2.2 Bridging Information

Reference: UNEP/FAO/RC/CRC.3/4

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 criterion (b) (iii) of Annex II, where the notifying Party has used a risk evaluation from another country or international body as the basis for its national decision.

At its third meeting, the Conference of the Parties agreed that, in order to satisfy criterion (b) (iii) of Annex II to the Rotterdam Convention, bridging information providing evidence of the prevailing conditions in the notifying country would have to be submitted. It was further agreed that the working paper on bridging information would need to be developed further in order to accommodate the consideration of global risk evaluations as experience was gained.

At its first meeting, the CRC considered an initial draft of this working paper which was further discussed and amended at its third meeting.

Introduction

1. When examining notifications made in accordance with Article 5 of the Rotterdam Convention, the Chemical Review Committee must establish whether criteria b (i), b (ii) and b (iii) of Annex II have been met. The *working paper on the application of criteria (b) (i), (b) (ii) and (b) (iii) of Annex II* includes practical examples where the Committee has determined that these criteria have been met. Meeting criterion (b) (iii), i.e. that a final regulatory action was based on a risk evaluation involving prevailing conditions within the party taking the action, has proven particularly difficult. Other than conducting risk evaluations by themselves, notifying countries may use risk evaluations and/or exposure assessments completed in another country or from an international risk evaluation.

2. This document provides guidance on the sort of information that will need to be considered by the Chemical Review Committee in determining that the conditions in the country which completed the original risk evaluation and exposure assessments or risk evaluations carried out under other international agreements or conventions, such as the Montreal Protocol on substances that deplete the ozone layer or the Stockholm Convention on Persistent Organic Pollutants (POPs), are similar to and compatible with those prevailing in the notifying country.

3. For those countries whose national regulatory programmes require the use of risk evaluations but which lack the capacity and resources to perform such evaluations, these guidelines may also be of interest.

4. It is important to note that when a Party submits a notification of final regulatory action, the risk evaluation and the "bridging" information must be sufficient to fulfil the criteria in Annex II (b) (iii) for this notification to be a trigger for further consideration under the Convention.

5. The Chemical Review Committee will consider such bridging information on a case-by-case basis. In reviewing the information, the Committee will apply the following principles:

(a) Exposure or potential exposure is a key element;

(b) The information should be science-based, on the best available knowledge;

(c) The information should also be sufficiently detailed to enable the Chemical Review Committee to make an assessment.

6. The following elements, if relevant for the final regulatory decision, should be considered in comparing the exposure scenario in the country that completed the original risk evaluation or the relevance of the exposure scenarios considered in the international risk evaluation to the conditions prevailing in the notifying country that has used that risk evaluation in support of its notification of final regulatory action. They address both human health and environmental exposure.

A. Pesticides

7. Information to facilitate a comparison of human exposure between countries or to demonstrate relevance of an international risk evaluation could include:

(a) The form in which the chemical was used in both countries or a comparison of the form in which the chemical is used in the notifying country to those which were considered in the international evaluation;

(i) Formulation type:

a. Liquid, powdered, granular and so on;

b. Concentration of active ingredient(s);

(ii) Contaminants:

(b) How the chemical is used in both countries or a comparison of the use conditions in the notifying country to those which were considered in the international evaluation;

(i) Use pattern:

a. Type of use (agricultural pesticide, non-agricultural pesticide, use as disinfectants, vector control, wood preservatives)

b. Rate, frequency and period of application

c. Method of application (spray, drip, dip)

d. Application equipment (back pack sprayer, air blast sprayer etc.)

e. Greenhouse, field application, post-harvest, other

f. Storage conditions

(ii) If applied in the field: climatic or geographic conditions, comparability between the countries or relevance of the conditions and assumptions of the international evaluation (e.g. ozone depletion is most relevant in polar regions but might still pose problems at lower latitudes and higher altitudes, or chemicals with persistent, bioaccumulating and toxic properties such as POPs, or chemicals derived from certain heavy metals such as mercury might pose problems for human health in the notifying country, e.g. via the food chain)

(c) Risk mitigation measures in both countries - relevance of restrictions/precautions on use in the country that undertook the risk evaluation or relevance of recommended risk mitigation measures from international evaluations, such as:

(i) Human health effects:

a. Requirement for protective clothing, whether it is typically available and/or feasible in the country reporting the regulatory action

b. Special application equipment, whether it is typically available and/or feasible in the country reporting the regulatory action

c. Occupational exposure limit.

8. Information to facilitate a comparison of environmental exposure:

(a) The form in which the chemical was used in both countries or a comparison of the use conditions in the notifying country to those which were considered in the international evaluation:

(i) Formulation type:

a. Liquid, powdered, granular, etc.

b. Concentration of active ingredient(s)

(ii) Contaminants

(b) How the chemical is used in both countries or a comparison of the use conditions in the notifying country to those which use forms were considered in the international evaluation:

(i) Use pattern:

a. Rate and frequency of application

b. Method of application (spray, drip, dip, etc.)

c. Application equipment (back pack sprayer, air blast sprayer, etc.)

d. Greenhouse, field application, post-harvest, etc.

(ii) If applied in the field, environmental conditions such as climatic conditions, soil type and non-target organisms; comparability between the two countries or relevance of the conditions and assumptions of the international evaluation (e.g. ozone depletion is most relevant in polar regions but might still pose problems at lower latitudes and higher altitudes or chemicals with persistent,

bioaccumulating and toxic properties such as POPs, or chemicals derived from certain heavy metals such as mercury might pose problems in the environment of the notifying country)

(c) Risk mitigation measures - relevance of restrictions/precautions on use in the country that undertook the risk evaluation or relevance of recommended risk mitigation measures from international evaluations, such as:

(i) Effects on non-target organisms:

a. Buffer zones to protect sensitive areas such as water bodies or species habitats; whether such zones are enforceable in the notifying country

(ii) Other environmental effects.

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

(a) How the presence of a chemical in the environment, results in (actual or potential) exposure of humans or organisms in the environment. Actual exposure can be directly measured. Potential 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.

B. Industrial chemicals

9. Information to facilitate a comparison of human exposure between countries or to demonstrate relevance of conditions considered in an international risk evaluation could include information on:

(a) Workers

(b) General population

(c) End users

(d) Others (for example specific subgroups of the population such as children, pregnant women or the elderly)

10. Information to facilitate a comparison of environmental exposure between countries or to demonstrate relevance of conditions considered in an international risk evaluation:

(a) Soil, air, water

(b) Habitat

(c) Wildlife.

11. Description of events leading to exposure either as described in the notification of another country or in the international evaluation such as one or several of the following examples:

(a) Production process: e.g., where releases to air during production or processing of the chemical leads to general population exposure;

(b) Patterns of storage and distribution;

(c) Patterns of use: e.g., where the product is used on fabric, consumers are subjected to dermal exposure from clothing made from the treated fabric;

(d) Patterns of disposal: e.g., disposal of chemical on land leads to ground water contamination.

12. Description of the key factors, such as one or several of the following examples, affecting the chain of events leading to exposure:

(a) The form in which the chemical was used in both countries or a comparison of the use conditions in the notifying country to those which were considered in the international evaluation:

(i) Formulation type (where appropriate)

(ii) Concentration of the chemical

(iii) Contaminants.

(b) If release is associated with the production process, description of the production process:

(i) What are the key factors affecting release?

a. Open or closed

b. Waste water treatment (if relevant)

(ii) What options exist for controlling release or exposure?

a. Exposure limits

b. Protective equipment.

(c) If release is associated with storage and distribution, description of the storage and distribution process:

(i) What are the key factors affecting release?

(ii) What options exist for controlling release or exposure?

(d) If release is associated with use, description of use:

(i) What are the key factors affecting release?

(ii) What options exist for controlling release or exposure?

(iii) Hazard communication

(e) If release is associated with disposal, description of the disposal process:

(i) What are the key factors affecting release?

(ii) What options exist for controlling release or exposure?

12. Any other relevant information demonstrating similarity in conditions as described by another notifying country, e.g. incident reports, monitoring data, or relevance of the conditions and assumptions of the international evaluation (e.g. ozone depletion is most relevant in polar regions but might still pose problems at lower latitudes and higher altitudes or chemicals with persistent, bioaccumulating and toxic properties such as POPs, or certain heavy metals such as mercury or their compounds might pose problems to human health (e.g. via the food chain) or in the environment of the notifying country).

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

(a) How the presence of a chemical in the environment results in (actual or potential) exposure of humans or organisms in the environment. Actual exposure can be directly measured. Potential exposure can be estimated, e.g. by using models.

(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.