or Bisphenol A bis(diphenyl phosphate) (BDP)	NI	L	L	L	NI	L-M	Yes	NI	NI
Diphenyl cresyl phosphate (DCP)	NI	M	L	L-M	Yes	M-H	Yes	Yes	Maybe (NI)
Triphenyl phosphate (TPP	L	L-M	L	L-M	Yes	M-H	No	No	No

NI : No Information/insufficient information
A/M : Aquatic and microbial
PBT: whether the alternative meets Washington State Department of Health's PBT criteria,
Ranking: H = high, M = medium, L = low concern based on available information: Ranking is based on US EPA, 2005.

Assessent of alternatives to deca-BDE for the Danish EPA (2006)

An assessment of key toxicological and environmental properties of selected alternatives to deca-BDE, among these TBBPA, was undertaken by Stuer-Lauridsen ***et al.*** (2006) for the Danish EPA. The summary results of the substances relevant for the present assessment are shown in Table 6.6.

A number of potential alternatives were included in a screening on data availability, and were deselected for the further assessment because of limited data available. Among these were RDP and BAPP (or BDP). The better data availability was the reason for selecting triphenyl phosphate (TPP) as representative for the phosphate flame retardants for the assessment.

As to human health no major differences in rating were found between TBBPA and TPP, whereas the TPP rated better than TBBPA with respect to persistence in the environment.

Contrary to the assessment from WSDH, but in accordance with the EU Risk Assessment, Stuer-Lauridsen ***et al.*** found that there was no evidence of bioaccumulation of TBBPA.

Table 6.6
Key toxicological and environmental properties of TBBPA and some potential alternatives. (original data from Stuer-Lauridsen *et al.,* 2006 – the table is here based on a revised table in Lassen et. al, 2007)

Substance	CAS No.	Data availability environment/health		CMR; ES	PBT
Tetrabromobisphenol A (TBBPA)	79-94-7	++	+++	C0/M-/R- ; E-/S-	P+/B-/T-
Ethylene bistetrabromophthalimide (EBTPI)	32588-76-4	+	++	C0/M-/R- ; E-/S0	P+/B-/T-
Tetrabromobisphenol A carbonate oligomer *	94334-64-2 71342-77-3	-	+	C0/M-/R0 ; E0/S0	P0/B0/T0
Triphenyl phosphate (TPP)	115-86-6	++	++	C0/M-/R- ; E0/S-	P-/B-/T-

Parameters: carcinogenicity (C), mutagenicity (M), reproductive toxicity (R), endocrine disrupting effects (E), sensibilisation (S), persistence (P), bioaccumulation(B) and aquatic toxicity (T). The symbol + indicate a potential hazard, - indicates no potential hazard identified and 0 indicates that no data are available.
* A As a worst case polymers are assessed by their monomer, in this case TBBPA

Assessment of alternatives to deca-BDE by Illinois Environmental Protection Agency (2007)

Illinois Environmental Protection Agency (IEPA, 2007) summarised toxicity data on non-halogenated alternatives to deca-BDE. They applied in their assessment a rating system based on a number of endpoints: Cancer, reproductive/developmental toxicity, systemic toxicity, local effects, acute environmental effects, chronic environmental effects and persistence, bioaccumulation and toxicity. TBBPA was not assessed and therefore the data cannot be used for comparison of TBBPA and possible alternatives. Based on the rating the agency grouped the potential alternatives into four groups : a) Potentially unproblematic, 2) Potentially problematic, 3) Insufficient data and 4) Not recommended.

Among the potentially unproblematic substances are some of the main alternatives to TBBPA in enclosures, which are reviewed as follows (IEPA, 2007):

- BAPP: Low Concern for most endpoints based on existing data and professional judgment; key data deficiencies include cancer, two-generation reproductive/developmental effects, and chronic aquatic toxicity studies; some concern due to generation of Bisphenol A, a chemical identified by the Agency as a probable endocrine disruptor, as a breakdown product, although no data on potential amounts were found.

- RDP: No Concern for reproductive/developmental effects; no chronic aquatic toxicity data; Low Concern for other effects based on existing data and professional judgment; key data deficiencies include cancer, chronic systemic effects, and chronic aquatic toxicity studies.

Aluminum trihydroxide and magnesium hydroxide are listed in the group of potentially unproblematic, but these substances cannot be considered immediate alternatives to the main additive uses of TBBPA.

The triphenyl phosphate and antimony trioxide were together with a number of other potential alternatives to deca-BDE included in the group of “Potentially problematic” with the following review (IEPA, 2007):

- Triphenyl phosphate: High Concern for acute and chronic aquatic toxicity (very wide range of fish lethality levels); Low Concern for other effects based on existing data and professional judgment; key data deficiencies include cancer and two-generation reproductive/developmental studies.

- Antimony trioxide: High Concern for blood effects; Moderate Concern for cancer and lung irritation effects; no data for reproductive/developmental and neurological effects; Low Concern for other effects; key data deficiencies include additional cancer studies, and reproductive/developmental and neurological effects studies.

Whereas Lauridsen ***et al.*** (2006) ranked the aquatic toxicity of triphenyl phosphate to be low, both the assessment from Illinois and Washington find that there is enough data for concluding that there is basis for a concern about acute and chronic aquatic toxicity.

Assessment of alternatives to HBCDD for Europan Chemicals Agency
In an assessment for the European Chemicals Agency of alternatives to HBCDD, IOM (2008) assessed a number of alternatives to HBCDD in HIPS which may also be considered alternatives to additive use of TBBPA (Table 6.7).

Table 6.7
Summary for Human health and environmental properties of selected alternatives to HBCDD used in HIPS

Substance	Human health	Environment
Antimony trioxide (ATO)	Potential human carcinogen and reproductive toxicant	Not readily biodegradable, low to moderate bioaccumulation potential
Ethylenebis (tetrabromo phthalimide)/ATO	Low toxicity	Not biodegradable and is persistent. Non-toxic.
Triphenyl phosphate	Chronic toxicant with effects on liver	Readily biodegradable, toxic to aquatic organisms
Resorcinol bis (biphenyl phosphate)	Chronic toxicant with effects on liver	Inherently biodegradable, may be persistent and bioaccumulative
Bis phenol A bis (biphenyl phosphate)	Limited data, likely to be of low toxicity	Poorly biodegradable. Non-toxic and is not bioaccumulative

Summary on health and environmental assessment
A number of alternatives to TBBPA exist which may potentially be less problematic than TBBPA, but data are missing for critical endpoints (e.g. carcinogenity). Phosphate esters have been mentioned as promising alternatives to deca-BDE, but considering that TBBPA, according to the EU Risk Assessment neither a CMR nor a PBT substance, the same conclusion cannot be drawn for TBBPA without more comprehensive data on the phosphate esters.

As TBBPA in general is used in conjunction with antimony trioxide (ATO) the comparison should in principle be done between the TBBPA/ATO flame retardant system and the alternatives. The fact that antimony trioxide is a carcinogen may influence the assessment of the TBBPA/ATO system, but none of the studies have included a common assessment of the two substances.

6.8 Conclusions for TBBPA

The main concern regarding TBBPA is its toxicity in the aquatic environment and possible effect on the endocrine system of breakdown products in the environment.

According to the EU Risk Assessment, TBBPA does not meet the criteria for being a CMR, a vPvB or a PBT substance. TBBPA is not on the Candidate List of SVHC substances currently proposed for inclusion in Annex XIV of REACH. When used additively TBBPA is used in conjunction with antimony trioxide (ATO) which is classified for carcinogenicity.

The main application of TBBPA used additively in EEE is in ABS plastic used for closures and structural parts of different types of EEE. The total content of additively used TBBPA in EEE marketed in the EU is estimated at some 8,000 tonnes/year assuming that 20% of the 40,000 tonnes/year in marketed EEE is used additively.

The additive use of TBBPA is not deemed essential as technically suitable alternative substances and materials are available and already used extensively today. The main alternatives for ABS/TBBPA/ATO systems are ABS with other brominated flame retardants and ATO or co-polymers (e.g. PC/ABS, PS/PPE, HIPS/PPO) with phosphate esters.

Costs - The prices of alternatives are typically 10-50% higher than ABS/TBBPA/ATO systems and it is estimated that the total incremental costs at the production level of replacing additively used TBBPA in all EEE may likely be some 5-30 million €/year depending on the actual alternatives being introduced (European prices). The costs may decrease over the years as result of a larger market for the alternatives.

TBBPA is typically used in plastic components where other RoHS substances have traditionally been used as well (e.g. octa-BDE and deca-BDE). The main extra administrative costs is estimated to be related to compliance control, where the extra costs would mainly relate to the costs of analysis as the sampling and sample preparation would be done in any case for control of other PBDEs in the parts.

Benefits - A number of alternatives to TBBPA exist which may potentially be less problematic than TBBPA, but data on the alternatives are missing for critical endpoints (e.g. carcinogenicity). Phosphate esters have been evaluated as promising alternatives to deca-BDE, but considering that TBBPA is neither a CMR, a vPvB nor a PBT substance, it may be considered necessary to have a more robust basis for decision on its inclusion in the RoHS directive.

7 References

Andersson, E. 2005. Hazardous substances in electrical and electronic equipment (EEE) - Expanding the scope of the RoHS directive. Swedish Chemicals Inspectorate (KemI) and Göteborg University.

Astrup A. and Å. Bergman. 2009: Hexabromocyclododecane (HBCDD) - a brominated flame retardant of "Very High Concern". Force Institute and Stockholm University, 2009.

BBP Information Centre. 2009. An information resource on the plasticiser butyl benzyl phthalate (BBP). An initiative of the European Council for Plasticisers and Intermediates (ECPI), Brussels. http://www.bbp-facts.com/

BKH. 2000. Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption. BKH Consulting Engineers and TNO Nutrition and Food Research for the European Commission. Annex 13. List of 146 substances with endocrine disruption classifications prepared in the Expert meeting. http://ec.europa.eu/environment/docum/pdf/bkh_annex_13.pdf

BSEF. 2009a. About tetrabromobisphenol A. Bromine Science and Environment Forum (BSEF), Brussels.

BSEF. 2009b. Brominated Flame Retardant TBBPA. Tetrabromobisphenol A for Printed Circuit Boards and ABS plastics. Bromine Science and Environment Forum (BSEF), Brussels.

Cadogan, D. 2006. Plasticisers: An update. Presentation at: Plasttekniske Dager, Oslo, 8-9 November 2006. Cadogan on behalf of European Council for Plasticisers and Intermediates (ECPI).

CEFIC. No date. TBBPA presention. Epoxy resins, Intermediate usage, ABS plastics & EU Risk Assessment of TBBPA. CEFIC and Plastics Europe. http://www.iclfr.com/brome/brome.nsf/7eddd01a22d7b740422566250043ed2c/6760ea3dc54dcdb242256fa40050f669/$FILE/TBBPA_RA_presentation.pdf

Corden, C. and M. Postle. 2002. Risk Reduction Strategy and analysis of advantages and drawbacks for octabromodiphenyl ether. RFA for U.K. Department for Environment, Food and Rural Affairs (DEFRA).

COWI. 2009a. Data on manufacture, import, export, uses and releases of benzyl butyl phthalate (BBP) as well as information on potential alternatives to its use. COWI in cooperation with Entec and IOM for European Chemicals Agency (ECHA), Helsinki.

COWI. 2009b. Data on manufacture, import, export, uses and releases of bis(2-ethylhexyl phthalate) (DEHP) as well as information on potential alternatives to its use. COWI in cooperation with Entec and IOM for European Chemicals Agency (ECHA), Helsinki.

COWI. 2009c. Data on manufacture, import, export, uses and releases of dibutyl phthalate (DBP) as well as information on potential alternatives to its use. COWI in cooperation with Entec and IOM for European Chemicals Agency (ECHA), Helsinki.

DIBP Annex XV. 2009. Annex XV dossier. Proposal for identification of a substance as SVHC(CMR). Diisobutyl phthalate. Accessed September 2009 at http://echa.europa.eu/doc/consultations/svhc/svhc_axvrep_germany_cmr_diisobutylphthalate_20090831.pdf

EC. 2008. Diantimony trioxide. CAS-No.:1309-64-4. Summary risk assessment report. European Communities, November 2008

EC. 2008a. Communication from the Commission on the results of the risk evaluation and the risk reduction strategies for the substances: sodium chromate, sodium dichromate and 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (tetrabromobisphenol). (2008/C 152/02)

EC. 2008b. Commission Recommendation of 30 May 2008 on risk reduction measures for the substances sodium chromate, sodium dichromate and 2,2′,6,6′-tetrabromo-4,4′-isopropylidenediphenol (tetrabromobisphenol A)(notified under document number C(2008) 2256).(2008/454/EC)

ECB. 2007. European Union Risk Assessment Report. Benzyl butyl phthalate. European Chemicals Bureau, Ispra.

ECB. 2004. European Union Risk Assessment Report. Dibutyl phthalate. European Chemicals Bureau, Ispra.

ECB. 2008. European Union Risk Assessment Report. bis(2-ethylhexyl)phthalate (DEHP). European Chemicals Bureau, Ispra.ECB. 2006. European Union Risk Assessment Report. 2,2’,6,6’-tetrabromo-4,4’-isopropylidenediphenol (tetrabromobisphenol-A or TBBP-A.).Part II – Human Health. European Chemicals Bureau, Ispra.

ECB. 2007. Draft Risk Assessment Report. 2,2’,6,6’-tetrabromo-4,4’-isopropylidenediphenol (tetrabromobisphenol-A). Draft of June 2007. (final RAR - Environment is still not publiched at the JRC website)

ECB. 2007. Review on production processes of decabromodiphenyl ether (Deca-BDE) used in polymeric applications in electrical and electronic equipment, and assessment of the availability of potential alternatives to Deca-BDE. European Chemicals Bureau, Institute of Health and Consumer Protection, Ispra. http://ecb.jrc.it/documents/Existing-Chemicals/Review_on_production_process_of_deca-BDE.pdf

ECB. 2008a. European Union Risk Assessment Report. Hexabromocyclododecane, Final Draft, May 2008. European Chemicals Bureau, Ispra.

ECB. 2008b. European Union Risk Assessment Report. Bis(2-ethylhexyl)phthalate (DEHP). European Chemicals Bureau, Ispra.

ECHA. 2009. Member State Committee support document for identification of hexabromocyclododecane and all major diastereoisomers identified as a substance of very high concern. European Chemicals Agency, Helsinki.

Europacable. 2009. Statistics accessed August 2009 at http://www.europacable.com/total.asp

GE. 2009. MSDS. DIELEKTROL-II FLUID. The General Electric Company. http://www.gepower.com/prod_serv/products/capacitors/en/downloads/dk2_dielektrol.pdf

General Electric. 2006. Danilo Boccardo and Monique van de Watering, GE Plastics BV, NL-Bergen op Zoom, personal communication 13 and 18 Apr 2006, as cited by Lassen ***et al.*** (2006).

Gregg T., T. Halldorson, W. Budakowski, G. Arsenault and C. Marvin. 2004 Isomer-specific analysis of hexabromocyclododecane by LC/MS/MS. . BFR 2004 proceedings 301-305.

Gross,. R., D. Bunke, C.-O. Gensch, S. Zangl and A. Manhart. 2008. Study on Hazardous Substances in Electrical and Electronic Equipment, Not Regulated by the RoHS Directive. Öko-institut e.V. for the European Commission.

ICL. 2009a. HIPS (V-2). ICL Industrial Products. http://www.iclfr.com/brome/brome.nsf/entry?readform&mf=viewFramesetSearchByGlobalCode/Application188?OpenDocument&ws=Pbu22

ICL. 2009b. Flame-Retardants for HIPS. ICL Industrial Products. http://www.iclfr.com/brome/brome.nsf/7eddd01a22d7b740422566250043ed2c/9a600ff4cf4c489cc22566820078addc/$FILE/HIPSGnlICLIP1.pdf

IEPA.2007. Report on alternatives to the flame retardant deca-BDE: Evaluation of toxicity, availability, affordability, and fire safety issues. A report

IOM. 2009. Data on manufacture, import, export, uses and releases of HBCDD as well as information on potential alternatives to its use. IOM in cooperation with BRE, PFA and Entec for European Chemicals Agency (ECHA), Helsinki.

KemI. 2006b: Survey and technical assessment of alternatives to TBBPA and HBCDD. PM 1/06, Swedish Chemicals Inspectorate, 2006.

KemI. 2006. Hexabromocyklododekan (HBCDD) och tetrabrombisfenol-A (TBBPA). Report 3/06, Swedish Chemicals Inspectorate, Solna [in Swedish].

Lassen C., A. Leisewitz and P. Maxson. 2006. Deca-BDE and alternatives in electrical and electronic equipment. Environmental Project no. 1141, 2006. COWI, Öko-Recherche and Concorde East/West for the Danish Environmental Protection Agency. www.mst.dk.

Lassen, C. F. Stuer-Lauridsen, K.-H. Cohr, T.T. Andersen, S. Havelund, A. Leisewitz and P. Maxson. 2007. Alternatives to deca-BDE in electrical and electronic equipment. Proceedings of Dioxin 2007, Tokyo 2-7 Sep 2007.

Lassen, C., S. Løkke and L.I. Andersen. 1999. Brominated flame retardants. Substance flow analysis and assessment of alternatives. Environmental Project No. 494. Danish Environmental Protection Agency, Copenhagen.

Lowell. 2005. Decabromodiphenylether: An Investigation of Non-Halogen Substitutes in Electronic Enclosure and Textile Applications. Prepared by Pure Strategies, Inc. for The Lowell Center for Sustainable Production.

University of Massachusetts - Lowell. Apr 2005. http://www.sustainableproduction.org/downloads/Deca-BDESubstitutesFinal4-15-05.pdf [downloaded 20 Feb 2006], as cited by Lassen ***et al.*** (2006).

Maag, J., C. Lassen, U.K. Brandt, J. Kjølholt, L. Molander and S.H. Mikkelsen. 2009. Identification and assessment of alternatives to selected phthalates. Environmental projects XX. Danish Environmental Protection Agency, Copenhagen. (draft of November 2009).

Munro, S., P. Jacobs and J. Bohan, Great Lakes Chemical Corporation. 2004. Flame retardant solutions for the electrical and electronic sector. Presentation at ADDCON 2004, 28-39 September 2004, Amsterdam.

Panasonic. 2006. Dale Swanson, Panasonic Shikoku Electronics Corp. of America. Personal communication, April 2006. , as cited by Lassen ***et al.*** (2006).

PlasticsEurope. 2007. Business Data and Charts 2007. PlasticsEurope Market Research Group(PEMRG).

Posner, S. 2008. Survey and technical assessment of alternatives to TBBPA and HBCDD. Swedish Chemicals Inspectorate, Solna.

Pure Strategies. 2005. Decabromodiphenylether: An investigation of non-halogen substitutes in electronic enclosure and textile applications. Pure Strategies, Inc. for the Lowell Center for Sustainable Production, University of Massachusetts Lowell. http://sustainableproduction.org/downloads/Deca-BDESubstitutesFinal4-15-05.pdf

SCENIHR. 2008. Opinion on the safety of medical devices containing DEHP-plasticized PVC or other plasticisers on neonates and other groups possibly at risk. Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). European Commission, Brussels.

SCHER. 2008. SCHER Opinion on the risk assessment report on 2,2',6,6'-tetrabromo-4,4'-isopropilidene diphenol (tetrabromobisphenol A), CAS 79-94-7, environmental part, 15 January 2008. Scientific Committee on Health and Environmental Risks (SCHER). European Commission, Brussels.

Stuer-Lauridsen, F., K.-H. Cohr and T.T. Andersen. 2007. Health and environmental assessment of alternatives to deca-BDE in electrical and electronic equipment. Environmental Project No. 1142. Danish Environmental Protection Agency, Copenhagen.

TURI. 2006. Five chemicals study. Toxics Use Reduction Institute (TURI), University of Massachusetts Lowell, for the Commonwealth of Massachusetts. Chapter on alternatives to DEHP available at: http://www.turi.org/library/turi_publications/five_chemicals_study/final_report/chapter_7_dehp#7.3

US EPA. 2005. Environmentally Preferable Options for Furniture Fire Safety Low-Density Furniture Foam. U.S. Environmental Protection Agency.

US EPA, 2008. Wire and cable insulation and jacketing: Life-cycle assessments for selected applications. Abt Associates for U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics.

Vestfrost. 2009. Personal communication. Vestfrost, Esbjerg, Denmark.

Washington State. 2006. Polybrominated Diphenyl Ether (PBDE). Chemical Action Plan: Final Plan. Department of Ecology Publication No. 05-07-048. Washington State Department of Health.

Wilkinson, S. N. Duffy and M. Crowe. 2001.Waste from Electrical & Electronic Equipment in Ireland: A Status Report.