

# Order Adding a Toxic Substance to Schedule 1 to the Canadian Environmental Protection Act, 1999

## *Statutory authority*

*Canadian Environmental Protection Act, 1999*

## *Sponsoring departments*

Department of the Environment and Department of Health

## REGULATORY IMPACT ANALYSIS STATEMENT

*(This statement is not part of the Order.)*

## ***Issue and objectives***

Canadians depend on chemical substances that are used in hundreds of goods, from medicines to computers, fabrics, and fuels. Unfortunately, some chemical substances can negatively affect our health and the environment when released in a certain quantity or concentration in the environment. Scientific assessment of hexabromocyclododecane (HBCD) reveals that this substance exhibits toxicity characteristics in both aquatic and terrestrial species and concluded that hexabromocyclododecane is entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity as defined under paragraph 64(a) of the *Canadian Environmental Protection Act, 1999* (CEPA 1999 or the Act).

The objective of the proposed *Order Adding a Toxic Substance to Schedule 1 to the Canadian Environmental Protection Act, 1999* (hereinafter referred to as the proposed Order), made under subsection 90(1) of CEPA 1999, is to add hexabromocyclododecane, which has the molecular formula  $C_{12}H_{18}Br_6$ , to the List of Toxic Substances in Schedule 1 of CEPA 1999, as per the recommendation of the scientific screening assessment report.

This addition enables the Minister of the Environment and the Minister of Health (the Ministers) to develop proposed regulations or instruments to manage human health and environmental risks posed by this substance under CEPA 1999. The Ministers may, however, choose to develop instruments outside of the purview of CEPA 1999 to manage these risks.

## ***Description and rationale***

### Background

Approximately 23 000 substances (often referred to as “existing” substances) were reported to be in use in Canada between January 1, 1984, and December 31, 1986. These substances are found on the *Domestic Substances List* (DSL), but many of these have never been assessed to determine whether they meet any of the toxicity criteria set out in section 64 of CEPA 1999. Section 73 of CEPA 1999 requires that substances on the DSL be “categorized” to determine which of them pose the greatest potential for exposure to the general population as well as which of them are persistent or bioaccumulative and inherently toxic to human beings or non-human organisms. Pursuant to section 74 of CEPA 1999, substances that have met categorization criteria must undergo an assessment to determine whether they meet any of the criteria set out in section 64.

The Ministers completed the categorization exercise in September 2006. Of the approximately 23 000 substances on the DSL, about 4 300 were identified as needing further attention.

Prior to the categorization exercise, a pilot project for screening assessments was initiated by Environment Canada and Health Canada in 2001. The pilot project was undertaken in order to

- refine the screening assessment process;
- develop and adopt new tools and approaches for screening assessments;
- develop approaches for setting priorities for screening assessments; and
- engage stakeholders on these new approaches and priority-setting.

This pilot project initially identified 123 substances, including hexabromocyclododecane (HBCD), which were anticipated to meet the categorization criteria for

- being persistent and/or bioaccumulative and inherently toxic to human and non-human organisms; and/or
- having a high potential of exposure to Canadians.

Therefore, a screening assessment was initiated for HBCD as part of this pilot project. Furthermore, the categorization exercise confirmed HBCD to be a high priority for assessment of ecological risk as it was found to meet the criteria for persistence, bioaccumulation potential and inherent toxicity to aquatic organisms.

Internationally, the European Chemicals Agency (ECHA) has announced its intent to prohibit HBCD from commerce (including imported products). As of June 2011, any person who wishes to produce or import HBCD or a product containing HBCD must submit a notification to ECHA. Companies can apply for authorization under the REACH Regulation to continue to use HBCD and products containing HBCD beyond mid-2013, when the prohibition would come into force. Individual European countries such as Denmark, Germany, Norway, and Sweden are also taking action on HBCD.

The United States have published an action plan for HBCD which states their intent to consider initiating action under the *Toxic Substances Control Act* to address the manufacturing, processing, distribution in commerce, and use of HBCD. The U.S. Environmental Protection Agency (EPA) has established a partnership under its Design for the Environment (DfE) program to identify and evaluate alternatives to HBCD. The results of this project are expected in December 2013.

The substance HBCD was nominated for listing on the Stockholm Convention on Persistent Organic Pollutants (POPs) by Norway in 2008. Work is currently underway to support this proposal, and in 2013 the listing of HBCD could be considered by the Conference of the Parties. This would be dependent on the outcome of the risk management evaluation that will be considered at the seventh meeting of the POPs Review Committee in October 2011. In addition, the United Nations Economic Commission for Europe (UNECE) Convention on Long-range Transboundary Air Pollution (LRTAP) agreed that HBCD should be considered as a persistent organic pollutant as defined under the POPs Protocol. Risk management options are currently being discussed under the Protocol.

The screening assessment for HBCD was conducted to assess whether the substance meets the criteria set out in section 64 of CEPA 1999 — that is to determine whether the substance is entering or may enter the environment in a quantity or concentration or under conditions that

- have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
- constitute or may constitute a danger to the environment on which life depends; or
- constitute or may constitute a danger in Canada to human life or health.

When a substance is found to meet one or more of the criteria set out in section 64, a recommendation can be made that the substance be added to Schedule 1 of CEPA 1999.

The addition of a substance to Schedule 1 allows the Ministers to develop risk management instruments in order to meet their obligations under section 91 of CEPA 1999 (to propose a regulation or other regulatory instruments within two years of publication of the final assessment decision, and to finalize the instrument 18 months later). The Act enables the development of risk management instruments (such as regulations, guidelines or codes of practice) to protect the environment and human health. These instruments can be developed for any aspect of the substance's life cycle from the research and development stage through manufacture, use, storage, transport and ultimate disposal or recycling. A proposed risk management approach document, which provides an indication of where the Government will focus its risk management activities, has been prepared for HBCD and is available on the Chemical Substances Web site at [www.chemicalsubstanceschimiques.gc.ca/challenge-defi/hexabromo-eng.php#a2](http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/hexabromo-eng.php#a2).

The draft screening assessment for HBCD was published on the Chemical Substances Web site, and the statement recommending addition to Schedule 1 was published in the *Canada Gazette*, Part I, on August

28, 2010, for a 60-day public comment period ([www.chemicalsubstanceschimiques.gc.ca/challenge-defi/hexabromo-eng.php#a1](http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/hexabromo-eng.php#a1)).

The assessment summary, conclusions and an overview of the public comments received during the public comment period are presented below.

#### Substance description, assessment summary and conclusions

The primary application of HBCD is as a flame retardant in polystyrene foams that are used as thermal insulation materials in the construction industry. A second application is as flame retardant for textiles used in residential and commercial upholstered furniture, transportation seating, wall coverings and draperies. Minor uses include addition to latex binders, adhesives, and paints and to high-impact polystyrene and styrene-acrylonitrile resins for electrical and electronic equipment.

The available data indicates that demand for HBCD has increased since 2000. Global demand for HBCD was estimated at 16 700 tonnes in 2001, representing 8.2% of total demand for brominated flame retardants that year, placing HBCD third in global production of brominated flame retardants. Global demand for HBCD increased the following two years, and was estimated at 21 400 tonnes/annum in 2002, and at 22 000 tonnes/annum in 2003. Results from the *Notice with Respect to Certain Substances on the Domestic Substances List (DSL)*, published under section 71 and conducted for the year 2000, indicated that HBCD was not manufactured in Canada at that time. Amounts imported into Canada in the same year were in the range of 100 000 to 1 000 000 kg.

Environmental monitoring and sampling studies document the presence of HBCD in many media, including air, water, soil, sediment, biota and sewage biosolids. The highest concentrations in the environment have been reported near urban and industrial sources. Analyses of sediment core samples show a clear trend of increasing concentrations of HBCD since the 1970s, confirming the stability of the substance in deep sediments for periods of more than 30 years. As well, there is evidence of increasing HBCD levels in North American and European biota, both within species and along food chains.

The substance HBCD has demonstrated toxicity in both aquatic and terrestrial species, with significant adverse effects on survival, reproduction and development reported in algae, daphnids and annelid worms. Recent studies also indicate potential toxicological effects in fish and mammals. Scientific evidence also indicates that HBCD is persistent in the environment, and is bioaccumulating in organisms and biomagnifying in food webs in Canada and internationally.

Evidence that a substance is highly persistent and bioaccumulative, as defined in the *Persistence and Bioaccumulation Regulations* under CEPA 1999, taken together with potential for environmental release or formation and potential for toxicity in organisms, provides a significant indication that the substance may enter the environment under conditions that may have harmful long-term ecological effects. Substances that are persistent remain in the environment for a long time after being released, increasing the potential magnitude and duration of exposure. Substances that have long half-lives in air and water and partition into them in significant proportions have the potential to cause widespread contamination. Releases of small amounts of bioaccumulative substances may lead to high internal concentrations in exposed organisms. Highly bioaccumulative and persistent substances are of special concern, since they may biomagnify in food webs, resulting in very high internal exposures, especially to top predators. In addition, the analysis of risk quotients determined that HBCD concentrations in the Canadian environment have the potential to cause adverse effects in populations of pelagic and benthic organisms since the risk quotients exceeded one. Although the risk quotients did not exceed one for soil organisms and wildlife, it must be considered that the presence of even small amounts of HBCD in the environment warrants concern for all organisms in light of strong evidence that the substance is environmentally persistent and bioaccumulative.

#### Conclusion

Based on the information available, it is proposed to conclude that HBCD is entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity as defined under paragraph 64(a) of CEPA 1999. Hexabromocyclododecane is thus recommended for addition to Schedule 1 of CEPA 1999.

The presence of HBCD in the environment results primarily from human activity and the available data regarding persistence and bioaccumulation indicates that the substance meets the criteria set out in the *Persistence and Bioaccumulation Regulations*, made under CEPA 1999. The substance thus meets the criteria for implementation of virtual elimination of releases to the environment as defined under

subsection 77(4).

The final screening assessment report, the proposed risk management approach document and the complete responses to comments received on HBCD were published and may be obtained from the Chemical Substances Web site at [www.chemicalsubstances.gc.ca](http://www.chemicalsubstances.gc.ca) or from the Program Development and Engagement Division, Gatineau, Quebec K1A 0H3, 819-953-7155 (fax), [substances@ec.gc.ca](mailto:substances@ec.gc.ca) (email).

### **Alternatives**

The following measures can be taken after an assessment is conducted under CEPA 1999:

- adding the substance to the Priority Substances List for further assessment (when additional information is required to determine if a substance meets the criteria in section 64 or not);
- taking no further action in respect of the substance; or
- recommending that the substance be added to the List of Toxic Substances in Schedule 1, and where applicable, the implementation of virtual elimination.

It has been concluded in the final screening assessment report that HBCD is entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity as defined under paragraph 64(a) of CEPA 1999. Adding this substance to Schedule 1, which will enable the development of regulations or other risk management instruments, is therefore the best option.

### **Benefits and costs**

The screening assessment concluded that HBCD met the criteria under paragraph 64(a) and recommended the substance be added to Schedule 1 of the Act. This addition enables the Ministers to develop proposed regulations or instruments to manage risks posed by this substance under CEPA 1999. These include instruments such as pollution prevention plans, guidelines or codes of practice. The Ministers may, however, choose to develop instruments outside of the purview of the Act to help protect human health and the environment. The Ministers will assess costs and benefits and consult with the public and other stakeholders during the development of these risk management proposals.

### **Consultation**

On August 28, 2010, the Ministers published a summary of the scientific assessment for HBCD in the *Canada Gazette*, Part I, for a 60-day public comment period. The risk management scope document was also released on the same date, outlining the preliminary options being examined for the management of HBCD, which was proposed to be toxic under section 64 of CEPA 1999. Prior to this publication, Environment Canada and Health Canada informed the governments of the provinces and territories through the CEPA National Advisory Committee (NAC) of the release of the screening assessment report, the risk management scope documents, and the public comment period mentioned above. No comments were received from CEPA NAC.

During the 60-day public comment period, a total of six submissions were received from four industry associations, three submissions were received from two companies, and three submissions ([see footnote 1](#)) were received from four non-governmental organizations. All comments were considered in developing the final assessment.

Comments were also received on the risk management scope document. They were considered when developing the proposed risk management approach document, which is also subject to a 60-day public comment period.

Below is a summary of some key comments regarding the scientific assessment of HBCD, as well as responses to these comments. The complete responses to comments are available via the Government of Canada's Chemical Substances Web site, address, fax number or email listed above.

**Comment:** A manufacturer commented that it disagrees with the draft assessment's interpretation of degradation product data, in particular the persistence data for 1,5,9-cyclododecatriene (CDT). The commenter maintained that studies cited in the screening assessment demonstrate CDT is not persistent.

**Response:** The lack of evidence for complete mineralization of HBCD, along with other factors, supports the conclusion that HBCD is persistent in sediment. The assessment examined primary degradation products of HBCD (e.g. CDT) in sediment to more fully characterize potential ecological impacts of HBCD.

The studies cited in the screening assessment have demonstrated that CDT is subject to primary degradation, and that low concentrations of CDT biodegrade to carbon dioxide under enhanced aerobic biodegradation testing conditions. However, information is not available on CDT's biodegradation under the low oxygen conditions that are most likely to prevail in subsurface soil and sediment compartments (to which HBCD preferentially partitions). Environment Canada recognizes that due to limited information, there remains some uncertainty with respect to CDT's stability in sediment. The final assessment has been modified to clearly reflect that CDT's stability in sediment remains uncertain due to limited information.

Comment: An industry manufacturer and two NGOs commented that further clarity on the oral exposure from mouthing textiles scenario for infants and toddlers is necessary.

Response: The oral exposure from mouthing textiles scenario has been updated in the screening assessment report and two approaches for characterizing potential exposure via the oral route from textiles are presented.

Comment: Four NGOs commented that the HBCD assessment does not take into consideration vulnerable populations, including Arctic populations.

Response: The Government of Canada disagreed and clarified that the information and approach used for the HBCD assessment included environmental media and human biomonitoring data from the Canadian Arctic, use of conservative inputs, conducting age-specific exposure assessments as well as consideration of vulnerable life stages in selection of critical effects for the characterization of risk to human health.

### ***Implementation, enforcement and service standards***

The proposed Order would add HBCD to Schedule 1 of CEPA 1999, thereby allowing the Ministers to meet their obligation to publish proposed regulations or other management instruments within 24 months after the publication of the final screening assessment, which will be fall 2013. Also, the risk management instruments will be finalized within 18 months after the publication of the proposal, which will be spring 2015. Developing an implementation plan, a compliance strategy or establishing service standards are not considered necessary without any specific risk management proposals. An appropriate assessment of implementation, compliance and enforcement will be undertaken during the development of proposed regulations or control instrument(s) respecting preventive or control actions for HBCD.

### ***Contacts***

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## **PROPOSED REGULATORY TEXT**

Notice is hereby given, pursuant to subsection 332(1) ([see footnote a](#)) of the *Canadian Environmental Protection Act, 1999* ([see footnote b](#)), that the Governor in Council, on the recommendation of the Minister of the Environment and the Minister of Health, pursuant to subsection 90(1) of that Act, proposes to make the annexed *Order Adding a Toxic Substance to Schedule 1 to the Canadian Environmental Protection Act*,

1999.

Any person may, within 60 days after the date of publication of this notice, file with the Minister of the Environment comments with respect to the proposed Order or a notice of objection requesting that a board of review be established under section 333 of that Act and stating the reasons for the objection. All comments and notices must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be sent by mail to the Executive Director, Program Development and Engagement Division, Department of the Environment, Gatineau, Quebec K1A 0H3, by fax to 819-953-7155 or by email to substances@ec.gc.ca.

A person who provides information to the Minister of the Environment may submit with the information a request for confidentiality under section 313 of that Act.

Ottawa, December 1, 2011

JURICA ČAPKUN  
*Assistant Clerk of the Privy Council*

**ORDER ADDING A TOXIC SUBSTANCE TO SCHEDULE 1 TO THE CANADIAN ENVIRONMENTAL  
PROTECTION ACT, 1999**

**AMENDMENT**

**1. Schedule 1 to the *Canadian Environmental Protection Act, 1999* ([see footnote 2](#)) is amended by adding the following:**

Hexabromocyclododecane, which has the molecular formula  $C_{12}H_{18}Br_6$

**COMING INTO FORCE**

**2. This Order comes into force on the day on which it is registered.**

[50-1-o]

[Footnote 1](#)

One submission was signed by two non-governmental organizations.

[Footnote 2](#)

S.C. 1999, c. 33

[Footnote a](#)

S.C. 2004, c. 15, s. 31

[Footnote b](#)

S.C. 1999, c. 33

**NOTICE:**

The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with extensible hypertext markup language (XHTML 1.0 Strict).

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