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Chemical Review Committee
Second meeting
Geneva, 13–17 February 2006
Item 4 (b) of the provisional agenda*

Operational procedures for the Chemical Review Committee: clarification of criteria for accepting information under subparagraphs b (i), b (ii) and b (iii) of Annex II of the Rotterdam Convention

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

Note by the secretariat

1. At its first meeting, the Chemical Review Committee established two task groups to consider questions regarding how to determine whether notifications of candidate chemicals met criteria (b) (i), (ii) and (iii) in Annex II of the Convention.

2. One task group examined how to determine whether criterion (b) (i), on whether data have been generated according to scientifically recognized methods, and criterion (b) (ii), on whether data reviews have been performed and documented according to generally recognized scientific principles and procedures, had been met. The task group was requested to draft guidance aimed at eliminating ambiguity and improving consistency in referring to those criteria in the analysis of notifications, as concerns had been raised on the sources of information provided in notifications. The Committee agreed that the chair of the task group, working in consultation with the secretariat, would refine the product of the task group's deliberations for submission to the Committee at its second session.

3. The Committee also noted that many of the new notifications on candidate chemicals did not meet criterion (b) (iii) of Annex II concerning whether a national regulatory action has been taken on the basis of a risk evaluation involving prevailing conditions in the notifying Party. Notifications frequently included a hazard assessment, but information on actual or expected exposure under

* UNEP/FAO/RC/CRC.2/1.

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prevailing conditions was lacking. Accordingly, the Committee agreed that there was a need for further guidance to countries on how to document or explain the exposure component of the risk evaluation.

4. A second task group was to identify the sort of information that could be included in an exposure evaluation. In its work, that group drew on guidance already that had already been developed in a working document on risk evaluation (UNEP/FAO/RC/CRC.1/13), as well as policy guidance on bridging information (UNEP/FAO/RC/CRC.1/11). The task group prepared a paper, and it was agreed that it would be further developed and considered by the Committee at its second session.

5. In view of the interrelationship between criteria b (i), (b) (ii) and (b) (iii) it was proposed, in consultation with the Chair of the Chemical Review Committee, that the work of the two task groups be combined into a single working paper for consideration at the second meeting of the Committee.

6. Annexed to this note is an initial draft working paper on the application of criteria b (i), (b) (ii) and (b) (iii) based on the work of the task groups established at the first meeting of the Chemical Review Committee.

Action by the Committee

7. The Committee may wish to:

(a) Review the draft working paper as a basis for guiding the work of the Committee in the application of criteria (b) (i), (b) (ii) and (b) (iii) to notifications of final regulatory actions;

(b) Identify further risk evaluations submitted in support of candidate chemicals that meet criteria (b) (i), (b) (ii) and (b) (iii), in particular regarding exposure that reflects prevailing conditions in the notifying country, in order that they might be included in further revisions of the working paper;

(c) Request the Conference of the Parties at its third meeting to invite designated national authorities to provide more complete information on the exposure assessment component of their risk evaluations when submitting notifications of final regulatory action.

Annex

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.

I. 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:
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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.

II. 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 recognized sources[1]. Information referenced from such sources is considered to have met criteria (b) (i) and (b) (ii).

8. 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.

9. 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. On the one hand, hazard information is not for the most part generated nationally, but is drawn from a range of 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.

10. 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 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 (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.

- 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. Other documents, such as national or regional assessments, would need to be examined on a case-by-case basis.

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

[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.

- Criteria (b) (i) and (b) (ii) would be met, provided that the data are from an internationally recognized source. Other documents, such as national or regional assessments, would need to be examined on a case–by-case basis.

III. Application of criterion (b) (iii)

11. 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[2]. 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.

12. In preparing the initial draft of the present working paper, it became apparent that it is very difficult to try and cover every possible exposure scenario that the Committee might be expected to encounter. It is therefore suggested that it might be more useful to capture the experience of the Committee in reviewing notifications as a series of case studies or illustrative examples that might guide further work.

13. In line with this approach, the examples in document UNEP/FAO/RC/CRC.1/13 have been taken as the basis upon which to develop further guidance on how to document or explain the exposure component of a risk evaluation and have been combined with the results of the brainstorming undertaken at the first meeting of the Committee.

14. This initial list of examples is intended to facilitate further discussion of this issue at the second meeting of the Committee. 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.

[2] Report of the Chemical Review Committee on the work of its first meeting (UNEP/FAO/RC/CRC.1/28), para. 39.

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 Union notification regarding methyl parathion (UNEP/FAO/RC/CRC.1/28, annex V, para. 10).

- 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, paras. 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 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.

- Specific example to be identified

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, para. 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.

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. A case example is the European Union notification regarding methyl parathion (UNEP/FAO/RC/CRC.1/28, annex V, para. 10).

- The 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.

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

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

(a) How does the presence of a chemical lead to human and environmental (actual or expected) exposure? Actual exposure can be directly measured. Expected exposure can be estimated. Possible factors… [to be developed if necessary]

(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). A case example is the Jordan notification of endosulfan considered at the fifth session of the Interim Chemical Review Committee. (UNEP/FAO/PIC/ICRC5/15, paras. 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, which stated 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) Indirect exposure may also be considered to include the action of a chemical on another system, such as when ozone-depleting substances result in increased exposure to damaging ultraviolet (UV) radiation*. Human exposure to UV-B depends upon an individual's location (latitude and altitude), the duration and timing of outdoor activities (time of day, season of the year) and precautionary behavior (use of sunscreen, sunglassesand 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 is the Canadian notification regarding carbon tetrachloride considered at the first session of the Chemical Review Committee (UNEP/FAO/RC/CRC.1/28, annex V, paras. 31–32).

- Canada banned carbon tetrachloride based on a conclusion that it had an 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 (excerpted from UNEP/FAO/RC/CRC.1/28, annex V, section E).

* *There was an initial discussion of this issue at the second meeting of the Conference of the Parties (Report of the Conference of the Parties on the work of its second meeting, UNEP/FAO/RC/COP.2/19, paras. 45–47). The issue is further considered in document UNEP/FAO/RC/CRC.2/4 as the basis for further guidance from the Conference of the Parties at its third meeting.*