

## **CRC-14/4: Hexabromocyclododecane – notification of final regulatory action**

*The Chemical Review Committee,*

*Recalling* Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,

1. *Concludes* that the additional notification of final regulatory action for hexabromocyclododecane submitted by Canada<sup>1</sup> meets the criteria set out in Annex II to the Convention;
2. *Adopts* the rationale for the Committee's conclusion set out in the annex to the present decision;
3. *Recalls* its decision CRC-13/2, whereby it recommended, on the basis of notifications of final regulatory actions for hexabromocyclododecane submitted by Japan and Norway, that the Conference of the Parties list hexabromocyclododecane in Annex III to the Convention as an industrial chemical, and its decision CRC-14/2, whereby it adopted the draft decision guidance document for that chemical and decided to forward it to the Conference of the Parties for its consideration;
4. *Decides* that, as the Conference of the Parties at its ninth meeting will consider the recommendation by the Committee in its decision CRC-13/2 and the draft decision guidance document adopted by the Committee in its decision CRC-14/2, consequently the Committee will at present take no further action on the additional notification submitted by Canada.

### **Annex to decision CRC-14/4**

#### **Rationale for the conclusion by the Chemical Review Committee that the notification of final regulatory action submitted by Canada in respect of hexabromocyclododecane in the industrial category meets the criteria of Annex II to the Rotterdam Convention**

1. The notification on hexabromocyclododecane from Canada has been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. The notification underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether or not the notification appeared to meet the requirements of the Convention.
2. The notification, the supporting documentation and results of the preliminary review were made available to the Chemical Review Committee for their consideration (documents UNEP/FAO/RC/CRC.14/6, UNEP/FAO/RC/CRC.14/INF/9).

**(a) Scope of the regulatory action notified by Canada,**

3. The regulatory action notified by Canada relates to the industrial uses of hexabromocyclododecane (CAS Nos. 25637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8). The notification states that the manufacture, use, sale, offer for sale or import of hexabromocyclododecane, as well as expanded and extruded foams and their intermediary products containing hexabromocyclododecane used in building/construction applications, are prohibited, with a limited number of exemptions. The substance has been regulated under the Prohibition of Certain Toxic Substances Regulations, 2012, as amended in 2016, issued under the Canadian Environmental Protection Act, 1999 (CEPA). The regulatory action came into force on 1 January 2017.

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<sup>1</sup> See UNEP/FAO/RC/CRC.14/6.

**(b) Annex II, paragraph (a) criterion**

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

4. The Committee confirms that the regulatory action was taken to protect the environment. The notification states that hexabromocyclododecane has met the legislative criteria for persistence, bioaccumulation and toxicity to aquatic life. It has been 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. The final regulatory action is intended to protect the Canadian environment from risks associated with the manufacture, use, sale, offer for sale, or import of hexabromocyclododecane and certain products containing hexabromocyclododecane (UNEP/FAO/RC/CRC.14/6, sect. 2.4.2 of the Canadian notification).

5. The major end-use applications of hexabromocyclododecane have been in the production of flame-retarded expanded polystyrene (EPS) and extruded polystyrene (XPS), which were mostly used as insulation materials in the building and construction industry. These applications accounted for approximately 99% of the hexabromocyclododecane use in Canada (UNEP/FAO/RC/CRC.14/6 section 2.3.1 of the Canadian notification).

6. The Canadian risk management objective for hexabromocyclododecane is to achieve the lowest technically and economically feasible level of release of the substance into the Canadian environment (UNEP/FAO/RC/CRC.14/6, sect. 2.4.2.2 of the Canadian notification).

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

**(c) Annex II, paragraph (b) criteria**

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

- (i) Data have been generated according to scientifically recognized methods;*
- (ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;*

8. The notification states that the final regulatory action was based on a risk evaluation. It refers to the Screening Assessment Report on Hexabromocyclododecane, CAS No. 3194-55-6, prepared by Environment Canada and Health Canada, November 2011 (UNEP/FAO/RC/CRC.14/6, sect. 2.4.1 of the Canadian notification). This report is provided by Canada along with other supporting information in document UNEP/FAO/RC/CRC.14/INF/9. Also contained in the Screening Assessment Report is information on studies, and excerpts or English-language summaries of studies, that are relevant to Canada or its geographical region, its citizens, and species native to these areas. Information on alternatives to the substance for its flame-retardant uses is also included in the supporting documentation.

9. The Screening Assessment Report on Hexabromocyclododecane (Environment Canada and Health Canada, November 2011) uses a large volume of available relevant data and studies that are of reliable quality, from the published original scientific literature, review and assessment documents (such as the European Chemicals Agency Support Document for Identification of hexabromocyclododecane as a Substance of Very High Concern, October 2008), and industry research reports. The data and studies, which cover both hazard and exposure information, are mainly from Europe and North America, including Canada. These are fully referenced in the Screening Assessment Report. Descriptions of the toxicological and ecotoxicological properties of hexabromocyclododecane are summarized in sections 3.2.2 and 3.2.3 of the Canadian notification.

10. The Screening Assessment Report on Hexabromocyclododecane (Environment Canada and Health Canada, November 2011) has undergone external written scientific peer review, and comments received were considered in the production of the final report. Also, the draft of the

Screening Assessment Report was subject to a 60-day public comment period (p. 8 of UNEP/FAO/RC/CRC.14/INF/9).

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

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

12. The notification from Canada indicates that the regulatory action was based on a risk evaluation and that it was relevant to the environment. The notification specifically cites the Screening Assessment Report on Hexabromocyclododecane prepared by Environment Canada and Health Canada, November 2011 (UNEP/FAO/RC/CRC.14/6, sect. 2.4 of the Canadian notification).

13. The Screening Assessment Report prepared by Environment Canada and Health Canada addresses conditions prevailing in Canada, and the findings have been evaluated against Canadian legislative criteria: namely, it is concluded that hexabromocyclododecane meets one or more of the criteria set out in section 64 of the Canadian Environmental Protection Act, 1999, and meets the criteria for persistence and bioaccumulation in the Persistence and Bioaccumulation Regulations.

14. Summarized in sections 3.2.2 and 3.2.3 of the notification from Canada is evidence of exposure of consumers in Canada to hexabromocyclododecane, and of its detection in the environment (including remote areas of the Arctic). Some temporal trends are noted, such as the increase in hexabromocyclododecane levels in birds and marine mammals. There is a reference to a report indicating that hexabromocyclododecane is ubiquitous in the Arctic.

15. In section 3.2.3 of the Canadian notification, it is stated that the analysis of risk quotients has determined that hexabromocyclododecane concentrations in the Canadian environment have the potential to cause adverse effects in populations of pelagic and benthic organisms but are unlikely to result in direct adverse effects to soil organisms and wildlife. However, it is also stated that the presence of even small amounts of hexabromocyclododecane in the environment warrants concern in the light of strong evidence that the substance may be environmentally persistent and bioaccumulative.

16. The Canadian notification (sect. 3.2.3) also states that the available information on the persistence, bioaccumulation potential, ecotoxicity, use and potential release of hexabromocyclododecane in Canada therefore suggests that this substance has the potential to cause ecological harm in Canada.

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

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

**(d) Annex II, paragraph (c) criteria**

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

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

19. The Canadian final regulatory action prohibits the manufacture, use, sale, offer for sale or import of hexabromocyclododecane, as well as EPS and XPS and their intermediary products containing hexabromocyclododecane used in building/construction applications. These applications account for approximately 99% of the use of hexabromocyclododecane in Canada. The final regulatory action provides for a limited number of exemptions.

20. The final regulatory action therefore severely restricts hexabromocyclododecane (as opposed to banning it). Prior to these amendments, there was no risk management in place respecting preventive or control actions for hexabromocyclododecane in Canada.

21. The final regulatory action is intended to achieve virtual elimination of releases of the substance into the environment, under subsection 65 (3) of CEPA 1999. The risk management objective for hexabromocyclododecane is to achieve the lowest technically and economically feasible level of release of the substance into the Canadian environment (Proposed Risk Management Approach, contained in UNEP/FAO/RC/CRC.14/INF/9).

22. The Committee therefore confirms that the criterion in paragraph (c) (i) is met.

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

23. Release of hexabromocyclododecane into the environment may occur during manufacture, processing, transportation, use, improper handling, improper storage or containment, product usage and disposal of the substance or products containing the substance.

24. Since the final regulatory action is intended to achieve virtual elimination of the releases of the substance into the Canadian environment, and the risk management objective for hexabromocyclododecane is to achieve the lowest technically and economically feasible level of release of the substance into the Canadian environment, it would be expected that the final regulatory action would result in a significant reduction in risks to the environment in Canada.

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

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

26. Canada indicates that the Parties to the Stockholm Convention have agreed on the listing of hexabromocyclododecane in Annex A with some specific exemptions for production and use (UNEP/FAO/RC/CRC.14/6, sect. 2.5.2 of the Canadian notification). Substances listed in Annex A to the Stockholm Convention are targeted for global elimination. As a persistent organic pollutant, hexabromocyclododecane has hazardous properties and is subject to long-range transport. Any state or region in which exposure or release is possible may find the regulatory action relevant.

27. The Committee therefore confirms that the criterion in paragraph (c) (iii) is met.

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

28. Hexabromocyclododecane was listed in Annex A to the Stockholm Convention in 2013, and most Parties to the Convention have accepted this listing. Parties agreed, as part of that listing, to include specific exemptions for use and production. Only a few Parties have taken up this exemption. This suggests that production and use of hexabromocyclododecane continue, and that ongoing trade can be expected, although it should now be very much reduced.

29. The Committee therefore confirms that the criterion in paragraph (c) (iv) is met.

30. The Committee confirms that the criteria of paragraph (c) of Annex II are met.

**(e) Annex II, paragraph (d) criterion**

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

31. There is no indication in the notification or the supporting documentation that intentional misuse of hexabromocyclododecane prompted the final regulatory action.

32. On the basis of the above point, the Committee confirms that the criterion in paragraph (d) of Annex II is met.

**(f) Conclusion**

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

34. Taking into account the fact that the Committee, at its thirteenth meeting, concluded that the notifications of final regulatory action for hexabromocyclododecane submitted by Japan and Norway met the criteria in Annex II and recommended to the Conference of the Parties that it consider listing the chemical in Annex III in the industrial chemical category, the Committee agrees to proceed with that recommendation, and to forward the draft decision guidance document based on those two notifications to the Conference of the Parties, together with the information that an additional notification from Canada has been reviewed and found to meet the criteria set out in Annex II to the Convention.