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Chemical Review Committee
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Item 6 (b) (i) of the provisional agenda*

Operational procedures for the Chemical Review Committee: working procedures and policy guidance forwarded from the Conference of the Parties: policy guidance: preparation and use of focused summaries

Policy guidance: preparation and use of focused summaries

Note by the secretariat

1. At its second session, the interim Chemical Review Committee recommended that, before the Secretariat forwarded verified notifications for review, the designated national authority should, if possible, submit a focused summary of the information used in support of the regulatory action, and cited in the notification of final regulatory action, for use by the Committee (UNEP/FAO/PIC/ICRC.2/11, para. 28).

2. The interim Chemical Review Committee further considered this issue at its third and fourth sessions. A draft working paper and a worked example of a focused summary were available to theCommittee at its fourth session (UNEP/FAO/PIC/ICRC.4/5). The Committee agreed that focused summaries were complementary to the process of regulatory action and would facilitate its work and approved the working paper on the preparation and use of focused summaries, as amended, for transmission to the Intergovernmental Negotiating Committee at its tenth session (UNEP/FAO/PIC/ICRC.4/18, para. 47).

3. At its tenth session the Negotiating Committee took note of the working paper on the preparation and use of focused summaries prepared by the interim Chemical Review Committee (UNEP/FAO/PIC/INC.10/15) and invited designated national authorities to prepare focused summaries, on a voluntary basis, using the information at their disposal (UNEP/FAO/PIC/INC.10/24, para. 85). The

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process, as noted by the Negotiating Committee at its tenth session, was posted on the Rotterdam Convention web site.

4. At its first meeting, the Conference of the Parties agreed to forward the paper on the preparation of focused summaries to the first meeting of the Chemical Review Committee for its consideration. The working paper on focused summaries is annexed to the present note.

5. The Committee is invited to review the paper and consider its adoption. The Committee may also wish to consider forwarding a request to the Conference of the Parties at its second meeting to invite designated national authorities to prepare focused summaries, on a voluntary basis, using the information at their disposal.

Annex

I. WORKING PAPER ON THE PREPARATION AND USE OF FOCUSED SUMMARIES

Purpose of focused summaries

1. Focused summaries are important tools in facilitating the work of the Interim Chemical Review Committee in reviewing notifications of final regulatory actions for banned or severely restricted chemicals which are candidates for inclusion in the interim prior informed consent procedure.

2. Focused summaries should summarize the notification of final regulatory action while ensuring that an adequate level of detail is provided so that the basis for the regulatory action is clearly presented. They should demonstrate how the notification fulfils the criteria in Annex II of the Convention by providing a summary of key decisions and key findings, with references to the associated documents.

3. Designated national authorities (DNAs) are invited to submit focused summaries of the information used in support of regulatory actions when providing supporting documentation for review by the Interim Chemical Review Committee. The use of a focused summary by the Committee is not intended to establish a new obligation for DNAs but remains a voluntary action aimed at facilitating the work of the Committee. Focused summaries should also assist DNAs in putting together a notification of final regulatory action for banned or severely restricted chemicals.

4. The format and content of focused summaries are flexible. They should focus on the information which a Government has considered in support of its final regulatory action. Documentation already produced and published by national Governments may be adequate as focused summaries. Focused summaries should be as informative and as short as possible; depending on the nature of the notification, they could be in the order of 10 pages in length. In situations where the supporting documentation is not available in English, the focused summary would be that part of the documentation which is translated into that language.

II. OUTLINE/KEY HEADINGS TO INCLUDE IN A FOCUSED SUMMARY

A. Introduction

5. This section should provide a brief statement/summary of the final regulatory actions and the reasons for the action taken (e.g. occupational health concerns, environmental concerns). It may include:

(a) The events that led to the final regulatory action;

(b) The significance of the regulatory action, e.g., one use or many uses, level or degree of exposure;

(c) An overview of the regulatory system of the notifying country, if relevant;

(d) The scope of the regulatory action: a precise description of the chemicals subject to the regulatory action.

B. Risk evaluation

6. This section should contain evidence, as available, that a risk evaluation was carried out under the prevailing conditions of the notifying country. It should confirm that the criteria in Annex II, subparagraph (b) have been met. It may include:

(a) Key findings of the national risk evaluation;

(b) Key data reviews consulted together with a brief description;

(c) Reference to national studies, e.g. toxicological and ecotoxicity studies;

(d) A summary of actual or potential human exposure and/or environmental fate.

III. RISK REDUCTION AND RELEVANCE TO OTHER STATES

7. This section should contain evidence that the control action is of relevance to other States. It may include information on the following:

(a) Estimates of the quantity of chemicals used, or imported/exported, at the time of the regulatory action and, if possible, information on ongoing trade;

(b) Relevance of the control action to other States, i.e. those with similar conditions of use;

(c) Comments on the typical use of the chemical in the notifying country, with comments on possible misuse if appropriate.

WORKED EXAMPLE OF A FOCUSED SUMMARY – MONOCROTOPHOS

A. Introduction

1. This section should provide a brief statement/summary of the final regulatory action and the reasons for the action taken (e.g. occupational health concerns, environmental concerns). It may include:

(a) The events that led to the final regulatory action

The registration of monocrotophos and all products was withdrawn as the result of a review of monocrotophos conducted by the Australian National Registration Authority for Agricultural and Veterinary Chemicals (NRA) and its advisory agencies.

(b) Significance of the regulatory action, e.g., one use or many uses, level or degree of exposure

From 9 December 1999, the Australian registration of monocrotophos was cancelled by the NRA. The NRA's decision cancels the registrations and all relevant approvals, and halts further imports. Use of monocrotophos will be phased out over a year to allow current stocks of monocrotophos to be used up. This was seen as the lowest-risk option for disposing of existing stocks of monocrotophos, in the light of risks associated with product recall, storage and disposal. It also allows users time to change over to other pesticides. Wholesale supply of products to cease by 30 June 2000; retail sale to cease by 31 December 2000; and all minimum recommended levels will be withdrawn from 30 June 2002.

(c) An overview of the regulatory system of the notifying country, if relevant

The NRA is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals. The NRA's Existing Chemicals Review Programme (ECRP) systematically examines agricultural and veterinary chemicals registered in the past to determine whether they continue to meet current standards for registration. Chemicals for review are chosen according to predetermined, publicly available selection criteria. The review's findings are based on information collected from a variety of sources, including data packages and information submitted by registrants, information submitted by members of the public, questionnaires sent to key user/industry groups and Government organizations, and literature searches.

(d) Scope of the regulatory action: a precise description of the chemicals subject to the regulatory action

Australia has withdrawn registration for monocrotophos and all products with a phase-out period of one year, ending 30 June 2002 for existing stocks. The Australian MRLs for monocrotophos are to be withdrawn on 30 June 2002.

B. Risk evaluation

2. This section should contain evidence, as available, that a risk evaluation was carried out under the prevailing conditions of the notifying country. It should confirm that criteria in Annex II, subparagraph (b) have been met. It may include:

(a) Key findings of the national risk evaluation

Australia's risk evaluation took into account toxicology and public health; occupational health and safety; environmental impact; trade impact; and availability of lower-risk alternatives. The review concluded that continued use of monocrotophos would pose an unacceptably high risk to workers, to wildlife, especially avian and aquatic species, and to trade. The environmental risk of monocrotophos use is primarily through exposure of non-target species. Monocrotophos is very highly toxic to birds

exposed on an acute oral and subacute dietary basis. Monocrotophos was determined to be the cause of mortality or was strongly implicated in a large number of bird-kill incidents affecting a wide variety of avian species. Monocrotophos posed serious risks to birds even when application was performed in a manner consistent with label directions. Monocrotophos is also highly toxic to freshwater invertebrates. The human health risk arises because monocrotophos is a potent cholinesterase inhibitor and applicators and workers are potentially at risk of acutely toxic effects. In laboratory studies on rats and rabbits, monocrotophos was found to induce maternal toxicity and developmentally toxic effects (runting), but no major teratological abnormalities, at low doses.

(b) Key data reviews consulted together with a brief description

FAO/WHO, 1995. Pesticide Residues in Food – 1995 evaluations. Part II - Toxicological and Environmental. Joint Meeting on Pesticide Residues (JMPR); WHO Geneva WHO/PCS/96.48.

FAO/WHO, 1993. Pesticide Residues in Food – 1993; Report, Joint Meeting on Pesticide Residues (JMPR); FAO Plant Production and Protection Paper 122.

FAO/WHO, 1995. Pesticide Residues in Food – 1995; Report, Joint Meeting on Pesticide Residues (JMPR); FAO Plant Production and Protection Paper 133.

WHO/PCS/96.3. World Health Organization, IPCS, Geneva.

USEPA, 1985. Guidance for the re-registration of manufacturing use and certain end use pesticide products containing monocrotophos. USEPA, Washington, D.C. (Sept. 1985).

USEPA, 1985. Pesticide fact sheet No 72: Monocrotophos. USEPA, Washington D.C.

(c) Reference to national studies, e.g. toxicological and ecotoxicity studies

The NRA review of monocrotophos, January 2000. NRA Review Series 00.1. National Registration Authority for Agricultural and Veterinary Chemicals. (http://www.nra.gov.au/chemrev/chemrev.shtml)

National Registration Authority for Agricultural and Veterinary Chemicals (NRA) Board Resolution 793, Action 99-77a, 9 December, 1999.

(d) Summary of actual or potential human exposure and/or environmental fate

Human exposure assessment

General public: The only exposure path relevant to the general public was considered to be food. An estimate of monocrotophos intake was derived from the Australian Market Basket Survey. This procedure is based on measured monocrotophos residues found in food surveys rather than assuming that the pesticide is present at the maximum residue limit (MRL). In 1994, the estimated intake in the group with the highest consumption of monocrotophos residues (toddlers aged two) was 7.2 ng/kg bw/day which accounts for less than 3 per cent of the acceptable daily intake (ADI).

Workers: In accordance with internationally accepted practice, the occupational risk assessment was based on hazard characterization and worker exposure. The latter took into consideration the mixing, loading and application activities involved in the use of the pesticide. However, there were no measured worker exposure studies for mixing, loading or application of monocrotophos and therefore, the United Kingdom Prediction Operator Exposure Model (UKPOEM) was used to estimate exposure, from which margins of exposure (MOE) for the Australian use pattern were determined wherever possible.

The conclusions of the occupational health and safety assessment were that:

- High-volume air-blast spraying of fruit and vegetables posed a high and unacceptable risk for workers applying monocrotophos, even if mixer/loader exposure was eliminated.

- High-volume and low-volume boom-spraying on flowers, tomatoes, French beans and maize are not supported as the risk is unacceptable.

- Ground-spraying on broadacre crops is not supported as the risk is unacceptable.

- Aerial spraying is the only application method which was supported because of the comparatively minimal likely exposure to users.

Environmental exposure assessment

Australia's environmental assessment calculations using standard methodology showed that there was a high risk to birds from the use of monocrotophos when avian food items were sprayed. There was also a high aquatic risk to sensitive invertebrates from spray drift at all application rates, except for boom-spray applications at 140 g a.i/ha, where, provided suitable measures to reduce spray drift are in place, the risk is moderate. The risk to bees and other non-target insects was high. There is also a potentially high risk to aquatic organisms from runoff if rain occurs within days of application.

C. Risk reduction and relevance to other states

3. This section should contain evidence that the control action is of relevance to other States. It may include information on the following:

(a) Estimates of the quantity of chemicals used, or imported/exported, at the time of the regulatory action and, if possible, information on ongoing trade

No information

(b) Relevance of the control action to other States, i.e. those with similar conditions of use

The restriction of use of monocrotophos should be considered by all States because of the high risk associated with all uses but particularly ground spraying, of monocrotophos even when rigorous occupational health and safety practices are employed. The Australian review identified risks to users, trade and the environment and especially to avian and aquatic species.

Alternatives: The following alternatives are considered to pose lower risks to workers and the environment. World Health Organization hazard classifications are provided as an aid to the consideration of relative risks. The classifications are for active constituents. Actual hazard depends on formulations.

Moderately hazardous: chlorpyrifos, diazinon; dimethoate; fenitrothion

Slightly hazardous: azamethiphos; malathion.

(c) Comments on the typical use of the chemical the notifying country, with comments on possible misuse if appropriate

Typical and supported uses of monocrotophos were: aerial application to bananas, potatoes, and broadacre crops including tobacco, cereals, wheat, oilseeds and cotton; high-volume air-blast spraying of fruit and vegetables; high-volume and low-volume boom-spraying on flowers, tomatoes, French beans and maize; ground spraying on broadacre crops. After the NRA review, aerial spraying was the only application method which was supported because of the comparatively minimal likely exposure to users.