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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
Fifth meeting
Rome, 23–27 March 2009
Item 4 (b) (viii) of the provisional agenda*

Listing of chemicals in Annex III of the Rotterdam Convention: review of notifications of final regulatory actions to ban or severely restrict a chemical: hexachlorobutadiene

Hexachlorobutadiene

Note by the Secretariat

1. Under Article 5 of the Rotterdam Convention, when the Secretariat has received at least one notification from each of two prior informed consent (PIC) regions containing the information required in Annex I to the Convention, it shall forward the notifications and accompanying documentation to the members of the Chemical Review Committee. The Committee shall review the documentation provided in such notifications and, in accordance with the criteria set out in Annex II to the Convention, recommend to the Conference of the Parties whether the chemical in question should be included in Annex III to the Convention and whether a decision guidance document should be drafted.

2. The Secretariat has received two notifications relating to hexachlorobutadiene that meet the information requirements of Annex I from two PIC regions (North America (Canada) and Asia (Japan)). Summaries of those notifications were included in PIC Circular XXVIII of December 2008 and PIC Circular XXII of December 2005, respectively. The notifications, as received from the notifying countries, are set out in the annex to the present note.

3. The supporting documentation provided by Canada and Japan may be found in documents UNEP/FAO/RC/CRC.5/11/Add.1 and Add.2, respectively.

4. A list of other notifications previously considered by the Chemical Review Committee is set out in document UNEP/FAO/RC/CRC.5/INF/4.

* UNEP/FAO/RC/CRC.5/1.

K0842871 101208

Annex

Notification of final regulatory action on hexachlorobutadiene by Canada

Notification of final regulatory action on hexachlorobutadiene by Japan

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

Country: Canada

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	Hexachlorobutadiene (HCBD)
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	perchlorobuta-1,3-diene
1.3	**Trade names and names of preparations**	1,1,2,3,4,4-hexachloro-1,3-butadiene; hexachloro-1,3-butadiene; perchlorobutadiene; perchloro-1,3-butadiene; 1,3-hexachlorobutadiene; dolen-pur; gp-40-66:120; hexachlorobuta-1,3-diene;
1.4	**Code numbers**	
1.4.1	CAS number	87-68-3
1.4.2	Harmonized System customs code	Not Available
1.4.3	Other numbers (specify the numbering system)	RTECS: EJ0700000 UN: 2279 EPA Codes: K016; K018; K028; K030; U128; D033

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

The *Prohibition of Certain Toxic Substances Regulations, 2005* prohibit the manufacture, use, sale, offer for sale and import of toxic substances listed in Schedules 1 and 2 to the Regulations. HCBD is found on Schedule 1, which lists prohibited toxic substances subject to total prohibition, with the exception of incidental presence.

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

Prohibition of Certain Toxic Substances Regulations, 2005 (SOR/2005-41) under the *Canadian Environmental Protection Act*, 1999.

2.2.3 Date of entry into force of the final regulatory action

May 15, 2005

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

HCBD has never been commercially produced in Canada. It is produced as a by-product during the production of certain chlorinated chemicals, such as tetrachloroethylene, trichloroethylene, vinyl chloride, allyl chloride, epichlorohydrin and carbon tetrachloride.

In the past, HCBD was imported into Canada for use as a solvent, but it is no longer imported

or used.

HCBD was used as a solvent for C_4 and higher hydrocarbons and elastomers, as a hydraulic fluid, as a heat transfer liquid in transformers and as a chemical intermediate in the production of chlorofluorocarbons and lubricants. It was also used to recover chlorine-containing gas in chlorine plants, in gyroscopes and in insulating fluids.

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

Use or uses prohibited by the final regulatory action

The Regulations prohibit the manufacture, use, sale, offer for sale or import of HCBD, or a mixture or product containing HCBD, unless the substance is incidentally present.

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

The Regulations do not apply to HCBD that is:

- contained in a hazardous waste, hazardous recyclable material or non-hazardous waste;
- contained in a control product (e.g., pesticide);
- present as a contaminant in a chemical feedstock used in a process from which there are no releases of the substance and provided that the substance is destroyed or completely converted in that process to a substance that is not listed in Schedule 1 or 2 of the Regulations; or
- used in a laboratory for analysis; in scientific research; or as a laboratory analytical standard.

The Regulations also establish a permit system that provides a mechanism for temporarily exempting certain applications of a substance listed in the Regulations. A permit may be granted only if the Minister of the Environment is satisfied that there is no technically or economically feasible alternative or substitute available for the substance. In addition, the Minister must be satisfied that measures have been taken to minimize or eliminate any harmful effects of the substance on the environment and human health. Finally, the applicant must provide an implementation plan that identifies specific timelines for eliminating the substance. Each permit lasts for 12 months, and can be renewed only twice.

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

Canadian Environmental Protection Act Priority Substances List Assessment Report: Hexachlorobutadiene (2000)

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

Expected effect of the final regulatory action

2.4.2.2 Is the reason for the final regulatory action relevant to the environment? ☒ Yes ☐ No

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

The *Canadian Environmental Protection Act*, 1999 (CEPA 1999) requires the Ministers of the Environment and of Health to prepare and publish a Priority Substances List that identifies substances, including chemicals, groups of chemicals, effluents and wastes that may be harmful to the environment or constitute a danger to human health.

The Act also requires both Ministers to assess these substances and determine whether they are "toxic" or capable of becoming "toxic" as defined in the Act, which states:

"a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that

(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;

(b) constitute or may constitute a danger to the environment on which life depends; or

(c) constitute or may constitute a danger in Canada to human life or health."

A description of the approach to assessment of the environmental effects of Priority Substances is available in the document "Environmental Assessments of Priority Substances under the Canadian Environmental Protection Act, Guidance Manual Version 1.0 March 1997" (http://www.ec.gc.ca/substances/ese/eng/psap/guidman2.cfm). It should be noted that the approach outlined in this document has evolved to incorporate recent developments in risk assessment methodology, which will be addressed in future releases.

Relevant data were identified from existing review documents, published reference texts and on-line searches conducted between January and April 1996. A list of the databases searched can be found in the Assessment Report.

A survey of Canadian industry was carried out under authority of Section 16 of the original CEPA (1988). Companies were required to provide information on uses, releases, environmental concentrations, effects or other data on HCBD that were available to them if they met the trigger quantity of 1 kg of HCBD per year. Data obtained after November 30, 1997 were not considered in the assessment unless they were critical data received during the 60-day public review of the report (July 1 to August 30, 2000).

Canadian sources of HCBD were minor at the time the Report was published, but potentially numerous and included possible releases in landfill leachates, releases during refuse combustion and releases as a by-product in the production of some chlorinated chemicals. Until shortly before the Report was published, the most significant point source of HCBD in Canada appeared to be the Cole Drain, which discharges into the St. Clair River at Sarnia, Ontario, and includes outfalls from an industrial landfill and a few industrial companies. Since 1998, the discharge from the Cole Drain has been practically eliminated. The inadvertent production and use of HCBD in the United States are other potential sources of HCBD to the Canadian environment via long-range transport through the atmosphere or transboundary movement in shared water systems.

When released into the environment, HCBD partitions somewhat to air, soil, water and sediments, but tends to remain mostly in the compartment to which it was released. HCBD is slowly removed from the atmosphere by photooxidation, with an estimated half-life of up to three years. Evidence for long-range transport of HCBD exists, as the substance has been detected in samples taken from various sediment depths in Great Slave Lake. HCBD biodegrades slowly in aerobic water, with an estimated half-life of up to a year, but it would persist considerably longer under anaerobic conditions. HCBD accumulates in the tissues of freshwater organisms, with a maximum reported bioconcentration factor of 19 000, but it is quite easily metabolized and there fore does not biomagnify through food chains. Available data indicate that HCBD meets the criteria for persistence and bioaccumulation according to the *Persistence and Bioaccumulation Regulations* of CEPA 1999.

HCBD was detected in Canadian surface waters, sediments, aquatic organisms and, occasionally, air. Concentrations of HCBD in Canadian surface water were lower than the adverse effects thresholds predicted for sensitive pelagic aquatic organisms. Concentrations of HCBD in the sediment of highly contaminated sections of the St. Clair River were high enough that sensitive benthic organisms could experience adverse effects because of their inability to move to less contaminated areas.

Based on available data, it has been concluded that HCBD is entering the environment in a quantity or concentration or under conditions that have an immediate or long-term harmful effect on the environment or its biodiversity. Therefore, HCBD is considered to be "toxic" as defined under Paragraph 64(a) of CEPA 1999.

Expected effect of the final regulatory action

HCBD is not currently used, sold, produced, imported or exported in Canada. The only way to ensure that it is not introduced into the Canadian market is through a ban. Furthermore, because HCBD meets the criteria for persistence and bioaccumulation, the Canadian federal government has proposed that HCBD be subject to virtual elimination provisions of CEPA 1999. The prohibition on manufacture, use, sale, offer for sale, or import of HCBD will work towards the objective of virtual elimination.

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	Not Available	Not Available
imported	Not Available	Not Available
exported	Not Available	Not Available
used	Not Available	Not Available

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

Because HCBD is not used, sold, produced, imported or exported in Canada, the Regulations are meant to ensure that it is not introduced into the Canadian market. Any state and region in a similar situation may find these Regulations relevant.

2.5.3 Other relevant information that may cover:

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

Given that the Regulations prohibit the manufacture, use, sale, offer for sale and import of HCBD, which is not currently manufactured, used, sold, offered for sale or imported into Canada, there should be no significant impact on industry and compliance costs are expected to be minimal. Incremental costs to government resulting from the Regulations, including administrative and enforcement costs, are expected to be minimal as well.

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

Not Available

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

Not Applicable

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

Abiotic Atmospheric Effects

It was calculated that HCBD would have a tropospheric half-life of 840 days in the northern hemisphere and 290 days in the southern hemisphere. These half-lives are sufficiently long to allow HCBD to reach the stratosphere and react with the ozone present there.

Worst-case calculations were made to determine if HCBD has the potential to contribute to depletion of stratospheric ozone, ground-level ozone formation or climate change.

The Ozone Depletion Potential (ODP) was calculated to be 0.07 relative to the reference compound CFC-11, which has an ODP of 1. The Photochemical Ozone Creation Potential (POCP) was estimated to be 0.01 relative to the value of an equal mass of the reference compound ethene, which has a POCP of 100. The Global Warming Potential (GWP) was calculated to be 0.037 relative to the reference compound CFC-11, which has a GWP of 1. These figures imply that HCBD is not likely to contribute significantly to ground-level ozone formation, but it does have the potential to contribute somewhat to depletion of stratospheric ozone and to climate change.

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
Not Available	Not Available
Not Available	Not Available

Other classification systems e.g. EU, USEPA	Hazard class
Not Available	Not Available
Not Available	Not Available

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

HCBD is a clear, colourless liquid with the following properties:

- empirical molecular formula: C_4Cl_6 [1]
- molecular weight of 260.76 g/mol [1]
- water solubility of 3.20 mg/L at 25°C [1] or 0.00032 g/100 mL [2]
- log K_{ow} of 4.90 [1]
- vapour pressure of 20Pa at 20°C [1]
- Henry's law constant of 1044 Pa·m^3/mol [1]
- density of 1.68 [2]
- melting point of -21°C [2]
- boiling point of 210°C [2]

Reference

[1] *Canadian Environmental Protection Act* Priority Substances List Assessment Report: Hexachlorobutadiene (2000)

[2] ChemFinder.com Database and Internet Searching (www.chemfinder.com)

3.2.2 Description of toxicological properties of the chemical

Based on results of studies conducted in experimental animals, the kidney appears to be the target organ of HCBD-induced toxicity. Kidney tumours have also been observed in rats following long-term exposure to HCBD, but only at doses associated with non-neoplastic renal effects.

Reference

Canadian Environmental Protection Act Priority Substances List Assessment Report:

Hexachlorobutadiene (2000)

3.2.3 Description of ecotoxicological properties of the chemical

Pelagic Organisms

HCBD preferentially accumulates in the livers of fish. Once in the liver, it can be biotransformed into polar metabolites that will reach the kidneys via the bile and could become nephrotoxic in fish.

The available data on toxicity for sensitive receptors indicate that chronic effects occur at concentrations an order of magnitude below those causing acute effects. In most cases, freshwater fish and marine crustacea are more sensitive than their marine and freshwater counterparts, respectively.

The lowest available chronic value was a 28-day Lowest-Observed-Effect Concentration (LOEC) of 13 µg/L reported for the fathead minnow (Pimephales promelas), based on survival and growth. No chronic data on toxicity were identified for aquatic invertebrates. The lowest identified acute value was a 96-hour LC_{50} of 32 µg/L for the marine mysid shrimp, Mysidopsis bahia. For fish, the lowest identified acute value was a 96-hour LC_{50} of 90 µg/L for the goldfish. In other studies, acute toxicity was reported only at concentrations of HCBD above 100 µg/L. The most sensitive freshwater invertebrate identified was the aquatic sowbug, Asellus aquaticus, with a 96-hour LC_{50} of 130 µg/L. Bacteria and plants are less sensitive to HCBD than fish or invertebrates.

Benthic Organisms

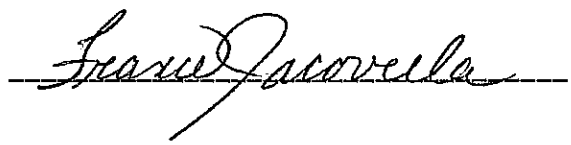
There were no acute or chronic toxicity studies using benthic organisms identified for HCBD. In the absence of such data, the water-sediment Equilibrium Partitioning approach can be used to estimate a Critical Toxicity Value (CTV) for HCBD for benthic organisms. The principle behind this approach is that sediment organic carbon is the main factor influencing partitioning of non-polar organic compounds into sediments. For HCBD, the CTV for benthic organisms can be estimated to be 20.8 µg/g dry weight. This is calculated by multiplying CTV for the most sensitive freshwater pelagic invertebrate (fathead minnow) by the organic carbon/water partition coefficient and the organic content of the sediment (based on the mean organic carbon content for all surficial sediment samples from the St. Clair River in 1994).

Reference

Canadian Environmental Protection Act Priority Substances List Assessment Report: Hexachlorobutadiene (2000)

SECTION 4 DESIGNATED NATIONAL AUTHORITY

Institution	Environment Canada Environmental Stewardship Branch Chemical Sectors Directorate Chemicals Management Division
Address	Place Vincent Massey 351 St. Joseph Blvd., 17th Floor Gatineau, QC K1A 0H3 Canada
Name of person in charge	France Jacovella
Position of person in charge	Executive Director, Chemicals Management Division
Telephone	(819) 956-5263
Telefax	(819) 994-0007
E-mail address	CDS-SDC@ec.gc.ca

Date, signature of DNA and official seal: 

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
00100 Rome, Italy
Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@pic.int

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 8177
Fax: (+41 22) 917 8082
E-mail: 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.

Interim 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

IMPORTANT: See instructions before filling in the form

COUNTRY: JAPAN

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	**IDENTITY OF CHEMICAL**	
1.1	**Common name**	Hexachlorobutadiene
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	Hexachlorobutadiene
1.3	**Trade names and names of preparations**	Hexachlorobutadiene
1.4	**Code numbers**	
1.4.1	**CAS number**	87-68-3
1.4.2	**Harmonized System customs code**	2903.29
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 is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ ☐ This notification replaces all previously submitted notifications on this chemical.
	Date of issue of the previous notification: _____

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

PLEASE RETURN THE COMPLETED FORM TO:

Interim Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

OR

Interim Secretariat for the Rotterdam Convention
UNEP Chemicals

11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

International classification systems	Hazard class
IARC	Group 3
UN Recommendations on the Transport of Dangerous Goods	UN Number 2279

Other classification systems	Hazard class

1.7	Use or uses of the chemical
1.7.1	☐ **Pesticide**
	Describe the uses of the chemical as a pesticide in your country:
1.7.2	☑ **Industrial**
	Describe the industrial uses of the chemical in your country:
	Solvents.

1.8	Properties
1.8.1	**Description of physico-chemical properties of the chemical**

CAS Number : 000087-68-3
Chem Name : HEXACHLOROBUTADIENE
Mol Formula: C4Cl6
Mol Weight : 260.76Melting Pt : -21 deg C
Boiling Pt : 215 deg C
Water Solubility:
Value : 3.2 mg/L
Temp : 25 deg C
Type : EXP
Ref : BANERJEE,S ET AL. (1980)
Log P (octanol-water):
Value : 4.78
Type : EXP
Ref : HANSCH,C ET AL. (1995)
Vapor Pressure:
Value : 0.22 mm Hg
Temp : 25 deg C
Type : EXP
Ref : DAUBERT,TE & DANNER,RP (1989)
pKa Dissociation Constant:
Value :
Temp :
Type :
Ref :
Henry's Law Constant:
Value : 0.0103 atm-m3/mole
Temp : 20 deg C
Type : EXP
Ref : WARNER,HP ET AL. (1987)
Atmospheric OH Rate Constant:
Value : 3E-014 cm3/molecule-sec
Temp : 25 deg C
Type : EST
Ref : MEYLAN,WM & HOWARD,PH (1993)

Source; Syracuse Research Corporation (SRC)
http://www.syrres.com/esc/physdemo.htm

1.8.2	**Description of toxicological properties of the chemical**

(Rat, oral repeated dose toxicity) pathological alteration in kidney more than at 2mg/kg/day. Active metabolite of HCBD accumulates in kidney and is toxic to kidney. Decreased body weights at birth more than at 20mg/kg/day. Decreased body weights of newborn pup more than at 7.5mg/kg/day. The rate fall of conception, and implantation prevention at 75mg/kg/day
(Rat, oral repeated dose toxicity)Adenoma and Carcinoma of renal tubule
(Rat and mouse, half life time) in 72 hrs
(MRL) 0.2μg/kg/day

1.8.3	**Description of ecotoxicological properties of the chemical**

Groups of 12 female and four male Japanese quails (Coturnix coturnix japonica) were exposed to a diet containing hexachloro-butadiene at levels of 0, 0.3, 3, 10 or 30 mg/kg diet for 90 days. Each cage contained three females and one male of the same dose group. Feed analysis indicated levels close to the nominal values. Adults were all histopathologically examined. Eggs were collected on days 37-46, 64-73, and 81-90. Six adults died during the study: 4 at 0.3 mg/kg, 1 at 10 mg/kg, and 1 at 30 mg/kg, but this was not considered to be related to treatment. The survival of chicks from eggs collected on days 81-90 was decreased at 10 mg/kg only. Egg production, the percentage of fertile eggs, the percentage of hatchable eggs, and eggshell thickness were unaffected compared to controls (Schwetz et al., 1974).

SOURCE : IPCS/ENVIRONMENTAL HEALTH CRITERIA 156
http://www.inchem.org/documents/ehc/ehc/ehc156.htm

PART II: FINAL REGULATORY ACTION

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**			
	Ban on manufacture, import, sale and use			
2.2.2	**Reference to the regulatory document**			
	• Law Concerning the Evaluation of Chemical Substances and Regulation of their Manufacture, etc. (abbrev. the Chemical Substances Control Law) and its Enforcement Order			
2.2.3	**Date of entry into force of the final regulatory action**			
	April 1, 2005			

2.3	**Was the final regulatory action based on a risk or hazard evaluation?**	☑ **Yes**	☐**No**
	If yes, give information on such evaluation		
	The government of Japan anticipates that persistent and highly bio-accumulative chemical substances with long-term toxicity (e.g. PCBs) may cause irreversible environmental pollution and have adverse effects on human health or environment. In order to prevent environmental pollution, the Chemical Substances Control Law stipulates that hazardous properties of chemicals should be checked based on the existing knowledge or by the tests which are consistent with the methods of the OECD Test Guidelines, conducted by the OECD GLP facilities. If persistent and highly bio-accumulative properties with long-term toxicity are detected from chemical substances, they are classified as Class I Specified Chemical Substances and are subject to the final regulatory action (ban on manufacture, import and use).		
	Reference to the relevant documentation		

The result of Inspection for safety of existing chemical substances by the government of Japan

BIODEGRADATION AND BIO ACCUMULATION DATA OF EXISTING CHEMICALS
(by The Chemicals Evaluation and Research Institute, Japan: CERI)
http://qsar.cerij.or.jp/cgi-bin/DEGACC/result_head.cgi?STRID=01401&LANG=ENG

2.4	**Reasons for the final regulatory action**		
2.4.1	**Is the reason for the final regulatory action relevant to the human health?**	☑ **Yes**	☐ **No**
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers		
	It is based on the result that existing toxic data were evaluated synthetically.		
	Reference to the relevant documentation		
	Internal documents at the time of the examination.		
	Expected effect of the final regulatory action		
	Should result in reduced human exposure to this substance as its use is phased out.		

2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	☐ **Yes**	☑ **No**
	If yes, give summary of the known hazards and risks to the environment		
	Reference to the relevant documentation		
	Expected effect of the final regulatory action		

2.5	**Category or categories where the final regulatory action has been taken**	
2.5.1	**Final regulatory action has been taken for the chemical category**	☑ **Industrial**
	Use or uses prohibited by the final regulatory action	
	All uses	
	Use or uses that remain allowed	
	n/a	

2.5.2	**Final regulatory action has been taken for the chemical category**	☐ **Pesticide**
	Formulation(s) and use or uses prohibited by the final regulatory action	

	Formulation(s) and use or uses that remain allowed

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	**Year**
Produced	n/a	
Imported	n/a	
Exported	n/a	
Used	n/a	

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

2.7	**Other relevant information that may cover:**
2.7.1	**Assessment of socio-economic effects of the final regulatory action**

2.7.2	**Information on alternatives and their relative risks**
2.7.3	**Relevant additional information**

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	Ministry of Economy, Trade and Industry (METI) Ministry of the Environment (MOE) Ministry of Health, Labour and Welfare (MHLW)
Address	METI: 1-3-1 Kasumigaseki, Chiyoda-ku, Tokyo 100-8901, Japan MOE: 1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8975, Japan MHLW: 1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8901, Japan

Telephone	METI: +81-3-3501-0080 MOE: +81-3-5521-8253 MHLW: +81-3-3595-2298
Telefax	METI: +81-3-3580-6347 MOE: +81-3-3581-3370 MHLW: +81-3-3593-8913
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