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OPERATIONAL PROCEDURES FOR THE INTERIM CHEMICAL REVIEW COMMITTEE

ISSUES ASSOCIATED WITH THE IMPLEMENTATION OF THE OPERATIONAL PROCEDURES:

COMMON AND RECOGNIZED PATTERNS OF USE OF SEVERELY
HAZARDOUS PESTICIDE FORMULATIONS

Note by the secretariat

1. The purpose of the present note is to identify issues for consideration by the Interim Chemical Review Committee when reviewing information on common and recognized patterns of use relevant to proposals for severely hazardous pesticide formulations submitted in accordance with article 6 of the Convention.

A. Background

2. At the first meeting of the Interim Chemical Review Committee, work was initiated on a report form to facilitate the collection and reporting of information on severely hazardous pesticide formulations in support of proposals under article 6 of the Convention. It is evident that consideration should also be given to better defining the type of information needed by the Committee in complying with the requirement in part 1 of Annex IV for the provision of information on "Common and recognized patterns of use of the formulation in the proposing party". This information will be important to the work of the Committee, as in its review of a proposal for a severely hazardous pesticide formulation it is to take into account the criteria in Annex IV, part 3, in particular:

* UNEP/FAO/PIC/ICRC.3/1.

- (a) Reliability of the evidence indicating that use of the formulation in accordance with common or recognized practices within the proposing party, resulted in the reported incidents;
- (b) Relevance of such incidents to other States with similar climate, conditions and patterns of use of the formulation;
- (c) That intentional misuse is not in itself an adequate reason to list a formulation in Annex III.

B. Defining the problem

3. There are widely varying views on what constitutes common and recognized patterns of use largely as a result of the varying levels of control over pesticide uses that exist under different regulatory systems. In developed countries common use may be considered equivalent to the legal use, e.g., those uses listed on the product label. In countries with a less developed regulatory infrastructure, however, the degree to which individual pesticide formulations are regulated and the role of the label in the national regulatory process varies widely such that common use practices may be more difficult to define.

4. The key challenge is determining what information is needed to characterize common and recognized patterns of use in a country and also how it might be collected.

5. The present paper identifies some of the issues associated with collecting information on common and recognized patterns. It also considers how it might be combined with other information available to the Committee and the possible use of surrogate or generic data to characterize pesticide use in developing countries.

C. Issues to consider

1. Widely differing methods of regulating pesticides in developing countries and their direct implications for defining common and recognized patterns of use

6. There is a need for a clear understanding of how individual formulations are regulated and managed in countries submitting proposals for severely hazardous pesticide formulations. For example:

(a) The pesticide active ingredient is registered or authorized for agricultural use perhaps on specific crops but individual formulations are not regulated;

(b) The pesticide active ingredient and individual formulations may be authorized for use in agriculture in general and not restricted to specific crops;

(c) For countries that do not have an active pesticide control scheme in place label claims will be those made by the manufacturer or formulator, which may not necessarily be relevant to the conditions of use in a specific country.

7. In such cases there is little or no control over how the individual formulations available in the market place are used. As a result common and recognized patterns of use will necessarily include uses other than those that may be on the label and should not be considered to represent illegal or misuse.

2. Type of information needed to characterize common and recognized patterns of use – what is available to the Interim Chemical Review Committee

8. The incident report form submitted by a Party in support of a proposal to include a severely hazardous pesticide formulation in Annex III will contain basic information on how a formulation is regulated and used in a proposing country (see UNEP/FAO/PIC/ICRC3/5), part A of the form requesting information on the “regulatory” status of the formulation in the country and part B providing a description of how the formulation was used in the specific incident reported.

9. Part A of the form requests the following information regarding the formulation:

- (a) Is it registered / permitted for use in the country?
- (b) What uses are permitted?
- (c) Are there any handling or applicator restrictions specified as a condition of registration;
- (d) Information on the extent of use, such as the number of registrations or production or sales quantity;
- (e) Other information on how the formulation is commonly used in the country

10. Consideration is needed as to whether or not additional information on common and recognized patterns of use in the reporting country, over and above that provided in the completed incident report form (part A and part B), might be required by the Committee.

11. The secretariat is to collect relevant information related to the formulation listed in part 2 of Annex IV. The information to be collected includes the toxicological and ecotoxicological properties of the formulation, incidents related to the formulation in other states and risk or hazard evaluations where available. The quantity of formulation specific information that will be available is likely to be limited. It is not clear to what extent information on closely related formulations or the active ingredients under consideration might also be collected for consideration by the Committee.

12. Given the likelihood that only limited formulation-specific information may be available to the Committee under point (i) in part 2 of Annex IV (“Other information which the Chemical Review Committee may identify as relevant is also to be collected”), further thought is needed as to what other information might be useful to the Committee in its consideration of individual proposals. It is clear that at least some of this information might only be identified on a case-by-case basis; however, an understanding of what this might realistically be expected to include would facilitate a proactive approach to preparing for the work of the Committee.

3. Collecting country specific information on common and recognized patterns of use for individual formulations

13. In preparing a proposal on a severely hazardous pesticide formulation for consideration by the Committee, the designated national authority is to provide information on common and recognized patterns of use for the specific formulation.

14. Current information on how individual formulations are typically used in a country may be very difficult for a designated national authority to collect. It is not clear whether or to what extent such information is routinely collected or documented and, where it has been collected, whether it is readily available to a designated national authority.

15. A systematic approach by designated national authorities to the collection of information on common and recognized patterns of use for a formulation could include the development and circulation of a questionnaire. Alternatively extension personnel, non-governmental organizations including the pesticide industry, commodity groups, public interest groups or project staff providing technical assistance might all possibly play a role in assisting a designated national authority in collecting or verifying use information.

16. Where information on use of a specific formulation is provided from sources other than the designated national authority, e.g., industries, public interest groups or commodity groups, the Committee will need to consider how it might be used. This would be important particularly in those situations where it suggested a different pattern of use from that presented by the designated national authority.

4. Alternative to collecting specific information on common and recognized patterns of use for individual formulations

17. Given the difficulty in collecting information on the use of individual pesticide formulations a different approach may be warranted. This could include a combination of information specific to the pesticide or formulation in question (that included in parts 1 and 2 of Annex IV), as well as more generic information on pesticide use in countries that could be made available to the Committee. This could involve consideration of at least three elements:

- (a) Inherent toxicity of the active ingredient or formulation;
- (b) Conditions of registration (e.g., the need for personal protective equipment) for the active ingredient and the same or similar formulations in countries with more developed regulatory infrastructure;
- (c) Information on how pesticides are commonly used in developing countries or countries with economies in transition. This latter information would not have to be country-specific, it might be based on information on common agricultural practices associated with certain commodities, or how pesticides are generally applied in such countries, e.g., the use of backpack sprayers, accessibility to personal protective equipment.

D. Next steps

18. The Interim Chemical Review Committee may wish to consider the issues identified in the present paper, the information available through a completed incident report form and, in the light of its experience with actual proposals for severely hazardous pesticide formulations, consider the need for further work.
