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OPERATIONAL PROCEDURES FOR THE INTERIM CHEMICAL REVIEW COMMITTEE:

ISSUES ASSOCIATED WITH IMPLEMENTATION OF THE OPERATIONAL PROCEDURES: PREPARATION AND USE OF FOCUSED SUMMARIES

Note by the Secretariat

1. The purpose of this note is to provide the Interim Chemical Review Committee with a working paper on the preparation and use of focused summaries. Annexed to this note is a draft working paper that briefly describes the purpose of a focused summary, provides an outline of what a focused summary of the information used by a country in support of their notifications of final regulatory action should contain, as well as, a worked example.

2. At its second session, the Interim Chemical Review Committee (ICRC) reviewed its operational procedures and agreed that, before the secretariat forwards verified notifications to it for review, the designated national authority, in response to a request by the secretariat for the documentation cited in the notification of final regulatory action, 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. The Committee also agreed that examples of focused summaries should, in the future, be circulated to designated national authorities (UNEP/FAO/PIC/ICRC.2/11).

3. At its third session, the ICRC established a break-out group to develop an outline for a focused summary and guidelines for their preparation. The Committee noted that the focused summary was aimed at facilitating their work in making decisions on chemicals, and was not intended to replace documentation referenced in the notification of final regulatory action. In follow-up to these recommendations, Australia prepared an example of a focused summary on the basis of the documentation for monocrotophos.

* UNEP/FAO/PIC/ICRC.4/1.

For reasons of economy, this document is printed in a limited number. Delegates are kindly requested to bring their copies to meetings and not to request additional copies.

4. The report of the break out group established at the third session of the Committee and the worked example prepared by Australia have been combined to form the draft working paper.

Annex I

WORKING PAPER ON THE PREPARATION AND USE OF FOCUSSED SUMMARIES

PURPOSE OF A FOCUSED SUMMARY

A focused summary is an important tool in facilitating the work of the Interim Chemical Review Committee in reviewing candidate chemicals' notifications of final regulatory actions for banned or severely restricted chemicals.

A focused summary 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. It should demonstrate how the notification applies to the criteria in Annex II of the Convention by providing a summary of key decisions and key findings with references to the associated documents.

Designated National Authorities (DNAs) are requested to submit a focused summary of the information used in support of a regulatory action when providing the 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. It should also assist a DNA in putting together a notification of final regulatory action for banned or severely restricted chemicals.

The format and content of the focused summary is flexible. It should focus on the information that a government has considered in support of its final regulatory action. Documentation already produced and published by national Governments may be adequate as a focused summary. The focused summary should be as informative and as short as possible, depending on the nature of the notification it could be in he 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 that is translated

OUTLINE/KEY HEADINGS TO INCLUDE IN A FOCUSED SUMMARY

I. INTRODUCTION

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

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

(b) Significance of 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) Scope of the regulatory action – precise description of the chemicals subject to the regulatory action.

II. RISK EVALUATION

This section should provide evidence that a risk evaluation was carried out under the prevailing conditions of the notifying country. It should confirm that criteria Annex II (b) are met. May include:

(a) Key findings of the national risk evaluation;

(b) Key data reviews consulted and a brief description;

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

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

III. RISK REDUCTION AND RELEVANCE TO OTHER STATES

This section should provide evidence that the control action is of relevance to other States. Could 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 to other States, i.e. those with similar conditions of use;

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

WORKED EXAMPLE OF A FOCUSSED SUMMARY – MONOCROTOPHOS

I. INTRODUCTION

This section should provide a brief statement/summary of the final regulatory actions and the reasons for the actions taken (e.g. occupational health concerns, environmental concerns). Could 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 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 stock 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. The wholesale supply of products to cease by 30 June 2000; retail sale to cease by 31 December 2000; and all MRLs 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 Program (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 pre-determined, 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 organisations, and literature searches.

(d) Scope of the regulatory action – 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 to be withdrawn on 30 June 2002.

II. RISK EVALUATION

This section should provide evidence that a risk evaluation was carried out under the prevailing conditions of the notifying country. It should confirm that criteria Annex II (b) are met. 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, wildlife, especially avian and aquatic species and 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 sub-acute 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 for 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 and 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 MRL. In 1994, the estimated intake in the group with the highest consumption of monocrotophos residues (toddlers aged two) was 7.2 nanograms/kg bw/d. This intake accounts for less than 3% of the ADI.

Workers: In accordance with internationally accepted practice, the occupational risk assessment was based on hazard characterisation 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 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 OH&S 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 or low-volume boom-spraying on flowers, tomatoes, French beans and maize is not supported as the risk is unacceptable.
- Ground-spraying on broad-acre crops is not supported as the risk is unacceptable.

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

Environmental exposure assessment

Australia's environmental assessment calculations using standard methodology show that there was a high risk to birds from the current 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.

III. RISK REDUCTION AND RELEVANCE TO OTHER STATES

This section should provide evidence that the control action is of relevance to other States. Could 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 to other States, i.e. those with similar conditions of use;

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

Alternatives: the following alternatives are considered to pose lower risks to workers and the environment. World Health Organisation hazard classifications are provided as an aid to consideration of relative risks. These 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 within the notifying country, with comments on possible misuse (if appropriate).

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