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

Working paper on the application of criteria (b) (i), (b) (ii) and (b) (iii) of Annex II

Note by the Secretariat

1. The Chemical Review Committee developed a working paper on the application of criteria (b) (i), (b) (ii) and (b) (iii) of Annex II to the Rotterdam Convention to assist it in judging whether a notification of final regulatory action meets those criteria. The working paper was developed with the understanding that it could be amended in the light of experience gained.

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

3. The amended working paper includes a further example of a notification illustrating conditions of use and anticipated exposure in the notifying country and aims:

(a) To indicate clearly that, to establish whether criteria (b) (i) and (ii) are met, both hazard and risk information should be taken into account;

(b) To emphasize that criteria (b) (i), b (ii) and b (iii) should be considered as a whole.

4. The Committee may wish to consider the amended working paper, which is intended to facilitate its future work, with the understanding that it will be further updated as necessary.

* UNEP/FAO/RC/CRC.6/1.

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Annex

Policy guidance:

Working paper on the application of criteria (b) (i), (b) (ii) and (b) (iii) of Annex II

The purpose of this paper is to assist the Chemical Review Committee (CRC) in judging the acceptability of a notification of final regulatory action with respect to criteria (b) (i) (b) (ii) and (b) (iii) 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 supporting documentation is to be reviewed by the Committee.

This working paper, originally considered at the second meeting of the CRC, was developed based on the findings of two task groups established by the Committee at its first meeting. The guidance was amended to include further examples based on the experience gained at the second and third meetings of the CRC and guidance provided by the third meeting of the Conference of the Parties. Subsequent to the fifth meeting of the CRC the guidance has been further revised with an additional example and explanations based on experience gained. The guidance will continue to evolve in the light of future experience.

Risk evaluation: working paper on the application of criteria (b) (i), (b) (ii) and (b) (iii) of Annex II

Introduction

1. The present working paper is divided into three chapters: chapter I provides a brief background on 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 provides guidance aimed at eliminating ambiguity and improving consistency in referring to criteria (b) (i) and (b) (ii) in the analysis of the notifications; chapter 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.

Background

2. 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 information requirements of Annex I were the basis for the notification of regulatory action form which was developed to provide a standardized format for reporting national final regulatory actions.

3. The information contained in the notification of final regulatory action and accompanying supporting documentation are considered by the Committee in the light of the criteria for the inclusion of chemicals in Annex III of the Convention set out in Annex II of the Convention.

4. Annex II states:

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

. . .

(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.

Application of criteria (b) (i) and (b) (ii)

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

6. 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 eco-toxicological properties.

7. In submitted notifications, this includes lists of physicochemical parameters such as melting and boiling points or lists of toxicological or eco-toxicological endpoints including LD50 and LC50 data for a range of laboratory animals, birds and fish. In most 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 hazard information.

8. 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) for hazard information.[2]

9. 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.

10. 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 hazard information from internationally recognized reference sources as well as information on exposure under the prevailing conditions in the notifying country.

11. On the one hand, hazard information 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 met criteria (b) (i) and (b) (ii). On the other hand, 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.

12. 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 hazard and exposure information to each follows:

[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) as well as data from decision-guidance documents.

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

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

- For both hazard and exposure information, 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.

- For both hazard and exposure information, criteria (b) (i) and (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 have been 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.

- For hazard information, criteria (b) (i) and (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.
- For exposure information, criteria (b) (i) and (ii) would not be met because it would not be possible to verify whether 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.

- For hazard information, 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.
- For exposure information, the Committee needs to examine and establish on a case-by-case basis whether the data provided were reviewed in the context of the conditions prevailing in the notifying Party.

13. In order to establish whether criteria (b) (i) and (ii) have been completely met, both risk and exposure information should be considered.

Application of criterion (b) (iii)

14. 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.

15. 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

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

examples identified during that meeting would be included in subsequent revisions of the document.[4]

16. At its third meeting, the Conference of the Parties endorsed the approach recommended in the secretariat's note, namely that in order for criterion (b) (iii) to be met, bridging information providing evidence of the prevailing conditions in the notifying country would need to be submitted. [5]

17. 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.

18. 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. This guidance is intended to be interpreted flexibly.

Example 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 that reflect the prevailing conditions 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 guidance that has been developed on common and recognized patterns of use of severely hazardous pesticide formulations (UNEP/FAO/RC/CRC.9) may be relevant to certain elements of this discussion.

For acutely toxic pesticides or industrial chemicals, this 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.

Examples

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

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

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

- 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 Community. 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.

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 minimise 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 1 b, 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 use of the chemical may be sufficient, with no specific information on exposure needed. A case example is the Jamaica 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, WHO Classification. 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 condition makes wearing protective clothing uncomfortable. Use of the product without protective clothing presents unacceptable risk to farmers.
- 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 chemical-specific risk evaluations taking into account the prevailing conditions of exposure within Jamaica.

Example 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 Committee 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 Committee confirmed 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 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.

For both pesticides and industrial chemicals, this could include a description of 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.9) may be relevant to certain elements of this discussion.

Examples

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

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

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 Community. 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.

- 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 LC50 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)

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. 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.

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 is clearly deemed unacceptable.

Example 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[6] 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 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**.**

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