Rotterdam Convention
on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

FORM FOR NOTIFICATION

OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

Country: Norway

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	Decabromodiphenyl ether (decaBDE)
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	Bis(pentabromodiphenyl) ether, 2,3,4,5,6-Pentabromo-1-(2,3,4,5,6-pentabromophenoxy)benzene, 1,1'-Oxybis(pentabromobenzene), decabromodiphenyl oxide, bis(pentabromophenyl) oxide, decabromo biphenyl oxide, decabromo phenoxybenzene, benzene 1,1' oxybis-, decabromo derivative, decaBDE, DBBE, DBBO, DBDPO
1.3	**Trade names and names of preparations**	Commercial decaBDE mixture, technical decaBDE, technical DeBDE, BDE-209, DE-83R, Nonnen DP 10, Plasafety EBR 700, Saytex 102E, Tardex 100, Bromkal 82-ODE, Bromkal 70-5
1.4	**Code numbers**	
1.4.1	CAS number	1163-19-5
1.4.2	Harmonized System customs code	
1.4.3	Other numbers (specify the numbering system)	EINECS No: 214-604-9

1.5 Indication regarding previous notification on this chemical, if any

1.5.1 ☑ This is a first time notification of final regulatory action on this chemical.

1.5.2 ☐ This notification replaces all previously submitted notifications on this chemical.

Date of issue of the previous notification:

SECTION 2 FINAL REGULATORY ACTION

2.1 The chemical is: ☑ **banned** **OR** ☐ **severely restricted**

2.2 Information specific to the final regulatory action

2.2.1 Summary of the final regulatory action

It is prohibited to produce, import, export, sell and use decabromodiphenyl ether in pure form, in preparations, in products, and in parts of products containing greater than or equal to 0,1 % by weight of decabromodiphenyl ether.

2.2.2 Reference to the regulatory document, e.g. where decision is recorded or published.

Regulation of brominated flame retardants in chapter 1 to 7 "Regulations relating to restrictions on the manufacture, import, export, sale and use of chemicals and other products hazardous to health and the environment (Product Regulations)" by Ministry of the Environment. Act no 922 of 1 June 2004.

2.2.3 Date of entry into force of the final regulatory action

01.04.2008 amended 01.07.2013

2.3 Category or categories where the final regulatory action has been taken

2.3.1 All use or uses of the chemical in your country prior to the final regulatory action

Decabromodiphenyl ether has been used as a flame retardant in polymers and high impact polystyrene (HIPS) with end-uses in electrical and electronic equipment. It is also known to be used in plastics and textile industries.

2.3.2 Final regulatory action has been taken for the category ☑ Industrial

Use or uses prohibited by the final regulatory action

Decabromodiphenyl ether is regulated by §2-7 and 2a-3 of the Regulations relating to restrictions on the manufacture, import, export, sale and use of chemicals and other products hazardous to health and the environment (Product Regulations), Act no. 922 of 1 June 2004.

Chapter 2. Regulated substances, preparations and products

2-7. Brominated flame retardants

It is prohibited to manufacture, import, export, place on the market and use substances or preparations that contain 0.1 per cent by weight or more of decabromodiphenyl ether (CAS No. 1163-19-5).

It is prohibited to manufacture, import, export and place on the market products or flame retardant parts of products that contain 0.1 per cent by weight or more of decabromodiphenyl ether (CAS No. 1163-19-5).

The use of decabromodiphenyl ether in electrical and electronic products is regulated by chapter 2a.

2a-3 Restricted substances in EEE

It is prohibited to produce, import, export and make available on the market EEE in which the content of lead, mercury, hexavalent chromium, polybrominated biphenyls (PBBs) or polybrominated diphenyl ethers (PBDEs) in homogeneous materials exceeds 0.1 per cent by weight or of cadmium exceeds 0.01 per cent by weight.

Homogeneous material means one material of uniform composition throughout or a material, consisting of a combination of materials that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes.

For EEE in following categories the restriction of substances shall apply from:

a) Category 8 and 9: 22 July 2014

b) Category 8 in vitro diagnostic medical devices: 22 July 2016

c) Category 9 industrial monitoring and control instruments: 22 July 2017

d) EEE that have not previously been regulated and are not covered by a) to c): 22 July 2019

Use or uses that remain allowed (only in case of a severe restriction)

2-7. Brominated flame retardants

The prohibitions in the first and second paragraph do not apply if the substance is used in
a) vehicles that are approved under the currently prevailing version of the regulations of 4 October 1994 No. 918 regarding technical requirements and approval of vehicles, parts and equipment,
b) aircraft registered in the Aircraft Register pursuant to Act of 11 June 1993 No. 101 relating to aviation,
c) vessels registered in the Shipping Register pursuant to the Norwegian Maritime Code of 24 June 1994 No. 39 or the Norwegian International Ship Register pursuant to Act of 12 June 1987 No. 48 relating to the Norwegian International Ship Register or
d) rolling stock for use on railways, including tramways, underground railways, suburban lines and similar forms of rail transport.

2a-3 Restricted substances in EEE

The restriction of substances does not apply to applications listed in Appendix 1 and 2. Exemptions for EEE in category 1-7, 10 and 11 are valid for up to five years, and category 8 and 9 up to seven years.

The restriction of substances does not apply to reused spare parts, recovered from EEE placed on the EEA market before 1 July 2006 and used in equipment placed on the EEA market before 1 July 2016, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer.

The importer and the distributor shall notify all previous sales personnel and the Norwegian Environment Agency if they believe or have reason to believe that an EEE does not comply with the requirement in the first paragraph.

2.3.3 Final regulatory action has been taken for the category ☐ Pesticide

Formulation(s) and use or uses prohibited by the final regulatory action

Formulation(s) and use or uses that remain allowed (only in case of a severe restriction)

2.4 Was the final regulatory action based on a risk or hazard evaluation?

☑ **Yes**

☐ **No** (If no, you may also complete section **2.5.3.3**)

2.4.1 If yes, reference to the relevant documentation, which describes the hazard or risk evaluation

Risk Assessment of bis(pentabromophenyl) ether (decabromodiphenyl ether), CAS Number: 1163-19-5 EINECS Number: 214-604-9, Final Draft of October 2007. European Commission 2002.
Including: Update of the risk assessment of bis(pentabromophenyl) ether (decabromodiphenyl ether). European Commission 2004 and 2007.

Norwegian action plan on brominated flame retardants (2002; 2009).

UNEP/POPS/POPRC.9.2. Proposal to list decabromodiphenyl ether (commercial mixture, c-decaBDE) in Annex A, B and/or C to the Stockholm Convention on Persistent Organic Pollutants

2.4.2 Summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.

2.4.2.1 Is the reason for the final regulatory action relevant to human health?

☑ Yes

☐ No

If yes, give summary of the hazard or risk evaluation related to human health, including the health of consumers and workers

On the basis of a general concern over the use of brominated flame retardants (BRF), a national action plan was set up by the Norwegian authorities in 2002 (later updated in 2009) focusing on five priority substances including c-decaBDE. BFRs, including c-decaBDE, were also officially included in the national goal for substantially reducing emission of certain hazardous substances by 2020 as described in a white paper to the parliament (Ministry of Environment, Norway, 2003).

Norwegian monitoring data show detectable levels in several environmental compartments. High concentrations of BDE209 the main component of decaBDE, is detected at some locations. In sediments and water BDE209 is the domination PBDE congener. BDE209 is also detected in biota (mussels and fish) and in leakage from landfills (TA-2006). BDE209 is also present in terrestrial environment; moss samples from locations covering Norway from north to south, west to east reveal that BDE209 is the predominant congener. BDE209 was also present in moose (Mariussen et al., 2008).

PBDE exposure through food and the resulting serum levels have been investigated in Norway. In food samples analyzed for BDE209 high levels were found in eggs, vegetable oil, ice cream and biscuits, while the highest amounts were found in dairy products, which include milk, cheese, and butter. The calculated exposure to BDE209 was 1.5 (mean) and 1.4 (median) ng/kg bw per day, which is higher than the exposure to ΣPBDEs of other PBDE. Results indicate that intake of BDE209 and ΣPBDEs have different dietary sources and that dairy products proved to be the most important dietary source of BDE209 exposure. Serum levels of BDE209 were not analyzed in these samples (Knutsen et al., 2008).

Thomsen et al. 2007 found high levels of BDE209 (10 ng / g lipid) in pooled serum samples from Norwegian humans. A similar study detected an average of 2.26 ng / g lipid in plasma from pregnant women from the Bodø region (TA-2303). The reason for this large difference in BDE 209 levels is not known. Thomsen et al. have previously reported BDE209 as the dominant congener of PBDE congeners analyzed and this was also confirmed in the study of women from Bodø.These results are much higher than found in a similar study on blood plasma from Swedish men. The above information is summarized in (TA-2303).

Household dust and occupational exposure is thought to be the main sources for exposure to BDE-209 and other congeners present in c- decaBDE. Toddlers and infants have a higher daily intake of dust and dairy products than adults, and higher serum levels of BDE209 have been found in children less than 5 years compared to their parents. PBDE congener composition was also different in the children compared to their parents indicating possible debromination to more bioaccumulative and toxic congeners (US EPA 2010).

Some professions are exposed to higher decaBDE than the average population and other workers. Foam recycling workers, carpet installer and PC technicians are reported to have higher serum levels of BDE209 than control groups. In a Swedish study employees at a recycling plant and rubber mixers had higher levels of BDE209 in serum than control. Samples taken during and after 5 weeks of vacation revealed that BDE-209 and other highly brominated PBDE congeners had lower half-life than the lower brominated congeners. (US EPA 2010).

In animal studies of amphibian, fish and rodents exposed to BDE209 at vulnerable stages such as the developmental phase, effects on hormonal axis as the thyroid and steroid is of concern (EU RAR 2004, 2007 and 2012, UK EA 2007, UNEP/POPS/POPRC. 9.2). Although the toxicology data of BDE209 is ambiguous, some studies indicate negative effect on neurological development at low doses.

Norwegian authorities banned decaBDE based on its potential PBT properties and the general concern about the ubiquitous presence and increase of decaBDE in the environment including the Norwegian Arctic and a concern for presence of decaBDE in human matrices and human health. The concern for increased levels of persistent PBDEs due to continuously debromination from the pool of decaBDE in the environment.

References

TA-2006. Screening of selected new organic contaminants - brominated flame retardants, chlorinated paraffins, bisphenol-A and trichlosan (2004). SFT, Norway. In Norwegian only.

Mariussen E, Steinnes E, Breivik K, Nygaard T, Schlabach M, Kalas JA (2008). Spatial patterns of polybrominated diphenyl ethers (PBDEs) in mosses, herbivores and a carnivore from the Norwegian terrestrial biota. Sci Total Environ 404:162–70.

Knutsen et al (2008), Dietary exposure to brominated flame retardants correlates with male blood levels in a selected group of Norwegians with a wide range of seafood consumption. Mol. Nutr. Food Res. 2008, 52, 217 – 22

(TA-2303). Bromerte flammehemmere i blodprøver fra gravide kvinner i Bodø (2007). SFT, Norway. In Norwegian only.

Risk Assessment of bis(pentabromophenyl) ether (decabromodiphenyl ether), CAS Number: 1163-19-5 EINECS Number: 214-604-9, Final Draft of October 2007. European Commission 2002. Including: Update of the risk assessment of bis(pentabromophenyl) ether (decabromodiphenyl ether). European Commission 2004, 2007 and 2012.

UNEP/POPS/POPRC.9.2. Proposal to list decabromodiphenyl ether (commercial mixture, c-decaBDE) in Annex A, B and/or C to the Stockholm Convention on Persistent Organic Pollutants

Environmental risk evaluation report: 1,1'- (Ethane-1,2-diyl)bis[penta-bromobenzene], Environment Agency, UK, 2007

US EPA 2010. An Exposure Assessment of polybrominated diphenyl ethers. National Center for Environmental Assessment Office of Research and Development. U.S. Environmental Protection Agency Washington, DC. EPA/600/R-08/086F, May 2010.

Expected effect of the final regulatory action

Reduction of risk to human health.

2.4.2.2 Is the reason for the final regulatory action relevant to the environment?

☑ Yes

☐ No

If yes, give summary of the hazard or risk evaluation related to the environment

The evaluation of decaBDE gives rise to concern for long term effects in the environment. In Norway BDE209 has been investigated and detected in a number of studies. Furthermore BDE209 has been found in various environmental compartments in the Arctic, including the Norwegian Arctic, and can undergo long-range environmental transport (Hermanson et al., 2010, Environment Canada 2010a, Mariussen et al. 2008).

Norwegian monitoring data shows that BDE209 deposited to the Arctic environment is bioavailable to the organisms living there and that BDE-209 is widespread in Arctic food webs (de Wit et al 2006, 2010).

Norwegian environmental monitoring studies investigating congener pattern and levels of PBDEs in eggs and plasma of glaucous gulls breeding at Bjørnøya in the Arctic revealed detectable levels of BDE209 in bird plasma comparable to levels found in liver samples of birds located at more southern parts of Europe (TA-2006). Similar results were reported in liver samples from glaucous gulls from Svalbard (RAR update, 2004). The concerns about occurrence of decaBDE in the environment have now been further strengthened. These resent studies from the Arctic document the occurrence of decaBDE in birds from remote areas in the Arctic.

In Norway, high levels of BDE209 were detected in sediments and BDE209 represented up to 90% of ΣPBDEs (TA-2252). A study conducted in Lake Mjøsa in the Southern part of Norway revealed that BDE209 was the dominant congener (50-90%) in sediments and waste water in many areas (TA-2104).

DecaBDE (BDE-209) dominates completely in all sediment samples, representing more than 97% of ΣPBDE all sediment sites in Åsefjorden and surrounding areas in the western part of Norway. PBDEs are also found in the lower trophic levels of the food chain in Åsefjorden (TA-2146).

The interquartile range of ΣPBDE in sediments sludge from landfills and sewage sludge treatment plants was 3–800 ng/g d.w. (dry weight), with the highest concentrations in sewage sludge. BDE-209 was the dominating congener, but BDE-47 and BDE-99 were also found in relatively high proportions. Furthermore, in all marine sediment samples BDE-209 were the most dominant congeners and for 7 of the samples BDE-209 represented more than 90% of ΣPBDE (TA-2096).

Sediment samples from outside a marina downstream (Muusøya, close of the city of Drammen, southern Norway) showed significantly elevated concentrations with a high percentage of BDE-209. In all the fish samples from the inner Drammensfjord was BDE-209 detected. The concentrations were in general low (0.1–20% of ΣPBDE), but the results are in accordance with new knowledge about BDE-209 as a bioavailable substance (TA-2051).

BDE209 is also detected in aquatic biota such as mussels, fish and in leakage from landfills (TA-2006).

BDE209 is also present in terrestrial environment; moss samples from locations covering Norway from north to south, west to east reveal that BDE209 is the predominant congener. DecaBDE was also present in moose and lynx (Mariussen et al., 2008).

In animal studies of amphibian, fish and rodents exposed to BDE209 at vulnerable stages as the developmental phase, effects on hormonal axis as the thyroid and steroid is of concern. Although the toxicology data of BDE209 is ambiguous, some studies indicate negative effect on neurological development at low doses.

The general concern about the ubiquitous presence and increase of decaBDE in the environment and the concern for increased levels of persistent PBDEs due to continuously debromination from the pool of decaBDE in the environment, together with the risk for endocrine disrupting effects of the mix of PBDE congeners to organisms at vulnerable stages, led Norwegian authorities to ban further use of decaBDE.

References:

De Wit, C. A., M. Alaee, et al. (2006). "Levels and trends of brominated flame retardants in the Arctic." Chemosphere 64(2): 209-233.

De Wit CA, Herzke D, Vorkamp K. (2010). Brominated flame retardants in the Arctic environment — trends and new candidates. Sci Total Environ 408(15):2885-2918

Hermanson, M. H., E. Isaksson,et al., (2010). "Deposition history of brominated flame retardant compounds in an ice core from Holtedahlfonna, Svalbard, Norway." Environ Sci Technol 44(19): 7405-7410.

Mariussen E, Steinnes E, Breivik K, Nygaard T, Schlabach M, Kalas JA (2008). Spatial patterns of polybrominated diphenyl ethers (PBDEs) in mosses, herbivores and a carnivore from the Norwegian terrestrial biota. Sci Total Environ 404:162–70.

Risk Assessment of bis(pentabromophenyl) ether (decabromodiphenyl ether), CAS Number: 1163-19-5 EINECS Number: 214-604-9, Final Draft of October 2002. European Commission 2007.
Including: Update of the risk assessment of bis(pentabromophenyl) ether (decabromodiphenyl ether). European Commission 2004.

TA-2006, Norwegian Pollution Control Authority (SFT) 2004. Screening of selected new organic contaminants - brominated flame retardants, chlorinated paraffins, bisphenol-A and trichlosan. (Niva rapport nr. 4809-2004)

TA- 2252, Climate and Pollution Agency, Norway 2007. Kartlegging av bromerte flammehemmere, klor- og bromorganiske forbindelser, kvikksølv og metylkvikksølv i fjorder nær Ålesund. Report in Norwegian only.

TA-2104, Norwegian Pollution Control Authority (SFT) 2005. Vurdering av bromerte flammehemmere til Mjøsa fra deponier, kommunale renseanlegg og elver. Report in Norwegian only.

TA-2146, Norwegian Pollution Control Authority (SFT) 2006. Kartlegging av utvalgte miljøgifter i Åsefjorden og omkringliggende områder. Bromerte flammehemmere,klororganiske forbindelser, kvikksølv og tribromanisol. Report in Norwegian only.

TA-2096, Norwegian Pollution Control Authority (2005). Screening of selected new organic contaminants 2004. Brominated flame retardants, perfluorinated alkylated substances, irgarol,diuron, BHT and dicofol.

TA-2051, Norwegian Pollution Control Authority 2004. Miljøgifter i sedimenter og fisk i Mjøsa, Drammensvassdraget og Drammensfjorden, oppfølgende undersøkelser i 2004

Expected effect of the final regulatory action

Reduction of risk to the environment.

2.5 Other relevant information regarding the final regulatory action

2.5.1 Estimated quantity of the chemical produced, imported, exported and used

	Quantity per year (MT)	Year
produced		
imported		
exported		
used		

2.5.2 Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions

Similar concerns to those identified are likely to be encountered in other countries where the substance is used.

2.5.3 Other relevant information that may cover:

2.5.3.1 Assessment of socio-economic effects of the final regulatory action

2.5.3.2 Information on alternatives and their relative risks

e.g. IPM, chemical and non-chemical alternatives

Alternatives to decaBDE in all applications are available including non-chemical alternatives (US EPA, 2006 and 2007). Furthermore, a number of alternative flame retardant (FR) available as a substitute for decaBDE in EE products (Danish EPA, 2006). Alternatives include other brominated FRs and other chemical FR.

References:

DecaBDE Study: A Review of Available Scientific Research, US EPA, 2006

Report on Alternatives to the Flame Retardant DecaBDE: Evaluation of Toxicity, Availability, Affordability, and Fire Safety Issues, US EPA, 2007.

Deca-BDE and Alternatives in Electrical and Electronic Equipment, Danish EPA, 2006.

2.5.3.3 Basis for the final regulatory action if other than hazard or risk evaluation

2.5.3.4 Additional information related to the chemical or the final regulatory action, if any

SECTION 3 PROPERTIES

3.1 Information on hazard classification where the chemical is subject to classification requirements

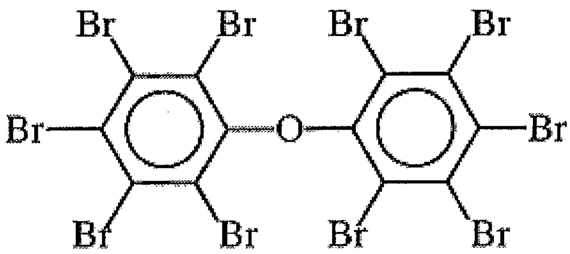
International classification systems e.g. WHO, IARC, etc.	Hazard class

Other classification systems e.g. EU, USEPA	Hazard class
EU	Decabromodiphenyl ether is not currently classified for environmental or health effects.

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Structural formula:



Physical state (at n.t.p): Decabromodiphenyl ether is a fine, white to off-white crystalline powder, depending on the manufacturer.

Chemical formula	$C_{12}H_2Br_{10}O$
Molecular weight	959.2
Melting point	300-310°C
Boiling point	Decomposes at >320°C
Vapour pressure	$4.63.10^{-6}$ Pa
Water solubility	<0.1 µg/L (column elution method)
Log octanol/water partition coefficient (K_{ow})	6.27 (measured - generator column method)
Bromine content	about 83%
Relative density	3.0

Commercially supplied decabromodiphenyl ether consists predominantly of the decabromodiphenyl ether congener (BDE-209) (≥97%), with low levels of other brominated diphenyl ether congeners such as nonabromodiphenyl ether (0.3-3%) and octabromodiphenyl ether (0-0.04%).

Reference

Risk Assessment of bis(pentabromophenyl) ether (decabromodiphenyl ether), CAS Number: 1163-19-5 EINECS Number: 214-604-9, European Commission 2002.

Including: Update of the risk assessment of bis(pentabromophenyl) ether (decabromodiphenyl ether). European Commission 2004 and 2007

Environmental risk evaluation report: 1,1'- (Ethane-1,2-diyl)bis[penta-bromobenzene], Environment Agency, UK, 2007

3.2.2 Description of toxicological properties of the chemical

Toxicokinetics, metabolism and distribution

In male rats it was found that the majority (90 %<) of detected radioactivity were detected in the faeces 72 h after oral exposure of rats to radiolabeled decaBDE. Results indicate after analysis of the feces that 22%, 42% and 45% of the radioactivity present at day 1, 2 and 3 respectively was present as 8 phenolic metabolites. DecaBDE is metabolised via oxidative debromination, as deduced from the presence of debrominated dihydroxylated diphenyl oxides. The remaining radioactivity present in the feces was identified as unchanged decaBDE. In mice exposed to radiolabelled decaBDE at postnatal day 3, 10 or 19, radioactivity was found in the brain, liver and heart 24 h after exposure. During 7 days of exposure levels in brain increased for the mice exposed at postnatal day 3.

Only limited data on human toxicokinetic are available. Data from monitoring indicate that decaBDE can be absorbed into the body and are distributed to the blood, adipose tissue and maternal milk. There are no data available on the rate of elimination or of bioaccumulation of decaBDE in human adipose tissue. Low levels of decaBDE are found both in breast milk, but serum levels of decaBDE and lower brominated BDE in the breast-fed child and a 5 year old child was found to be higher than the levels in the parents.

Recent laboratory work with fish shows that decaBDE can be metabolised in the liver to form lower PBDE congeners, with typically nona- to hepta- or hexabromodiphenyl ethers being found (some of which are considered to be vPvB substances). The extent of metabolism appears to vary amongst different fish species. In birds BDE-209 was metabolized to nona- and octaBDE. There is also evidence from the feeding study with cows that nonaBDE congeners may be more accumulative than decaBDE. This should be taken into account since commercial decaBDE products typically contain up to 3% nonabromodiphenyl ether congeners.

Acute toxicity

DecaBDE exhibits a low acute oral, dermal and inhalation toxicity.

Repeated dose toxicity

The subchronic and chronic oral toxicity of decaBDE is low. NOAELs of 7,000 mg/kg/day (in male mice) and 2,800 mg/kg/day (in male rats) were obtained in subchronic studies (90 days). In chronic studies (2 years), in mice, LOAEL of 3,200 mg/kg/day (in male) was established and in rats, NOAEL (systemic toxicity) of 1,120 mg/kg/day (in male) and LOAEL (local effects) of 1,120 mg/kg/day were established with only moderate effects observed either at this dose when LOAEL was established or at the just above tested dose when NOAEL was determined.

Carcinogenicity

In male mice signs of carcinogenicity were shown by increased incidence of hepatocellular adenomas or carcinomas (combined) in the low dose group and marginally increased incidence of thyroid gland follicular cell adenomas or carcinomas (combined) in both dosed groups. Several non-neoplastic lesions were observed at increased incidence, the most notable being thyroid gland follicular cell hyperplasia. In male and female rats some evidence of carcinogenicity as shown by a dose-dependent increased incidence of neoplastic nodules of the liver.

Mutagenicity

Studies using different bacterial tests as well as in vivo experiments provided negative results. DecaBDE does not exhibit any cytogenetic effects *in vitro* or *in vivo*.

Developmental and reproductive toxicity

No adverse effects have been observed in mice and rats exposed in utero or during lactation, but some studies indicate possible adverse effects on the reproductive system in male offspring.

Several studies indicate that decaBDE disrupt the steroid- and thyroid hormone system. In frog

tadpole metamorphosis, which is regulated by both thyroid hormones and glucocorticoid, is disrupted. Based on this study an aquatic NOEC of around 0.001 mg/L (1 µg/L) for delayed metamorphosis in *Xenopus laevis* tadpoles was indicated (ECHA 2012). In fish thyroid and possibly steroid hormone system was affected after 28 days exposure to ~10 ug BDE-209/ g food followed by a depuration period. Both reduced circulating T3 and T4, and deiodinase activity was observed.
In rats modulation of sex steroid hormone pathway has been reported as reduced adrenal CYP17 activity in females, increased seminal vesicle/coagulating gland weights and increased expression of hepatic CYP1A and CYP2B in males after 28 days oral exposure to BDE-209.
In mice exposed to BDE-209 from gestation day 0-17, anogenital distance, sperm-head abnormalities, and testicular histopatology were significantly affected in mice exposed to 1500 mg/kg. Sperm DNA damage, H2O2 generation, and vacuolization of interstitial cells in the testis was observed in mice exposed to 10 mg/kg. Vacuolization of Leydig cells indicates accumulation of hormone precursors.

Behavioral disturbances observed in the mature rats and mice exposed to decaBDE as neonatales raise concern about possible developmental neurotoxicity in children.

Debromination of BDE-209 to lower brominated PBDEs is of high concern. There is mounting evidence that BDE-209 is debrominated to lower brominated PBDEs in the environment and in biota and that also other degradation products is formed (PBDF, PXDD/ PXDF and HBB). Observed debromination products detected range from mono- to nonaBDEs, and include POPs listed in the Stockholm Convention. Furthermore evidence for mixture toxicity between PBDEs is provided by Kortenkamp 2014, who evaluated the likelihood and type of combination effects between BDE-209 and other PBDEs to humans and wildlife.

Reference

Risk Assessment of bis(pentabromophenyl) ether (decabromodiphenyl ether), CAS Number: 1163-19-5 EINECS Number: 214-604-9, European Commission 2002.
Including: Update of the risk assessment of bis(pentabromophenyl) ether (decabromodiphenyl ether). European Commission 2004, 2007. and 2012

Toxicological review of decabromodiphenyl ether (BDE-209), (CAS No: 1163-19-5). In support of Summary Information on the Integrated Risk Information System (IRIS). U.S. Environmental Protection Agency, Washington,DC. EPA/635/R-07/008F

UNEP/POPS/POPRC.9.2. Proposal to list decabromodiphenyl ether (commercial mixture, c-decaBDE) in Annex A, B and/or C to the Stockholm Convention on Persistent Organic Pollutants

Kortenkamp, A., O. Martin, R. Evans, M. Faust and T. Backhaus (2014). Risk of combination effects between decabromodiphenyl ether and other polybrominated diphenyl ethers, Norwegian Environmental Protection Agency, Oslo, Norway. (in press): 152pp.

3.2.3 Description of ecotoxicological properties of the chemical

Bioaccumulation

BMFs >1 were found for the following predator/prey combinations: walleye/white suckers (BMF 2.0), walleye/white fish (BMF 6.8), emerald shiner/zooplankton (BMF 33), white suckers/zooplankton (BMF 9.9), burbot/emerald shiner (BMF 2.4), burbot/mussels (BMF 1.9), white fish/zooplankton (2.9) and goldeye/zooplankton (BMF 34) (Law et al 2006). Furthermore, Jenssen et al 2007 found a BMF of 2.2 from polar cod to harbor seals.

Persistency

Based on the information in the original risk assessment reports (EC, 2002 and ECB, 2004) decaBDE is likely to be highly persistent in the environment, and so is considered to meet the vP criterion. This conclusion is further supported by monitoring data, which show that the substance is widely distributed in the environment, and present in the Arctic. The slow rate of degradation could nevertheless still lead to the formation of other substances that are of concern (including some that are considered to meet the PBT/vPvB criteria).

DecaBDE is present in many types of aquatic and terrestrial wildlife species also in vulnerable stages as bird eggs. The debromination ability of species tested raise concern for production of more toxic and bioaccumulative congeners. Furthermore, the observed effects on fish thyroid hormone pathway and effects on tadpole metamorphosis are of concern. Although the available ecotoxicity data from controlled laboratory study for the decaBDE indicate no adverse toxicological effects in terrestrial organisms tested, and it was considered unlikely that significant acute or chronic toxic effects would occur in aquatic organisms at concentrations up to the water solubility limit, some studies show effect on behavioral of fish and birds that might reduce their ability to reproduce and survive in the environment.
The pool of decaBDE in the environment gives a continuous exposure to the organisms and function as a source for production of more bioaccumulative and toxic PBDEs.

Reference

Risk Assessment of bis(pentabromophenyl) ether (decabromodiphenyl ether), CAS Number: 1163-19-5 EINECS Number: 214-604-9, Final Draft of October 2002. European Commission 2007.

Including: Update of the risk assessment of bis(pentabromophenyl) ether (decabromodiphenyl ether). European Commission 2004, 2007 and 2012

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