



**United Nations
Environment Programme**

**Food and Agriculture Organization
of the United Nations**

Distr.: General
15 May 2006

Original: English

**Rotterdam Convention on the Prior
Informed Consent Procedure for Certain
Hazardous Chemicals and Pesticides in
International Trade
Conference of the Parties
Third meeting
Geneva, 9–13 October 2006
Item 5 (d) of the provisional agenda***

**Implementation of the Convention: report of the Chemical Review
Committee on the work of its second meeting**

Risk evaluations under other multilateral environment agreements and their relevance to candidate chemicals

Note by the secretariat

I. Background

1. At its second meeting, the Conference of the Parties to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade considered the issue of procedures for risk evaluations under other multilateral agreements and requested the secretariat to prepare a paper, for consideration by the Chemical Review Committee at its second meeting, on how a substance whose trade was prohibited, severely restricted or managed in some way under other multilateral agreements should be treated under the Rotterdam Convention. The Chemical Review Committee discussed the paper, recommended a number of minor amendments and agreed to forward it for consideration by the Conference of the Parties at its third meeting. The paper, as amended, is annexed to the present note.

* UNEP/FAO/RC/COP.3/1.

II. Possible action by the Conference of the Parties

2. The Conference of the Parties may wish to review the paper and consider:

(a) Whether, in considering candidate chemicals for inclusion in Annex III to the Rotterdam Convention, the Chemical Review Committee may consider the assessment of the risks associated with the chemical under either the Montreal Protocol on Substances that Deplete the Ozone Layer or the Stockholm Convention on Persistent Organic Pollutants as adequate support for meeting criteria (b) (i) and (b) (ii) of the Rotterdam Convention; and

(b) The requirements for further bridging information, as described in the policy on bridging information agreed by the Chemical Review Committee at its first meeting (UNEP/FAO/RC/CRC.1/11), including the quality and quantity of such bridging information, to demonstrate that the final regulatory action of the notifying Parties has been taken as a consequence of a risk evaluation which involved prevailing conditions within the Party taking the action; in other words, that criterion (b) (iii) of Annex II to the Rotterdam Convention has been met.

Annex

Risk evaluations conducted under the Montreal Protocol on Substances that Deplete the Ozone Layer and the Stockholm Convention on Persistent Organic Pollutants

Background

1. At its second meeting, the Conference of the Parties considered the issue of procedures for risk evaluations under other multilateral agreements and requested the secretariat to prepare a paper, for consideration by the Chemical Review Committee at its second meeting, on how a substance whose trade was prohibited, severely restricted or managed in some way under other multilateral agreements should be treated under the Rotterdam Convention.

2. At its second meeting, the Chemical Review Committee discussed the paper and recommended the inclusion of some additional information for clarification. They agreed to forward the paper to the third meeting of the Conference of the Parties for consideration.

Introduction

3. The present paper has three chapters: chapter I briefly reviews the procedures for risk or hazard evaluation of the other multilateral environmental agreements which include chemicals potentially eligible for inclusion in Annex III to the Rotterdam Convention; chapter II includes examples of specific chemicals and considers how the evaluations of the individual multilateral environmental agreements apply to them; and chapter III reviews the number of chemicals that might be involved.

I. Risk or hazard evaluation procedures of relevant multilateral environmental agreements

A. Stockholm Convention on Persistent Organic Pollutants

4. The decision to include the original 12 chemicals in the Stockholm Convention during the negotiation process was based on an assessment process undertaken by the International Programme on Chemical Safety (IPCS). These chemicals were therefore included in the Stockholm Convention on the basis of a scientific risk assessment which was accepted by the Intergovernmental Negotiating Committee.

5. For new chemicals considered for inclusion in the Stockholm Convention, the Chemical Review Committee initially assesses the chemicals, taking into consideration four criteria, concerning persistence, bioaccumulation, toxicity and the potential for long-range transport in the environment. Where the Committee determines that these criteria have been met by a candidate chemical, it proceeds to draft a risk profile for that chemical. The risk profile under the Stockholm Convention provides more detailed information on the four criteria considered initially, and also information including data on possible sources (including production, use and release information), hazard assessments for the endpoints of concern, environmental fate and bioconcentration or bioaccumulation factors, monitoring data, exposure both in local areas and as a result of long-range transport, any national or international risk evaluations, assessments or profiles, labelling information, and the status of the chemical under other international conventions.

6. The Stockholm Convention also requires the preparation of an evaluation of possible control measures, which includes consideration of the efficacy and efficiency of possible control measures, alternatives, positive or negative social impacts, waste and disposal impacts, access to information and public education, status of control and monitoring capacity and any national or regional control actions taken. Inclusion of the chemical in the Stockholm Convention is decided by the Conference of the Parties, based on the recommendations of the Persistent Organic Pollutants Review Committee established under the Convention.

B. Montreal Protocol on Substances that Deplete the Ozone Layer

7. The procedure for assessing the hazard and risk of chemicals that are being considered for control under the Montreal Protocol entails a review of the chemical by the Parties and their assessment panels. Scientific experts on the Protocol's Scientific Assessment Panel carry out an evaluation of the potential of the substance to deplete the ozone layer, while a number of different emission scenarios are considered to measure the potential impact of differing assumptions of use. This results in a determination of the likelihood that use of the substance will lead to depletion of the ozone layer. This is not a general assessment of the risk of using a particular chemical, with consideration of a range of health or environmental effects, but rather a consideration only of the likelihood of the chemical to deplete the ozone layer.

8. The Environmental Effects Assessment Panel conducts evaluations regarding ozone depletion impacts on human health, terrestrial plants and aquatic ecosystems. This evaluation can be used to assess the potential impacts of releases of any of the ozone-depleting substances, based on a consideration of their ozone-depleting potential, rather than a specific evaluation of the effects of each of the individual chemicals. The Technology and Economic Assessment Panel conducts additional analyses of production and the feasibility of reduction and substitution of use of the chemical, on a chemical-by-chemical basis, and individual Parties may also perform analyses of emission scenarios which may help in the final decision-making on the level of control required for that substance.

II. Examples of the assessment of specific chemicals

A. Stockholm Convention on Persistent Organic Pollutants

9. There are two intentionally produced persistent organic pollutants included in the Stockholm Convention which are not yet included in the Rotterdam Convention: mirex and endrin.

10. The detailed report on the 12 original persistent organic pollutants was developed and published by IPCS in December 1995. For each of the 12 chemicals, including mirex and endrin, the report considered the chemical properties, toxicology and ecotoxicology, persistence and fate and exposure, based on internationally peer-reviewed documents.

11. For endrin, this specifically included information relating to studies in humans, including epidemiological data on workers in manufacturing plants, and studies on laboratory animals, including consideration of the carcinogenicity of endrin. Other information included in the study related to the toxicity to wildlife (both terrestrial and aquatic species), as well as information on persistence in the environment under differing conditions, the potential for long-range transport in a variety of media and the potential exposure to humans. In this study, the only noted exposure to endrin was through food.

12. For mirex, the information included a statement relating to the impact of mirex on the health of humans, studies on laboratory animals, the effects on plants and wildlife, persistence and fate and exposure assessment.

13. The study on the initial chemicals proposed for inclusion in the Stockholm Convention also included limited information on uses, sources, alternatives and the barriers to the adoption of alternatives. There was also a section presenting information on risk reduction, including information on risk management, prioritizing the risks and benefits, risk mitigation and assessing mitigation.

B. Montreal Protocol on Substances that Deplete the Ozone Layer

14. Two chemicals included in the Montreal Protocol following assessment of their potential for ozone depletion are of interest to the present study: carbon tetrachloride and methyl bromide.

15. Carbon tetrachloride was listed as a controlled substance under the Montreal Protocol by the Meeting of the Parties to the Protocol in 1990. The Parties carefully considered the 1989 report of the Scientific Assessment Panel, which had identified carbon tetrachloride as one of the substances with a very high ozone-depleting potential: defined as the ratio of steady-state calculated ozone column changes for each unit mass of a gas emitted into the atmosphere relative to the depletion for a mass unit emission of chlorofluorocarbon-11 (CFC-11).

16. Methyl bromide was listed on the basis of reports by the Scientific Assessment Panel published in 1989 and 1991. Those reports had shown methyl bromide to have significant ozone-depleting effects, and their analysis suggested steps for its control which would reduce the substance's adverse impacts on the ozone layer. Methyl bromide controls approved by the Parties in 1993 did, however, exempt the amounts of methyl bromide produced or used by Parties for quarantine and pre-shipment applications.

17. Assessment of those chemicals by the Scientific Assessment Panel was combined with the assessment of the effects of ozone depletion carried out by the Environmental Effects Assessment Panel to give an estimation of the expected effects on the ozone layer from the continued production, use and release of carbon tetrachloride or methyl bromide. The assessment of the Technology and Economic Assessment Panel provided additional information on the production of carbon tetrachloride and methyl bromide and the feasibility of the reduction of use of those chemicals and their replacement by other substances.

III Potential candidate chemicals for Annex III to the Rotterdam Convention and possible use of risk evaluations under other multilateral environmental agreements

A. Stockholm Convention on Persistent Organic Pollutants

18. For the two intentionally produced chemicals which are included in the Stockholm Convention but not included in the Rotterdam Convention, the use of the risk and hazard evaluation undertaken under the Stockholm Convention would appear to meet criteria (b) (i) (that the data used in taking the decision have been generated according to scientifically recognized methods) and (b) (ii) (that the data have been reviewed and documented according to generally recognized scientific principles and procedures) of Annex II to the Rotterdam Convention. Those two criteria may be considered to be met, as the review of the two chemicals in question was carried out as part of an international peer-reviewed process.

19. Criterion (b) (iii) of the Convention requires, however, that the action must be based on a risk evaluation involving prevailing conditions within the party taking the action. That criterion could not be met without some form of bridging information or consideration of the risks resulting from the use of the chemical within the country taking the action. A national policy decision taken by a country to ban all chemicals included in the Stockholm Convention may therefore not support inclusion in the Rotterdam Convention, unless the decision also includes information regarding concerns about exposures (or potential exposures) to the environment or humans in the country based on expected, current or previous patterns of use. For many of the persistent organic pollutants, significant adverse effects are seen in locations relatively distant from the point of origin and Governments may therefore not have carried out any direct studies on effects within their own country.

20. For chemicals proposed for inclusion in the Stockholm Convention, the risk profile developed by the Convention's Review Committee may similarly meet criteria (b) (i) and (b) (ii) of Annex II to the Rotterdam Convention relating to data generation and data review; it would need to be demonstrated, however, that any national ban or severe restriction taken by a country was based on prevailing conditions in the notifying party to allow criterion (b) (iii) to be met, before the chemical could be proposed for inclusion in the Rotterdam Convention.

B. Montreal Protocol on Substances that Deplete the Ozone Layer

21. There are a large number of chemicals currently controlled under the Montreal Protocol, which are presented both as groups, such as CFCs, hydrochlorofluorocarbons (HCFCs) or halons, and individual chemicals. The Montreal Protocol includes a large number of chemicals or groups of chemicals which may be proposed for inclusion in the Rotterdam Convention.

22. When chemicals are being considered for inclusion in the Rotterdam Convention, it would appear that an action taken on the basis of the inclusion of the chemical in the Montreal Protocol would meet criterion (a) of Annex II to the Convention, as that action would protect the environment (and indirectly protect human health). The use of the risk and hazard evaluation undertaken under the Montreal Protocol would meet criteria (b) (i) and (b) (ii), as the data would have been scientifically peer-reviewed and accepted by an international scientific assessment panel. That process of peer review

and acceptance of the data and data review meets the requirement that the data on which the decision was based should have been generated and reviewed according to scientifically recognized methods, principles and practices.

23. Without, however, some form of bridging information or consideration of the risks within the country taking the action, criterion (b) (iii), relating to prevailing conditions within the country taking the decision, could not be met. Such bridging information could take the form of a statement relating to the potential impact of depletion of the ozone layer on the health or environment of the country which has taken the decision, whether this was in the form of the direct impact of increased ultraviolet radiation on the notifying party, or a more indirect effect related to the general effects associated with the depletion of the ozone layer. The direct impact of the environmental effects to the ozone layer 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. 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. There are complex links, however, between changes in the ozone layer and climate change effects. Ozone-depleting substances 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.

IV. Possible action by the Conference of the Parties

24. The Conference may wish to consider whether, in considering candidate chemicals for inclusion in Annex III to the Rotterdam Convention, the Chemical Review Committee may consider the assessment of the risks associated with the chemical under either the Montreal Protocol or the Stockholm Convention as adequate support for meeting criteria (b) (i) and (b) (ii) of the Rotterdam Convention.

25. The Conference may also wish to consider the requirements for further bridging information, as described in the policy on bridging information agreed by the Chemical Review Committee at its first meeting (UNEP/FAO/RC/CRC.1/11), including the quality and quantity of such bridging information, to demonstrate that the final regulatory action of the notifying Parties has been taken as a consequence of a risk evaluation which involved prevailing conditions within the party taking the action; in other words, that criterion (b) (iii) of Annex II to the Rotterdam Convention has been met.
