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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

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Operational issues: working procedures and policy guidance developed to facilitate the Committee's work

Working paper on the application of the criteria in paragraph (b) of Annex II to the Rotterdam Convention

Note by the Secretariat

1. The Chemical Review Committee developed a working paper on the application of the criteria in paragraph (b) of Annex II to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. The purpose of the paper is to assist the Committee in judging whether a notification of final regulatory action meets those criteria. The working paper was originally developed by the Committee at its first meeting with the understanding that it would continue to evolve in the light of future experience. It was amended to include further examples based on the experience gained at subsequent meetings of the Committee. An intersessional drafting group was established at the Committee's seventh meeting with the mandate to further develop the working paper.

2. The annex to the present note contains the latest version of the working paper, amended to reflect the discussions at the Committee's seventh meeting and to include additional suggestions made by the drafting group in consultation with the Bureau and the Secretariat. It has not been formally edited by the Secretariat.

3. The amended working paper aims to indicate clearly that, to establish whether the criteria in paragraph (b) of Annex II have been met, both hazard and exposure information should be taken into account.

4. The Committee may wish to take note of the amended working paper, with the understanding that it will be further updated as necessary.

* UNEP/FAO/RC/CRC.8/1.

Annex

Policy guidance:

Working paper on the application of criteria (b) of Annex II

The purpose of this paper is to assist the Chemical Review Committee (CRC) in judging whether a notification of final regulatory action meets criteria (b) of Annex II of the Convention.

Annex II of the Convention sets out the criteria for listing banned or severely restricted chemicals in Annex III of the Convention. Paragraph (b) of Annex II requires that the CRC "*establish that the final regulatory action has been taken as a consequence of a risk evaluation.*" It further states that "*the evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question*" and lists three criteria (b (i) to (iii)) against which the notification of final regulatory action and supporting documentation are to be reviewed by the Committee.

This working paper was originally developed by the Committee at its first meeting. The guidance was amended to include further examples based on the experience gained at subsequent meetings of the CRC and guidance provided by the third meeting of the Conference of the Parties. The guidance will continue to evolve in the light of future experience.

The present working paper is divided into three chapters:

- Chapter I – background - outlines the relationship between the information requirements for notifications submitted under Article 5 of the Convention and the criteria set out in Annex II of the Convention for listing banned or severely restricted chemicals in Annex III of the Convention.
- Chapter II - application of criteria (b) (i) and (b) (ii) - provides guidance aimed at improving consistency in applying criteria (b) (i) and (b) (ii) in the analysis of the notifications.
- Chapter III - application of criterion (b) (iii) - provides an initial list of examples as a basis for further guidance to the Chemical Review Committee in defining minimum requirements for information on the exposure component of a risk evaluation. This list will be expanded on an ongoing basis as further practical experience is gained in reviewing candidate chemicals.

Chapter I - Background

1. Annex I of the Convention sets out the information requirements relevant to a notification of final regulatory action submitted under Article 5 of the Convention. The notifications of final regulatory action are submitted using a form which was developed in order to provide a standardized format for reporting national final regulatory actions. The form is based on the information requirements of Annex I.

2. In order to decide whether a chemical can be recommended for inclusion in Annex III, the Committee reviews the information contained in the notification of final regulatory action and accompanying supporting documentation in the light of the criteria in Annex II of the Convention.,

3. Annex II states:

> "In reviewing the notifications forwarded by the Secretariat pursuant to paragraph 5 of Article 5, the Chemical Review Committee shall:
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> . . .
>
> (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.

4. Under the Rotterdam Convention, it is generally agreed that a risk evaluation is neither hazard assessment nor risk assessment but something in between (UNEP/FAO/RC/CRC1/13). Risk evaluation comprises information on hazard and exposure. This means that risk evaluation is an evaluation of intrinsic toxicological and ecotoxicological properties and actual or expected relevant exposure, which may include information on actual incidents. In notifications of final regulatory actions to ban or severely restrict a chemical:

(a) Information on hazard is generally based on internationally accepted toxicological or ecotoxicological data, which are considered not to be area-/ country-/ location-specific;

(b) Information on exposure is to be related to the prevailing conditions of use in the notifying Party.

5. Therefore, the Committee is to establish that a risk evaluation considering the conditions in the Party has been undertaken and has resulted in the final regulatory action that has been notified. The Committee considers each of the three criteria in paragraph (b) one by one with regard to how the information provided in the notification and supporting documentation demonstrates that all criteria ((b) (i), (b) (ii) and (b) (iii)) are met.

6. This stepwise approach should assist the Committee in analysing the information provided by the notifying Party in order to reach an overall conclusion as to whether the entire criterion (b) is met. This can only be the case if all sub-criteria have been met.

Chapter II - Application of criteria (b) (i) and (b) (ii) of Annex II

7. Criteria (b) (i) and (b) (ii) are particularly relevant to two specific paragraphs of the information requirements listed in Annex I.

8. Paragraph 1 of Annex I sets out the information on the properties, identification and uses of a substance, including recognized names of the substance, relevant code numbers and hazard classification, as well as physico-chemical, toxicological and ecotoxicological properties.

9. In submitted notifications, this includes lists of physico-chemical parameters such as melting and boiling points or lists of toxicological or ecotoxicological endpoints including LD_{50} and LC_{50} data for a range of laboratory animals, birds and fish. In many countries this information is not generated nationally, but may be found in a range of internationally recognized sources.[1] Information referenced from such sources is considered to have met criteria (b) (i) and (b) (ii) for information set out in Paragraph 1 of Annex I.

10. At its third meeting, the Conference of the Parties endorsed the approach recommended by the Secretariat, namely that the Committee should consider risk evaluations under the Montreal Protocol and the Stockholm Convention as adequate support for meeting criteria (b) (i) and (b) (ii), as long as the Committee can establish that a risk evaluation considering the conditions in the Party has been undertaken.[2]

11. Paragraph 2 (a) of Annex I sets out specific information to be provided that describes the final regulatory action to ban or severely restrict the chemical. This includes information on the risk or hazard evaluation upon which the regulatory decision was based, reasons for the regulatory action relevant to human health or the environment, a summary of the hazards and risks presented by the chemical and the expected effect of the final regulatory action.

[1] Internationally recognized sources include the Pesticide Manual, documents generated by the Organization for Economic Cooperation and Development (OECD), the World Health Organization (WHO), the International Agency for Research on Cancer (IARC) and the United Nations Environment Programme (UNEP), Draft Assessment Reports from the EU as well as data from decision-guidance documents. More detailed data may be found in internationally recognized data bases (EU, EPA, IUPAC, IUCLID, etc.).

[2] Paragraph 66 of UNEP/FAO/RC/COP.3/26

12. In notifications, this information is generally in the form of a short written statement which briefly explains the risk or hazard evaluation on which the national regulatory action was based and a reference to the relevant documentation. The supporting documentation prepared by the country submitting the notification, including a focused summary, generally provides more detailed information regarding the basis for the regulatory action. The risk or hazard evaluation may include a combination of information on hazard from internationally recognized reference sources as well as information on actual or anticipated/estimated exposure under the prevailing conditions in the notifying country.

13. In order to establish whether criteria (b) (i) and (b) (ii) of Annex II have been completely met, information on hazard as well as on exposure should be considered.

14. Information on hazard is not for the most part generated nationally, but is drawn from a range of internationally recognized sources, and information from such sources is generally considered to have been generated according to scientifically recognized methods and data reviews have been performed and documented according to generally recognized scientific principles and procedures. Information on exposure relevant to prevailing conditions in the notifying country is largely generated at the national level, and whether or not this information meets criteria (b) (i) and (b) (ii) will need to be considered on a case-by-case basis.

15. There are four basic scenarios relevant to a consideration of criteria (b) (i) and (b) (ii) of Annex II and the information requirements of Annex I. A description of the scenarios and how criteria (b) (i) and (b) (ii) might apply for information on hazard and exposure to each follows:

Scenario 1: Data are not provided and there is no reference to a source of data in the notification or in the supporting documentation.

- Criteria (b) (i) and (b) (ii) would not be met.

Scenario 2: Data are provided but the source of the data is not referenced in the notification or in the supporting documentation.

- Criteria (b) (i) and (b) (ii) would not be met as it would not be possible to verify that the data have been generated according to scientific principles and procedures or that the data reviews were performed and documented according to generally recognized scientific principles and procedures.

Scenario 3: Data are not provided but there is a reference to a source of data in the notification or in the supporting documentation. Criteria (b) (i) and (b) (ii) would be met where the notifying country merely references a source document, without drawing out the specific information which they have used to make their decision, provided that the reference is to an internationally recognized source including a risk evaluation undertaken under the Stockholm Convention or the Montreal Protocol. Other documents, such as national or regional assessments, would need to be examined on a case-by-case basis.

- Criteria (b) (i) and (ii) would only be met if the CRC could verify that the data referenced were reviewed in the context of the conditions prevailing in the notifying Party.

Scenario 4: Data are provided and the source of the data is referenced in the notification or in the supporting documentation.

- Criteria (b) (i) and (b) (ii) would be met, provided that the data are from an internationally recognized source including a risk evaluation undertaken under the Stockholm Convention or the Montreal Protocol. Other documents, such as national or regional assessments, would need to be examined on a case–by-case basis.
- Criteria (b) (i) and (ii) would only be met if the CRC could establish on a case-by-case basis whether the data provided were reviewed in the context of the conditions prevailing in the notifying Party.

Chapter III - Application of criterion (b) (iii)

16. At its first meeting, the Committee decided to accept the policy guidance on risk evaluation in the context of the Rotterdam Convention contained in document UNEP/FAO/RC/CRC.1/13 as a work in progress and to amend it as necessary in the light of further experience[3]. In order to facilitate the work of the Committee in reviewing risk evaluations, the guidance set out some examples as a means of defining the minimum requirements for information regarding exposure.

17. At its second meeting, the Committee considered a working paper which had been developed by the Secretariat based on the work of the task groups established at the first meeting of the Committee (UNEP/FAO/RC/CRC.2/7). The meeting commended the secretariat on the paper which they said provided very useful guidance to the Committee. It was proposed that further examples identified during that meeting would be included in subsequent revisions of the document.[4]

18. The examples listed here are intended to serve as guidance to the Committee on how to document or explain the exposure component of a risk evaluation in order to facilitate its work and to help ensure transparency and consistency.

19. It is understood that the Committee will consider notifications on a case-by-case basis and that this list of examples will be expanded or refined as experience is gained in reviewing notifications in support of candidate chemicals.

1: Incidents involving direct exposure of humans

Information is required describing direct exposure to a chemical and any adverse effects resulting from that exposure. Thus, a description of the incident should be provided which may include, for example, the extent or number of casualties, its circumstances and a description of the signs, symptoms and/or effects.

a) Actual or measured exposure

This is based on a situation in which a country has taken a national regulatory action based on a risk evaluation which includes an assessment of exposure based on empirical or measured levels of a chemical in the notifying country.

Example

i) The regulatory action on DNOC notified by Peru and considered at the third session of the Interim Chemical Review Committee (ICRC) was based on hazard data supplemented by a study of poisoning incidents in the country. ICRC concluded that, taken together, the material demonstrated that there had been a risk evaluation that took into account prevailing conditions in that country (UNEP/FAO/PIC/ICRC.3/19, annex II).

b) Expected or anticipated exposure

This is based on the concept that a country can notify a national regulatory action that is based on expected exposure. Such exposure information might be developed based on modelling data generated by international organizations or other governments and adapted to the anticipated exposure and prevailing conditions in the notifying country. The use of models, *e. g.* to calculate anticipated exposure levels of humans and/or the environment, is an internationally recognized scientific practice, which is frequently applied as part of risk evaluations.

For acutely toxic pesticides or industrial chemicals, the description of the prevailing conditions in the notifying country could include information on the availability and common use of protective equipment or poisoning scenarios (if relevant and available), a description of how a chemical was used – or a description of the conditions of storage, transport or disposal and potential exposures in each scenario.

[3] Report of the Chemical Review Committee on the work of its first meeting UNEP/FAO/RC/CRC.1/28, paragraph 39.

[4] Report of the Chemical Review Committee on the work of its second meeting UNEP/FAO/RC/CRC.2/20, paragraphs 32-36).

The guidance that has been developed on common and recognized patterns of use of severely hazardous pesticide formulations (UNEP/FAO/RC/CRC. 6/INF/3) may also be relevant to certain elements of expected or anticipated exposure.

Examples

i) Comparison of mammalian and environmental toxicity data with anticipated exposure levels generated using models. A case example is the European Union notification regarding methyl parathion (UNEP/FAO/RC/CRC.1/28, annex V, paragraph 10).

- The risk evaluation of the pesticidal uses of methyl parathion concluded that, on the basis of the results of several exposure models, there were unacceptable risks to workers and non-target organisms (insects, birds, aquatic organisms and mammals) due to the acute and chronic toxic effects of methyl parathion. Consequently, the Chemical Review Committee at its first session decided that the notification and supporting documentation showed that the final regulatory action had been based on a chemical-specific risk evaluation taking into account the conditions of exposure within the European Union.

ii) For non-threshold carcinogens, there may be a national policy that no exposure is acceptable. Thus, a description of the anticipated use of the chemical may be sufficient, with no specific information on exposure needed. A case example is the Canadian notification of bis (chloromethyl) ether (UNEP/FAO/RC/CRC.1/28, annex V, paragraphs 25-26).

- Canada concluded that bis (chloromethyl) ether was a non-threshold carcinogen in humans. As a result it was understood that there is some probability of adverse effect at any level of exposure. Although levels at the time of the regulatory action did not pose a threat to human health, the regulatory action was put in place as a precautionary measure to protect the health of Canadians. This approach is consistent with the objective that exposure to non-threshold carcinogens be reduced wherever possible, and obviates the need to establish an arbitrary "de minimis" level of risk. Based on this, the Chemical Review Committee at its first session concluded that the supporting documentation showed that the final regulatory action had been based on chemical-specific risk evaluations taking into account the conditions of exposure within Canada.

iii) Pesticides with defined hazard classifications, *e. g*., WHO hazard classification 1a or 1b, may be subject to national policy that they not be registered based on the understanding that the prevailing conditions of use in a country will result in unacceptable risk to workers or the environment. In such a case, a description of the anticipated risk as a consequence of the use of the chemical in the notifying country may be sufficient. Data on actual, measured exposure "field measurements" in the notifying country are not mandatory.

- Specific example to be identified

iv) Use of risk evaluations from other countries or international bodies together with bridging information on anticipated exposure in the notifying country.
An example is the Jamaican notification for aldicarb (UNEP/FAO/RC/CRC.4/10).

- Jamaica carried out a risk evaluation using results of studies conducted by the United States and the International Programme on Chemical Safety (IPCS) to compare the worker exposure and leaching conditions with the conditions of use in Jamaica. This evaluation in Jamaica considered oral, dermal and inhalation toxicity for rats, rabbit and birds and WHO classification. Studies showed that the use of the product without protective clothing presented risks to farmers. Small-scale farmers in Jamaica do not have access to protective clothing as confirmed through a survey conducted in Jamaica. Furthermore, the hot tropical climatic conditions make wearing protective clothing uncomfortable. Therefore, the risks for small-scale farmers in Jamaica were considered unacceptable.
- Leaching of aldicarb to ground water was considered possible in Jamaica due to its solubility in water and the presence of underground rivers in limestone areas across Jamaica where much of the farming is done. The risk evaluation considered the conditions under which water was contaminated by aldicarb in the United States and found that the

same could occur in limestone areas in Jamaica. Even with the application of strong enforcement measures under conditions that were less susceptible to pollution than island ecologies like Jamaica, this did not prevent water contamination in the United States. The evaluation concluded that adults and children might be exposed to high levels of aldicarb due to water pollution combined with contamination of food.

- The Chemical Review Committee at its fourth session concluded that the supporting documentation showed that the final regulatory action had been based on a risk evaluation involving the prevailing conditions of exposure within Jamaica.

v) A risk evaluation has been made, but no consensus could be reached that prevailing conditions in the notifying country have been adequately taken into consideration. A case example is the notification for paraquat from Sweden (CRC.5/8 and addenda; CRC.6/9, Add. 1-4)

- Prior to the decision to ban paraquat in 1982, Sweden undertook a risk evaluation based on a dossier on the toxicological profile of paraquat, which also contained information on poisoning cases worldwide. The regulatory authority had concluded that mechanical failure of spraying equipment or protective clothing could lead to excessive and potentially fatal exposure of workers. Since no antidote or remedial cure exits, the risk was considered unacceptable. Environmental concerns (persistence in soil) were mentioned as an additional reason for the ban.
- However, no bridging information between the worldwide poisoning cases and the conditions in Sweden had been provided. The Chemical Review Committee at its sixth session thus concluded that criterion (b) of Annex II had not been met.

2: Incidents involving direct exposure of the environment (wildlife, livestock, etc.)

Information is required describing the direct exposure to the chemical and the adverse effects resulting from that exposure. Thus, a description of the incident should be provided, which may include, for example, the extent or number of casualties, its circumstances and a description of its effects.

a) Actual or measured exposure

For both pesticides and industrial chemicals this could include a description of how a chemical was used and/or a description of the conditions of storage, transport or disposal and potential environmental exposures in each scenario.

Examples

i) Comparison of toxicity data for fish and monitoring data (measured exposures in surface water). A case example is the notification by the Netherlands regarding methyl bromide (UNEP/FAO/RC/CRC.1/28, annex V, paragraph 3).

- The risk evaluation of the Netherlands focused on the behaviour and effects of methyl bromide in air, groundwater and surface water. The estimated concentration in groundwater amounted to approximately 100 µg/L, based on a soil degradation half-life of about 15 days and a sorption constant of about 2.5 L/kg. The measured concentrations in surface water amounted to approximately 9 mg/L, which resulted in the expectation of a very high risk for fish (LC_{50} (96h) 3.9 mg/L). The Chemical Review Committee at its first session agreed that the evaluation of the risks to aquatic organisms met the requirements of the criterion with respect to the prevailing conditions of use in the Netherlands.

ii) Comparison of toxicity data for fish and observation of effects on non-target organisms including fish and other aquatic organisms following application of endosulfan to rice paddies in Thailand for the control of golden apple snail. (UNEP/FAO/RC/CRC.2/20, Annex II, paragraph 3).

- The Chemical Review Committee confirmed at its second session that Thailand had severely restricted endosulfan, as commonly used in Thailand, by banning emulsifiable concentrate and granular formulations, whereas the use of capsulate formulation remained

registered. This decision was based on a national risk evaluation as follows: a survey in five provinces to assess the use of endosulfan for golden apple snail control in paddy fields showed that approximately 94 per cent of farmers used pesticides and that, of those, 60–76 per cent used endosulfan. There were no measured concentrations of endosulfan in the treated paddies however the death of fish and other aquatic organisms was reported in every province and emulsifiable concentrate (EC) and granule (GR) formulations were known to be very toxic to fish and aquatic organisms.

b) Expected or anticipated exposure

This is based on the concept that a country can notify a national regulatory action that is based on expected exposure. Such exposure information might also be developed based on modelling data that is generated by international organizations or other governments and adapted to the anticipated exposure and prevailing conditions in the notifying country. The use of models, *e. g.* to calculate anticipated exposure levels of humans and/or the environment, is an internationally recognized scientific practice, which is frequently applied as part of risk evaluations.

For both pesticides and industrial chemicals, the description of the prevailing conditions in the notifying country could include information on how a chemical was used, or a description of the conditions of storage, transport or disposal and potential environmental exposures in each scenario.

The guidance developed on common and recognized patterns of use of severely hazardous pesticide formulations (UNEP/FAO/RC/CRC.6/INF/3) may be relevant to certain elements of expected or anticipated exposure.

Examples

i) Comparison of mammalian and environmental toxicity data with anticipated exposure levels generated using models. Case examples include the following:

- Methyl-parathion - European Union (EU) notification (UNEP/FAO/RC/CRC.1/28, annex V, paragraph 10).

The risk evaluation of the pesticidal uses of methyl parathion concluded that, on the basis of the results of several exposure models, there were unacceptable risks to workers and non-target organisms (insects, birds, aquatic organisms and mammals) due to the acute and chronic toxic effects of methyl parathion. Consequently, the Chemical Review Committee decided at its first session that the EC notification demonstrated that the final regulatory action had been based on chemical-specific risk evaluations taking into account the conditions of exposure within the European Union.

- Endosulfan - Netherlands notification (UNEP/FAC/RC/CRC.2/20 annex II, paragraph 2).

The Netherlands notification banned all uses of endosulfan on basis of a national risk evaluation. It was found that application of endosulfan according to good agriculture practice would result in surface water concentrations that would significantly affect aquatic organisms (especially fish). Emission of endosulfan to surface water will occur as a result of spraying drift during application. The surface water concentration of endosulfan during application was estimated with a dispersion model. Assuming a drift emission factor of 10 per cent, an endosulfan concentration of 0.014 mg/l was calculated. A comparison of this concentration with the lowest LC_{50} for fish (0.00017 mg/l) results in a risk quotient of 82, which was considered unacceptable.

- Dicofol – Netherlands notification (UNEP/FAO/RC/CRC.2/20 annex III, paragraphs 1 and 2)

Dicofol is a persistent chemical. Laboratory experiments found the chemical to be highly accumulative (bioconcentration factor (BCF) of about 10,000), a property that might lead to effects via the food chain (secondary poisoning). In addition, further experiments revealed effects on the reproduction of owls and pigeons where eggshell thinning at a concentration of 3

mg/kg feed were demonstrated. Modelling estimations indicated that application (according to good agriculture practice) of dicofol would lead to exposure of fish-eating birds. Based on the BCF there is an estimation of about 30 mg/kg feed, assuming a diet of 100 per cent contaminated fish to be eaten by predatory birds. Concentration in fish and predatory birds may reach levels as a result of continuous build-up in the tissues which lead to significant adverse effects. This was deemed unacceptable. The risk evaluation concluded that, on the basis of the results of modelled exposure, there were unacceptable risks to non-target organisms (predatory birds feeding on fish) due to persistence and bioaccumulation of dicofol. Therefore, the Chemical Review Committee agreed at its second session that the notification demonstrated that the final regulatory action had been based on estimated concentrations of the chemical in the environment taking into account the prevailing conditions in the Netherlands.

- Azinphos methyl – Norway notification (UNEP/FAO/RC/CRC.6/16, annex II, paragraphs 8-11)

The notification from Norway demonstrated that the final regulatory action had been based on a comparison of ecotoxicological endpoints (no observed effect concentrations (NOECs) for fish and other aquatic organisms, derived from ecotoxicological tests and a microcosm study) with predicted environmental concentrations (PECs) in surface water. These PECs were determined using a standard calculation method taking into account the application rate in Norway, as well as a 30 meter buffer zone. The PEC thus calculated was 1.53 µg/L. When this was compared to the NOEC of 0.32 µg/L established from the microcosm study, the ratio of 5 indicated that the predicted concentration in surface water is 5 times higher than an acceptable concentration for the protection of aquatic species and was thus deemed unacceptable. This conclusion was also supported by actual concentrations from a monitoring programme in Norway, in which the detected concentrations in surface water were twice as high as the acceptable concentration for the protection of aquatic species. The Chemical Review Committee agreed at its sixth session that the notification from Norway met all the criteria in Annex II to the Convention

3: Indirect exposure via the environment (air, water, soil)

The description of indirect exposure via the environment should address the following:

(a) How the presence of a chemical in the environment results in human and environmental (actual or expected) exposure. Actual exposure can be directly measured. Expected exposure can be estimated.

(b) An explanation of how the exposure relates to the problem which was the reason for the regulatory action, taking into account the hazards of the chemical, would facilitate the work of the Committee.

Examples

i) The presence of a chemical in the environment in itself is not sufficient to meet criteria b (iii).

- Endosulfan – Jordan notification (UNEP/FAO/PIC/ICRC5/15, paragraphs 39–41)

Jordan had banned endosulfan because it was persistent in the environment and residues had been found in soil. The decision to ban endosulfan had been based on research findings pointing to the chemical's carcinogenic properties and statements that it was found in groundwater. Information available to the Committee (monitoring data) indicated the presence of endosulfan in the soil, but no residues of endosulfan had been reported in groundwater in Jordan. At its fifth session, the Interim Chemical Review Committee concluded that it was not clear that presence in the soil would lead to human or environmental exposure.

ii) Some chemicals have characteristics that allow them to bioconcentrate or biomagnify[5] to levels that cause toxic effects. A regulatory action may have been taken as a precautionary measure to reduce or eliminate future risks to humans or wildlife. There may be special concerns with endangered species (environmental risk) or human subpopulations with high consumption of sea food and other traditional food (health risk). Thus, information about the

[5] Bioaccumulation is considered as a broader term covering both processes.

persistence, biomagnification/bioconcentration and toxic properties of the chemical together with a description of the use, releases and anticipated exposure to the chemical could be the basis of the decision. A case example includes the following:

- Mirex – Canadian Notification (UNEP/FAO/RC/CRC.2/20, annex III D)

Canada banned mirex because it is persistent, bioaccumulative and subject to transboundary movement. The decision to ban mirex was based on the fact that it has been demonstrated to cause cancer in laboratory animals and it is possibly carcinogenic in humans. Mirex contaminates several ecosystems in Canada. Human dietary exposure to mirex is generally low with the possible exception of the group dependant on a diet of fish or fish feeding birds from Lake Ontario and the St Lawrence River and of hunters eating game birds. At its second session, the Chemical Review Committee concluded that the final regulatory action had been based on chemical-specific risk evaluations, taking into account the conditions of exposure within Canada.

iii) Indirect exposure may also be considered to include indirect effects that result from the action of a chemical on another system. Such actions may in turn have direct and indirect impacts for example the direct impact of increased ultraviolet radiation on the notifying Party or an indirect impact as a result of the general effects associated with the release to the environment of a chemical that contributes to the depletion of the ozone layer.

Ozone depletion:

Direct effects: The direct impact to the environment by a chemical that depletes the ozone layer could include the resultant increase in exposure to the damaging effects of UV radiation. The extent of the effect on individual countries would vary with their geographical location, as certain areas of the globe (such as polar regions) are more affected by ozone depletion. For example ozone levels in equatorial regions have remained relatively stable, both throughout different seasons within a year and from year to year, while higher latitudes have demonstrated significant seasonal variations associated with the spring formation of 'ozone holes' over the poles. Human exposure to UV-B depends upon not only an individual's location (latitude and altitude) but also the duration and timing of outdoor activities (time of day, season of the year) and precautionary behaviour (use of sunscreen, sunglasses and protective clothing). An individual's skin colour and age can influence the occurrence and severity of some of the health effects from exposure to UV-B. There may also be effects on terrestrial plants, aquatic ecosystems and climate. A case example includes the following:

- Carbon tetrachloride - Canadian notification (UNEP/FAO/RC/CRC.1/28, annex V, paragraphs 31–32).

Canada banned carbon tetrachloride based on a conclusion that it had ozone-depleting potential and created indirect hazards via the environment. In the Canadian Arctic, UV levels can increase substantially from season to season, owing to the hole in the ozone layer, which is caused by ozone-depleting substances such as carbon tetrachloride. In the light of that, the Chemical Review Committee at its first session concluded that the final regulatory action had been taken as a consequence of a risk evaluation. Other supporting documentation showed that the final regulatory action had been based on chemical-specific risk evaluations taking into account the conditions of exposure within Canada (UNEP/FAO/RC/CRC.1/28, annex V, section E).

Indirect effects: There are complex links between changes in the ozone layer and climate change effects. Ozone-depleting substances may act as greenhouse gases and may therefore contribute to global warming, while it is not clear what effect actual depletions in the ozone layer may have on climate change. Releases of ozone-depleting substances may be considered to have a global effect and a Party may make statements relating to these effects as supporting information for its decision to ban the chemical.

- Specific example to be identified.

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