Rationale for the recommendation by the Chemical Review Committee to list tetrabromodiphenyl ether (tetraBDE) (CAS No. 40088-47-9, CAS No. 5436-43-1) and pentabromodiphenyl ether (pentaBDE) (CAS No. 32534-81-9, CAS No. 60348-60-9) as contained in pentabromodiphenyl ether commercial mixtures 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 and/or severely restrict pentabromodiphenyl ether commercial mixtures as industrial chemicals, together with the supporting documentation provided by those parties, the Committee was able to confirm 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.7/8/Add.1–4 and UNEP/FAO/RC/CRC.7/INF/3.

Canada

1. Scope of the notified regulatory action

The notified regulatory action relates to pentabromodiphenyl ether commercial mixtures (pentaBDE) and their industrial use as flame retardants. The notification from Canada states that pentaBDE is predominantly a mixture of tetrabromodiphenyl ether (tetraBDE), pentabromodiphenyl ether (pentaBDE) and hexabromodiphenyl ether (hexaBDE) congeners. The final regulatory action by Canada for polybrominated diphenyl ethers (PBDE) covers pentaBDE.

The decision made was to ban the use, manufacture, sale, offer for sale and import of PBDE congeners that met the criteria for virtual elimination under the Canadian Environmental Protection Act 1999 (CEPA 1999). The decision does not apply to PBDE in pest control products, or to polymers, resins or other mixtures containing PBDE congeners for use in a laboratory for analysis, in scientific research or as laboratory analytical standards or those present as contaminants (Polybrominated Diphenyl Ethers Regulations (SOR/2008-218) under CEPA 1999.

The notification included the properties, identification and uses of PBDE mixtures and the social and economic effects of the final regulatory action. The final regulatory action was taken to protect the environment, based on a risk evaluation by Environment Canada (Ecological Screening Assessment Report on Polybrominated Diphenyl Ethers, as required under CEPA 1999). The notification was found to comply with the information requirements of Annex I.

2. Criterion Annex II (a)

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

The regulatory action was taken to protect the environment. Pentabromodiphenyl ether commercial mixtures have been used as flame retardants that slow the ignition and spread of fire of plastics, which are the primary end use for flame retardants as a result of the inherent flammability of many polymers. As such, PBDEs can be found in many items, including building and automobile materials, carpet underlay, furniture polyurethane foam and electronic equipment, and are released to the environment during the product's manufacture (UNEP/FAO/RC/CRC.7/8 and Add.1).

Environment Canada, under CEPA 1999, proceeded to implement a hazard and risk assessment on PBDEs. The result was published in June 2006 in the Ecological

Screening Assessment Report, in which it was concluded that PBDEs were entering the environment in concentrations or under conditions that had or might have an immediate or long-term harmful effect on the environment or its biological diversity. Environment Canada's Ecological Screening Assessment Report indicated that the greatest potential risks from PBDEs in the Canadian environment were the secondary poisoning of wildlife from the consumption of prey containing elevated concentrations of PBDEs and effects on benthic organisms, which might result from elevated concentrations of certain PBDE congeners in sediments (UNEP/FAO/RC/CRC.7/8 and Add.1).

The notification describes the specific risks and outlines that the ban on the use of PBDEs significantly reduces the exposure of aquatic organisms and wildlife: therefore, the final regulatory action constitutes a preventative approach to ensure that pentabromodiphenyl ether mixtures are not reintroduced in Canada.

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;

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

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

Data relevant to the ecological screening assessment of PBDEs were identified in original literature, review documents and commercial and government databases and indices. In addition to retrieving the references from a literature database search, contacts were made with researchers, academics, industry and other government agencies to obtain relevant information on PBDEs (UNEP/FAO/RC/CRC.7/8 and Add.1).

The Canadian regulations on PBDE assure the quality of data gathered based on the use of an accredited laboratory under the International Organization for Standardization (standard ISO/IEC 17025: 2005), with all data acquired under these conditions generated according to scientifically recognized methods. The notification stated that the ecological screening assessment examined various supporting information that presented the most critical studies and lines of evidence supporting the conclusions.

The data and the assessment of the ecological screening assessment report were generated according to scientifically recognized methods, and the data reviews, as reflected in the reports, were performed according to generally recognized scientific principles and procedures.

The final regulatory action was taken as a consequence of a risk evaluation. This evaluation was based on screening assessments of substances that present or may present a risk to the environment or to human health and examined supporting information and developed conclusions based on a weight-of-evidence approach as required under section 76.1 of CEPA 1999.

The final regulatory action was based on the ecological screening assessment in Canada. The notification indicates that seven PBDEs were identified in a screening assessment under CEPA 1999 on the basis of their potential persistence and/or bioaccumulation in the environment and inherent toxicity to organisms. In addition, an industry survey on PBDEs was conducted in 2000 under CEPA 1999. The industry survey collected data on the Canadian manufacture, import, uses and releases of PBDEs (Environment Canada 2003) and also provided toxicological studies under section 70 of CEPA 1999.

In Environment Canada's Ecological Screening Assessment Report, risk quotients were used to identify potential for ecological effects and potential risks, such as persistence, bioaccumulation, chemical transformation and trends in ambient concentrations. The report indicates that the greatest potential risks from PBDEs, including tetra-BDE and penta-BDE, in the Canadian environment are the secondary poisoning of wildlife from the consumption of prey containing elevated concentrations of tetra-BDE and penta-BDE and the deleterious effects on benthic organisms, which may result from elevated concentrations of certain congeners in sediments that meet the criteria for persistence and bioaccumulation. The screening assessment also concluded that their presence in the environment was primarily the result of human activity (that is, releases from product manufacturing and processing, throughout the product life cycle).

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;

All uses as industrial chemicals are banned, as stated in document UNEP/FAO/RC/CRC.7/8 and Add.1. The regulatory action covers the manufacture, use, sale, offer for sale and import of PBDEs. This is expected to result in a significant reduction of the quantity of chemical used and the number of its uses.

(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;

The significant reduction of the quantity of chemical used is expected to cause an actual reduction of the risk to the environment, especially wildlife and benthic organisms.

(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;

The considerations that led to the regulatory action are generally expected to be applicable to other countries and regions.

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

There is ongoing international trade in the chemical (UNEP/FAO/RC/CRC.7/INF/3) and the chemical is subject to transboundary movement (UNEP/FAO/RC/CRC.7/8 and Add.1).

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 was no indication in the notification that concern about intentional misuse was the reason for the regulatory action. It is clearly stated that concern about environmental exposure such as deleterious effects on benthic organisms was the main reason for the final regulatory action.

European Community

1. Scope of the notified regulatory action

The notification from the European Community states that pentabromodiphenyl ether commercial mixture (pentaBDE) is predominantly a mixture of

tetrabromodiphenyl ether (tetraBDE), pentabromodiphenyl ether (pentaBDE) and hexabromodiphenyl ether (hexaBDE) congeners. PentaBDE was used in the European Community as a flame retardant additive for polyurethane (principally flexible foam for use in car seats, furniture and packaging) at typical loading of 10 per cent w/w. Several other uses have been reported in the literature (e.g., in textiles and electronics) but it is not known whether these currently occur in the European Community. The decision was to severely restrict previous uses and to prohibit all applications of pentaBDE as a substance and articles containing the substance in concentrations higher than 0.1 per cent by mass. The European Community member States were to apply the laws, regulations and administrative provisions necessary to comply with the Directive from 15 August 2004. Concentrations lower than 0.1 per cent remain allowed thereafter (UNEP/FAO/RC/CRC.7/8 and Add.2). The notification was found to comply with the information requirements of Annex I.

2. Criterion Annex II (a)

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

The regulatory action was taken to protect both human health and the environment as indicated in UNEP/FAO/RC/CRC.7/8 and Add.2. PentaBDE has been used as a flame retardant additive. The decision was based on a risk assessment 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 wastewater treatment plants, and mammals and birds exposed via accumulation through the food chain. Exposure of humans from all relevant sources was considered, including exposure from consumer products, through air, food and drinking water (humans exposed via environment) and exposure at the workplace. It was concluded that, although available data were insufficient in some respects, there were unacceptable risks to human health and the environment that necessitated regulatory action. The risks to workers were that the estimated body burden of pentaBDE arising from occupational exposure, mainly via dermal contact, was approximately four times greater than the no observable adverse effect level derived from the rodent study (liver effects). Unacceptable risks to humans were identified, including humans exposed through the environment and infants exposed through breast milk. Concerns for the aquatic and terrestrial environment were also identified from the production and/or use of polyurethane foams. This information is provided in UNEP/FAO/RC/CRC.7/8 and Add.2.

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;

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

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

The final regulatory action was taken as a consequence of a risk evaluation performed by one member State of the European Community, in the framework of Regulation (EEC) No 793/93. The evaluation was based on the review of scientific data generated for pentaBDE derivatives in the context of the conditions prevailing in the European Community (including current practices related to the life cycle of the substance). The results were then subject to peer review within the European Community by experts from member States and the opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment, an independent expert body,

was obtained. Data reviews were performed and documented according to scientifically recognized principles and procedures (UNEP/FAO/RC/CRC.7/8 and Add.2).

The notification from the European Community (UNEP/FAO/RC/CRC.7/8 and Add.2) indicated that the final regulatory action was based on a risk evaluation under conditions prevailing in the European Community.

Based on this evaluation, concerns were identified with regard to unacceptable risks to human health and the environment that necessitated regulatory action. The risks to workers were that the estimated body burden of pentaBDE arising from occupational exposure, mainly via dermal contact, was approximately four times greater than the no observable adverse effect level derived from the rodent study (liver effects). Other unacceptable risks were identified, including risks for humans exposed through the environment and infants exposed through breast milk. Concerns for the aquatic and terrestrial environment were also identified from production and/or use of polyurethane foams.

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;

PentaBDE has been used in the European Community as a flame retardant additive for polyurethane (principally flexible foam for use in car seats, furniture and packaging) at typical loading of 10 per cent w/w. The decision prohibited all applications of pentaBDE where concentrations exceeded 0.1 per cent by mass, from 15 August 2004. Concentrations lower than 0.1 per cent remained allowed thereafter. Since the use of the chemical was severely restricted it can be assumed that this regulatory action will result in a significant reduction of quantities of the chemical and the number of its uses.

(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;

The chemical was severely restricted, which will result in a significant reduction of risk to human health and the environment from exposure to pentaBDE at the local and regional levels within the European Community.

(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 in which the substance is used, particularly in developing countries.

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

Evidence of ongoing international trade was made available to the Committee in document UNEP/FAO/RC/CRC.7/INF/3.

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 was no indication in the notification that concern about intentional misuse was the reason for the regulatory action. It is clearly stated that concern about risks to workers from occupational exposure, in addition to the aquatic and terrestrial environment, were identified in connection with the production and/or use of polyurethane foams and were the main reasons for the final regulatory action.

Norway

1. Scope of the notified regulatory action

The final regulatory action relates to pentabromodiphenyl ether (pentaBDE) commercial mixtures and their industrial use. Pentabromodiphenyl ether commercial mixtures have been used in Norway as a flame retardant in electrical and electronic equipment, polyurethane foam, textiles and means of transportation. The final regulatory action bans all uses of these chemicals at concentrations equal to or greater than 0.1 per cent by weight (UNEP/FAO/RC/CRC.7/8 and Add.4). The notification was found to comply with the information requirements of Annex I.

2. Criterion Annex II (a)

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

The regulatory action was taken to protect both human health and the environment, as indicated in UNEP/FAO/RC/CRC.7/8 and Add.4. Norway's risk evaluation of pentaBDE was based on risk assessments undertaken by the European Community and a report by the Nordic Council of Ministers (UNEP/FAO/RC/CRC.7/8 and Add.4), in addition to scientific data that were considered particularly relevant to Norwegian conditions, as given in documents UNEP/FAO/RC/CRC.7/8 and Add.4. The national evaluation took into account production, use, environmental fate and behaviour, exposure and toxicity to humans and wildlife. Social and economic factors were also considered. All data evaluated indicated that pentaBDE was an important contaminant of the Norwegian environment and of sufficient concern for human health and wildlife to warrant a national ban.

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;

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

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

The evaluation was based on the review of scientific data generated for pentaBDE in the context of the conditions prevailing in Norway. The national evaluation took into account production, use, environmental fate and behaviour, exposure and toxicity to humans and wildlife. Data reviews were performed and documented according to generally recognized scientific principles and procedures.

The notification from Norway indicated that the final regulatory action was based on a risk evaluation under conditions prevailing in Norway.

In Norway, congeners of pentaBDE have been detected in a variety of biotic samples. They have been detected in, for example, human samples and in cod liver and mussels. High levels of pentaBDEs were detected in fish from the Norwegian lake Mjøsa. Further studies detected significant amounts of pentaBDEs in sediments and fish at various locations in Norway.

Based on this evaluation, there are concerns for serious damage to human health from prolonged exposure and concerns for breastfed babies. PentaBDE was found in most compartments of the Norwegian environment, mainly in fish, which is regarded as an important source of exposure to humans in Norway. This was considered alarming, especially for populations that depend on fish for their diet (e.g., indigenous people).

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;

PentaBDE has been used in Norway as a flame retardant in electrical and electronic equipment, polyurethane foam, textiles and means of transportation. The final regulatory action bans all uses of pentaBDE at concentrations equal to or greater than 0.1 per cent by weight. This will cause a significant decrease in the quantity of the chemical used or the number of its uses.

(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;

The banning of the chemical will result in a significant reduction of risk to human health and the environment.

(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;

The notification gave no indication of any geographical limitations to the final regulatory action. Similar concerns to those identified are likely to be encountered in other countries where the substance is used.

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

Since concentrations lower than 0.1 per cent remain allowed, this can be considered as evidence of ongoing international trade.

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 was no indication in the notification that concern about intentional misuse was the reason for the final regulatory action. Instead, concerns for human health and wildlife are mentioned as the main reasons for the 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 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 pentaBDE commercial mixtures in Annex III to the Rotterdam Convention in the industrial chemical category, and that a decision guidance document should be drafted on the basis of the notifications.