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Regulatory Proposal

PRO2016-02

Management of the Pesticide Re-evaluation Process

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1.0 Purpose

The purpose of this document issued by Health Canada's Pest Management Regulatory Agency (PMRA) is to communicate to members of the pesticide industry, user groups and other interested parties, the changes proposed to the re-evaluation process for registered pesticides and to invite comments on the steps as outlined below.

2.0 Background

The *Pest Control Products Act* requires the PMRA to initiate re-evaluations for each registered pesticide on a 15-year cycle, based on either its initial registration or the most recent major decision affecting the registration. At the time of their initial registration, these pesticides were considered acceptable (that is, met health, environment and value standards of the time). Since then, science may have evolved and additional information may be available that could affect the risk or value profile of a pesticide. Therefore, PMRA re-evaluates registered pesticides on a 15-year cyclical basis to determine whether their use continues to be acceptable according to current standards. Regulatory Directive DIR2012-02; *Re-evaluation Program Cyclical Re-evaluation* outlined the Agency's approach to cyclical re-evaluations. The current document describes in more detail, key elements of the re-evaluation review process, as well as performance targets for PMRA and industry.

Many stakeholders have communicated to PMRA the need for more engagement, transparency, and predictability of the program. Changes to current practice are being proposed to enhance predictability and transparency for registrants and the public, while taking into consideration the wide range of complexity of the scientific review work required in order to complete re-evaluations. Some of these proposed changes include; establishing clearer timelines for PMRA and industry to complete key steps, setting limits on the consideration of new information and requests for expansions of the pesticide use pattern, a longer public consultation step and more informative decision documents. As well, further opportunities for early stakeholder engagement have been introduced. These steps are described further in Section 4.0.

In the interest of seeking additional efficiencies, PMRA will be exploring greater alignment of our re-evaluation schedules with those of the United States Environmental Protection Agency or the consideration of work sharing for reviews where appropriate. PMRA will also continue the current practice of communication with other regulatory authorities regarding relevant science or regulatory issues.

3.0 Outreach

In order to improve transparency and predictability, the PMRA will inform the public of upcoming re-evaluation documents by publishing a multi-year work plan for the program, which will be updated annually. Additional tools such as conference calls or webinars may be offered by the PMRA periodically to update any interested stakeholders and the public on general status of the program.

For each re-evaluation, a project plan document outlining the anticipated focus of the re-evaluation, any additional information and/or new data required (as noted in the data call-in) as well as the associated timelines, may be published to Health Canada's website for public information. Documents associated with each re-evaluation, including published decision documents as well as notices, are available to the public, and these can be found currently in the PMRA Public Registry on the Pesticides and Pest Management portion of Health Canada's website at www.healthcanada.gc.ca/pmra. Final re-evaluation decision documents will include information regarding the timelines to implement these decisions, which are also communicated directly to product registrants. PMRA may consider additional communication tools, when needed, to better inform interested stakeholders including pesticide product users, retailers and consumers.

4.0 Management of the Pesticide Re-evaluation Process

The following sections provide a step-by-step description of the key elements of the re-evaluation review process and the time expected for each step (Appendix I). Re-evaluations are typically conducted in chronological order as initiated. There may, however, be situations where to maximize efficiency, the PMRA will align Health Canada's re-evaluation schedule with that of another international regulatory body or other parts of the Canadian federal government for work-sharing or collaboration purposes. PMRA will also continue the current practice of ongoing communication with other regulatory authorities regarding relevant science or regulatory issues. Other factors may result in the scheduling of re-evaluations earlier than the statutory deadline. For example, a cluster of similar actives might be re-evaluated as a group instead of strictly according to the statutory time requirement. It should also be noted that, whenever human health or environmental risks from pesticide exposure require prompt attention, PMRA will take appropriate regulatory action regardless of the re-evaluation review status.

4.1 Initiation (30 calendar days for registrant response)

The initiation date of the re-evaluation of an active ingredient will be generally based on the date of its initial registration. If there has been a more recent major regulatory decision of a type also referred to in section 28(1) of the *Pest Control Products Act* (such as a major amendment of the registration) this may be taken into consideration when determining the initiation of a cyclical re-evaluation. Upon the issuance of an initiation notice (under *Pest Control Products Act* Section 16) to the registrant(s), the data provider (typically the registrant of technical grade active ingredient) will be provided with 30 days to confirm their support for the re-evaluation. If none of the registrants provide support, all product registrations will be discontinued and the re-evaluation file will be closed. If support is provided, however, the re-evaluation will then move to the scoping step.

4.2 Scoping (120 days)

Regulatory Directive 2012-02; Re-evaluation Program Cyclical Re-evaluation, describes a focussed re-evaluation approach where the breadth and depth of the review will be commensurate with the complexity of the issues associated with a given pesticide. The PMRA will consider existing assessments previously conducted by the Agency to determine if they continue to meet the standards of modern science/policy for health and environment in all the

review areas (in other words, health, environment and value). Scoping reviews will also include scans of other information available including, but not limited to; incident reports, status of active ingredients in other jurisdictions, conditions of product use, etc.

Currently, the scoping review assists with identifying the expected complexity and depth of work required, as well as time needed, for completing the proposed decisions. In general, the scoping exercise will identify whether a re-evaluation will be of low, medium or high complexity.

A re-evaluation is considered to be of low complexity if all components of the re-evaluation may be adequately addressed by previous reviews and a detailed new evaluation is not warranted or the product labels may only need to be updated to meet current labelling requirements. A re-evaluation of medium complexity would typically not require additional information gathering, yet would include a detailed evaluation in some areas, such as revising risk assessments using current assumptions or more precise drinking water estimates. High complexity re-evaluations, which have the longest projected timeframes, are typically ones in which more information will be required (described in Section 4.3) in order to proceed with updating risk assessments. Evaluations could include, but are not limited to review of the new studies and the application of revised endpoints to exposure assessments. In some cases, an active ingredient with a large number of uses, emerging science issues or extensive monitoring data can add to the work needed to complete a proposed decision.

4.3 Information Gathering (90 days)

As noted above, the scoping exercise may determine that additional information is needed before proceeding to reviews. In these cases, the following substeps could be included:

Early stakeholder engagement – For certain complex re-evaluations, the PMRA may engage registrants and key stakeholders such as product user associations in collecting information to clarify parts of the current use pattern for an active ingredient in Canada. This information would help to reduce uncertainties that could result in conservative assumptions during the risk assessment (such as assuming that users apply the maximum number of product applications).

Verification of Use Pattern – The PMRA will also require the registrants to gather and provide information that will confirm the use pattern, in order to arrive at the most realistic basis for the PMRA risk assessments based on current usage; information that may include extent of use, details of certain application scenarios, etc.

Data Call-In – The PMRA will issue a request for additional information and/or studies when considered necessary to conduct the re-evaluation. A data call-in notice will be issued to the registrant (data provider) under the authority of Section 19 of the *Pest Control Products Act*. PMRA also sends a notice of the re-evaluation to other federal and provincial government departments, as per subsection 16(4) of the *Pest Control Products Act*.

At this point, a project plan document, outlining the anticipated focus of the re-evaluation, any additional information and/or new data required to proceed (that is, data call-in) as well as the associated timelines, may be published to Health Canada's website for public information.

4.4 Review (360 to 650 days)

Whether or not an information gathering step is needed, the re-evaluation will proceed to a review stage. The scoping step will have determined the depth and areas of evaluation that are needed, which will inform the estimated time to complete the evaluation. In this stage, evaluations will be conducted on the health and environmental risks, along with the value of the pesticide active ingredient and associated products. This step will include both risk assessment and risk management (that is, development of the proposal for additional mitigation of risks such as changes to product labels, removal of uses or cancellation of products), as well as related internal decision-making and preparation of the proposal document for publication.

For improved predictability to meet expected timelines, it is important that once the re-evaluation review stage begins, PMRA can proceed to complete these evaluations, without the need to consider further changes to the use pattern. Experience has shown that pre-market submissions that seek to add new uses through registration amendment cannot accurately reflect the findings of re-evaluation reviews on the same active ingredient until that work is completed. Nor can the re-evaluation incorporate the latest use pattern if this is constantly changing. For this reason, as part of this new process, PMRA will not advance the reviews of pre-market submissions requesting expansion of the use pattern for the active ingredient, until the re-evaluation risk assessment is completed.

Additionally, unless requested by PMRA for clarification, no new data or information will be considered during the review step (that is, once the 90 day Information Gathering step is completed). In the past, significant additional work has been required for PMRA to consider studies or new use information provided by registrants after risk assessments have been completed or to wait for studies that were under development to submit to other regulatory agencies. This practice will no longer be included in the process. However, it should be noted that if new information demonstrating increased risk does become evident (for example, submitted through the Incident Reporting program) PMRA will take this into account. In exceptional cases, if the initial risk assessment warrants, PMRA may publish a preliminary risk assessment as part of this review stage, to obtain specific information that would result in a more robust assessment, prior to proceeding with the development of the risk management proposal.

Review times

- Low – time estimated for review, internal decision-making and preparation of the document for public consultation is 360 days from the end of scoping step.
- Medium – time estimated for review through to document publication is 420 days from the end of scoping step.
- High – excluding the 90 days for information to be submitted, the time estimated for review through to document publication, is 650 days from the end of information gathering step.

As outlined in paragraph 19 (1)(c) of the *Pest Control Products Act*, for all re-evaluations, the PMRA will provide the registrant(s) [that is, data providers] with a reasonable opportunity to make representations in respect of any additional information that was used in PMRA evaluations.

4.5 Public Consultation (90 days)

As outlined under subsection 28(1) of the *Pest Control Products Act*, the PMRA will publish a proposed re-evaluation decision document (PRVD) for consultation. Documents for consultation are posted to Health Canada's website. In consideration of the need for various stakeholders as well as the public to have adequate time to provide comments and to recommend alternative risk management options when needed, the consultation period for the PRVD document will now be 90 days (instead of 60 days) from the date of publication. In order to proceed to regulatory decisions in a timely and predictable manner, however, extensions to this period will not be granted, nor will the re-evaluation be placed "on hold" in anticipation of studies being prepared for other regulatory agencies.

Where significant mitigation is being proposed (for example, cancellation of uses), the PMRA will provide a verbal pre-publication briefing to technical registrants and affected stakeholders to explain the basis of this proposal, up to two weeks before the publication date.

PMRA will consider all comments and information received during the consultation period and will develop the final regulatory decision using a science-based approach.

4.6 Final Decision (90 to 365 days)

Information received during the comment period may range from no comments, to extensive comments, such as suggestions for significant use pattern revision; alternative risk mitigation approaches; comments on the risk assessment methods and submission of new studies or published scientific literature. As a result, PMRA may need significant time to review studies or update the risk assessments and the resulting risk management outcome. The timelines expected to complete this step range from 90 days (if no comments) up to 365 days (significant comments and review required). If, as a result, there are significant changes from the original proposal, the PMRA will provide a verbal pre-publication briefing up to two weeks before the document publication date, similar to that for the PRVD. A final decision will then be published, which includes a summary of the comments received and the PMRA's response to those comments, as well as the final regulatory decision. Final re-evaluation decision documents will include information regarding any required changes to products, such as amended label statements or cancellation of products, and the timelines for registrants and, where needed for users, to implement the decision. This information will also be communicated directly to product registrants.

5.0 Performance Standard

The PMRA's performance standard for re-evaluations will be that 80% of the re-evaluations will be completed within the timeframe outlined in the five-year work plan.

As noted above, the extent of information and reviews required for re-evaluation range in complexity. Based on the scoping review, PMRA will estimate the complexity and depth of work required, as well as time needed for completing proposed decisions and final decisions when developing the work plan. It should be noted that the estimated total timelines include the allocated periods for provision of required information, such as 90 days for registrant response to the data call in (Appendix I).. As the re-evaluations proceed, additional factors, such as extensive new data during the consultation step, may affect the work required and consequently the target timelines. In these cases, adjustments will be reflected in the overall work plan for the program when it is updated on an annual basis.

6.0 Implementation

This process will apply to all pesticide active ingredients that will be initiated under cyclical re-evaluation beginning on 31 August 2016. It will also be implemented for re-evaluations previously initiated by the PMRA, where appropriate, for the remaining steps of those re-evaluations.

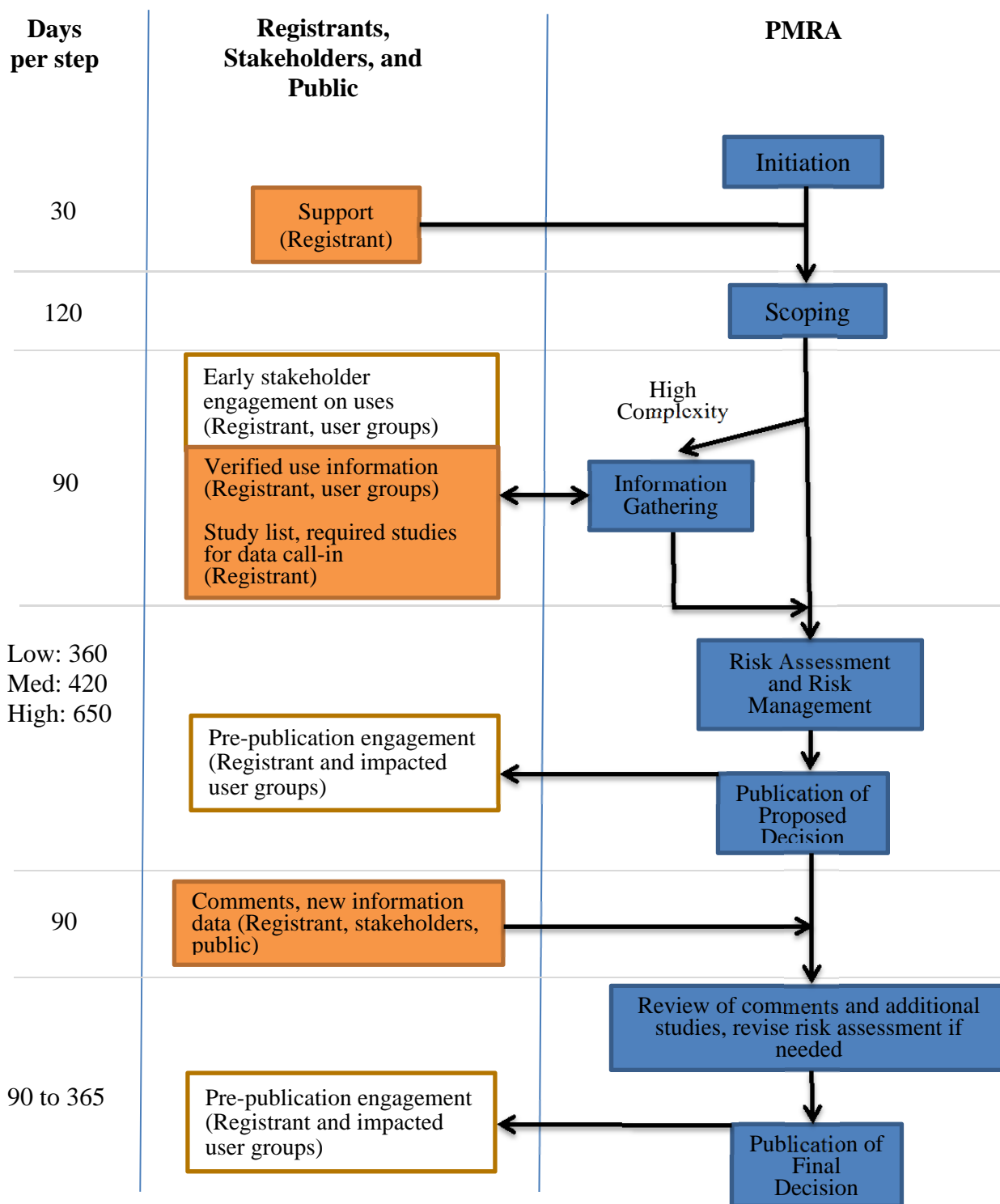
Consultation on this document

PMRA will accept comments on the re-evaluation process steps proposed in this Management of Re-evaluation Process document, within 60 calendar days. Please provide your comments to pmra@hc-sc.gc.ca by May 31, 2016, and include the following information:

- Your full name and organization;
- Your phone number; and,
- Your complete mailing address or email address.

The policy will then be finalized by August 31, 2016 and implemented for re-evaluation submissions.

Appendix I Re-evaluation Process



Total time: 23 - 45 months