Re-evaluation Note REV2010-18

Re-evaluation Program

This Re-evaluation Note outlines the Pest Management Regulatory Agency's (PMRA) new approach to re-evaluation.

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1.0 Introduction

Re-evaluation is the review of pesticide active ingredients and their end-use products on the basis of updated data and information to determine whether, and under what conditions, their continued registration is acceptable.

In 2001, the Pest Management Regulatory Agency (PMRA) implemented the four-program re-evaluation approach[1] for pesticides registered prior to January 1995. This approach is now reaching completion. As of September 2010, over 90% of the 401 active ingredients covered under the original approach have been addressed, with the vast majority of assessments resulting in changes to the conditions of use. A significant proportion of the active ingredients (over 20%) have been identified for phase-out (i.e. discontinuation) as a result of the PMRA's review or voluntarily discontinuation by their manufacturers. Very few active ingredients have been accepted for continued use without any label changes.

The *Pest Control Products Act* (PCPA) came into force in 2006, 5 years after the original re-evaluation approach was articulated. It specifies the legal foundation for re-evaluation and prescribes that the re-evaluation of all pesticides be initiated on a 15-year cycle to ensure that they continue to meet current scientific standards. Currently, 572 active ingredients are found in approximately 5000 pesticides registered under the PCPA in Canada. At the time of their initial registration, these pesticides were considered acceptable (i.e. met health, environment and value standards of the time). Since then, science has evolved, and additional information may be available which could affect the risk and value profile of a pesticide. It is incumbent on the PMRA to re-evaluate registration and post-registration decisions on a regular basis to determine whether the use of pesticides continues to be acceptable according to current standards.

This Re-evaluation Note presents and solicits comments on a renewed approach to cyclical re-evaluation which is in line with the requirements of the PCPA.

2.0 Key considerations for developing the proposed new approach

2.1 Requirements of Legislation

The PCPA requires the PMRA to initiate re-evaluations for each registered pesticide on a 15-year cycle, based on the date of either its initial registration or the most recent major decision affecting the registration. The Act also requires that a scientifically based approach be applied in evaluating the health and environmental risks and in determining whether those risks are acceptable. This provides for a systematic review of registered products on a regular basis and supports the ongoing incorporation of new methodologies, data and regulatory approaches into the evaluation and assessment of pesticides. Those may include, for example, new methods of risk evaluation and assessment, new methods of risk mitigation and new information about specific pesticides. In addition, the approach considers the unique characteristics of sensitive subpopulations among humans and other organisms.

[1] Described in the Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program approach.*

The PMRA is required to initiate a re-evaluation as per section 16 (2) of the PCPA:

> *"...the Minister shall initiate a re-evaluation of that product no later than one year after fifteen years have elapsed since the most recent decision"*, of a type referred to in the paragraph 28 (1) (a) or (b),

28(1)(a): "to grant or deny an application

- *(i) to register a pest control product that is or contains an unregistered active ingredient, or*
- *(ii) to register, or amend the registration of, a pest control product if the Minister considers that registration or amendment of the registration may result in significantly increased health or environmental risks;*

28(1)(b): "about the registration of a pest control product on completion of a re-evaluation or special review".

Re-evaluation of a pesticide is conducted as per section 16 (6):

> *"...After the re-evaluation is initiated , the Minister shall, in accordance with the regulations, if any, conduct any evaluations that the Minister considers necessary with respect to the health or environmental risks or the value of the pest control product and shall carry out the consultations required..."*

The PMRA may initiate a re-evaluation before the fifteen year statutory deadline as per section 16 (1):

> *"...The Minister may initiate the re-evaluation of a registered pest control product if the Minister considers that, since the product was registered, there has been a change in the information required, or the procedures used, for the evaluation of the health or environmental risks or the value of pest control products of the same class or kind."*

2.2 International Cooperation

In 1994, the Canadian government proposed a cost-effective re-evaluation program on the basis of cooperation between Canada and the U.S., and with other members of the Organisation for Economic Co-operation and Development (OECD).[2]

The PMRA is committed to continuing co-operation with international regulatory bodies regarding re-evaluation activities. Where appropriate, the PMRA will participate in joint reviews or work-sharing of documents and information relating to the review of a pesticide with other countries such as partners in the North American Free Trade Agreement (NAFTA) and OECD.[3]

[2] *Government Proposal for the Pest Management Regulatory System - October 1994*

[3] *Pest Management Regulatory Agency Strategic Plan 2008-2013*

In order to maximize efficiency, the PMRA will align Health Canada's re-evaluation schedule with that of the United States Environmental Protection Agency (USEPA), wherever appropriate.

2.3 Lessons learned from the "First Round" of Re-evaluation

While the original re-evaluation program has succeeded in ensuring that older pesticides meet modern standards, there have been challenges and lessons learned.

The original re-evaluation program addressed products registered from the late 1920's through to 1995. Many were registered before the existence of electronic databases, resulting in resource-intensive research and assessment of archived files. These demands will lessen as the PMRA begins to address active ingredients registered in 1995 or later, since the supporting data are more likely to be available in electronic form and study methods are more likely to resemble current requirements.

Further, because there was a long time lapse between the initial registration of these older active ingredients and their re-evaluation, science standards had generally evolved considerably since the last major review of the active ingredient resulting in more extensive data or review requirements. Again, these demands are expected to lessen in subsequent re-evaluations as the PMRA begins to address active ingredients with more up to date databases.

Lastly, stakeholders and Agency personnel have indicated that there is potential to improve the clarity of the scope and timelines of the re-evaluation process. The stages in the re-evaluation that will be open to consultation are being re-examined and will be clearly articulated in the final process.

3.0 Proposed new approach

3.1 General

This regulatory proposal describes a focussed re-evaluation approach where the breadth and depth of the review would be commensurate with the complexity of issues associated with a given pesticide.

This introduces a scoping phase early in the re-evaluation process during which the PMRA would complete an internal file review to assess the quality of the data already available to the Agency. This file review would include identifying recent evaluations for the active ingredient and a scan for new information such as new scientific literature and incident reports.

If a previous evaluation has not considered all available data or is not up-to-date, a new or revised evaluation may be required. For example, new scientific approaches, PMRA policies, or new scientific data and models could potentially result in modifications to the conditions of registration. The file review may conclude that the health and environmental risks and the value of the active ingredient need to be re-examined.

On the other hand, the file review may indicate that a previous evaluation in a specific area (e.g. dietary risk assessment) is acceptable as measured against current standards. The PMRA will complete an analysis to ensure that the conditions of use assessed in the previous evaluation remain reflective of the current situation – that is, nothing has changed substantially since the previous risk assessment. If this is the case, this component of the re-evaluation may be considered complete and the previous risk assessment will stand.

The PMRA may determine that all components of the re-evaluation are adequately addressed by previous reviews, and that additional evaluation is not warranted (i.e. that a pesticide satisfies the current standard of health and environmental risk and continues to be acceptable for registration).

This approach will permit the PMRA will to focus its review resources on those areas of risk assessment that require an update. In accordance with the PCPA, the PMRA's conclusions, including any proposed risk management measures, will be published for consultation and subsequent finalization.

3.2 Process

The proposed process is as follows:

Step 1 assess the information available to the PMRA including any information suggesting a change in risk or value; determine the scope of additional risk analyses and information required for the PMRA to make a re-evaluation decision;

Step 2 develop and publish a work plan, specifying areas to be re-evaluated; issue a data call-in for relevant studies;

Step 3 conduct re-evaluations of targeted areas;

Step 4 publish a proposed re-evaluation decision for consultation;

Step 5 publish a final re-evaluation decision;

Step 6 implement the decision.

Steps 1 and 2:

Clearly defining the scope of a re-evaluation is key to an efficient and targeted approach. Consequently, the first step is to complete an internal file review and assess information available on an active ingredient. Based on this internal file review, the PMRA will outline the anticipated focus of the re-evaluation and share this information with stakeholders.

During Steps 1 and 2 the PMRA may request additional information from registrants to supplement the existing information on file. This could include information on the use pattern and extent of use, new science, incident reports, and risk mitigation measures.

Steps 3, 4 and 5

Scientific re-evaluations are conducted during Step 3. On the basis of these, proposed regulatory decisions regarding the acceptability of continuing registration of the pesticide will be published for consultation.

A re-evaluation could result in one or more outcomes. The proposed regulatory decision could include continuing registration with no changes, adding additional protective measures to label instructions or removing certain uses or formulations from registration. It could identify additional information requirements as a condition of registration to confirm or refine the conclusions drawn. The PMRA may also choose to publish an interim re-evaluation decision and/or pursue interim risk mitigation, pending submission of this requested information. A pesticide registration could also be proposed for discontinuation because of unacceptable risks to human health or the environment of Canadians or unacceptable value.

Under the PCPA, a registration may be cancelled or amended prior to the conclusion of the re-evaluation, if during the course of the re-evaluation, there are reasonable grounds to believe that this is necessary to deal with a situation that endangers human health or safety or the environment.

In accordance with the PCPA, the PMRA will consult the public and stakeholders on proposed re-evaluation decisions, including any proposed risk management measures.

3.3 Scheduling

The initiation date of the re-evaluation for a specific active ingredient or cluster will be generally based on the date of the most recent regulatory decision of a type referred to in section 28(1) of the PCPA.

Other factors may influence prioritization resulting in the scheduling of re-evaluation earlier than the statutory deadline. For example, prioritization may be changed to cluster active ingredients where it makes sense to complete the re-evaluations as a group instead of strictly according to the statutory time requirements.

The PMRA will inform the public of the schedule by publishing workplans for the active ingredients subject to re-evaluation.

4.0 Special Review

Special review is another post-registration process by which the continuing acceptability of the risks and value of a product can be determined. It differs from cyclical re-evaluation in that it is not triggered by the amount of time that has elapsed since the last major risk assessment. Rather, a special review is triggered by new scientific evidence that provides the PMRA with reasonable grounds to believe that the health or environmental risks or value of the product are unacceptable. Such information may be derived from a variety of sources including, for example, federal or provincial departments, OECD member countries, incident reports made by applicants and registrants, or the public.

A special review is initiated and conducted in essentially the same manner as a re-evaluation. It must, of course, include an evaluation of the aspects of the product to which the new scientific evidence relates. However, it may be extended beyond those aspects to include any others that are considered to be necessary for the purpose of determining whether an affected registration continues to meet the prescribed standard of acceptability, or should be amended or cancelled.

Depending on the nature of the information, the triggering of a special review could result in the conduct of a complete re-evaluation. If the active ingredient is already under re-evaluation, the concern will be addressed during that process. If a re-evaluation has not yet been initiated when the special review is triggered, the re-evaluation schedule may be modified to enable the special review to be conducted in that context.

It is important to note that at any time during either a re-evaluation or a special review, the PMRA may take immediate regulatory action if there is sufficient evidence of unacceptable risk.

Under the PCPA, products are only registered after a determination that the health and environmental risks and the value of the pest control products are acceptable. As per section 2(2) of the PCPA (2002), acceptable risk is defined as follows:

> *"For the purposes of this Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration."*

In accordance with the PCPA, the PMRA will consult the public and stakeholders on proposed special review decisions, including any proposed risk management measures.

5.0 Next Step

The PMRA will accept written comments up to 60 days from the date of publication of this document. Please forward all comments to the PMRA Publications group (please see contact information on the cover page of this document).