

Rationale for the recommendation by the Chemical Review Committee to list hexabromodiphenyl ether (hexaBDE)) (CAS No. 36483-60-0, CAS No. 68631-49-2, CAS No. 207122-15-4); heptabromodiphenyl ether (heptaBDE)) (CAS No. 68928-80-3, CAS No. 446255-22-7, CAS No. 207122-16-5); octabromodiphenyl ether (octaBDE)) (CAS No. 32536-52-0); nonabromodiphenyl ether (nonaBDE)) (CAS No. 63936-56-1); and decabromodiphenyl ether (decaBDE)) (CAS No. 1163-19-5)) contained in commercial mixtures of OctaBDE in Annex III to the Rotterdam Convention

Introduction

In reviewing the notifications of final regulatory action by Canada, the European Community and Norway to ban (Canada and Norway) and to severely restrict (European Community) the use of commercial mixtures of octaBDE congeners as industrial chemicals, together with the supporting documentation provided by those parties, the Committee confirmed that those actions had been taken to protect the environment and human health. The notifications from those parties were found to meet the information requirements of Annex I and the criteria set forth in Annex II to the Rotterdam Convention.

The notification and supporting documentation were made available to the Committee for its consideration in documents UNEP/FAO/RC/CRC.7/10 and Add.1–4, UNEP/FAO/RC/CRC.7/13, UNEP/FAO/RC/CRC.7/14, UNEP/FAO/RC/CRC.7/INF/3, UNEP/FAO/RC/CRC.7/INF/4 and UNEP/FAO/RC/CRC.7/INF/11.

Canada

1. Scope of the notified regulatory action

The final regulatory action was taken for the category “industrial chemicals” to protect the environment. The decision made was to ban the uses of octaBDE commercial mixtures in Canada (UNEP/FAO/RC/CRC.7/10 and Add.1) as flame retardants that slow down the ignition and spread of fire.

2. Criterion Annex II (a)

Confirm that the final regulatory action has been taken in order to protect human health or the environment

The notification sets out the final regulatory action, which is a ban to protect the environment, and was based on a risk evaluation. Polybrominated diphenyl ethers are a group of chemical flame retardants that slow the ignition and spread of fire. In general, plastics are the primary end use for flame retardants due to the inherent flammability of many polymers. As such, octaBDE commercial mixtures can be found in many items such as building and automobile materials, carpet underlay, furniture foam and electronic equipment.

OctaBDE commercial mixtures were predominantly used in Canada in acrylonitrile butadiene styrene to provide flame retardance for business-equipment housings (UNEP/FAO/RC/CRC.7/10).

3. Criteria Annex II (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;*

Data relevant to the ecological screening assessment of octaBDE commercial mixtures were identified by the Canadian Environment Protection Act (CEPA) 1999, in peer-reviewed literature and commercial and government databases and indices. An

industry survey on octaBDE commercial mixtures was conducted for the year 2000 through a Canada Gazette notice issued pursuant to section 71 of CEPA 1999. This survey collected data on the Canadian manufacture, import, uses and releases of octaBDE commercial mixtures (Environment Canada 2003). Toxicological studies were also submitted by industry under section 70 of CEPA 1999 (section 2.4.2.2). Linkages with Stockholm Convention assessments are also made in the notification (UNEP/FAO/RC/CRC.7/10).

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

Canada undertook an ecological screening assessment and examined supporting information and developed conclusions on the risks of octaBDE commercial mixtures in the environment based on a weight-of-evidence approach as required under section 76.1 of CEPA 1999 (section 2.4.2.2 of the notification). The Canadian notification also includes evidence of information on octaBDE commercial mixtures from scientifically published documents (UNEP/FAO/RC/CRC.7/10).

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

The risk evaluation took into account exposure based on measured total (dissolved and particulate phases) octaBDE commercial mixtures mono- to hepta-BDE congeners in concentrations of approximately 6 pg/L in Lake Ontario and 158 pg/L in Lake Michigan waters (section 3.2.3 of the notification) to warrant virtual elimination from the environment in Canada. OctaBDE commercial mixtures have been detected in sediment and soil samples collected in North America, and high concentrations have been measured in sewage sludge. A study carried out in 2004 determined levels of octaBDE commercial mixtures in sediments from Lake Ontario. The total octaBDE commercial mixtures measured in sediment samples taken from 14 tributary sites ranged from approximately 12 to 430 µg/kg dw (section 3.2.3 of the notification).

The risk evaluation took into account these exposure data and the ecotoxicological endpoints for octaBDE commercial mixtures and the result was an unacceptable risk to aquatic organisms such as fish, molluscs and other invertebrates.

The assessment by the Canadian authorities in relation to the environment carried out in the context of the prevailing conditions in Canada resulted in the conclusion that octaBDE commercial mixtures were entering the environment in quantities or concentrations or under conditions that had or might have an immediate or long-term harmful effect on the environment or its biological diversity. The screening assessment also concluded that their presence in the environment resulted primarily from human activity (i.e., releases from product manufacturing and processing, and throughout the product life cycle). As a result, congeners of octaBDE commercial mixtures meet the conditions for virtual elimination, as set out in subsection 77(3) of CEPA 1999 (section 2.4.2.2 of the notification).

4. Criteria Annex II (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;*

The final regulatory action prohibited the manufacture, use, sale, offer for sale or importation of octaBDE commercial mixtures as flame retardants, which was the main use of octaBDE commercial mixtures. It therefore led to a significant decrease in the quantity of octaBDE commercial mixtures in use. The final regulatory action does not apply to any octaBDE commercial mixture that is present as a contaminant in a chemical feedstock used in a process from which it is not released, provided that the octaBDE commercial mixture is destroyed or completely converted in that process to a substance that is not an octaBDE commercial mixture (UNEP/FAO/RC/CRC.7/10).

- (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;*

Since the regulatory action is a ban, the source of octaBDE commercial mixtures to the environment will be removed, which will lead to a significant reduction of risk to the environment. Although persistence in the environment at some locations will cause elevated levels to be maintained for some time, removing this source of input will allow the gradual elimination of octaBDE commercial mixtures from the environment (UNEP/FAO/RC/CRC.7/10).

- (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;*

OctaBDE commercial mixtures could pose a risk to the environment wherever octaBDE commercial mixtures are used, particularly in developing countries, meaning that the relevance of the final regulatory action is not limited to Canada.

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

Evidence of ongoing international trade was made available to the Committee through the notifications, which show various quantities of octaBDE commercial mixtures being produced, imported, or used (in the case of the submission of the European Community) for various years. The focused summary provided by Norway also gives useful information on export, import and uses of this chemical in Norway.

5. Criterion Annex II (d)

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

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

European Community

1. Scope of the notified regulatory action

The notified regulatory action relates to octaBDE commercial mixtures and their industrial use as a flame retardant that slows the ignition and spread of fire. The decision made was to severely restrict the use of octaBDE commercial mixtures in the European Community to protect human health and the environment (UNEP/FAO/RC/CRC.7/10 and UNEP/FAO/RC/CRC.7/10/Add.2).

2. Criterion Annex II (a)

Confirm that the final regulatory action has been taken in order to protect human health or the environment.

The notification sets out the basis for the final regulatory action, which severely restricts the use of octaBDE commercial mixtures to protect human health and the environment and states that it was based on a risk or hazard evaluation (UNEP/FAO/RC/CRC.7/10).

OctaBDE commercial mixtures are used in the Community as flame retardants. These flame retardants are added to plastics and textiles to reduce flammability and improve fire safety. Further information provided by industry indicates that octaBDE commercial mixtures are primarily used in Europe in acrylonitrile-butadiene-styrene (ABS) polymers at 12–18 per cent weight loadings in the final product.

Other uses that have been reported for octaBDE commercial mixtures include nylon and low-density polyethylene, polycarbonate, phenol-formaldehyde resins and unsaturated polyethers and in adhesives and coatings (UNEP/FAO/RC/CRC.7/10).

3. Criteria Annex II (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;*

The evaluation was based on the review of scientific data generated for octaBDE commercial mixtures in the context of the conditions prevailing in the European Community (including current practices related to the life cycle of the substance) (UNEP/FAO/RC/CRC.7/10).

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

The documentation provided was evaluated and only data that were generated according to scientifically recognized methods were validated and used for the assessment. Data reviews were performed and documented according to generally recognized scientific principles and procedures (UNEP/FAO/RC/CRC.7/10).

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

A risk assessment was conducted covering emissions and consequent environmental impact and human exposures at each stage of the life cycle of the chemical, from production through processing, formulation and use to recycling and disposal. Protection goals for the environment included the atmosphere, aquatic organisms, sediment-dwelling organisms, soil-dwelling organisms, microorganisms in waste water treatment plants, and mammals and birds exposed via accumulation through the food chain. The exposure of humans from all relevant sources was considered, including exposures from consumer products, through air, food and drinking water and exposure at the workplace (UNEP/FAO/RC/CRC.7/10).

Two member States were designated to undertake the evaluation. The results were then subject to peer review during which the European Commission consulted experts in member States and obtained the opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment, an independent expert body.

It was concluded that there were unacceptable risks to human health and the environment that necessitated regulatory action (UNEP/FAO/RC/CRC.7/10).

Information on evaluations regarding human exposure, worker health, breast and cow milk contamination, in addition to risks related to the environment and the resulting danger of secondary poisoning, particularly through earthworms, was provided (UNEP/FAO/RC/CRC.7/10). Of particular concern was secondary poisoning as a result of the hexaBDE component in octaBDE commercial mixtures (via earthworms) from use in polymer applications. A combination of uncertainties, particularly linked to the risk assessment approach at the time for secondary poisoning and debromination, warranted regulatory action (UNEP/FAO/RC/CRC.7/10).

4. Criteria Annex II (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;*

The final regulatory action prohibited the placing on the market and use of octaBDE commercial mixtures in concentrations higher than 0.1 per cent by mass (UNEP/FAO/RC/CRC.7/10). It will therefore lead to a significant decrease in the quantity of the chemical in use.

- (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;*

It is expected that, since the regulatory action has restricted the source of octaBDE commercial mixtures to the environment, it will lead to a significant reduction of risk to human health and the environment from exposure to octaBDE commercial mixtures (UNEP/FAO/RC/CRC.7/10).

- (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;*

Similar health and environmental concerns could arise in other countries where the substance is used, particularly developing countries (UNEP/FAO/RC/CRC.7/10).

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

Evidence of ongoing international trade was made available to the Committee through the notifications, which show various quantities of octaBDE commercial mixtures being produced, imported, or used in various years (UNEP/FAO/RC/CRC.7/10). The focused summary provided by Norway also gives useful information on export, import and uses of this chemical in Norway.

5. Criterion Annex II (d)

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

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

Norway

1. Scope of the notified regulatory action

The notified regulatory action relates to octaBDE commercial mixtures and the industrial use of the chemical as flame retardant in polymers (ABS), high-impact polystyrene (HIPS) and in electrical and electronic equipment. The decision made was to ban the uses of octaBDE commercial mixtures in Norway (UNEP/FAO/RC/CRC.7/10 and Add.4).

2. Criterion Annex II (a)

Confirm that the final regulatory action has been taken in order to protect human health or the environment.

The notification sets out the basis for the final regulatory action, which is a ban on octaBDE commercial mixtures to protect human health and the environment, and states that it was based on a risk or hazard evaluation (UNEP/FAO/RC/CRC.7/10).

OctaBDE commercial mixtures were used in Norway as flame retardants in polymers (ABS), high-impact polystyrene (HIPS) and in electrical and electronic equipment (UNEP/FAO/RC/CRC.7/10).

3. Criteria Annex II (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;*

Norway made use of the European Union risk assessment report, in which data were generated according to scientifically recognized methods (UNEP/FAO/RC/CRC.7/10).

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

In a Norwegian study, investigation of 66 hobby fisherfolk showed clear associations between the concentrations of octaBDE commercial mixtures (BDE-153, BDE-154, BDE-138 and BDE-183) in serum and the subjects' age and intake of freshwater fish (UNEP/FAO/RC/CRC.7/10). The notification (section 2.4.2.2) further states that reviewed temporal trends of octaBDE commercial mixtures in eggs from three bird species, three locations and three sampling times (from 1983 to 2003) from northern Norway indicated that spatial differences were only observed for hexaBDE (BDE-153), and increases in the measured concentration from 1983 to 2003 were observed for hexaBDE (153 and 154) and heptaBDE (BDE-183). A detailed review conducted concluded that hexaBDE had much higher bioconcentration potential than the other components of octaBDE commercial mixtures and so was likely to have a higher potential to have adverse effects on organisms in the environment (UNEP/FAO/RC/CRC.7/10).

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

The notification states that research was carried out in Norway to determine human and environmental exposure to octaBDE commercial mixtures. Certain components of octaBDE commercial mixtures have been found in samples from the Norwegian population, and congeners of octaBDE have also been found in polar cod, ringed seals and mussels (UNEP/FAO/RC/CRC.7/10). The notification and the supporting documentation conclude that the final regulatory action was taken to protect human health and the environment and aims to reduce the risks identified based on assessments linked to local exposure (UNEP/FAO/RC/CRC.7/10).

In Norway, congeners of octaBDE commercial mixtures have been found in a variety of samples. They have been detected in human samples (section 2.4.2.1 of the notification) and in polar cod, ringed seals and mussels. In a study from Svalbard, congeners of octaBDE commercial mixtures were found to bioaccumulate in zooplankton, polar cod and ringed seals. Evidence was also found in the study that hexaBDE (BDE-153) biomagnified in the Arctic food chain (ringed seal to polar bear).

OctaBDE commercial mixtures are classified as "toxic" as a result of their effects on human health, with the risk phrases "may cause harm to unborn child", and "possible risk of impaired fertility". Studies and assessments provide evidence that octaBDE commercial mixtures may cause adverse effects, such as effects on reproductive organs and development. The effects of repeated exposure to octaBDE commercial mixtures consistently indicate that the liver is the key target organ, and liver effects have been observed in animal studies. It is assumed that in humans components of octaBDE commercial mixtures bioaccumulate in adipose tissue.

The notification states that the final regulatory action was based on a risk or hazard evaluation. According to data from the notification, congeners of octaBDE commercial mixtures resist degradation and thus have the potential to persist in the environment for a long time. These congeners have the potential to bioaccumulate and there is monitoring evidence of biomagnification. OctaBDE commercial mixtures have shown potential for long-range environmental transport. The analysis of chemical properties of octaBDE commercial mixtures appears to support this conclusion, as the Henry's law constant for these chemicals is very similar to those of acknowledged persistent organic pollutants. It is therefore expected that octaBDE commercial mixtures are subject to long-range environmental transport.

The notification also states that available monitoring data indicate that some heptaBDEs, in addition to hexaBDEs, have recently been found in organisms in the environment. This shows that uptake of some of the main components of the octaBDE commercial mixtures is occurring in the environment.

4. Criteria Annex II (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;*

The final regulatory action is a ban (UNEP/FAO/RC/CRC.7/10), and therefore has led to a significant decrease in the quantity of the chemical in use.

- (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;*

It is expected that, since the regulatory action is a ban, the source of octaBDE commercial mixtures to the environment will be removed, leading to a significant reduction of risk to human health and the environment (UNEP/FAO/RC/CRC.7/10).

- (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;*

Similar concerns to those identified are likely to be encountered in other countries where the substance is used (UNEP/FAO/RC/CRC.7/10).

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

Evidence of ongoing international trade was made available to the Committee through the notifications, which show various quantities of octaBDE commercial mixtures being produced, imported, or used (in the case of the submission by the European Community) for various years. The focused summary provided by Norway also gives useful information on export, import and uses of octaBDE in Norway.

5. Criterion Annex II (d)

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

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

Recommendations

The Committee concluded that the notifications of final regulatory action by Canada, the European Community and Norway met the information requirements of Annex I and the criteria set out in Annex II to the Rotterdam Convention. The Committee also concluded that the final regulatory actions taken by Canada, the European Community and Norway provided a sufficient basis to merit including octaBDE commercial mixtures in Annex III to the Rotterdam Convention in the industrial chemicals category and that a decision guidance document should be drafted on the basis of the notifications.