

## **CRC-13/2: Hexabromocyclododecane**

*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 notifications of final regulatory action for hexabromocyclododecane submitted by Japan and Norway<sup>1</sup> meet 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. *Recommends*, in accordance with paragraph 6 of Article 5 of the Convention, that the Conference of the Parties should list hexabromocyclododecane in Annex III to the Convention as an industrial chemical;
4. *Decides*, in accordance with paragraph 1 of Article 7 of the Convention, to prepare a draft decision guidance document for hexabromocyclododecane;
5. *Also decides*, in accordance with the process for drafting decision guidance documents set out in decision RC-2/2 and amended by decision RC-6/3, that the composition of the intersessional drafting group to prepare the draft decision guidance document for hexabromocyclododecane and the workplan of the group shall be as set out in annexes II and III, respectively, to the report of the Committee on the work of its thirteenth meeting.

### **Annex to decision CRC-13/2**

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

1. The notifications on hexabromocyclododecane from Japan and Norway have been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. These notifications underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether or not the notifications appeared to meet the requirements of the Convention.
2. The notifications, supporting documentation and results of the preliminary review were made available to the Chemical Review Committee for their consideration (documents UNEP/FAO/RC/CRC.13/8, UNEP/FAO/RC/CRC.13/INF/16, UNEP/FAO/RC/CRC.13/INF/17/Rev.2, UNEP/FAO/RC/CRC.13/INF/18).

#### **I. Japan**

##### **(a) Scope of the regulatory action notified by Japan**

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

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

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<sup>1</sup> See UNEP/FAO/RC/CRC.13/8.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14. The internal risk evaluation was based on the monitoring data from fiscal year 2009 to fiscal year 2012 and revealed a number of sites with a high ecological risk, while there were no sites with

any human health risk. The risk evaluation included a hazard assessment, an exposure assessment and risk estimation based on monitoring data, and an exposure assessment and risk estimation based on environmental releases estimated from manufacture data.

15. The Persistent Organic Pollutants Review Committee's risk profile<sup>2</sup> cites a Japanese study which found that hexabromocyclododecane levels in human milk appear to mirror the market consumption of hexabromocyclododecane. In mothers' milk from Japanese women (age 25–29) hexabromocyclododecane levels were below the detection limit in all samples collected during the 10-year period from 1973 to 1983, but then increased from 1988 onwards.

16. The Persistent Organic Pollutants Review Committee's risk profile states the developmental and neurotoxic potential of hexabromocyclododecane observed in animal studies give cause for concern when considering risks to human health, particularly for unborn babies and young children. This concern, along with the human milk monitoring study and results of other studies in the risk profile document on cord serum, suggests some risk to unborn babies and young children in Japan. Despite there being no quantification of the risk for the exposure levels provided, the risk is relevant given the observed bioaccumulation and biomagnification of hexabromocyclododecane.

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

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

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

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

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

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

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

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

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

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

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

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

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<sup>2</sup> UNEP/FAO/RC/CRC.13/INF/16.

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

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

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

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

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

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

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

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

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

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

**(f) Conclusion**

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

## **II. Norway**

**(a) Scope of the regulatory action notified by Norway**

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

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

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

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

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

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

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

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

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

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

36. The notification states that the final regulatory action was based on a risk or hazard evaluation. It references the European Commission Risk assessment for hexabromocyclododecane. The “conclusions and overall results” section of this report is provided by Norway among their supporting information. Also contained in the supporting information are studies and excerpts or English summaries of studies that are relevant to Norway or its geographical region, its citizens, species native to these areas, and alternatives to the substance for its flame retardant uses.

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

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

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

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

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

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

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

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

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

45. Given these properties, the detection of hexabromocyclododecane (sometimes with increasing trends from temporal studies) in Norwegian environmental monitoring, ecological and

human biomonitoring studies, the Committee concludes that the supporting information from Norway demonstrates an evaluation of the risk to its environment and citizens.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**(f) Conclusion**

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

**III Conclusion**

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

61. The Committee also concludes that the final regulatory actions taken by Japan and Norway provide a sufficient basis to merit including hexabromocyclododecane in Annex III to the Convention in the industrial chemical category and that a decision guidance document should be drafted on the basis of the notifications.