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

Chemical Review Committee
Fourteenth meeting
Rome, 11–14 September 2018
Item 4 (c) (i) of the provisional agenda*

Technical work: review of notifications of final regulatory action: hexabromocyclododecane

Hexabromocyclododecane: notifications from Japan and Norway reviewed by the Chemical Review Committee and the rationale for its conclusion

Note by the Secretariat

As referred to in document UNEP/FAO/RC/CRC.14/6, the annex to the present note sets out notifications of final regulatory action for hexabromocyclododecane in the industrial category from Japan and Norway reviewed by the Chemical Review Committee and the rationale for its conclusion. The present note, including its annex, has not been formally edited.

* UNEP/FAO/RC/CRC.14/1.

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Annex

Hexabromocyclododecane: notifications from Japan and Norway reviewed by the Chemical Review Committee and the rationale for its conclusion

List of documents:

1. Notification of final regulatory action for hexabromocyclododecane in the industrial category submitted by Japan and reviewed by the Chemical Review Committee.

2. Notification of final regulatory action for hexabromocyclododecane in the industrial category submitted by Norway and reviewed by the Chemical Review Committee.

3. Rationale adopted by the Chemical Review Committee for its conclusion on the notifications of final regulatory action for hexabromocyclododecane in the industrial category submitted by Japan and Norway.

ROTTERDAM CONVENTION

SECRETARIAT FOR THE ROTTERDAM CONVENTION
ON THE PRIOR INFORMED CONSENT PROCEDURE
FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES
IN INTERNATIONAL TRADE

UNEP

FORM FOR NOTIFICATION
OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

Country: Japan

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	**Hexabromocyclododecane**
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	**Hexabromocyclododecane**
1.3	**Trade names and names of preparations**	**Cyclododecane, hexabromo**

1.4 Code numbers

1.4.1	CAS number	25637-99-4
1.4.2	Harmonized System customs code	2903.89
1.4.3	Other numbers (specify the numbering system)	

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

This chemical is designated as Class I Specified Chemical Substances. It is prohibited to manufacture, import or use this chemical substance.

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

The Chemical Substances Control Law (CSCL) and its Enforcement Order

2.2.3 Date of entry into force of the final regulatory action

1st May, 2014

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

Flame retardant

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

Use or uses prohibited by the final regulatory action

All uses

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

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

Japanese government designates chemical substances that are persistent, highly bioaccumulative, and have long-term toxicity for humans as Class I Specified Chemical Substances to be banned under the CSCL. As a result of internal evaluation using the scientific data found in Risk profile prepared by POPs Review Committee, Japanese authorities concluded that this chemical meets the criteria to be designated as Class I Specified Chemical Substances under the CSCL.

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

This chemical is persistent, highly bioaccumulative and has long-term toxicity to humans.

Expected effect of the final regulatory action

Reduction of human exposure to this substance as its use is phased out.

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

Expected effect of the final regulatory action

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

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

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**

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Appearance at normal temperature and pressure: White odourless solid Water solubility:65.6µg/L (HBCD technical product, sum of α-HBCD, β-HBCD, γ-

HBCD)

Vapour pressure: 6.3 x 10^{-5}Pa (21 °C)

Log Kow: 5.62 (technical product)

Melting Point: 172-184℃, 201-205℃ (Range from approximately)

Boiling Point: Decomposes at>190℃

Reference

"Risk profile on Hexabromocyclododecane"
(adopted by the Persistent Organic Pollutants Review Committee at its sixth meeting)

3.2.2 Description of toxicological properties of the chemical

"Risk profile on Hexabromocyclododecane"
(adopted by the Persistent Organic Pollutants Review Committee at its sixth meeting) (2.4.5, "Human toxicity")

Reference

3.2.3 Description of ecotoxicological properties of the chemical

"Risk profile on Hexabromocyclododecane"
(adopted by the Persistent Organic Pollutants Review Committee at its sixth meeting)
(2.4.1 Ecotoxicity to aquatic organisms, 2.4.2 Toxicity in soil organisms and plants, 2.4.3 Toxicity in birds, 2.4.4 Toxicity in terrestrial mammals)

Reference

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	Global Environment Division, International Cooperation Bureau, Ministry of Foreign Affairs of Japan
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Date, signature of DNA and official seal: 10/31/2016

MINISTRY OF FOREIGN AFFAIRS · JAPAN

PLEASE RETURN THE COMPLETED FORM TO:

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Definitions for the purposes of the Rotterdam Convention according to Article 2:

(a) 'Chemical' means a substance whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial;

(b) 'Banned chemical' means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(c) 'Severely restricted chemical' means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(d) 'Final regulatory action' means an action taken by a Party, that does not require subsequent regulatory action by that Party, the purpose of which is to ban or severely restrict a chemical.

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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**	HBCDD, Hexabromocyclododecane
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	Hexabromocyclododecane, 1,2,5,6,9,10-hexabromocyclododecane
1.3	**Trade names and names of preparations**	Cyclododecane, hexabromo; HBCD; Bromkal 73-6CD; Nikkafainon CG 1; Pyroguard F 800; Pyroguard SR 103; Pyroguard SR 103A; Pyrovatex 3887; Great Lakes CD-75P™; Great Lakes CD-75; Great Lakes CD75XF; Great Lakes CD75PC (compacted); Dead Sea Bromine Group Ground FR 1206 I-LM; Dead Sea Bromine Group Standard FR 1206 I-LM; Dead Sea Bromine Group Compacted FR 1206 I-CM.

1.4 Code numbers

1.4.1	CAS number	CAS number 25637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8

1.4.2	Harmonized System customs code	
1.4.3	Other numbers (specify the numbering system)	EC Number 247-148-4, EC Number 221-695-9

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

Regulations to restrict production, import, export or sale of consumer products that contain HBCDD exciding certain limit values.

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

HBCD is regulated by Chapter 4 of the Regulation related to restrictions on the manufacture, import and placing on the market of chemicals and other products hazardous to the human health and the environment (Product Regulation) act no. 922 of June 2004. This is the Norwegian implementation of Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants and the implementation of the amendment to Annex I, the COMMISSION REGULATION (EU) 2016/293 of 1 March 2016.

2.2.3 Date of entry into force of the final regulatory action

9. July 2016

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

HBCD has been used to produce flame retarded expanded polystyrene (EPS) and extruded polystyrene (XPS) for onward use in building applications abroad.

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

Use or uses prohibited by the final regulatory action

It is prohibited to manufacture, import, export, placing on the market and use substances that contain 0.01 per cent by weight or more of hexabromocyclododecane (CAS number 25637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8).

It is prohibited to manufacture, import, export and make available on the market products or flame retarded parts of products that contain 0.01 per cent by weight or more of hexabromocyclododecane (CAS number 25637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8).

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

The use of hexabromocyclododecane, whether on its own or in preparations, in the production of expanded polystyrene articles, and the production and placing on the market of hexabromocyclododecane for such use, shall be allowed provided that such use has been authorised in accordance with Title VII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council(*), or is the subject of an application for authorisation submitted by 21 February 2014 where a decision on that application has yet to be taken.

The placing on the market and use of hexabromocyclododecane, whether on its own or in preparations, in accordance with this paragraph shall only be allowed until 26 November 2019 or, if earlier, the date of expiry of the review period specified in an authorisation decision or the date of withdrawal of that authorisation pursuant to Title VII of Regulation (EC) No 1907/2006.

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

n.a.

Formulation(s) and use or uses that remain allowed

(only in case of a severe restriction)

n.a.

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

[European Commission] Risk assessment hexabromocyclododecane, CAS-No.: 25637-99-4, EINECS No.: 247-148-4, Final Report May 2008. 492 pp.

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

HBCDD is used in several products, some of which are available to consumer, e.g. textiles in furniture, automobile interior textiles, construction boards, and mattress ticking. In most applications HBCDD is present as non-bound within a polymer, and may migrate from the polymer and be released. Consumers may be exposed to HBCDD by dermal, oral and respiratory rout. HBCDD has been detected in breast milk and plasma from Norwegian mothers. In 1986, 1993 and 2001, Norwegian breast milk samples from were obtained from 10-12 primiparous mothers living in a coastal area in the North (Tromsø), in a rural inland area (Hamar), and in an industrialized area in the South Norway (Skin/Porsgrunn). Samples collected in 1993 and 2001 in Tromsø, Hamar and Skien/Porsgrunn were pooled. From the 1986 study, only two individual samples from Tromsø were available. HBCDD was found in all samples, but at very varying levels, range 0.25-2 ng/g lipids. (Thomsen et al., 2003). HBCDD levels in plasma from 10 pregnant women living in Bodø, Norway and from 10 women living in Taimyr, Russia were analysed by LC-MS. The samples were collected in

august- December 2002. The women's ages were 20-35 and they had all giving birth to one child before. None of the locations had any known local HBCDD source. HBCDD was detected in more than half of the samples but at low concentrations, close to the limit of detection. The Norwegian samples median and range values were (pg/ml plasma): α-HBCDD 19 (<11-345), β-HBCDD 7 (5-343), γ-HBCDD 23 (7-317) and the Russian samples median and range values were: α-HBCDD 21(<11-51), β-HBCDD 8 (<5-126), γ-HBCDD 33 (13- 160). (Odland et al., 2005).

Expected effect of the final regulatory action

Reduced exposure levels to HBCD.

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

HBCDD is persistent in the environment and bioaccumulates. It has been detected widespread in the Norwegian environment in both remote and urban/suburban arias. Concerns are linked to the degree of bioaccumulation in several food chains and for Arctic organisms, in particular, which are affected by multiple stressors due to climate changes and high body burden of several pollutants.

HBCDD has been detected in effluent water and sludge in urban STPs in Norway. The concentration detected in the effluent water ranged from about 0.0005 µg HBCDD/l from Bekkelaget to about 0.025 µg HBCDD/l from Høvringen. The concentrations in sludge ranged from parts of µg HBCDD/kg dwt at Bekkelaget to about fifty in sludge from Høvringen (Fjeld et al., 2005). The authors also analysed leachate water and sludge from landfills. The concentrations of HBCDD in untreated leachate water, and sludge ranged from 0.00036-0.149 µg HBCDD/l, and 0.16-9.95 µg HBCDD/kg dw.t The highest concentrations were measured at the Djupvik landfill. The concentration in the rinsed sample was 34-67 % of that in the untreated water samples (Fjeld and co-workers, 2005).

A screening of the occurrence of HBCDD in the Norwegian environment was performed by Fjeld et al. (2005). Sediment samples were taken from the freshwater environment from 6 localities in the southern Norway. From each sampling station 5-8 samples were taken from the upper layer 0-2 cm.

Fjeld and co-workers (2006b) measured HBCDD in surface sediments in Lake Mjøsa in Norway. Elevated concentrations of HBCDD (8-21 µg HBCDD/kg dwt) were found outside of the town of Lillehammer and the Vingrom station, as compared to the commonly found levels (0.5-2 µg HBCDD/kg dwt). These elevated concentrations were considered to reflect that a textile factory in Lillehammer used HBCDD in their production in recent years. Only slightly elevated concentrations (2-6.5 µg HBCDD/kg dwt) were found at a few other urban sediment stations. The dated sediment core at the Vingrom station showed an evident increase in the HBCDD concentration from the late 1990s, with a maximum level in the surface layer. The other dated cores showed only a small increase in the HBCDD concentration towards the sediment surface.
Schlabach et al. (2002) measured HBCDD in sedimentation basins for leachate waters from six landfills in southern Norway. The concentrations ranged from below the detection limit in Drammen to 84 ng HBCDD/kg wwt in the landfill from Kristiansand. Sediment samples from the Drammens River had detectable concentrations of α-HBCDD and γ-HBCDD (Schlabach et al., 2004). Surprisingly high concentrations of approx. 8000 µg HBCDD/kg dwt have been detected in the Norwegian Åsnefjord, which receives waste water from e.g. an EPS formulator.

HBCDD has also been found in the biota in Norway. Fjeld and co-workers (2005) sampled mussels along the Norwegian coast and in Norwegian fjords. Most values ranged from about 0.2-2.3 µg HBCDD/kg wwt. However, concentrations from 55-329 µg HBCDD/kg wwt were detected in the Åsne fjord, where a manufacturer of EPS beads is situated.

Fjeld (2006a) reported concentrations of HBCDD in European smelt (Osmerus eperlanus), Vendace (coregonus albula), and Brown Trout (Salmo trutta trutta) from lake Mjösa in Norway. European smelt and Vendace are important preyfish for the trout. The concentrations detected in 2005 were 466 µg HBCDD/kg lwt (8.8 µg HBCDD/kg wwt), 374 µg HBCDD/kg lwt (10.7 µg HBCDD/kg wwt), 729 µg HBCDD/kg lwt (18 µg HBCDD/kg wwt) for the European smelt, the Vendace, and the Brown trout, respectively.

HBCDD is also transported with air and particles, and has been detected in moss (*Hylocomium splendens*) in Norway. The highest concentrations were detected on the south-southwest coast, and in general decreased from south to north. The concentrations detected span almost four orders of magnitude from below the limit of detection to 11114 µg HBCDD/kg wwt.

Murvoll and co-workers (2006) analysed yolk sac from newly hatched chicks of the European shag from the island Sklinna, 50 km of the coast of mid-Norway. HBCDD was detected in all specimens, with a mean concentration of 29 µg HBCDD/kg wwt, or 417 µg HBCDD/kg lwt. The concentration of HBCDD was higher than any of the PBDE congener.

Furthermore, HBCDD has been detected in remote areas as the Arctic. HBCDD has been measured in sediment in lake Ellasjøen at the arctic Bear Island, north of Norway (Christensen et al., 2004). The α- and γ- diastereomers of HBCDD were detected in sediment at 1-2 cm depth, i.e. from the period 1973-1987. HBCDD was not found in the layers from the period 1987-2001 nor from the period 1934-1973. The β- diastereomer was not at all found.

Jenssen et al. (2004) measured brominated flame retardants (including HBCDD) in the arctic marine food web in the Svalbard area in the North-Atlantic. The concentration of HBCDD increased with increasing trophic level, except for the polar bear which may indicate a capability of metabolising the substance for the polar bear. No HBCDD was detected in the lower pelagic zooplankton species Calanus glacialis, Thysanoessa inermis, and Parrratemisto libellula. The levels detected in polar cod, ringed seal, and polar bear ranged from 5-25 µg HBCDD/kg lwt, 15-35 µg HBCDD/kg lwt, and 5-15 µg HBCDD/kg lwt, respectively. Gabrielsen et al. (2004) measured halogenated organic contaminants, including HBCDD, in adipose tissue of Polar Bears from Svalbard north of Norway in the arctic region. The arithmetic mean value was 25.6 µg HBCDD/kg wwt, with a range of 9.7-45 µg HBCDD/kg wwt (all of the 15 measurements were above the limit of detection)

Temporal trends:
Knudsen et al. (2005) analysed eggs from Atlantic puffins, Herring gull, and Kittywake from northern Norway (Hornøya and Røst) from 1983, 1993, and 2003. The HBCDD levels have increased with a factor about 5-8 over 20 years from 1.1-2.9µg/kg wwt 1983 to 6.1-17 µg/kg wwt 2003.
Bytingsvik and co-workers (2004) reported a temporal trend for HBCDD in Atlantic cod (liver) caught at the estuary of river Glomma, as the concentration increased significantly, 8 or 3-4 times from 1998 to 2003, when expressed on a wwt or lwt basis, respectively.

Expected effect of the final regulatory action

Reduced levels of HBCDD in the Norwegian environment and thus reduced risk of adverse effect on the wildlife.

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	n.a.	
imported	58 tonnes (Cas no 25637-99-4)	2012
exported	16 tonnes (Cas no 25637-99-4)	2013
used		

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

The Stockholm Convention has agreed on listing HBCDD in Annex A (ban), with exemption for production and use in expanded polystyrene and extruded polystyrene in buildings. The global ban was introduced 26 of November 2014.

2.5.3 Other relevant information that may cover:

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

HBCDD has traditionally, not been used in EPS or XPS for constructions/buildings in Norway. Since this are the main use of HBCDD low socio-economic effects are expected from of the final regulatory action.

2.5.3.2 Information on alternatives and their relative risks, e.g. IPM, chemical and non-chemical alternatives

US-EPA, United states Environmental Protection Agency: Flame retardant alternatives for hexabromocyclododecane (HBCD). Final report June 2014.

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

In addition to the hazard and risk evaluation, this regulation was also introduced as a result of obligations under the Stockholm Convention.

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

n.a.

SECTION 3 PROPERTIES

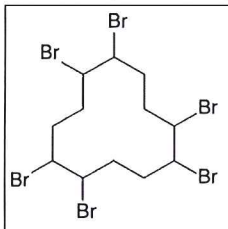
3.1 Information on hazard classification where the chemical is subject to classification requirements

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

Other classification systems e.g. EU, USEPA	Hazard class
EU (CLP regulation; Regulation (EC) 1272/2008)	Repr.2, H361 (Suspected of damaging fertility or the unborn child). Lact., H362 (May cause harm to breast-fed children)
DSD Classification (Directive 67/548/EEC)	Repr. Cat. 3; R 63 (Possible risk of harm to the unborn child), R64 (May cause harm to breastfed babies)

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical



Chemical name: Hexabromocyclododecane

Molecular formula: $C_{12}H_{18}Br_6$

Molecular weight: 641.7 g/ mol

Melting point: Ranges from approximately: 172-184 °C to 201-205 °C

Boiling point: Decomposes at >190 °C

Vapor pressure: 6.3·10-5 Pa (21 °C)

Water solubility: For technical HBCDD this ranges from 46.3 µg/l in saltwater to 65.6 µg/l in freshwater at 20 ºC based on the sum of the water solubilities of the individual diastereoisomers (Wildlife International 2004a and 2004b). The solubility of the individual diastereoisomers also differs, with solubilities ranging from 2.4 µg /l for γ-HBCD to 48 µg /l for α- HBCD in freshwater at 20 °C.

Log Kow: 5.625 (25 °C) (Technical HBCD)

Stereoisomers and purity of commercial products:

1,2,5,6,9,10-HBCD has six stereogenic centers and, in theory, 16 stereoisomers could be formed (Heeb et al. 2005). However, in commercial HBCD only three of the stereoisomers are commonly found. Depending on the manufacturer and the production method used, technical HBCD consists of 70-95 % γ-HBCD and 3-30 % of α- and β-HBCD (European Commission, 2008).

Reference

Heeb NV, Schweizer WB, Kohler M and Gerecke AC. Structure elucidation of hexabromocyclododecanes - a class of compounds with a complex stereochemistry. Chemosphere 2005; 61: 65-73.

[European Commission] Risk assessment hexabromocyclododecane, CAS-No.: 25637-99-4, EINECSNo.: 247-148-4, Final Report May 2008. 492 pp.

3.2.2 Description of toxicological properties of the chemical

Toxico-kinetics, metabolism and distribution: HBCDD can be absorbed from the gastro-intestinal tract, and the highest concentrations are subsequently reached in adipose tissue and muscles followed by liver, and with much lower activities present in lung, kidney, blood, brain, and gonads. The relative bioaccumulation factor is 99:11:1 for α-, β- and γ- HBCDD. HBCDD is excreted mainly through faeces with minor elimination in urine, and three polar metabolites as well as unextractable radioactivity have been detected. Elimination from body fat appears to be markedly slower than from other tissues, with an elimination half-life of the three diastereomers possibly being in the order of weeks to months.

Acute toxicity:

The substance has low acute toxicity at oral or dermal exposure in rodents.

Repeated dose toxicity:

Repeated dose studies with oral exposure in rats and mice resulted in increased liver weight and effects on the pituitary weight and thyroid hormone parameters. A LOAEL of 22.5 mg/kg was proposed for repeated dose.

Carcinogenicity:

Available studies indicates that HBCDD lacks significant carcinogenic potential.

Mutagenicity:

Available studies indicates that HBCDD lacks significant genotoxic potential in vitro as well as in vivo.

Developmental and reproductive toxicity:

A NOAEL of 10 mg/kg/day has been deduced in a two-generation reproductive toxicity study in rats. The NOAEL is based on dose-dependent decrease in fertility-index and a reduced number of primordial follicles. Other effects observed was effect on liver and thyroid weight and TSH hormone level, and increased mortality during lactation.

Neonatal HBCDD exposure may cause developmental neurotoxic effects as illustrated by statistically significant changes in spontaneous behaviour, learning and memory defects. Male mice exposed orally with a single dose at day 10 postnatal (brain growth spurt in mice), were tested for behaviour effects at 3 months age. Clear effects were seen on all parameters tested at 13.5 mg/kg, and on some at 0.9 mg/kg, giving an indicative LOAEL of 0.9 mg/kg/day from this study (Eriksson et al., 2006, as described in the EU Risk assessment for HBCDD 2008).

HBCDD inhibited the high affinity uptake of neurotransmitters (dopamine and glutamate) into synaptosomes at similar concentration levels as previously shown for polychlorinated biphenyls (PCBs) (Mariussen and Fonnum, 2003, as described in the EU Risk assessment for HBCDD 2008).

Reference

[European Commission] Risk assessment hexabromocyclododecane, CAS-No.: 25637-99-4, EINECS No.: 247-148-4, Final Report May 2008. 492 pp.

3.2.3 Description of ecotoxicological properties of the chemical

HBCDD fulfil the criteria of the European Chemical Agency for substances of very high concerns due to the persistence to abiotic and biotic degradation, high bioaccumulation and high toxicity to some aquatic organisms.

Persistence:

No or little degradation has been observed in water, soil and sediments. Furthermore, HBCDD adsorbs to particles which slow down the degradation

Air: $T_{1/2}$ ~ 51.2 hours (Wania 2003, as referred in EC 2008)

Water: $T_{1/2}$ ~ 1140 hours (Wania 2003, as referred in EC 2008)

Soil: $T_{1/2}$ ~ 112-119 days (12°C) for γ-HBCDD diastereomer

Aerobic sediment: $T_{1/2}$ ~ 197 days (recalculated to 12°C) for γ-HBCDD in a simulation study.

Bioaccumulation

From two flow-through bio-concentration tests with fish. A BCF of 18 100 in fathead minnow was chosen as a representative value in the EU risk assessment.

HBCDD levels have been shown to increase with trophic levels in a freshwater system: Fjeld (2006a) reported concentrations of HBCDD in European smelt

(Osmerus eperlanus), Vendace (coregonus albula), and Brown Trout (Salmo trutta trutta) from lake Mjösa in Norway. European smelt and Vendace are important preyfish for the trout. The concentrations detected in 2005 were 466 µg HBCDD/kg lwt (8.8 µg HBCDD/kg wwt), 374 µg HBCDD/kg lwt (10.7 µg HBCDD/kg wwt), 729 µg HBCDD/kg lwt (18 µg HBCDD/kg wwt) for the European smelt, the Vendace, and the Brown trout, respectively.

HBCDD has also been detected in other organisms high in rank in their food-chain such as birds, seals, marine fish, dolphins, harbour porpoise and polar bear.

Toxicity

HBCDD is toxic to aquatic organisms such as Daphnia magna, a 21d-NOEC of 3.1 µg/l has been derived for a flow-through test.

HBCDD is not acute toxic to fish: In rainbow trout, no mortalities or other effects were observed in a 4-week toxicity test at a concentration of about 6.8 µg/l (mean measured concentration 2.5 µg/l).

Reference

[European Commission] Risk assessment hexabromocyclododecane, CAS-No.: 25637-99-4, EINECS No.: 247-148-4, Final Report May 2008. 492 pp.

SECTION 4 DESIGNATED NATIONAL AUTHORITY

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Definitions for the purposes of the Rotterdam Convention according to Article 2:

(a) 'Chemical' means a substance whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial;

(b) 'Banned chemical' means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(c) 'Severely restricted chemical' means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(d) 'Final regulatory action' means an action taken by a Party, that does not require subsequent regulatory action by that Party, the purpose of which is to ban or severely restrict a chemical.

Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
Thirteen meeting
Rome, 23–27 October 2017

Report of the Chemical Review Committee on the work of its thirteenth meeting

Annex I

Annex to decision CRC-13/2

Rationale for the conclusion by the Chemical Review Committee that the notifications of final regulatory action submitted by Japan and Norway in respect of hexabromocyclododecane in the industrial category meet the criteria of Annex II to the Rotterdam Convention

1. The notifications on hexabromocyclododecane from Japan and Norway have been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. These notifications underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether or not the notifications appeared to meet the requirements of the Convention.

2. The notifications, supporting documentation and results of the preliminary review were made available to the Chemical Review Committee for their consideration (documents UNEP/FAO/RC/CRC.13/8, UNEP/FAO/RC/CRC.13/INF/16, UNEP/FAO/RC/CRC.13/INF/17/Rev.2, UNEP/FAO/RC/CRC.13/INF/18).

I. Japan

(a) Scope of the regulatory action notified by Japan

3. The regulatory action notified by Japan relates to the industrial uses of hexabromocyclododecane (CAS 25637-99-4). The notification stated that the manufacture, import and use of hexabromocyclododecane are banned. The regulatory document cited was the Chemical Substances Control Law and its Enforcement Order. The Chemical Substances Control Law came into force on 1 May 2014.

(b) Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

4. The Committee confirms that the regulatory action was taken to protect human health. The notification cited the persistence, bioaccumulation and long-term toxicity to humans. The regulatory action was put in place to reduce human exposure to the substance.

5. In Japan, hexabromocyclododecane had been used as a flame retardant.

6. The notification cited the information on hexabromocyclododecane from the risk profile document prepared by the Persistent Organic Pollutants Review Committee of the Stockholm Convention and provided as supporting information document UNEP/FAO/RC/CRC.13/INF/17. The risk profile document summarizes the adverse effects on human health with exposure and monitoring data from various regions of the world, including some monitoring data from Japan.

7. The Committee confirms that the criterion in paragraph (a) of Annex II is met.

(c) Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;

8. The notification states that the final regulatory action was based on a risk or hazard evaluation. In the notification, reference is made to the risk profile document for hexabromocyclododecane prepared by the Persistent Organic Pollutants Review Committee of the Stockholm Convention.

9. The notifying Party also provided the risk profile document as supporting information (UNEP/FAO/RC/CRC.13/INF/16).

10. At its third meeting, the Conference of the Parties endorsed the approach recommended by the Secretariat, namely that the Committee should consider risk evaluations under the Montreal Protocol and the Stockholm Convention as adequate support for meeting the criteria in paragraph (b) (i) and (ii), as long as the Committee was able to establish that a risk evaluation considering the conditions in the Party has been undertaken. Japan based its regulatory action on the scientific data found in the risk profile for hexabromocyclododecane as prepared by the Persistent Organic Pollutants Review Committee of the Stockholm Convention.

11. The Committee confirms that the criteria in paragraph (b) (i) and (ii) of Annex II are met.

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

12. The notification from Japan indicates that the regulatory action was based on a risk or hazard evaluation, which is provided with a focused summary in English, and also includes the risk profile document for hexabromocyclododecane as prepared by the Persistent Organic Pollutants Review Committee of the Stockholm Convention.

13. When a substance is listed by the Stockholm Convention and is on the market in Japan, the Japanese Government conducts a risk evaluation on the substance and its potential risks to inform regulatory measures. This internal risk evaluation, in combination with the risk profile document for hexabromocyclododecane, were supplied as supporting information by Japan in document UNEP/FAO/RC/CRC.13/INF/17/Rev.2. A brief summary in English of that risk evaluation was provided along with the table of contents of the risk evaluation.

14. The internal risk evaluation was based on the monitoring data from fiscal year 2009 to fiscal year 2012 and revealed a number of sites with a high ecological risk, while there were no sites with any human health risk. The risk evaluation included a hazard assessment, an exposure assessment and risk estimation based on monitoring data, and an exposure assessment and risk estimation based on environmental releases estimated from manufacture data.

15. The Persistent Organic Pollutants Review Committee's risk profile1 cites a Japanese study which found that hexabromocyclododecane levels in human milk appear to mirror the market consumption of hexabromocyclododecane. In mothers' milk from Japanese women (age 25–29) hexabromocyclododecane levels were below the detection limit in all samples collected during the 10-year period from 1973 to 1983, but then increased from 1988 onwards.

16. The Persistent Organic Pollutants Review Committee's risk profile states the developmental and neurotoxic potential of hexabromocyclododecane observed in animal studies give

[1] UNEP/FAO/RC/CRC.13/INF/16.

cause for concern when considering risks to human health, particularly for unborn babies and young children. This concern, along with the human milk monitoring study and results of other studies in the risk profile document on cord serum, suggests some risk to unborn babies and young children in Japan. Despite there being no quantification of the risk for the exposure levels provided, the risk is relevant given the observed bioaccumulation and biomagnification of hexabromocyclododecane.

17. Consequently, the Committee confirms that the criterion in paragraph (b) (iii) of Annex II is met.

18. The Committee confirms that the criteria of paragraph (b) of Annex II are met.

(d) Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

19. The Japanese notification does not provide estimated quantities of hexabromocyclododecane previously imported, produced or used. The notification cites previous industrial uses in Japan. The regulatory action reported by Japan is a ban on all industrial uses.

20. Some sampling from Japan is reported in the risk profile document on hexabromocyclododecane that suggest an increased usage of this chemical since the 1990s and reports on its use in insulation boards and textiles in Japan.

21. Therefore the Committee confirms that the criterion in paragraph (c) (i) is met.

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

22. Citing the hazards posed by the substance to human health, the ban notified by Japan would be expected to lead to a significant reduction in risk by banning industrial uses and preventing new uses from being introduced into the country. The results of the internal evaluation of environmental risks showed that they would be significantly decreased upon banning hexabromocyclododecane. The notifying Party states that a reduction in human exposure is the expected effect of this regulatory action as the use of the substance is phased out.

23. The Committee confirms that the criterion in paragraph (c) (ii) is met.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

24. Japan does not cite information in its notification regarding the applicability of the considerations leading to this regulatory action to other regions. However, the notifying Party provided the risk profile on hexabromocyclododecane prepared by the Persistent Organic Pollutants Review Committee, which indicates that global action is warranted as a result of its long-range environmental transport leading to significant adverse human health and environmental effects.

25. Given the hazards associated with, and long-range transport of, this substance as described in the risk profile of the Persistent Organic Pollutants Review Committee, any state or region where exposure or release is possible may find the regulatory action relevant.

26. Therefore the Committee confirms that the criterion in paragraph (c) (iii) is met.

(iv) Whether there is evidence of ongoing international trade in the chemical;

27. No information on the trade in hexabromocyclododecane appears in the information collected by the Secretariat. However, hexabromocyclododecane is listed to Annex A to the Stockholm Convention and Parties agreed as part of that listing to include specific exemptions for use and production. This suggests that the production and use of hexabromocyclododecane continues and that ongoing trade can be expected.

28. Therefore the Committee confirms that the criterion in paragraph (c) (iv) is met.

(e) Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

29. There is no indication in the notification or supporting documentation that concerns over the intentional misuse of hexabromocyclododecane prompted the regulatory action.

30. Based on the above point the Committee confirms that the criterion in paragraph (d) of Annex II is met.

(f) Conclusion

31. The Committee concludes that this notification of final regulatory action by Japan meets the criteria set out in Annex II to the Convention.

II. Norway

(a) Scope of the regulatory action notified by Norway

32. The regulatory action notified by Norway relates to the industrial uses of hexabromocyclododecane (CAS 23637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8). The notification stated that the production, import, export and sale of consumer products containing hexabromocyclododecane were severely restricted. The substance is regulated by chapter 4 of the regulation related to restrictions on the manufacture, import and placing on the market of chemicals and other products hazardous to human health and the environment (Product Regulation) act no. 922 of June 2004, which represents the Norwegian implementation of Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants and the implementation of the amendment to Annex I, the Commission Regulation (EU) 2016/293 of 1 March 2016. The regulatory action came into force on July 9, 2016.

(b) Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

33. The Committee confirms that the regulatory action was taken to protect human health and the environment. The notification cited exposures to consumers through consumer products, and to babies through human breast milk. The persistence and bioaccumulation of hexabromocyclododecane and its detection in various samples from Norway were cited as risks to the environment.

34. Hexabromocyclododecane had been used as a flame retardant in the production of expanded polystyrene and extruded polystyrene for onward use in building applications abroad, though this activity has not occurred in Norway itself.

35. The Committee confirms that the criterion in paragraph (a) of Annex II is met.

(c) Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;

36. The notification states that the final regulatory action was based on a risk or hazard evaluation. It references the European Commission Risk assessment for hexabromocyclododecane. The “conclusions and overall results” section of this report is provided by Norway among their

supporting information. Also contained in the supporting information are studies and excerpts or English summaries of studies that are relevant to Norway or its geographical region, its citizens, species native to these areas, and alternatives to the substance for its flame retardant uses.

37. Documentation submitted by Norway included the toxicological and ecotoxicological properties, which are referenced as from the European Commission Risk assessment for hexabromocyclododecane. Hazard endpoints are provided in the Flame Retardant Alternatives For Hexabromocyclododecane Final Report (June 2014) by the United States Environmental Protection Agency.

38. The supporting documentation from Norway included a number of citations and technical reports, including monitoring studies conducted in Norway.

39. With respect to the European Commission risk assessment document, the risk assessment report is peer-reviewed by the Scientific Committee on Health and Environmental Risks, which gives its opinion to the European Commission on the quality of the risk assessment.

40. Materials, methods and references are contained in the reporting and publications provided as supporting information by Norway.

41. The United States Environmental Protection Agency report on alternatives to hexabromocyclododecane cites published scientific articles.

42. The Committee confirms that the criteria in paragraphs (b) (i) and (b) (ii) of Annex II are met.

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

43. The notification from Norway indicates that the regulatory action was based on a risk or hazard evaluation and that it was relevant to both human health and the environment. The notification specifically cites the European Commission risk assessment for hexabromocyclododecane. Summarized in the body of the notification from Norway is evidence of exposure to consumers in Norway, its detection in the environment (including remote areas of the arctic), biota, fish, moss, yolk sac of newly hatched chicks. Some temporal trends are noted.

44. Hazard endpoints are provided in the supporting information from Norway as part of the United States Environmental Protection Agency report on flame retardant alternatives. High or very high hazards are noted for developmental effects, acute aquatic toxicity, and chronic aquatic toxicity. Hexabromocyclododecane is highly persistent and has very high bioaccumulation.

45. Given these properties, the detection of hexabromocyclododecane (sometimes with increasing trends from temporal studies) in Norwegian environmental monitoring, ecological and human biomonitoring studies, the Committee concludes that the supporting information from Norway demonstrates an evaluation of the risk to its environment and citizens.

46. Consequently, the Committee confirms that the criterion in paragraph (b) (iii) of Annex II is met.

47. The Committee confirms that the criteria of paragraph (b) of Annex II are met.

(d) Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

48. The Norwegian notification provides quantities of hexabromocyclododecane that were imported and exported in 2012 and 2013, respectively. The notification cites industrial uses as a flame retardant in the production of formulations for expanded polystyrene and extruded polystyrene though the production of polystyrene has not taken place in Norway itself.

49. The regulatory action reported by Norway is a severe restriction on industrial uses that prohibit the manufacture, import, export, placing on the market and use of substances that contain 0.01 per cent by weight or more of hexabromocyclododecane. A time-limited exemption has been allowed for the use of hexabromocyclododecane in the production of expanded polystyrene articles and for the production and placing on the market of hexabromocyclododecane for such use.

50. Therefore the Committee confirms that the criterion in paragraph (c) (i) is met.

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

51. Citing the hazards posed by the substance to human health and the environment, the severe restriction notified by Norway with its time-limited exemptions would be expected to lead to a significant reduction in risk by limiting the allowable uses and preventing new uses from being introduced to their country.

52. The Committee confirms that the criterion in paragraph (c) (ii) is met.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

53. Norway indicates that the Parties to the Stockholm Convention have agreed on the listing of hexabromocyclododecane in Annex A with some specific exemptions for production and use. Substances listed in Annex A of the Stockholm Convention are targeted for global elimination. As a persistent organic pollutant, hexabromocyclododecane has hazardous properties and is subject to long-range transport. Any state or region where exposure or release is possible may find the regulatory action relevant.

54. Therefore the Committee confirms that the criterion in paragraph (c) (iii) is met.

(iv) Whether there is evidence of ongoing international trade in the chemical;

55. Hexabromocyclododecane is listed to Annex A of the Stockholm Convention and Parties agreed as part of that listing to include specific exemptions for use and production. Norway's notification is for a severe restriction with certain, time-limited uses allowed. This suggests that production and use of hexabromocyclododecane continues, and ongoing trade can be expected.

56. Therefore the Committee confirms that the criterion in paragraph (c) (iv) is met.

(e) Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

57. There is no indication in the notification or supporting documentation that concerns over the intentional misuse of hexabromocyclododecane prompted the regulatory action.

58. Based on the above point the Committee confirms that the criterion in paragraph (d) of Annex II is met.

(f) Conclusion

59. The Committee concludes that the notification of final regulatory action submitted by Norway meets the criteria set out in Annex II to the Convention.

III Conclusion

60. The Committee concluded that the notifications of final regulatory action submitted by Japan and Norway met the information requirements of Annex I and all the criteria set out in Annex II to the Convention.

61. The Committee also concludes that the final regulatory actions taken by Japan and Norway provide a sufficient basis to merit including hexabromocyclododecane in Annex III to the

Convention in the industrial chemical category and that a decision guidance document should be drafted on the basis of the notifications.
