Rationale for the recommendation by the Chemical Review Committee to list Perfluorooctanesulphonic acid (PFOS) (CAS No. 1763-23-1), PFOS potassium salt (CAS No. 2795-39-3), PFOS ammonium salt (CAS No. 29081-56-9), PFOS lithium salt (CAS No. 29457-72-5), PFOS diethanolamine salt (CAS No. 70225-14-8), Perfluorooctane sulfonyl fluoride (PFOSF or POSF) (CAS No. 307-35-7) in Annex III to the Rotterdam Convention

In reviewing the notifications of final regulatory action by Canada, the European Union and Japan to ban perfluorooctane sulfonate (PFOS), its salts and precursor (CAS No 1763-23-1 (acid), 29081-56-9 (ammonium salt), 70225-14-8 (diethanolamine (DEA) salt), 2795-39-3 (potassium salt), 29457-72-5 (lithium salt), 307-35-7 (perfluorooctane sulfonyl fluoride or PFOSF)) 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.7/7 and Add.1–3, UNEP/FAO/RC/CRC.7/INF/3 and UNEP/FAO/RC/CRC.7/INF/8.

Canada

1. Scope of the notified regulatory action

The final regulatory action was taken for PFOS and its salts and precursors in the category industrial chemicals to protect the environment. The manufacture, use, sale, offer for sale or import of PFOS, its salts and its precursor are prohibited with a limited number of exemptions (UNEP/FAO/RC/CRC.7/7).

The principal applications of PFOS and its salts and precursor before the regulatory action were as water, oil, soil and grease repellents for use on surface and paper-based applications such as rugs and carpets, fabric and upholstery and food packaging. PFOS, its salts and its precursor also had specialized chemical applications, for example as firefighting foams, hydraulic fluids, carpet spot removers, mining and oil well surfactants, fume suppressant and other specialized chemical formulations (UNEP/FAO/RC/CRC.7/7).

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. It was based on a risk evaluation taking into account ecological and environmental behaviour. PFOS has been detected in fish and in Canadian wildlife located far from known sources or manufacturing facilities, indicating that PFOS may undergo long-range transport. Unlike many other persistent organic pollutants, some perfluorinated substances, such as PFOS, are present as ions in environmental media and partition preferentially to proteins in the liver and blood rather than to lipids. Therefore, the bioaccumulation potential of PFOS may not be related to the typical mechanisms associated with bioaccumulation in lipid-rich tissues (UNEP/FAO/RC/CRC.7/7).

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 stated data upon which the hazard identification and risk assessment were based were generated according to recognized testing methods or taken from peer-reviewed literature (Canadian Environmental Protection Act, 1999 (CEPA 1999)).

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

The physicochemical data are published in scientific peer-reviewed literature, which shows that they are based on scientifically recognized testing methods. The environmental risk evaluation has been carried out by Canadian authorities according to recognized scientific principles and procedures (UNEP/FAO/RC/CRC.7/7).

(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 the conditions prevailing in Canada since it was based on both hazard and exposure data collected in Canada on a variety of aquatic and terrestrial species, including aquatic plants, invertebrates and vertebrates and terrestrial invertebrates, birds and mammals (UNEP/FAO/RC/CRC.7/7).

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 regulatory action severely restricts the use of PFOS and its salts and precursors in Canada. It is estimated that the regulatory action would substantially reduce the release of PFOS into the environment (UNEP/FAO/RC/CRC.7/7 and UNEP/FAO/RC/CRC.7/INF/8).

(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 notification outlines that the prohibition on the manufacture, use, sale and import of PFOS and its salts and precursors works towards the objective of virtual elimination of the substance. Therefore the prohibition is expected significantly to reduce exposure, which will result in a reduction of risk for Canada's environment (UNEP/FAO/RC/CRC.7/7 and UNEP/FAO/RC/CRC.7/INF/8).

(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 final regulatory action are applicable to other countries and regions and are not limited to specific circumstances, in particular since PFOS is a persistent organic pollutant and represents a risk to the environment worldwide.

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

Canada reported that the whole quantity used in 2006 had been imported. This indicates that there is still international trade (UNEP/FAO/RC/CRC.7/7).

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.

The notification does not mention any involvement of intentional misuse in the regulatory decision-making process (UNEP/FAO/RC/CRC.7/7).

European Union

1. Scope of the notified regulatory action

The major use of PFOS and its salts in consumer applications was to provide grease, oil and water resistance to materials such as carpets, leather/apparel, textiles/upholstery, paper and packaging and coatings, and in industrial and household cleaning products.

Industrial/professional use of PFOS in smaller volumes, which is continuing after the regulatory action, has been confirmed in the following sectors in the European Union: metal (chromium) plating, firefighting foams, photographic industry, semiconductor industry and aviation industry (UNEP/FAO/RC/CRC.7/7).

The use of perfluorooctonate sulfonates has been severely restricted by the regulatory action taken in the European Union. The placing on the market and the use of PFOS as a substance or in mixtures in concentrations equal to or higher than 0.005 per cent by weight is prohibited. Furthermore, PFOS may not be placed on the market in semi-finished products or articles, or parts thereof, if the concentration of PFOS is equal to or higher than 0.1 per cent by weight. Firefighting foams placed on the market before 27 December 2006 are also allowed, until 27 June 2011, in order to limit emissions to those of existing stocks (UNEP/FAO/RC/CRC.7/7).

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 human health and the environment. The toxicity associated with oral route exposure was confirmed, as was the high persistency of PFOS. It bioconcentrates in fish and it has been detected in tissue of wild birds and fish, in surface water and sediment, wastewater treatment plant effluent, sewage sludge and landfill leachate. (UNEP/FAO/RC/CRC.7/7).

Data on the exposure revealed that levels of PFOS in the blood serum of workers were significantly higher than in the serum of the general population. In addition, levels of PFOS in the blood serum of populations living in the neighbourhood of industrial plants were found to be higher compared to the general population (UNEP/FAO/RC/CRC.7/7).

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 stated data upon which the hazard identification and risk assessment were based originate from recognized testing methods, peer-reviewed literature and peer-reviewed scientific reports (UNEP/FAO/RC/CRC.7/7/Add.2).

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

The data were reviewed in scientific reports and by scientific committees according to recognized scientific principles and procedures (UNEP/FAO/RC/CRC.7/7/Add.2).

(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 based on an evaluation of the risks arising from the use of PFOS in the European Union. Data on the exposure of workers and of

the general population were considered. In addition, levels of PFOS in the blood serum of populations living in the neighbourhood of industrial plants were compared with data from the general population. Furthermore, risks to fish, mammals, birds and bees were considered under the prevailing conditions in the European Union (UNEP/FAO/RC/CRC.7/7).

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 use of PFOS has been severely restricted in the European Union and it is therefore expected that the quantity used will significantly decrease (UNEP/FAO/RC/CRC.7/7).

(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;

As a result of the expected reduction of the quantity of PFOS used in the European Union it is expected that exposure of humans and the environment will decrease, which will lead to a significant reduction of risk for human health and the environment (UNEP/FAO/RC/CRC.7/7).

(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 final regulatory action are not limited to a geographical area or to specific circumstances (UNEP/FAO/RC/CRC.7/7).

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

The Organization for Economic Cooperation and Development (OECD) report referenced in the notification showed that PFOS has been imported into OECD countries, which indicates that there is still international trade (UNEP/FAO/RC/CRC.7/7).

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 contamination of surface water and exposure of aquatic organisms was the main reason for the final regulatory action (UNEP/FAO/RC/CRC.7/7).

Japan

1. Scope of the notified regulatory action

Prior to the regulatory action PFOS was used in metal plating, photo masks in semiconductors, etching agents, photo resists, firefighting foams and other applications. PFOSF was used as a precursor for the production of PFOS (UNEP/FAO/RC/CRC.7/7).

The final regulatory action taken by Japan prohibits all manufacture, import and uses of PFOS and PFOSF. The following uses remain allowed: etching agents for voltage filters or high-frequency compound semiconductors, photo resists for

semiconductor production, photo films for industrial purposes and firefighting foams (UNEP/FAO/RC/CRC.7/7).

2. Criterion Annex II (a)

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

PFOS is persistent, highly bioaccumulative and chronically toxic to humans. PFOS fulfils the criteria for adverse effects. It has demonstrated toxicity for mammals in repeated dose studies at low concentrations, in addition to rat reproductive toxicity, with mortality of pups occurring shortly after birth (UNEP/FAO/RC/CRC.7/7/Add.3).

The Japanese Government designates chemical substances that are persistent and highly bioaccumulative and show chronic toxicity for humans as Class I Specified Chemical Substances to be banned under the Chemical Substances Control Law (CSCL). As a result of internal evaluation using the scientific data found in the risk profile prepared by the Persistent Organic Pollutants Review Committee of the Stockholm Convention on Persistent Organic Pollutants, the Japanese authorities concluded that the chemical met the criteria for designation as a Class I Specified Chemical Substance under CSCL. Class I Specified Chemical Substances are banned under CSCL to protect human health and the environment (UNEP/FAO/RC/CRC.7/7).

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 data were used under the Stockholm Convention and are considered to be scientifically sound, which means that they were generated according to scientifically recognized methods and that data reviews were performed and documented according to generally recognized scientific principles and procedures (UNEP/FAO/RC/CRC.7/INF/8). In addition the exposure data were generated in Japan according to scientifically recognized methods (UNEP/FAO/RC/CRC.7/7/Add.3).

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

The data were used under the Stockholm Convention and are considered to be scientifically sound, which means that they were generated according to scientifically recognized methods and that data reviews have been performed and documented according to generally recognized scientific principles and procedures (UNEP/FAO/RC/CRC.7/INF/8). In addition the exposure data were generated in Japan according to scientifically recognized methods (UNEP/FAO/RC/CRC.7/7/Add.3).

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

The notification and the supporting documentation provide sufficient evidence that the final regulatory action was based on a risk evaluation involving prevailing conditions in the notifying party (UNEP/FAO/CRC/7/7/Add.3).

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;

Since the manufacture, import and most uses have been prohibited, it can be expected that the regulatory action will lead to a significant decrease of the chemical used (UNEP/FAO/RC/CRC.7/7).

(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;

As a result of the significant reduction in the quantity of the chemical used it can be expected that exposure will be reduced, which will also lead to a reduction of risks to human health (UNEP/FAO/RC/CRC.7/7).

(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 final regulatory action are not limited to a geographical area or to specific circumstances since they are linked to the inherent characteristics of PFOS and PFOSF (UNEP/FAO/RC/CRC.7/7).

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

The notification does not provide evidence of international trade. Evidence of international trade is, however, presented 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.

The notification does not include any indication that intentional misuse was involved in the decision to adopt the final regulatory action (UNEP/FAO/RC/CRC.7/7).

Recommendations

The Committee concluded that the notifications of final regulatory action by Canada, the European Union and Japan 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 Union and Japan provided a sufficient basis to merit including PFOS, its salts and its precursor PFOSF 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.