



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

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### Chemical Review Committee

#### Thirteenth meeting

Rome, 23–27 October 2017

Item 5 (b) (vi) of the provisional agenda\*

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

## Hexabromocyclododecane: notifications of final regulatory action

### Note by the Secretariat

## I. Introduction

1. In accordance with paragraph 5 of Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, the Secretariat has received three notifications of final regulatory action for hexabromocyclododecane that meet the requirements of Annex I to the Convention from Parties in the following two prior informed consent regions:

- (a) Asia: China (industrial),<sup>1</sup> Japan (industrial);<sup>2</sup>
- (b) Europe: Norway (industrial).<sup>3</sup>

2. The notifications received from the notifying Parties are set out in the annex to the present note. Supporting documentation provided by China, Japan and Norway is set out in documents UNEP/FAO/RC/CRC.13/INF/16, UNEP/FAO/RC/CRC.13/INF/17 and UNEP/FAO/RC/CRC.13/INF/18, respectively.

## II. Proposed action

3. The Committee may wish:

- (a) To review the information provided in the notifications and supporting documentation from China, Japan, and Norway related to hexabromocyclododecane in accordance with the criteria set out in Annex II to the Convention;
- (b) If it concludes that the notifications meet the criteria set out in Annex II to the Convention, to recommend to the Conference of the Parties that the chemical in question be made subject to the prior informed consent procedure and, accordingly, be listed in Annex III to the Convention, and to agree on a workplan for the preparation of a draft decision guidance document on hexabromocyclododecane.

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\* UNEP/FAO/RC/CRC.13/1.

<sup>1</sup> See PIC Circular XLV, June 2017.

<sup>2</sup> See PIC Circular XLIV, December 2016.

<sup>3</sup> See PIC Circular XLIV, December 2016.

## **Annex**

### **Notifications of final regulatory action for hexabromocyclododecane**

- A. Notification of final regulatory action for hexabromocyclododecane in the industrial category submitted by China**
- B. Notification of final regulatory action for hexabromocyclododecane in the industrial category submitted by Japan**
- C. Notification of final regulatory action for hexabromocyclododecane in the industrial category submitted by Norway**



## ROTTERDAM CONVENTION

SECRETARIAT FOR THE 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:**

P.R.China

### SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

**1.1 Common name**

Hexabromocyclododecane  
1,2,5,6,9,10-hexabromocyclododecane and its main  
diastereoisomers

**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; HBCD; Bromkal 73-6CD;  
Nikkafainon CG 1; Pyroguard F 800;  
Pyroguard SR 103; Pyroguard SR 103A; Pyrovatex 3887; Great  
Lakes CD-75P™; GreatLakes 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**

25637-99-4 (hexabromocyclododecane)  
3194-55-6 (1,2,5,6,9,10-hexabromocyclododecane)  
134237-50-6 ( $\alpha$ -hexabromocyclododecane)  
134237-51-7 ( $\beta$ -hexabromocyclododecane)  
134237-52-8 ( $\gamma$ -hexabromocyclododecane)

**1.4.2 Harmonized System customs  
code**

2903890020

1.4.3 Other numbers  
(specify the numbering  
system)

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**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:  
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**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

Since December 26<sup>th</sup>, 2016, the production, use, import and export of hexabromocyclododecane have all been banned in China except for the specific exemption.

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

According to Announcement No.[2016]84 by MEP and 10 other ministries :  
Announcement on "Stockholm Convention on Persistent Organic Pollutants (POPs): entry into force of the amendment to Annexes A to list hexabromocyclododecane".

2.2.3 Date of entry into force of the final regulatory action

December 26th, 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

used mainly as flame retardant

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

Use or uses prohibited by the final regulatory action

The production, use, import and export of hexabromocyclododecane have all been banned in China except for the followings:

1. The production, use, import and export of hexabromocyclododecane used for expanded polystyrene and extruded polystyrene in buildings ( used mainly as flame retardant ) will be allowed within the validity of specific exemption. The validity of the specific exemption will be terminated in 5 years after the amendment taking into effect in China (on December 25, 2021).
2. The production, use, import and export of hexabromocyclododecane used for laboratory-scale research or as a reference standard will be allowed.

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

- 1、 Expanded polystyrene and extruded polystyrene in buildings ( used mainly as flame retardant )
- 2、 Used for laboratory-scale research or as a reference standard

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)

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

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

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

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

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

☐ No

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

Expected effect of the final regulatory action

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

**Other relevant information regarding the final regulatory action**

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

	Quantity per year (MT)	Year
produced		
imported		
exported		
used		

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

Other relevant information that may cover:

Assessment of socio-economic effects of the final regulatory action

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

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

On July 2, 2016, the 21<sup>st</sup> meeting of the 12<sup>th</sup> Session of the Standing Committee of the National People's Congress reviewed and approved the amendment of enlisting hexabromocyclododecane to Annex A of Stockholm Convention on Persistent Organic Pollutants (POPs), and the amendment has entered into force since December 26, 2016 in our country.



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

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## 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.


Other classification systems  
e.g. EU, USEPA

EU	Acute aquatic toxicity (Category 1) Chronic aquatic toxicity (Category 1)

### 3.2 Further information on the properties of the chemical

#### 3.2.1 Description of physic-chemical properties of the chemical

Property	Value	Reference
Chemical formula	C <sub>12</sub> H <sub>18</sub> Br <sub>6</sub>	
Molecular weight	Molecular weight 641.7	
Physical state	Physical state White odour less solid	
White odourless solid		
Melting point	Ranges from approximately: 172-184 °C to 201-205 °C	Smith et al. (2005)

	<p>190 °C, as an average value, was used as input data in the EU risk assessment model EUSES.</p> <p>179-181 °C <math>\alpha</math>-HBCD</p> <p>170-172 °C <math>\beta</math>-HBCD</p> <p>207-209 °C <math>\gamma</math>-HBCD</p>	
Boiling point	Decomposes at >190 °C (see also text below)	Peled et al. (1995)
Density	<p>2.38 g/cm<sup>3</sup></p> <p>2.24 g/cm<sup>3</sup></p>	<p>Albemarle Corporation (1994)</p> <p>Great Lakes Chemical Corporation (1994)</p>
Vapour pressure	6.3·10 <sup>-5</sup> Pa (21 °C)	Stenzel and Nixon (1997)
Partition coefficient noctanol/ water	<p>Log Kow = 5.62 (technical product)</p> <p>5.07 ± 0.09 <math>\alpha</math>-HBCD</p> <p>5.12 ± 0.09, <math>\beta</math>-HBCD</p> <p>5.47 ± 0.10 <math>\gamma</math>-HBCD</p>	<p>MacGregor and Nixon (1997)</p> <p>Hayward et al. (2006)</p>
Henry's Law constant	<p>0.75 Pa×m<sup>3</sup>/mol</p> <p>Calculated from the vapour pressure and the watersolubility (66µg/l)</p>	
Flash point	Not applicable	
Auto flammability	Decomposes at >190 °C	
Flammability	Not applicable-flame retardant	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	
Conversion factor	<p>1 ppm = 26.6 mg/m<sup>3</sup></p> <p>1 mg/m<sup>3</sup> = 0.037 ppm</p>	

Reference

Report of the Persistent Organic Pollutants Review Committee on the work of its sixth meeting Addendum Risk profile on hexabromocyclododecane

3.2.2 Description of toxicological properties of the chemical

LD50 Oral - rat - > 20.000 mg/kg

Reference

Guidechem Chemical Network, Chemical Manufacturers Dictionary

3.2.3 Description of ecotoxicological properties of the chemical

Toxicity to fish : LC50 - *Oncorhynchus mykiss* (rainbow trout) - 0.003 mg/l - 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 - *Daphnia* - > 3.2 mg/l - 48 h

Toxicity to algae : EC50 - Algae - 0.009 mg/l - 72 h

Reference

Guidechem Chemical Network, Chemical Manufacturers Dictionary

SECTION 4

DESIGNATED NATIONAL AUTHORITY

Institution

Solid Waste and Chemicals Management Center C/O  
Ministry of Environmental Protection/Department of Soil  
Environmental Management

Address

No. 1, Yuhuananlu, Chaoyang District, 100029 Beijing China

Name of person in charge

Ding Qiong

Position of person in charge

Chief Engineer

Telephone

+86-10-84665941

Telefax

+86-10-84634708

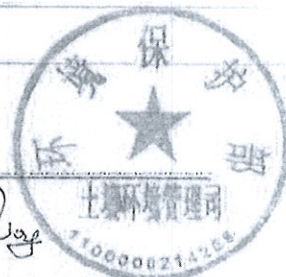
E-mail address

Dingqiong@mepscc.cn

Date, signature of DNA and official seal:

丁琼

Ding Qiong



March, 23rd, 2017.



**PLEASE RETURN THE COMPLETED FORM TO:**

Secretariat for the Rotterdam Convention  
Food and Agriculture Organization  
of the United Nations (FAO)  
Viale delle Terme di Caracalla  
00153 Rome, Italy  
Tel: (+39 06) 5705 2188  
Fax: (+39 06) 5705 3224  
E-mail: [pic@fao.org](mailto:pic@fao.org)

**OR**

Secretariat for the Rotterdam Convention  
United Nations Environment  
Programme (UNEP)  
11-13, Chemin des Anémones  
CH – 1219 Châtelaine, Geneva, Switzerland  
Tel: (+41 22) 917 8296  
Fax: (+41 22) 917 8082  
E-mail: [pic@pic.int](mailto:pic@pic.int)

**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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(2)

## 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: \_\_\_\_\_

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**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 ☒ Yes  
or hazard evaluation?

☐ 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 ☒ Yes  
health?

☐ 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 ☐ Yes  
environment?

☐ No

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



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Expected effect of the final regulatory action

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**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**

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**2.5.3 Other relevant information that may cover:**

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

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

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

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

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**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: 65.6 µg/L (HBCD technical product, sum of α-HBCD, β-HBCD, γ-
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HBCD)

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

Log Kow: 5.62 (technical product)

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

Boiling Point: Decomposes at >190°C

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
Address	2-2-1 Kasumigaseki, Chiyoda-ku, Tokyo, 100-8919 Japan
Name of person in charge	Hiroyuki Nishiura
Position of person in charge	Director, Global Environment Division
Telephone	+81 3 5501 8245
Telefax	+81 3 5501 8244
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Date, signature of DNA and official seal: 10/31/2016



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Secretariat for the Rotterdam Convention  
Food and Agriculture Organization  
of the United Nations (FAO)  
Viale delle Terme di Caracalla  
00153 Rome, Italy  
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Fax: (+39 06) 5705 3224  
E-mail: pic@fao.org

**OR**

Secretariat for the Rotterdam Convention  
United Nations Environment  
Programme (UNEP)  
11-13, Chemin des Anémones  
CH - 1219 Châtelaine, Geneva, Switzerland  
Tel: (+41 22) 917 8296  
Fax: (+41 22) 917 8082  
E-mail: pic@pic.int

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

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(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: \_\_\_\_\_

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**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 exceeding 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 ☒ Yes or hazard evaluation?**

☐ **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):  $\alpha$ -HBCDD 19 (<11-345),  $\beta$ -HBCDD 7 (5-343),  $\gamma$ -HBCDD 23 (7-317) and the Russian samples median and range values were:  $\alpha$ -HBCDD 21(<11-51),  $\beta$ -HBCDD 8 (<5-126),  $\gamma$ -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 areas. 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  $\mu\text{g}$  HBCDD/l from Bekkelaget to about 0.025  $\mu\text{g}$  HBCDD/l from Høvringen. The concentrations in sludge ranged from parts of  $\mu\text{g}$  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  $\mu\text{g}$  HBCDD/l, and 0.16-9.95  $\mu\text{g}$  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 Mjøsa 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  $\alpha$ - and  $\gamma$ - 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  $\beta$ - 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 *Parratemisto libellula*. The levels detected in polar cod, ringed seal, and polar bear ranged from 5-25  $\mu\text{g}$  HBCDD/kg lwt, 15-35  $\mu\text{g}$  HBCDD/kg lwt, and 5-15  $\mu\text{g}$  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  $\mu\text{g}$  HBCDD/kg ww, with a range of 9.7-45  $\mu\text{g}$  HBCDD/kg ww (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 Kittiwake 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 1.1-2.9  $\mu\text{g}/\text{kg}$  ww 1983 to 6.1-17  $\mu\text{g}/\text{kg}$  ww 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 ww 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.

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## 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**

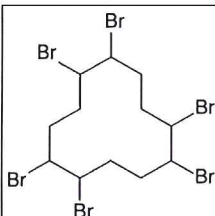
e.g. EU, USEPA

**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:  $6.3 \cdot 10^{-5}$  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 °C 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 %  $\gamma$ -HBCD and 3-30 % of  $\alpha$ - and  $\beta$ -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  $\alpha$ -,  $\beta$ - and  $\gamma$ - 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:  $T_{1/2} \sim 51.2$  hours (Wania 2003, as referred in EC 2008)

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

Soil:  $T_{1/2} \sim 112-119$  days ( $12^{\circ}\text{C}$ ) for  $\gamma$ -HBCDD diastereomer

Aerobic sediment:  $T_{1/2} \sim 197$  days (recalculated to  $12^{\circ}\text{C}$ ) for  $\gamma$ -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 Mjøsa 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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22/8-2016

Christel Moræus Olsen

### PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention **OR**

Secretariat for the Rotterdam Convention

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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.