

## **CRC-15/2: Decabromodiphenyl ether**

*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 decabromodiphenyl ether submitted by Japan, Norway and Canada<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 list decabromodiphenyl ether (CAS No. 1163-19-5) 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 decabromodiphenyl ether;
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 decabromodiphenyl ether 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 fifteenth meeting.<sup>2</sup>

### **Annex to decision CRC-15/2**

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

1. The notifications on decabromodiphenyl ether from Japan, Norway and Canada 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, the supporting documentation and the results of the preliminary review were made available to the Chemical Review Committee for their consideration (documents UNEP/FAO/RC/CRC.15/5, UNEP/FAO/RC/CRC.15/INF/9/Rev.1, UNEP/FAO/RC/CRC.15/INF/10/Rev.1, UNEP/FAO/RC/CRC.14/INF/11).

#### **I. Japan**

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

3. The regulatory action notified by Japan relates to the industrial uses of decabromodiphenyl ether (CAS No. 1163-19-5). The notification states that it is prohibited to manufacture, import, and use this chemical substance. It also states that all uses are prohibited by the final regulatory action, and that no uses remain allowed. The substance has been designated as a Class 1 Specified Chemical Substance under the Chemical Substances Control Law (CSCL) of Japan and its Enforcement Order.

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<sup>1</sup> See UNEP/FAO/RC/CRC.15/5.

<sup>2</sup> UNEP/FAO/RC/CRC.15/7.

The regulatory action came into force on 1 April 2018 (UNEP/FAO/RC/CRC.15/5, sect. 2 of the Japanese notification).

**(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 human health and the environment from decabromodiphenyl ether.

5. The notification states that this chemical is persistent, highly bioaccumulative and has long-term toxicity to humans, based not only on the scientific evaluation by the Persistent Organic Pollutants Review Committee of the Stockholm Convention but also domestic risk evaluation in Japan (UNEP/FAO/RC/CRC.15/5, sect. 2.4.2.1 of the Japanese notification).

6. As a result of internal evaluation using the scientific data in Japan, the Japanese authorities concluded that this chemical met the criteria to be designated as a Class I Specified Chemical Substance under the CSCL (UNEP/FAO/RC/CRC.15/5, sect. 2.4.1 of the Japanese notification).

7. The notification also states that BDE-209, the main component of c-decaBDE, exerts reproductive, developmental, endocrine and neurotoxic effects in aquatic organisms, mammals and birds. Effects on growth, survival and mortality are also reported (UNEP/FAO/RC/CRC.15/5, sect. 3.2.2 of the Japanese notification).

8. The final regulatory action is intended to lead to a reduction of exposure to humans and the environment from decabromodiphenyl ether as its use is phased out (UNEP/FAO/RC/CRC.15/5, sects. 2.4.2.1 and 2.4.2.2 of the Japanese notification).

9. The information summarized in the notification is contained in the supporting document (UNEP/FAO/RC/CRC.15/INF/9/Rev.1).

10. The Committee therefore 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;*

11. The notification states that the final regulatory action was based on a risk evaluation. It references the risk assessment for chemical substances contained in products, decabromodiphenyl ether, CAS No. 1163-19-5, prepared by the National Institute of Technology and Evaluation (NITE), Ministry of Economy, Trade and Industry, Ministry of Health, Labour and Welfare, Japan, in September 2017, and the environmental risk assessment of short-chain chlorinated paraffins and decabromodiphenyl ether, prepared by the Ministry of Environment, Japan, 22 September 2017 (UNEP/FAO/RC/CRC.15/5, sect. 2.4.1 of the Japanese notification).

12. The supporting documentation provided with the Japanese notification contains English summaries of the two above-mentioned reports, as well as the full reports in Japanese. A separate summary note combining information from these reports was also included (UNEP/FAO/RC/CRC.15/INF/9/Rev.1).

13. The physico-chemical properties, and information on toxicological properties, contained in sections 3.2.1 and 3.2.2 of the notification, are referenced as from the risk profile on

decabromodiphenyl ether (commercial mixture, c-decaBDE) prepared by the Persistent Organic Pollutants Review Committee of the Stockholm Convention (UNEP/POPS/POPRC.10/10/Add.2).

14. The summary document included in the supporting information notes that the Japanese risk assessment used the toxicity effect level and minimal risk level (MRL) from the hazard assessment report on polybrominated diphenyl ethers (PBDEs) from the United States of America Agency for Toxic Substances and Disease Registry (ATSDR) of March 2017. For the estimation of exposure amounts, eight exposure scenarios in total were set for environments inside houses and cars where the products to be investigated are used or exist, and the estimation equations according to the exposure scenarios and the parameters required for the estimated equations were set. The exposure scenarios and parameters were set according to the environment where the products to be investigated are used or exist, or the use conditions of the products. Each parameter was set based on the investigation result of the existing literature. For the parameters on which there was no sufficient validity check or insufficient information, tests for the products containing BDE-209 were conducted at NITE Product Safety Technology Centre and Hokuriku Regional Office and the results were also used (UNEP/FAO/RC/CRC.15/INF/9/Rev.1).

15. An environmental risk assessment of decabromodiphenyl ether was carried out based on environmental monitoring data which was implemented and released by the Japanese Government from 2003 to 2017.

16. The above-mentioned data, studies and reports are considered to have been generated according to scientifically recognized methods and documented according to generally recognized scientific principles and procedures.

17. 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;*

18. In the summary of the human health risk assessment by NITE, it is noted that decabromodiphenyl ether (BDE-209) is mainly used as flame retardant for resins and textiles and is contained in consumer products such as electrical appliances, plastic products and car seats. NITE therefore conducted the risk assessment on the health effects for Japanese people who are exposed to BDE-209 via those products indoors and in a car interior. Based on data from Japanese investigations, together with information from overseas risk assessments, furniture, car fabrics, and indoor and car-interior dust were set as the exposure sources to be investigated. Adults and children under the age of 6, living in Japan, were set as the target groups of people in this risk assessment. The reason why the assessment included young children was due to their intake behaviours such as holding objects in their mouth and licking objects, or through dust, being different to the intake of adults.

19. The estimated human exposure (EHE) per day was calculated by summing the exposure amounts estimated for each of the eight exposure scenarios. As the EHE values for adults and children were substantially different, they were averaged, using a 6-year span for children and a 64-year span for adults, to obtain an average lifetime EHE over 70 years.

20. The total estimated human exposure (EHE) of BDE-209 in ng/kg/day was then compared with the toxicity effect value (hazard assessment value), derived from the ATSDR results, to obtain a Hazard Quotient (HQ). As the lifetime average exposure value was less than the hazard assessment value, a HQ of less than 1 (0.6) was obtained, indicating the risk is not at a level of concern.

21. Since BDE-209 has been banned in Japan under the CSCL, it is expected that the exposure amount will become smaller than the average EHE used in the risk assessment in the future, thus further decreasing the level of risk (UNEP/FAO/RC/CRC.15/INF/9/Rev.1).

22. The environmental risk assessment of decabromodiphenyl ether was carried out based on environmental monitoring data. When comparing the D value or predicted no-effect concentration (PNEC) of the human and the high-level predator based on the predicted maximum exposure amount and decabromodiphenyl ether toxicity data, at present, it has become clear that there are risk

concerns (UNEP/FAO/RC/CRC.15/INF/9/Rev.1). D value is the Hazard Evaluation Value, which is the lowest observed adverse effect level (LOAEL)/uncertainty factors.

23. The future environmental risk was estimated based on the scenario that the production, import and use of decabromodiphenyl ether would be prohibited in the future. As a result, the environmental risk was reduced in the scenario of prohibition of production, import and use of decabromodiphenyl ether, and the predicted maximum exposure amount was predicted to be lower than the D value or PNEC of the human and the high-level predator based on decabromodiphenyl ether toxicity data (UNEP/FAO/RC/CRC.15/INF/9/Rev.1).

24. Therefore, it was considered that there is no need to take additional measures, such as collection of products, to prevent progression of environmental pollution. However, it was considered necessary to continuously carry out environmental monitoring of decabromodiphenyl ether in the future and to take necessary measures according to the situation (UNEP/FAO/RC/CRC.15/INF/9/Rev.1).

25. Given this information from the human health and environmental risk assessments, the Committee concludes that the notification and supporting information from Japan demonstrates an evaluation of the risk to its people and the environment.

26. The Committee therefore confirms that the criterion in paragraph (b) (iii) of Annex II is met.

27. 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;*

28. The notification indicates that the use of decabromodiphenyl ether in Japan in 2016 was about 502 tonnes – there was 500 tonnes produced and 80 tonnes exported (UNEP/FAO/RC/CRC.15/5, sect. 2.5.1 of the Japanese notification).

29. The Japanese final regulatory action prohibits the manufacture, import, and use of decabromodiphenyl ether (UNEP/FAO/RC/CRC.15/5, sect. 2.2.1 of the Japanese notification). The notification also indicates that all uses are prohibited by the final regulatory action and that no uses remain allowed (UNEP/FAO/RC/CRC.15/5, sect. 2.3.2 of the Japanese notification), and that the final regulatory action is a ban (UNEP/FAO/RC/CRC.15/5, sect. 2.1 of the Japanese notification).

30. As a result of the final regulatory action under the Japanese CSCL, which entered into force on 1 April 2018, the uses of decabromodiphenyl ether in Japan are expected to have ceased.

31. 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;*

32. Release of decabromodiphenyl ether into the environment may occur during manufacture, processing, throughout the service life of products and articles containing it, and at disposal of the substance or products containing the substance.

33. Since the final regulatory action prohibits the manufacture, import and use of decabromodiphenyl ether, it would be expected that the final regulatory action would lead to a reduction in the exposure of people and the environment to decabromodiphenyl ether as its use is phased out, resulting in a significant reduction in risks to human health and the environment in Japan.

34. 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;*

35. Information was not provided in the notification on this criterion, however, it is noted that decabromodiphenyl ether has been listed in Annex A to the Stockholm Convention with specific exemptions for production and use. Substances listed in Annex A to the Stockholm Convention are targeted for global elimination, through prohibition of manufacture, import and use. As a persistent organic pollutant, decabromodiphenyl ether 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.

36. 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;*

37. According to the information in document UNEP/FAO/RC/CRC.15/INF/4, the last time Japan imported decabromodiphenyl ether was in the fiscal year 2015 (1 April 2015–31 March 2016); Japan once manufactured decabromodiphenyl ether but discontinued this in the fiscal year 2017; and Japan does not continue to export decabromodiphenyl ether.

38. Decabromodiphenyl ether was listed in Annex A to the Stockholm Convention in 2017 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 decabromodiphenyl ether continues, and ongoing trade can be expected, although it should now be very much reduced.

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

40. 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.*

41. There is no indication in the notification that concerns about intentional misuse prompted the regulatory action.

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

**(f) Conclusion**

43. The Committee concludes that the 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**

44. The regulatory action notified by Norway relates to industrial uses of decabromodiphenyl ether (CAS No. 1163-19-5). Commercial decabromodiphenyl ether is described as consisting predominantly of decabromodiphenyl ether (BDE-209) ( $\geq 97$  per cent), with low levels of nonabromodiphenyl ether (0.3-3 per cent), and octabromodiphenyl ether (0-0.04 per cent).

45. The notification stated that the production, import, export, sale and use of decabromodiphenyl ether in pure form, in preparations, in products, and in parts of products containing greater than or equal to 0.1 per cent by weight, are prohibited.

46. The substance has been regulated under the “Regulations relating to restrictions on the manufacture, import, export, sale and use of chemicals and other products hazardous to health and the environment (Product Regulations)”, by the Ministry of the Environment, Act No. 922 of 1 June

2004. The regulatory action came into force on 1 April 2008 and was amended 1 July 2013. The final regulatory action therefore essentially bans the use of decabromodiphenyl ether (UNEP/FAO/RC/CRC.15/5, sect. 2 of the Norwegian notification).

**(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;*

47. The Committee confirms that the regulatory action was taken to protect human health and the environment from decabromodiphenyl ether.

48. The notification states that on the basis of a general concern over the use of brominated flame retardants, a national action plan was set up by the Norwegian authorities in 2002 (later updated in 2009) focusing on five priority substances including commercial decabromodiphenyl ether (c-decaBDE). Norwegian monitoring data show detectable levels of decabromodiphenyl ether in several environmental compartments, and high concentrations of BDE-209, the main component of c-decaBDE, is detected at some locations. High levels of BDE-209 were found in food samples and pooled serum samples (UNEP/FAO/RC/CRC.15/5, sect. 2.4.2.1 of the Norwegian notification).

49. Norwegian authorities banned decabromodiphenyl ether based on its potential persistent, bioaccumulative and toxic (PBT) properties and the general concern about the ubiquitous presence and increase of decabromodiphenyl ether in the environment, including the Norwegian Arctic, and a concern over the presence of decabromodiphenyl ether in human matrices and human health (UNEP/FAO/RC/CRC.15/5, sect. 2.4.2.1 of the Norwegian notification).

50. The notification also states that the evaluation of decabromodiphenyl ether gives rise to concern over long-term effects in the environment. In Norway, BDE-209 has been investigated and detected in a number of studies. Norwegian monitoring data shows that BDE-209 deposited to the Arctic environment is bioavailable to the organisms living there and that BDE-209 is widespread in Arctic food webs (UNEP/FAO/RC/CRC.15/5, sect. 2.4.2.2 of the Norwegian notification).

51. The general concern about the ubiquitous presence and increase of decabromodiphenyl ether in the environment and the concern for increased levels of persistent PBDEs due to continuous debromination from the pool of decabromodiphenyl ether in the environment, together with the risk of endocrine-disrupting effects of the mix of PBDE congeners to organisms at vulnerable stages, led Norwegian authorities to ban further use of decabromodiphenyl ether (UNEP/FAO/RC/CRC.15/5, sect. 2.4.2.2 of the Norwegian notification).

52. The final regulatory action is intended to lead to a reduction in risk to human health and the environment from decabromodiphenyl ether and products containing decabromodiphenyl ether (UNEP/FAO/RC/CRC.15/5, sects. 2.4.2.1 and 2.4.2.2 of the Norwegian notification).

53. The Committee therefore 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;*

54. The notification states that the final regulatory action was based on a risk evaluation. It references the Final Draft of October 2007 of the Risk Assessment of bis(pentabromophenyl) ether (decabromodiphenyl ether), CAS No. 1163-19-5, EINECS Number 214-604-9, prepared by the European Commission 2002 (including updates of 2004 and 2007); the Norwegian action plan on brominated flame retardants (2002, 2009); and the proposal to list decabromodiphenyl ether

(commercial mixture, c-decaBDE) in Annex A, B and/or C to the Stockholm Convention on Persistent Organic Pollutants by Norway, UNEP/POPS/POPRC.9/2 (UNEP/FAO/RC/CRC.15/5, sect. 2.4.1 of the Norwegian notification). The European Union risk assessment Report 2002 and a 2003 summary risk assessment report are provided by Norway among their supporting information in document UNEP/FAO/RC/CRC.15/INF/10/Rev.1. Information on alternatives to decabromodiphenyl ether for its flame-retardant uses is also included in the supporting documentation.

55. The physico-chemical properties, and information on toxicological and ecotoxicological properties are referenced as from the European Union risk assessment, 2002, as updated in 2004, 2007 and 2012. Also referenced, in respect of toxicological properties, are the Norwegian proposal to list decabromodiphenyl ether in Annex A, B and/or C of the Stockholm Convention (UNEP/POPS/POPRC.9/2); a toxicological review of decabromodiphenyl ether (BDE-209), (CAS No. 1163-19-5), produced in support of summary information on the integrated risk information system (IRIS), by the United States Environmental Protection Agency, EPA/635/R-07/008F; and a report on the risk of combination effects between decabromodiphenyl ether and other PBDEs, prepared for the Norwegian Environmental Protection Agency, 2014 (UNEP/FAO/RC/CRC.15/5, sect. 3.2 of the Norwegian notification).

56. The notification states that the final regulatory action was based on a risk evaluation. A list of documents supporting the final regulatory action is provided in document UNEP/FAO/RC/CRC.15/INF/10/Rev.1. The European Union risk assessment 2002 uses a large volume of then available relevant scientific data and studies that are of a reliable quality on the emissions of and exposure to decabromodiphenyl ether and the effects thereof on the environment and human health. Only data that had been generated according to scientifically recognized methods were validated and used for the evaluation.

57. In addition, other referenced research studies, which cover both hazard and exposure information, including studies in Norwegian territory, have been published in peer-reviewed scientific journals or are peer-reviewed departmental reports (UNEP/FAO/RC/CRC.15/5, sects. 2.4.2.1 and 2.4.2.2 of the Norwegian notification).

58. The notification indicates that decabromodiphenyl ether was not classified for environmental or health effects in 2014 (UNEP/FAO/RC/CRC.15/5, sect. 3.1 of the Norwegian notification).

59. Since all the above-mentioned data, studies and reports had been generated according to scientifically recognized methods, and data reviews have been performed and documented according to generally recognized scientific principles and procedures, 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;*

60. Norwegian monitoring data show detectable levels of decabromodiphenyl ether in several environmental compartments, and high concentrations of BDE-209, the main component of decabromodiphenyl ether, is detected at some locations. BDE-209 has been detected in sediments, water, and in biota – moss, mussels, fish, and in moose and lynx, among other species (UNEP/FAO/RC/CRC.15/5, sect. 2.4.2.2 of the Norwegian notification).

61. Norwegian monitoring data show that BDE-209 deposited to the Arctic environment is bioavailable to the organisms living there and that BDE-209 is widespread in Arctic food webs (de Wit et al., 2006, 2010). Norwegian environmental monitoring studies investigating congener pattern and levels of PBDEs in eggs and plasma of glaucous gulls breeding at Bjørnøya in the Arctic revealed detectable levels of BDE-209 in bird plasma comparable to levels found in liver samples of birds located at more southern parts of Europe. Similar results were reported in liver samples from glaucous gulls from Svalbard (UNEP/FAO/RC/CRC.15/5, sect. 2.4.2.2 of the Norwegian notification).

62. In animal studies of amphibians, fish and rodents exposed to BDE-209 at vulnerable stages such as the developmental phase, effects on the hormonal axis such as the thyroid and steroid are of

concern. Although the toxicology data of BDE-209 is ambiguous, some studies indicate negative effects on neurological development at low doses (UNEP/FAO/RC/CRC.15/5, sects. 2.4.2.1 and 2.4.2.2 of the Norwegian notification).

63. The notification states that the evaluation of decabromodiphenyl ether gives rise to concern regarding long-term effects in the environment. The general concern about the ubiquitous presence and increase of decabromodiphenyl ether in the environment, together with the risk of endocrine-disrupting effects of the mix of PBDE congeners to organisms at vulnerable stages, led Norwegian authorities to ban further use of decabromodiphenyl ether (UNEP/FAO/RC/CRC.15/5, sects. 2.4.2.1 and 2.4.2.2 of the Norwegian notification).

64. In food samples analysed in Norway for BDE-209, high levels were found in eggs, vegetable oil, ice cream and biscuits, while the highest amounts were found in dairy products, which include milk, cheese, and butter. However, household dust and occupational exposure are thought to be the main sources for exposure to BDE-209 and other congeners present in c-decaBDE. Toddlers and infants have a higher daily intake of dust and dairy products than adults, and higher serum levels of BDE-209 have been found in children of less than 5 years compared to their parents. Some professions are exposed to higher levels of decabromodiphenyl ether than the average population and other workers. Foam recycling workers, carpet installers and PC technicians are reported to have higher serum levels of BDE-209 than control groups (UNEP/FAO/RC/CRC.15/5, sect. 2.4.2.1 of the Norwegian notification).

65. High levels of BDE-209 (10 ng/g lipid) have been found in pooled serum samples from the Norwegian population. A similar study detected an average of 2.26 ng/g lipid in plasma from pregnant women from the Bodø region of Norway (UNEP/FAO/RC/CRC.15/5, sect. 2.4.2.1 of the Norwegian notification).

66. The widespread presence of decabromodiphenyl ether in the environment warrants concern in the light of strong evidence that the substance is environmentally persistent and bioaccumulative, through debromination to lower brominated PBDEs.

67. The potential PBT properties of decabromodiphenyl ether and a concern over its presence in human matrices and effects on human health, were also contributory reasons for the Norwegian ban on decabromodiphenyl ether.

68. A significant amount of scientific monitoring data from Norwegian studies is presented in the Norwegian notification (UNEP/FAO/RC/CRC.15/5, sects. 2.4.2.1 and 2.4.2.2).

69. Given this information on the detection of decabromodiphenyl ether in Norwegian environmental monitoring, and human and ecological biomonitoring studies, the Committee concludes that the notification and supporting information from Norway demonstrate an evaluation of the risk to its environment.

70. The Committee therefore confirms that the criterion in paragraph (b) (iii) of Annex II is met.

71. 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;*

72. The Norwegian final regulatory action prohibits the manufacture, import, export, sale and use of substances or preparations that contain 0.1 per cent by weight or more of decabromodiphenyl ether. It is also prohibited to manufacture, import, export and place on the market products or flame-retardant parts of products that contain 0.1 per cent by weight or more of decabromodiphenyl ether. The prohibition in respect of products and parts of products also applies to electrical and electronic equipment (EEE). For some categories of EEE, the restrictions took effect over a period of time, from July 2014 until July 2019. There are some limited uses that remain allowed. The Norwegian

notification indicates this is a ban (UNEP/FAO/RC/CRC.15/5, sect. 2.3.2 of the Norwegian notification).

73. As a result of the final regulatory action the number of uses in Norway was significantly reduced.

74. 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;*

75. Release of decabromodiphenyl ether into the environment may occur during manufacture, processing, throughout the service life of products and articles containing it, and during disposal of the substance or products containing the substance.

76. Since the final regulatory action is intended to protect the Norwegian people and environment from risks associated with chemicals and other products, including decabromodiphenyl ether, that are hazardous to health and the environment, by prohibiting the manufacture, import, export, sale and use, it would be expected that the final regulatory action would result in a significant reduction in risks to human health and the environment in Norway.

77. 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;*

78. The notification from Norway states that similar concerns to those identified are likely to be encountered in other countries where the substance is used (UNEP/FAO/RC/CRC.15/5, sect. 2.5.2 of the Norwegian notification).

79. In addition, it is noted that decabromodiphenyl ether has been listed in Annex A to the Stockholm Convention with specific exemptions for production and use. Substances listed in Annex A to the Stockholm Convention are targeted for global elimination, through prohibition of manufacture, import and use. As a persistent organic pollutant, decabromodiphenyl ether 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.

80. 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;*

81. Decabromodiphenyl ether was listed in Annex A to the Stockholm Convention in 2017 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 decabromodiphenyl ether continues, and ongoing trade can be expected, although it should now be very much reduced.

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

83. 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.*

84. There is no indication in the notification that concerns about intentional misuse prompted the regulatory action.

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

**(f) Conclusion**

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

### **III. Canada**

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

87. The regulatory action notified by Canada relates to the industrial uses of PBDEs that have the molecular formula  $C_{12}H_{(10-n)}Br_nO$ , in which n is between 4 and 10 inclusive. This group includes tetrabromodiphenyl ether (CAS No. 40088-47-9), pentabromodiphenyl ether (CAS No. 32534-81-9), hexabromodiphenyl ether (CAS No. 36483-60-0), heptabromodiphenyl ether (CAS No. 68928-80-3), octabromodiphenyl ether (CAS No. 32536-52-0), nonabromodiphenyl ether (CAS No. 63936-56-1), and decabromodiphenyl ether (CAS No. 1163-19-5).

88. This notification for PBDEs replaces previously submitted notifications by Canada for pentabromodiphenyl ether commercial mixture and octabromodiphenyl ether commercial mixture on 14 October 2010.

89. The notification stated that the manufacture, use, sale, offer for sale or import of PBDEs, including decabromodiphenyl ether, and all products that contain PBDEs, except for manufactured items, are prohibited. The substance has been regulated under the Prohibition of Certain Toxic Substances Regulations, 2012, as amended in 2016, made under the Canadian Environmental Protection Act, 1999 (CEPA). The regulatory action came into force on 23 December 2016. The final regulatory action therefore essentially bans the use of PBDEs, including decabromodiphenyl ether (UNEP/FAO/RC/CRC.15/5, sects. 1 and 2 of the Canadian notification).

**(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;*

90. The Committee confirms that the final regulatory action was taken to protect the environment from PBDEs, including decabromodiphenyl ether.

91. The notification states that the earlier Canadian screening assessment of PBDEs (2006) concluded that PBDEs, including decabromodiphenyl ether, were 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, and thus met the legislative criteria set out in CEPA (UNEP/FAO/RC/CRC.15/5, sect. 2.4.1 of the Canadian notification).

92. Environment Canada's Ecological Screening Assessment Report on Polybrominated Diphenyl Ethers (PBDEs) (2006) indicated that the greatest potential risks from PBDEs in the Canadian environment are the secondary poisoning of wildlife from the consumption of prey containing elevated concentrations of PBDEs, and effects on benthic organisms. PBDEs have been detected in remote sites around the world, including the Canadian Arctic (in air, lakes and biota), suggesting PBDEs, including decabromodiphenyl ether, undergo long-range transport (UNEP/FAO/RC/CRC.15/5, sect. 2.4.2.2 of the Canadian notification).

93. The major end-use applications of PBDEs, including decabromodiphenyl ether, has been as flame retardants, mostly in consumer products such as furniture, televisions and computers. At the time the Prohibition of Certain Toxic Substances Regulations were amended (2016), there were no known Canadian importers or users of the decabromodiphenyl ether commercial mixture. In addition, the use of decabromodiphenyl ether in products which are not manufactured items (e.g., adhesives, sealants, caulking) has been phased out. Until recently, the aerospace sector was using products that contain decabromodiphenyl ether for specialist applications but has since completed the transition to alternate products that do not contain decabromodiphenyl ether. The three main manufacturers of decabromodiphenyl ether commercial mixture operating in the United States

voluntarily ceased exports to Canada in 2013 (UNEP/FAO/RC/CRC.15/5, sect. 2.3.1 of the Canadian notification).

94. 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 PBDEs, including decabromodiphenyl ether, and certain products containing PBDEs, including decabromodiphenyl ether (UNEP/FAO/RC/CRC.15/5, sect. 2.4.2.2 of the Canadian notification).

95. The information summarized in the notification is contained in the supporting document UNEP/FAO/RC/CRC.15/INF/11.

96. The Committee therefore 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;*

97. The notification states that the final regulatory action was based on a risk evaluation. It references the Ecological Screening Assessment Report on Polybrominated Diphenyl Ethers (PBDEs), prepared by Environment Canada, June 2006, and the Ecological State of the Science Report on Decabromodiphenyl Ether (decaBDE) Bioaccumulation and Transformation, prepared by Environment Canada, August 2010 (UNEP/FAO/RC/CRC.15/5, sect. 2.4.1 of the Canadian notification). These reports are provided by Canada among their supporting information in document UNEP/FAO/RC/CRC.15/INF/11. Also contained in the Screening Assessment Report and the State of the Science Report is information on studies and excerpts of studies that are relevant to Canada or its geographical region, and species native to these areas. Information on alternatives to the substance for its flame-retardant uses is also included in the supporting documentation.

98. The physico-chemical properties submitted by Canada along with the ecotoxicological properties are referenced as from the Screening Assessment Report on PBDEs, prepared by Environment Canada, June 2006 (UNEP/FAO/RC/CRC.15/5, sect. 3.2 of the Canadian notification).

99. The available information on persistence, bioaccumulation and toxicity, as well as the risk quotient analysis for pelagic, benthic, and soil organisms, and wildlife consumers, indicate that PBDEs, including decabromodiphenyl ether, have the potential to cause ecological harm in Canada (summarized from document UNEP/FAO/RC/CRC.15/5, sect. 3.2.3 of the Canadian notification.).

100. A list of documents supporting the final regulatory action is provided in documents UNEP/FAO/RC/CRC.15/5 and UNEP/FAO/RC/CRC.15/INF/11.

101. The Screening Assessment Report on PBDEs (Environment Canada, June 2006) uses a large volume of then-available relevant data and studies that are of a reliable quality, from the published original scientific literature, review documents, and commercial and government databases and indices. In addition to literature database searches, direct contact was made with researchers, industry and others to obtain relevant information on PBDEs. Further, an industry survey on PBDEs for the year 2000 collected data on the Canadian manufacture, import, uses and releases of PBDEs. Toxicological studies were also submitted by industry under Section 70 of CEPA. Data and studies, which cover both hazard and exposure information, are mainly from Europe and North America, including Canada.

102. The Ecological State of the Science Report on Decabromodiphenyl Ether (decaBDE) (Environment Canada, August 2010) provides an updated analysis of bioaccumulation and transformation of decabromodiphenyl ether, by summarizing the evidence considered in the Screening Assessment, and then examining the relevant new science published up to 25 August

2009. This analysis confirmed that decabromodiphenyl ether did not meet the bioaccumulation criteria as defined in the Persistence and Bioaccumulation Regulations under CEPA. However, some studies showed that levels of decabromodiphenyl ether were steadily rising in some biota, and in some cases, measured concentrations were considered high. Although it was noted that uncertainties remain, the report considered that it was reasonable to conclude that decabromodiphenyl ether may also contribute to the formation of bioaccumulative and/or potentially bioaccumulative transformation products, such as lower brominated BDEs, in organisms and the environment.

103. The Screening Assessment Report on PBDEs and the Ecological State of the Science Report on Decabromodiphenyl Ether (decaBDE) have undergone external written scientific peer review/consultation and comments received were considered in the production of the final reports. Also, the draft of the Ecological State of the Science Report was subject to a 60-day public comment period.

104. Since all the above-mentioned data, studies and reports had been generated according to scientifically recognized methods, and data reviews were performed and documented according to generally recognized scientific principles and procedures, 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;*

105. PBDEs were among the substances selected for a pilot project for screening assessments under CEPA, on the basis of their potential persistence and/or bioaccumulation in the environment and inherent toxicity to organisms. The Screening Assessment Report prepared by Environment Canada addresses prevailing conditions within Canada and the findings have been evaluated against Canadian legislative criteria: namely, it is concluded that PBDEs, including decabromodiphenyl ether, were 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, and thus met the criteria set out in paragraph 64 (a) of CEPA. It was concluded that while all PBDEs, including decabromodiphenyl ether, met criteria for persistence, only tetra- to hexabromodiphenyl ether met the legislative criteria for bioaccumulation. However, the analysis also noted that decabromodiphenyl ether could accumulate to some degree in biota and debrominate to the bioaccumulative and persistent transformation products, the lower brominated diphenyl ether homologues.

106. A significant amount of scientific monitoring data from Canadian studies is presented in the Ecological Screening Assessment Report on Polybrominated Diphenyl Ethers (PBDEs), and the Ecological State of the Science Report on Decabromodiphenyl Ether (decaBDE) Bioaccumulation and Transformation (Environment Canada, August 2010) (UNEP/FAO/RC/CRC.15/INF/11, sects. 2.1.2 and 2.2.2, and appendices A and B).

107. Summarized in section 3.2.3 of the notification from Canada is evidence of the detection of PBDEs in all environmental media as well as sewage sludge, and there is evidence that their levels in the North American environment are increasing. Results were reported on biota in the Canadian Arctic and some temporal trends are noted such as the increase in PBDE levels in marine mammals, such as ringed seals and beluga whales.

108. Further, it is stated that the analysis of risk quotients indicates that the greatest potential for risk from PBDEs in the Canadian environment is due to the secondary poisoning of wildlife from the consumption of prey containing elevated pentabromodiphenyl ether and octabromodiphenyl ether congener concentrations. Also, it indicated that elevated concentrations of components of pentabromodiphenyl ether in sediments may present risk to benthic organisms. The risks associated with these congeners may be due to debromination of highly brominated PBDEs, such as decabromodiphenyl ether.

109. Although, overall, the available data does not show that decabromodiphenyl ether itself meets the numeric criteria for bioaccumulation, as defined in the Persistence and Bioaccumulation Regulations under CEPA, some studies have shown concentrations of decabromodiphenyl ether to be increasing steadily in some wildlife species. In some cases, such as in the tissues of kestrel,

sparrowhawk, peregrine falcon, glaucous gull, red fox, shark, harbour porpoise, and whitebeaked dolphin, measured concentrations of decabromodiphenyl ether are interpreted as high.

110. The screening assessment also concluded that the presence of PBDEs in the environment results primarily from human activity.

111. Given the information on hazardous properties, the detection of PBDEs, including decabromodiphenyl ether, in Canadian environmental monitoring and ecological biomonitoring studies, it was concluded that PBDEs, including decabromodiphenyl ether, were 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, and thus met the criteria set out in paragraph 64 (a) of CEPA. The Committee thus concludes that the notification and supporting information from Canada demonstrates an evaluation of the risk to its environment.

112. The Committee therefore confirms that the criterion in paragraph (b) (iii) of Annex II is met.

113. 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;*

114. The Canadian final regulatory action prohibits the manufacture, use, sale, offer for sale or import of PBDEs, including decabromodiphenyl ether, and all products that contain PBDEs, except for manufactured items. The final regulatory action provides for a limited number of exemptions.

115. The Canadian notification indicates this is a ban, and no uses are shown as remaining allowed. The notification also outlines that PBDEs were previously regulated under the Polybrominated Diphenyl Ethers Regulations 2008 which were the subject of two previous notifications of final regulatory action in 2010. These regulations were repealed and replaced by the Prohibition of Certain Toxic Substances Regulations 2012, as amended in 2016. The regulatory controls on PBDEs that already existed were maintained and were expanded by the regulatory amendments to cover all PBDEs, including decabromodiphenyl ether, and products containing them, except for manufactured items.

116. 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 PBDEs, including decabromodiphenyl ether, and certain products containing PBDEs.

117. As a result of the final regulatory action under the Prohibition of Certain Toxic Substances Regulations 2012, as amended in 2016, together with the earlier Polybrominated Diphenyl Ethers Regulations 2008, the number of uses in Canada was significantly reduced.

118. 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;*

119. Since the final regulatory action is intended to protect the Canadian environment from risks associated with PBDEs, including decabromodiphenyl ether, by prohibiting the manufacture, use, sale, offer for sale, or import, it would be expected that the final regulatory action would result in a significant reduction in risks to the environment in Canada. The information that no PBDEs have been manufactured in Canada after 2000, and that less than 0.1 tonne of decabromodiphenyl ether has been imported and used since 2006, would indicate the effectiveness of the Canadian regulatory action.

120. The Committee therefore 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;*

121. It is noted that the Parties to the Stockholm Convention have agreed on the listing of decabromodiphenyl ether in Annex A with specific exemptions for production and use (UNEP/FAO/RC/CRC.15/5, sect. 2.5.2 of the Canadian notification). Substances listed in Annex A to the Stockholm Convention are targeted for global elimination through prohibition of manufacture, import and use. As a persistent organic pollutant, decabromodiphenyl ether 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.

122. 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;*

123. Decabromodiphenyl ether was listed in Annex A to the Stockholm Convention in 2017 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 decabromodiphenyl ether continues, and ongoing trade can be expected, although it should now be very much reduced.

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

125. 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.*

126. There is no indication in the notification or the supporting documentation that concerns about the intentional misuse prompted the regulatory action.

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

**(f) Conclusion**

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

## **IV. Conclusion**

129. The Committee concludes that the notifications of final regulatory action submitted by Japan, Norway and Canada meet all the criteria set out in Annex II to the Convention.

130. The Committee also concludes that the final regulatory action taken by Japan, Norway and Canada provide a sufficient basis for including decabromodiphenyl ether (CAS No. 1163-19-5) in Annex III to the Convention in the industrial category and that a decision guidance document should be drafted on the basis of the notifications.