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**Rotterdam Convention on the Prior  
Informed Consent Procedure for Certain  
Hazardous Chemicals and Pesticides in  
International Trade  
Conference of the Parties  
Fifth meeting**

Geneva, 20–24 June 2011

Item 5 (a) of the provisional agenda\*

**Matters related to the implementation of the Convention:  
status of implementation**

**Current regulatory processes for chemicals and their  
relationship to the definitions of banned or severely restricted  
chemicals in Article 2 of the Rotterdam Convention**

**Note by the Secretariat**

1. At its fourth 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 reviewed a document prepared by the Secretariat on implementation issues (UNEP/FAO/RC/COP.4/11) that provided the results of an initial review of information collected over the previous 10 years and possible emerging trends over the previous five years in the implementation of the key provisions of the Convention. The document was intended to review progress and identify lessons that could be learned with regard to notifications of final regulatory action, severely hazardous pesticide formulations and import responses.

2. After discussion of the information, by its decision RC-4/1, the Conference of the Parties requested the Secretariat to undertake a review of the current regulatory processes for chemicals to determine their relationship to the definitions of banned or severely restricted chemicals in Article 2 of the Convention and to submit the results of its review for the consideration of the Conference of the Parties at its next ordinary meeting. The annex to the present note sets out that review.

**Possible action by the Conference of the Parties**

3. The Conference of the Parties may wish:

(a) To consider the experience gained by parties in submitting notifications of final regulatory action on hazardous industrial chemicals and pesticides pursuant to Article 5 of the Convention;

(b) To consider the observations made in the review with regard to the possible relationship of regulatory decisions to control industrial chemicals and pesticides to the definitions of banned and severely restricted chemicals in Article 2 of the Convention;

\* UNEP/FAO/RC/COP.5/1/Rev.1.

- (c) To develop recommendations for actions that would lead to improved notification activities by parties pursuant to Article 5.

## Annex

# Current regulatory processes for chemicals and their relationship to the definitions of banned or severely restricted chemicals in Article 2 of the Rotterdam Convention

## Introduction

1. Article 2 of the Rotterdam Convention includes the following definitions of a “banned chemical” and a “severely restricted chemical”:

“Banned chemical” means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment;

“Severely restricted chemical” means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment.

2. Article 5 of the Convention requires each party that has adopted a final regulatory action to ban or severely restrict a chemical to notify the Secretariat in writing of such action as soon as possible and no later than 90 days after the date on which the action takes effect. A notification sent in accordance with this provision must contain the information required by Annex I to the Convention, where available.

3. In order for a chemical to be considered for listing in Annex III to the Convention, the Secretariat must have received at least one notification of final regulatory action to ban or severely restrict it from each of two prior informed consent regions.

4. Notifications of final regulatory action constitute a key element in the successful operation of the Convention. These notifications facilitate information exchange on potentially hazardous chemicals and the identification of chemicals that are potential candidates for listing in Annex III to the Convention and, consequently, for inclusion in the prior informed consent procedure.

5. At the fourth meeting of the Conference of the Parties, during discussion of the progress that had been achieved in implementing the Convention, some representatives observed that the number of parties submitting notifications and the number of notifications made by parties were lower than expected. One possible reason for this was that the definitions of “banned” and “severely restricted” chemicals found in the Convention might not accord with the types of regulatory decisions that were being taken at the national level by parties.

6. Pursuant to the request made in decision RC-4/1, the Secretariat undertook a review of current regulatory processes for chemicals to determine their relationship to the definitions of banned or severely restricted chemicals in Article 2 of the Convention. Its findings are set out below.

## Regulatory processes for pesticides

7. Regulatory processes were developed for pesticides well before they were introduced for industrial chemicals. It was recognized that, as pesticides were biologically active, it was necessary to have a thorough understanding of their proposed applications, efficacy in controlling pests, and physical, chemical and toxicological properties before their use and consequent release into the environment. Typically, up to several hundred pesticide active ingredients may be registered in a country, with thousands of formulations based on those active ingredients.

8. In many developed countries, legislation was developed as early as the 1940s and 1950s that required industry to submit extensive test data that demonstrated both efficacy and safety as a prerequisite for securing permission to market a pesticide. In this process, usually referred to as

“pre-market registration”, Governments typically register each pesticide and each proposed use for the pesticide, including whether the product is intended for use by professional applicators, farmers and other user groups, and/or the public.

9. The pre-market registration process includes an assessment of both the active ingredient and a representative formulation that comprises the active substance together with other chemicals commonly used in commercial formulations, such as solvents and emulsifiers. The full formulation of a pesticide must be disclosed during the pre-market registration process and, while the assessment focuses on the active ingredient, programmes also evaluate the health and environmental risks of other chemicals that are included in commercial mixtures.

10. Current data requirements for the registration of pesticides are significantly more stringent than those that were in place several decades previously. This translates into significant costs for the proponent of a pesticide to be placed on the market — in some cases exceeding tens of millions of dollars for a full pre-market registration data package. Pesticide manufacturers carefully weigh the costs of bringing a product to market against the potential return on their investment. As manufacturers are aware of the types of concerns that regulatory officials have regarding health and environmental risks, they are less likely to seek to register a pesticide if test data identify concerns about key criteria that will be evaluated in the pre-market registration process. This behaviour on the part of industry may lead to the registration of safer pesticides that do not require extraordinary controls to be imposed, thereby contributing to the submission of fewer notifications under Article 5 of the Convention.

11. In addition to the pre-market registration scrutiny that is required for pesticides, many national programmes subject pesticides to post-registration research and monitoring studies to determine whether environmental and occupational risks have been adequately identified during pre-market registration review.

12. Some national programmes also make provision for a systematic re-evaluation of in-use pesticides after a period of field use to ensure that products that may have been registered many years previously are re-evaluated against more modern standards and data requirements. Industry may be requested to provide new or additional data or face deregistration of the product. If the re-evaluation process determines that the risks associated with the use of a pesticide are unacceptable, then the use of the pesticide may be controlled more tightly or, in cases in which the risks are determined to be unmanageable, the registration for specific uses or for the pesticide may be cancelled. Pesticides subjected to such controls should meet the Convention’s definitions for “banned” and/or “severely restricted” chemicals and the submission of notifications under Article 5 would be expected in such cases.

13. Significant costs may be associated with any tests that may be required during the re-evaluation of a pesticide. The cost of such tests may be sufficiently high that a registrant will allow a pesticide registration to lapse if the product does not seem likely to yield a sufficient return on the testing costs. The decision to let a registration lapse, however, may also be made by a registrant if it appears likely that unacceptable health or environmental risks will be identified by such tests. A regulator may not be in a position to determine the reason behind a registrant’s decision to allow a registration to lapse and this can prevent a party from determining whether it has an obligation to submit a notification under Article 5 in such cases. This behaviour on the part of industry may contribute to the lower than expected number of notifications under Article 5.

14. Developed countries have cooperated in their pesticides programmes through the Organization for Economic Cooperation and Development (OECD) since 1971. This has resulted in the development of standard test methods for physical, chemical and toxicological properties, good laboratory practices for the conduct of the test methods, and an agreement on the mutual acceptance of data produced using the tests according to good laboratory practices. This approach reduced the need for repetitive testing in connection with the registration of pesticides in multiple jurisdictions and prevented the creation of possible non-tariff barriers to trade. With the continuing exchange of information on risk assessment and risk management practices, this cooperative activity has provided for informed decision-making for pesticides that are undergoing registration or re-evaluation at the same time in more than one country.

15. Currently, there appear to be fewer pesticide active ingredients being developed and introduced to the market, a factor that may contribute to fewer notifications being required under Article 5. Furthermore, in comparison with earlier generations of pesticides, newer pesticides tend to be:

- (a) Less toxic;

- (b) Based on a more holistic approach to pest and pesticide management;
- (c) More targeted, with a narrower spectrum of activity and reduced effects on non-target organisms;
- (d) Limited in their range of uses (e.g., there are specific crop-pest combinations) and less likely to have their original registrations expanded for additional uses;
- (e) Applied through improved application methods that minimize adverse effects on applicators, non-target organisms and the environment.

16. Such factors could result in fewer health and environmental concerns being identified for newer pesticides and, therefore, fewer notifications being required under Article 5.

17. In addition to the detailed points made above, the following general observations are offered with regard to the possible relationship of regulatory decisions made in the registration and re-evaluation of pesticides to the definitions of “banned” and “severely restricted” chemicals in Article 2 of the Convention:

(a) Increasingly, specific uses of pesticides are being reduced, and pesticides withdrawn from national markets by their registrants or withdrawn from pre-market registration or re-evaluation review because of economic factors, i.e., the costs of performing the tests would exceed likely future profits;

(b) There are problems in interpreting the term “severely restricted” when a number of regulatory decisions have been made over an extended period of time, resulting in a gradual reduction and/or eventual phase-out of the production and/or use of older pesticides. This raises the question of what threshold criteria could be used to determine when an individual control becomes a severe restriction;

(c) A registrant may decide not to develop further data for a pesticide in the pre-market registration phase or decide not to resubmit the pesticide dossier for the re-evaluation process if the chances are that, due to persistent, bioaccumulative and toxic characteristics or unacceptable effects on human health and the environment, the pesticide will not be approved. In such cases, these pesticides are neither banned nor severely restricted, even though they have not been approved for use. In such cases, a notification would not be made under Article 5.

### **Regulatory processes for industrial chemicals**

18. While up to several hundred pesticide active ingredients may be registered in a country, there are tens of thousands of industrial chemicals in commercial use at any time and the mix of chemicals is constantly changing as older chemicals are withdrawn from use while new ones are introduced to commerce at the rate of a few hundred each year. Unlike pesticides, existing industrial chemicals have not been registered for use and many countries are unaware of the identities or quantities of chemicals in use within their borders.

19. Furthermore, most industrial chemicals in use at any given time are produced in relatively small quantities, as demonstrated by the following data from the European Union and Japan:<sup>1</sup>

(a) About 1 per cent of all chemicals on the market are produced in volumes greater than 1 million tonnes per year, and these account for more than 75 per cent of the total annual production volume of all chemicals;

(b) About 90 per cent of all chemicals on the market are produced in volumes of less than 10,000 tonnes per year, and these account for about 1 per cent of the total annual production volume of all chemicals.

20. As a consequence of the global production, distribution and transformation of industrial chemicals, there are currently hundreds of thousands of products, articles and formulations containing these chemicals in the global marketplace. The increased globalization of industry has resulted in the shift of large-scale production of many basic chemicals to developing countries, with the need for regulatory oversight for industrial chemicals increasingly appreciated by Governments in countries at all levels of development.

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<sup>1</sup> Organization for Economic Cooperation and Development, *OECD Environmental Outlook for the Chemicals Industry* (Paris, 2001).

21. Regulatory approaches used to assess and manage industrial chemicals differ significantly from those used for pesticides. In general, the approaches used in making decisions on health and environmental risk assessments for industrial chemicals have been designed:
- (a) To address the large numbers of both new and existing (i.e., in-use) chemicals;
  - (b) To reflect the reality that there are often much fewer data available for industrial chemicals than there are for pesticides;
  - (c) To incorporate screening processes for industrial chemicals based on such properties as persistence in environmental media, bioaccumulation potential and inherent toxicity and the potential for large-scale production or release of a chemical to the environment.
22. Separate processes are in place in many parties for assessing the health and environmental risks of new and existing industrial chemicals. Both processes were, however, implemented more recently than those for pesticides and they are more common in developed countries than in developing countries, especially in the case of processes for new chemicals. This is due in large part to several initiatives on industrial chemicals that were developed in the 1970s by the OECD member countries.
23. Regulatory programmes were introduced for existing industrial chemicals in many developed countries in the 1970s, in many cases as a reaction to the identification by OECD member countries in 1973 of the need for international action to control the use and release to the environment of mercury<sup>2</sup> and polychlorinated biphenyls.<sup>3</sup> Legislation developed during this period provided Governments with the power to compel industry to submit commercial, health and environmental information on specified chemicals, to conduct risk assessments and to impose risk management measures for chemicals that posed unacceptable levels of risk to human health or the environment.
24. OECD member countries subsequently fostered the development of systematic approaches<sup>4,5</sup> to prioritizing, assessing and managing the risks posed by existing industrial chemicals during the 1980s and 1990s. These approaches have been implemented at the national level by many developed countries. OECD member countries also initiated a large-scale programme to develop basic data sets for thousands of high-production-volume industrial chemicals – an activity that continues today.
25. Within the European Union, the REACH Regulation (Registration, Evaluation, Authorization and Restriction of Chemicals) entered into force on 1 June 2007. It streamlines and improves the former legislative framework on chemicals of the European Union.<sup>6</sup> The main aims of the regulation are to ensure a high level of protection of human health and the environment from the risks that can be posed by chemicals, to promote alternative test methods and the free circulation of substances on the internal market and to enhance competitiveness and innovation. It makes industry responsible for assessing and managing the risks posed by chemicals and providing appropriate safety information to their users. In parallel, the European Union can take additional measures on highly dangerous substances where there is a need for complementary action at the European Union level. The European Chemicals Agency was established to manage all matters pertaining to the REACH regulation and the classification, labelling and packaging of substances and mixtures.
26. Another significant measure to control existing industrial chemicals is the Montreal Protocol on Substances that Deplete the Ozone Layer to the Vienna Convention for the Protection of the Ozone Layer, which was developed in 1987 and is being implemented by 196 parties. Widely regarded as a successful international environmental treaty, the implementation of the Protocol has effectively controlled or eliminated the production and/or use of over 300 industrial chemicals. Funding under the Protocol's financial mechanism has enabled developing countries to establish units at the country level to implement national requirements under the Protocol. Countries at all stages of development have implemented effective control measures within agreed time frames and many chemicals have been successfully eliminated from the global marketplace or had their uses severely restricted.

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2 Recommendation of the Council on Measures to Reduce all Man-Made Emissions of Mercury to the Environment, 1973 [C(73)172/Final].

3 Decision of the Council on Protection of the Environment by Control of Polychlorinated Biphenyls, 1973 [C(73)1(Final)].

4 Decision-Recommendation of the Council on the Systematic Investigation of Existing Chemicals, 1987 [C(87)90/Final].

5 Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Existing Chemicals, 1990 [C(90)163/Final].

6 [http://ec.europa.eu/enterprise/sectors/chemicals/reach/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm)

27. Regulatory programmes for screening industrial chemicals before their commercialization were introduced in some developed countries in the 1970s. In 1982, OECD member countries agreed upon a minimum set of data that could be used by member countries in the pre-market evaluation of new industrial chemicals,<sup>7</sup> including data to assess the health and environmental risks posed by such chemicals. While pesticides require pre-market submission of extensive data sets before their registration for use, however, new industrial chemicals require much less data to be submitted, resulting in reduced costs and less rigorous conditions of use.
28. Some regulatory programmes for new industrial chemicals provide for the regulator to request test data additional to the minimum requirements; to impose limits on permitted uses; or to require future notification if additional uses are proposed or if quantities that are produced, imported or used exceed specified amounts.
29. In general, new regulatory programmes for industrial chemicals tend to employ simpler regulatory approaches than those for new pesticides as a result of the:
- (a) Much larger number of industrial chemicals for which notifications are required;
  - (b) Relatively limited amounts of data and information that are submitted in notifications;
  - (c) Short time frames typically involved in the decision-making process as a result of the large number of notifications;
  - (d) Fact that many industrial chemicals are never intended to be introduced into the environment and may only exist in closed systems (e.g., chemicals that are site-limited intermediates used to produce other chemicals);
  - (e) Fact that uses of industrial chemicals are determined by their physical and chemical properties, not their biological activity (which is the determining characteristic for pesticides).
30. The following general observations are offered with regard to the possible relationship of regulatory decisions made in the evaluation of new and existing industrial chemicals to the definitions of “banned” and “severely restricted” chemicals in Article 2 of the Convention:
- (a) Control measures have been implemented in all countries under the Montreal Protocol to ban or severely restrict ozone-depleting substances, which include 345 industrial chemicals (e.g., chlorofluorocarbons, hydrochlorofluorocarbons, hydrobromofluorocarbons and halons). Thus, a party to the Rotterdam Convention would be expected to submit notifications under Article 5 following its implementation of controls on these chemicals. As at 31 October 2010, seven parties had submitted 16 notifications on seven ozone-depleting substances;
  - (b) Control measures are also being developed and implemented under the Stockholm Convention on Persistent Organic Pollutants to eliminate or restrict the production and use of several industrial chemicals and pesticides. Many of the persistent organic pollutants that were included when the Stockholm Convention entered into force in 2004 were also included in Annex III to the Rotterdam Convention. New persistent organic pollutants are, however, now being added to the Stockholm Convention and parties will be banning and/or severely restricting them. This affords an opportunity for parties to both conventions to ensure the coordinated implementation of their obligations under both conventions by submitting notifications, as appropriate, under Article 5 of the Rotterdam Convention when they implement national control measures for the new persistent organic pollutants;
  - (c) A party to the Rotterdam Convention would be expected to submit a notification under Article 5 for a control action taken under its regulatory programme for industrial chemicals that prevents the introduction into commerce of a chemical that would pose risks to health or the environment if so introduced. Since the Convention entered into force in February 2004, one notification has been submitted as a result of a control action on a new industrial chemical;<sup>8</sup>
  - (d) A decision to limit the use or uses of a new industrial chemical might not trigger the need to make a notification under Article 5 because the regulatory action was actually initiating the use of the chemical rather than causing a reduction of prior use;
  - (e) A party to the Rotterdam Convention would be expected to submit a notification under Article 5 for a control action under its existing chemicals programme to ban or severely restrict the use of an existing chemical to reduce the risks posed to health or the environment;

7 Decision of the Council concerning the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals, 1982 [C(82)196/Final].

8 PIC Circular XXVIII (December 2008): NCC ether [CAS No. 94097-88-8], submitted by Canada.

(f) As some existing industrial chemicals have numerous uses, implementing a control on one use of such a chemical (e.g., a ban on all consumer uses) may not trigger a notification requirement under Article 5 if the decrease in the quantity of the chemical in use is not great enough to satisfy the definition of a “severely restricted chemical” in Article 2 of the Convention because uncontrolled uses of the chemical involve significant quantities of it;

(g) In general, as developed-country parties have well-developed regulatory infrastructures for new and existing industrial chemicals, they would be expected to submit notifications of final regulatory actions that meet all the requirements of the Convention (Article 5 and Annex I).

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