Regulatory Directive DIR2016-04

Management of Pesticides Re-evaluation Policy

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1.0 Purpose

The purpose of this document issued by Health Canada's Pest Management Regulatory Agency (PMRA) is to describe the re-evaluation process for registered pesticides in Canada.

2.0 Background

In Canada, pest control products, or pesticides, are regulated by PMRA under the authority of the *Pest Control Products Act*. The Act prescribes both pre-market and post-market assessment of pesticides to determine the acceptability or continued acceptability of the health and environmental risks and value of a product for registration in Canada. Re-evaluation is one of the post-registration processes provided for under the *Pest Control Products Act*.

According to subsection 16(1) in the *Pest Control Products Act*, PMRA may initiate a re-evaluation of a registered pesticide if there has been a change in the information required or the procedures used by PMRA to determine that the pesticide meets health, environment and value standards. In addition, subsection 16(2) of the *Pest Control Products Act* requires PMRA to initiate re-evaluations for each registered pesticide on a 15-year cycle, based on the most recent major decision affecting the registration, including its initial registration. 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 to determine whether the use of these products continues to be acceptable according to current standards.

PMRA has updated its re-evaluation process, which includes the adoption of this new Regulatory Directive and associated internal processes aimed at enhancing transparency, predictability, and stakeholder engagement. This current Regulatory Directive replaces Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*. This current Directive describes the re-evaluation process by establishing performance targets for PMRA and stakeholders including timelines to complete key steps; provides guidance on the consideration of new information; clarifies the public consultation period; and outlines PMRA's commitments on the publication of documents.

In the interest of seeking additional efficiencies, PMRA currently explores alignment of re-evaluation schedules with those of the United States Environmental Protection Agency or work sharing opportunities for reviews where appropriate. PMRA will also continue collaborating with other regulatory authorities regarding relevant science or regulatory issues.

Documents associated with each re-evaluation, including published decision documents as well as notices requesting additional information (for example, test data), are available to the public and can currently be found in PMRA's Public Registry on the Pesticides and Pest Management portion of Health Canada's website. PMRA uses various communication tools, including webinars and re-evaluation work plans, to better inform the public and engage stakeholders including pesticide product users, retailers and consumers during the re-evaluation process.

3.0 Objective of the Re-evaluation Program

The objective of PMRA's re-evaluation program is to protect the health and environment of Canadians by making evidence-based decisions regarding registered pesticides. PMRA achieves this by:

- Re-evaluating registered pesticides on a cyclical basis to verify that they continue to meet current standards with regards to health and environmental risks and value. This is accomplished by considering the use of new methodologies, data, and scientific approaches into the evaluation and assessment of pesticides.
- Taking an approach to re-evaluation such that the scope of each review is commensurate with the complexity of science issues associated with a given pesticide.
- Following an efficient, predictable and transparent process to enable multi-year planning of re-evaluations, monitor their completion, and report to Canadians on the outcomes of re-evaluations.
- Fostering collaboration with stakeholders to improve the quality and timeliness of new scientific and use-pattern information provided to PMRA in support of the assessments.
- Collaborating with domestic and international government partners to maximize opportunities to exchange information in order to reach sound regulatory decisions and share outcomes of re-evaluations in a timely manner.
- Enhancing communication and engagement with the public, users and interest groups to achieve greater transparency and involvement in decision making; increased awareness of pesticide re-evaluation decisions and implementation of risk mitigation measures as required.

4.0 Pesticide Re-evaluation Review Process

Subsections 4.1 to 4.6 provide a step-by-step description of the key elements of the re-evaluation review process and the timeline associated with each step (Appendix I).

Re-evaluation planning
Under the *Pest Control Products Act*, PMRA may initiate a re-evaluation of a registered pesticide if the information required or the procedures used in evaluating the pesticide's health or environmental risks or the value have changed. In addition, the *Pest Control Products Act* requires PMRA to initiate re-evaluations for each registered pesticide on a 15-year cycle, based on the date of the most recent major decision affecting the registration, including its initial registration.

As part of its multi-year re-evaluation planning, PMRA explores opportunities to maximize efficiency by aligning Health Canada's re-evaluation schedule with that of other international regulatory bodies, or other parts of the Canadian federal government. Other factors may be considered in the scheduling of re-evaluations earlier than the statutory requirement such as clustering similar active ingredients and re-evaluating them as a group. It is important to note that whenever human health or environmental risk concerns require prompt attention, PMRA will take appropriate regulatory action regardless of the re-evaluation review status.

To improve transparency for the public and support preparation by registrants for re-evaluations, PMRA publishes a multi-year work plan listing scheduled re-evaluations. PMRA updates this work plan annually to reflect changes to the schedule.

4.1 Initiation (30 days)

The initiation date of the re-evaluation of pest control products containing a particular active ingredient is generally based on the date of its initial registration, or the date of the last completed re-evaluation. 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 is taken into consideration in determining the initiation date of a cyclical re-evaluation. To initiate a re-evaluation, PMRA issues (an) initiation notice(s) (under *Pest Control Products Act* section 16) to the registrant(s), and posts an announcement summarising the notice(s) on the PMRA's Public registry. Upon the issuance of an initiation notice, the data provider (typically the registrant of the technical grade active ingredient) has 30 days to confirm their support for the re-evaluation (that is, continued support for the registration) and to provide a list of existing studies and any study that is underway along with the anticipated completion date.

If support is provided, the re-evaluation proceeds to the scoping step. Alternatively, once the registrant has notified PMRA, in accordance with subsection 22(1) of the *Pest Control Products Act* that a pesticide will be discontinued, PMRA cancels the registration of the active ingredient and associated end-use products, as per subsection 22(3) of the *Pest Control Products Act*; closes the re-evaluation file; and updates PMRA's multi-year re-evaluation work plan.

At this point, 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*.

4.2 Scoping (120 days)

The breadth and depth of the re-evaluation is commensurate with the complexity of the issues associated with a given pesticide. PMRA considers previously conducted assessments to determine if they continue to meet the standards of current science/policy for health and environment in all review areas (that is, health, environment and value). Scoping reviews also include scans of other available information including, but not limited to: public literature, incident reports, status of active ingredients in other jurisdictions, and conditions of product use.

The scoping exercise identifies whether a re-evaluation will be of a Category 1, Category 2 or Category 3. These designations represent the amount of time and effort required to complete the re-evaluation and do not reflect or imply the level of risk associated with the pest control product or its active ingredient.

- Category 1 re-evaluations have the longest projected timeframes and typically require the submission of information (refer to information gathering step) prior to proceeding with updating the risk assessments. Evaluations could include, but are not limited to review of the new studies and the application of revised toxicology endpoints in exposure assessments. In some cases, an active ingredient with a large number of uses, emerging science issues, and/ or extensive monitoring data can contribute to the increased level of

effort and longer review timeline required to complete a proposed decision document.

- Category 2 re-evaluations typically do not require additional information to be submitted to PMRA, yet they may include a detailed evaluation of some areas, such as updating a risk assessment using current assumptions or including additional new information in drinking water estimates.
- Category 3 re-evaluations are those in which all components may be adequately addressed by previous reviews and a detailed new evaluation is not warranted; however, the outcome of a Category 3 re-evaluation could still require that product labels be updated to meet current labelling requirements.

4.3 Information Gathering (90 days)

At the onset of this step, PMRA publishes a project plan for Category 1 and 2 re-evaluations, outlining the areas of focus of the review, associated timelines, and additional information and/or data that was requested from registrants to proceed with the review.

As noted above, the scoping exercise helps determine whether additional information is required before proceeding to the review phase. Thus, at the information gathering step PMRA engages interested stakeholders by using any or all of the following mechanisms:

Early stakeholder engagement: PMRA engages key registrants and 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 is important in reducing uncertainties that may otherwise lead to unrealistic assumptions being applied during the risk assessment.

Verification of Use Pattern: PMRA requires the registrants to gather and provide information that confirms the use pattern including extent of use (that is, details of certain application scenarios), in order to arrive at the most realistic basis for risk assessments.

Data Call-In: The re-evaluation will be based on existing databases of registrant supplied and, published data, and information from other jurisdictions and regulatory authorities. In certain cases, PMRA will issue a data call-in for additional information and/or studies when considered necessary to conduct the review. A data call-in notice is issued under the authority of subsection 19(1) of the *Pest Control Products Act*.

Additional tools such as conference calls or webinars may be offered by PMRA to update any interested stakeholders and the public on the general status of re-evaluations.

4.4 Science Review (450 to 750 days)

Review timelines

- Category 1 re-evaluations – time allocated for review is up to 750 days
- Category 2 re-evaluations – time allocated for review is up to 510 days
- Category 3 re-evaluations – time allocated for review is up to 450 days

In this step, evaluations will be conducted on the health and environmental aspects, along with the value of the pesticide active ingredient and associated end use products, as necessary. 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 necessary), and the drafting of the proposed decision document for publication.

Communication and data submission
If during the course of the review, PMRA identifies a need for simple clarifications from registrants or grower groups, a request for information to the appropriate group will be issued. A 10 day timeline will be provided for a response, unless the request merits a longer timeline.

Stakeholders are strongly encouraged to submit information within the 90 day information gathering period, which precedes the review. No new data or information will be considered during the review; unless required by PMRA under *Pest Control Products Act* paragraph 19(1)*(a)*. However, PMRA will take into account new information demonstrating increased risk (for example, information submitted through the incident reporting program). After the science review is completed, and the proposed re-evaluation decision is published for consultation, any new information may be submitted to PMRA.

In exceptional cases, PMRA may publish a preliminary risk assessment as part of this review step, if the initial risk assessment warrants it. The purpose is to obtain specific information prior to proceeding with the development of the risk management proposal.

Pre-market submissions
PMRA sometimes receives pre-market submissions to expand, or change use-patterns, or to make substantial amendments to the conditions of registration while a re-evaluation is underway. Thus, in order to reach consistent and timely regulatory decisions, PMRA coordinates the review of these pre-market submissions and the science review component of the re-evaluation. Consequently, PMRA applies any updated science findings to any subsequent (pre-market and post-market) decisions.

In order to balance the timely nature of certain pre-market submissions, PMRA processes minor use submissions, emergency registration requests, and minor label amendment submissions once they are received, irrespective of whether or not a re-evaluation for the same pesticide has been initiated.

Representation
In accordance with section 19 of the *Pest Control Products Act*, PMRA provides registrants, before the evaluations are completed, an opportunity to make representations on any additional data that PMRA is using in its review - that were not submitted by the registrant. Registrants have 30 days to make representations. Subsequently, PMRA assesses the registrant's comments, within 30 days, in order to complete the evaluations.

Technical Briefings
For re-evaluation outcomes indicating the need for substantial changes to the use pattern, technical briefings may be offered to stakeholders in advance of the publication of the proposed and final regulatory decisions.

Following the completion of the review, PMRA prepares the proposed re-evaluation decision (PRVD) and associated documentation for publication. As outlined under subsection 28(1) of the *Pest Control Products Act*, PMRA publishes a PRVD for consultation. Documents for consultation are posted on Health Canada's website within 90 days of completing the review step.

4.5 Public Consultation (90 days)

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 appropriate, the consultation period for the PRVD document is 90 days from the date of publication. PMRA considers all comments and information received during the consultation period. All stakeholders and the public are encouraged to be engaged in the consultation process and submit information to support PMRA's development of the final regulatory decision.

4.6 Final Decision (90 to 450 days)

Information received during the comment period may range from no comments, to submission of extensive comments and documents. The latter could include: 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. During this period, PMRA provides registrants with the opportunity to make representations and holds technical briefings, as needed.

The timelines to complete this step range from 90 days (no comments) up to 450 days (significant information provided requiring extensive data review).

As done during the review step, prior to the publication of the proposed decision, technical briefings may be offered.

A final decision, which includes a summary of the comments received and PMRA's response to those comments, as well as the final regulatory decision, is published at the end of this phase. Final re-evaluation decision documents include information regarding any required changes to products, such as amended label statements or cancellation of products, and it also includes the timelines to implement decisions. This information is also communicated directly to product registrants.

5.0 Performance Standard

PMRA's performance standard is for 80% of the re-evaluations to be completed within the timeframe outlined in the published re-evaluation work plan.

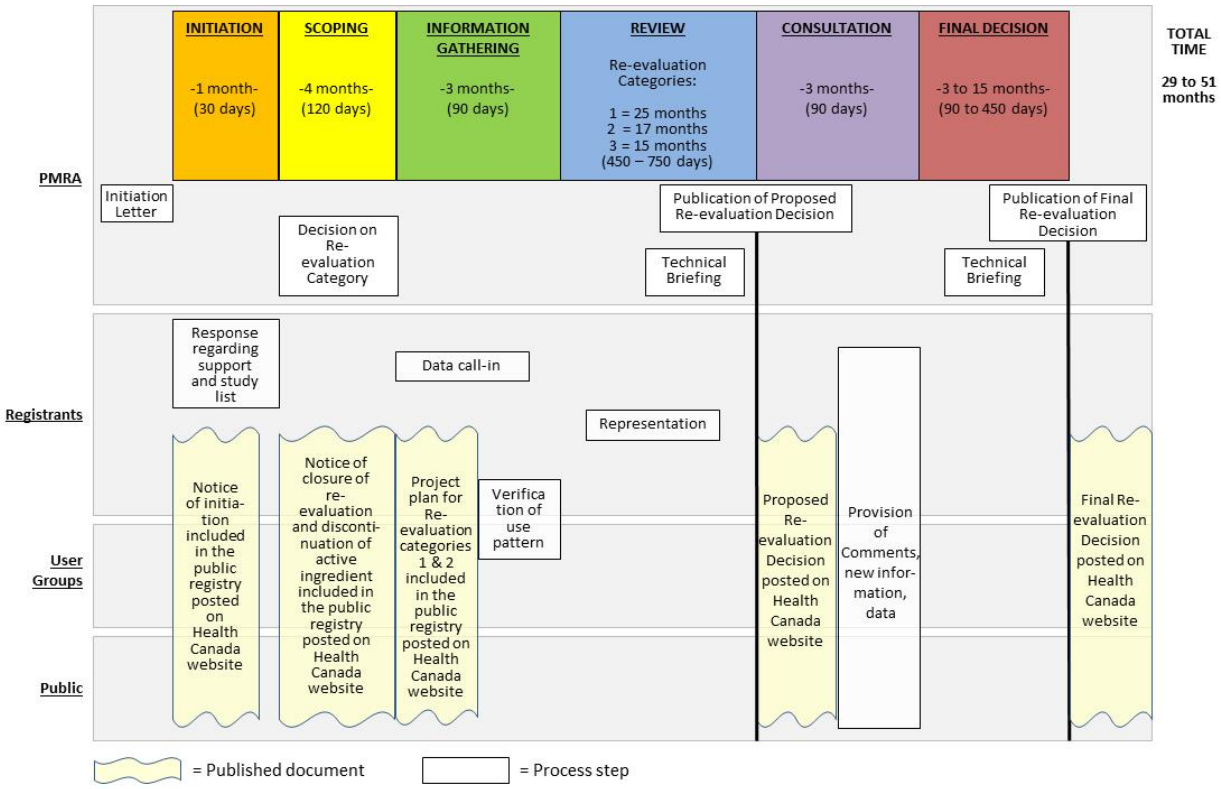
As noted above, the extent of information and reviews required for re-evaluation range in complexity. Based on the scoping review, PMRA will estimate the complexity and depth of work required, as well as time needed for completing proposed decisions and final decisions (Appendix I). It should be noted that the estimated timelines include the allocated periods for

provision of required information, such as the timeline for registrant's response to the data call in. As the re-evaluation proceeds, additional factors, such as extensive new data received 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 applies to all pesticide re-evaluations that are initiated as of 1 December 2016. Re-evaluations previously initiated by PMRA will transition to the new approach for the remaining steps (scoping, review, etc).

Appendix I Management of Re-evaluation Process



Appendix II Stakeholder Comments and PMRA Responses

Health Canada's Pest Management Regulatory Agency (PMRA) received comments from stakeholders in response to the policy proposal (PRO2016-02) entitled *Management of the Pesticide Re-evaluation Process*, published in March 2016. PMRA has consolidated and summarized the comments received and provides responses below.

1. Comments on work-sharing and collaborating with other regulatory authorities

a. The joint registration process that has been implemented between Canada and the United States is an important tool, but it needs to be expanded to include a joint re-evaluation process.

PMRA Response
As described in the policy (Section 4.0), PMRA will continue to pursue opportunities to align the Canadian re-evaluation schedule with that of other international regulatory bodies, such as the United States Environmental Protection Agency, for work-sharing or collaboration purposes. Scheduling of collaborative work will allow for more efficient planning with respect to data requests, as well as for efficiencies in review of studies and relevant scientific literature. PMRA and United States Environmental Protection Agency will align the timing of key science work for certain pesticides; however, regulatory decisions are made within the constraints of their respective legislative requirements.

b. Communicate with other pesticide regulators to identify/discuss potential divergent decisions and discuss with registrants. In the event that PMRA's re-evaluation decision is different from other regulatory authorities, registrants should be informed.

PMRA Response
PMRA and United States Environmental Protection Agency communicate regularly with respect to ongoing re-evaluations, as well as relevant science/regulatory issues. Regulatory decisions are reached independently according to the respective country's legislative requirements.

Publication of the proposed decision, and technical briefings held prior to the publication of the proposed and final decisions, when substantial changes to the use pattern are needed, are two mechanisms through which PMRA provides information about Canadian regulatory decisions.

c. Any changes to the planned schedule as a result of collaboration should be shared publically as soon as possible.

PMRA Response
PMRA will inform registrants of any changes to the re-evaluation timelines and will update the public via the annual update to the multi-year work plan.

d. Clarify how other parts of the Canadian federal government will be involved in work-sharing or collaboration on re-evaluations.

PMRA Response
PMRA collaborates with other Branches within Health Canada and other federal government departments such as Department of Fisheries and Oceans, Environment and Climate Change Canada and Agriculture and Agri-Food Canada to conduct research and monitoring in support of pesticide re-evaluations. Input from these organizations also supports the testing/validation of assumptions in pesticide risk assessments.

2. Comments related to the planning of re-evaluations

a. To promote transparency and allow for better planning by registrants, PMRA should specify the planned date of re-evaluations.

PMRA Response
In general, re-evaluations will be initiated on a 15-year cycle, based on the date of the most recent major decision affecting the registration, which includes its initial registration. The five year work plan identifying the re-evaluations and special reviews that PMRA will be carrying out from 2015-2020 was published in February 2016. The updated plan will be published annually and is aimed to support registrants planning.

b. It is recommended that PMRA begin the initiation and scoping phases two to three years ahead of the anticipated start date of the re-evaluation to allow registrants sufficient time to conduct the requested studies and provide data to PMRA before the start of the review.

PMRA Response
While initiating the scoping step several years in advance is possible, it is not deemed efficient to scope too far in advance as information can become dated and this may necessitate, in some cases, re-doing the scoping a few years later. The recently published five year work plan (2015-2020) provides a list of re-evaluations that have recently been initiated. PMRA's commitment to publish the updated plan annually is aimed to provide stakeholders sufficient time to prepare for their re-evaluation(s).

3. Comments related to the re-evaluation categories and project plans

a. The proposed classification of re-evaluations as low/medium/high could unduly raise public concerns about risk. A preferred approach may be to use a different classification system (that is, categories 1, 2, 3 or A, B, C). In addition, clearly explain the criteria that will be used to determine the re-evaluation category of an active ingredient.

PMRA Response
The Regulatory Directive has been revised to designate re-evaluations as category 1 (high), 2 (medium) or 3 (low) based on their complexity. The Directive further explains that the categories are based on the estimated length of time and effort to complete a re-evaluation, and does not reflect or imply the level of risk associated with the pesticide. The definition of each category is provided in Section 4.2 of the Regulatory Directive.

b. Concern that the ranking system could result in the re-evaluation of active ingredients being broken into parts by topics to reduce complexity. Recommend that re-evaluations be, whenever possible, complete and reflect the entire dossier.

PMRA Response
The classification system is intended to help define complexity and extent of work required for the re-evaluation of a particular active ingredient, as well as the timeframe to complete the review. It is not intended that the re-evaluation of an active ingredient be split into parts.

c. Request that registrants receive notification regarding the category classification that will be applied to the re-evaluation of their product(s), and clarification as to when project plans will be published.

PMRA Response
Registrants will receive a letter indicating the re-evaluation category and target review timelines.

As described in the Regulatory Directive, PMRA will also publish project plans for category 1 and 2 re-evaluations during the information gathering step. These project plans will include areas of focus of the review, any data required (as noted in the data call-in issued to the registrant), and the associated timelines to publish the proposed decision. Category 3 re-evaluations (low complexity) will not have published project plans; however, target publication dates for proposed and final decisions will be reflected in the five year re-evaluation work plan. Section 4.3 of the Directive has been updated.

4. Comments related to information gathering

a. PMRA should provide advance notice of when the information gathering period would commence.

PMRA Response
The five-year re-evaluation work plan and its annually published updates should be considered an important work-planning tool for grower groups and registrants. Stakeholders are encouraged to review the work plan to identify actives of interest to them, and if they so choose, they could begin information gathering from their members before PMRA officially requests information. Interested stakeholders can also monitor PMRA's Public Registry to view the Announcement of Re-evaluation sent to registrants during the initiation stage.

b. The PMRA should consider extension of re-evaluation timelines so that new studies (including those requested by the PMRA) can be conducted and the information can be used during the review phase. The 90 days identified in the information gathering phase is insufficient to produce and provide data.

PMRA Response
Of the cyclical re-evaluations carried out over the last two years, PMRA has requested the generation of new studies in only a few cases. Data lists will be requested from technical registrants at the initiation step so that industry can identify titles of relevant (existing and soon to be completed) studies earlier in the process. If new studies are requested by PMRA, adequate timelines for submission of those studies will be provided.

c. Require confirmation that PMRA will request available data from stakeholders during the information gathering phase and that new scientific information not explicitly requested by PMRA, but relevant to the re-evaluation, may also be submitted. Registrants should have the opportunity to provide any information that could help refine the decision.

PMRA Response
Once PMRA issues an initiation notice to the registrant(s), the data provider has 30 days to confirm their support for the re-evaluation and to provide a list of existing studies and any study that is underway along with the anticipated completion date. Registrants are encouraged to identify the full list of existing studies at the initiation step, and flag any studies they feel could help refine the decision. PMRA will review the list to identify which studies the registrant must provide to support the re-evaluation and, if necessary, contact the registrant for simple clarifications.

After a data call-in is issued, stakeholders are required to provide the requested information within the timelines identified by PMRA. In order to meet the published work plan targets, additional information that could help refine the decision will be accepted during the public consultation.

d. Concern that once the information gathering step is complete, a decision to only accept information that demonstrates increased risk will result in re-evaluation focussing on "worst-case" scenarios.

PMRA Response
Any available information that demonstrates increased or decreased risk should be identified early in the process. As indicated above, registrants are encouraged to identify the full list of existing studies at the initiation step, and flag any studies they feel could help refine the decision. Information requested by PMRA does not necessarily correspond to studies that demonstrate increased risk.

Furthermore, additional information can be provided to PMRA during the public consultation and will be reviewed and considered in the final decision. This is a new process that will ultimately demonstrate increased transparency regarding how new information is considered in the risk assessment, and how risks are managed.

5. Comments about stakeholder engagement

a. Stakeholder consultation should occur throughout the re-evaluation process.

PMRA Response
Partnership with all stakeholders is essential for successful delivery of the re-evaluation program. PMRA acknowledges that in the past, input from grower/user associations was limited, for the most part, to the public consultation step and also limited in reach. The new process broadens stakeholder engagement earlier in the process to increase awareness of on-going re-evaluations and encourage stakeholders to submit critical information on the Canadian use pattern to help inform PMRA's risk assessment.

Other engagement/information sharing steps have been added to the process, including:

- Conference calls/ webinars to update interested stakeholders and the public on general status of files – as needed on complex re-evaluations;
- During the review phase, PMRA may seek simple clarifications from registrants and grower groups;
- Technical briefings prior to the publication of proposed/final decisions when substantial changes to the use pattern may occur; and,
- Extended time to submit comments during the public consultation (90 days).

b. Request that registrants and growers be given opportunity to input on the use pattern/risk assessment.

PMRA Response
The new re-evaluation process identifies several opportunities for stakeholders to provide valuable input. Registrants and growers will have an opportunity to provide information relevant to the use pattern. Specifically, PMRA will publish at the onset of the information gathering step, the project plans for Category 1 and 2 re-evaluations. PMRA encourages registrants and growers to submit any available information (for example, current usage by commodity, extent of use and details on use scenarios) at this step of the process prior to the review phase. For certain re-evaluations, there may also be an early stakeholder engagement webinar to seek information on the use pattern.

c. Early and ongoing engagement with registrants would eliminate the need for publication of preliminary risk assessments, and revisions to risk assessment.

PMRA Response
As described in Section 4.4 of the policy, PMRA has established a mechanism to seek simple clarifications from registrants or grower groups during the course of the review. This clarification request is based on a similar process for pre-market submissions. However, if warranted by the risk assessment, PMRA may publish a preliminary risk assessment to obtain specific information that could result in a more accurate assessment. This approach will inform all stakeholders and the public about PMRA's concerns, and ensure transparency in PMRA's approach to addressing the risks.

d. Registrants should be made aware of proposed mitigations and label amendments as early as possible during the review phase, so that data can be provided to help refine assumptions or inform mitigation approaches. Requests for information and input on potential mitigations should be sent to registrants and other implicated stakeholders, after the preliminary risk assessment is completed and before issuing the proposed re-evaluation decision document.

PMRA Response
If, during the course of the review, PMRA identifies a need for simple clarifications from registrants or grower groups, a request for information to the appropriate group will be issued.

The policy indicates that where significant mitigation measures are considered, a technical briefing to all affected stakeholders may be held to explain the basis of the proposal. The original consultation document indicated that PMRA would provide these briefings up to two weeks before publication. Upon consideration of comments received from stakeholders, PMRA has removed the two-week time limit and will aim to brief interested stakeholders as far in advance as possible. PMRA will also use the public consultation to engage registrants and implicated stakeholders to provide comment on risk assessments and mitigation measures. The consultation period will be 90 days (increased from the current 60 day comment period) which will allow all stakeholders, including registrants, pesticide users, and the public to provide comments and information.

e. Confirm that registrants can continue to submit error corrections before decision documents are published.

PMRA Response
Registrants can submit any error corrections to PMRA along with any comments on the contents of the Proposed Re-Evaluation Decision during the public consultation. In the spirit of enhanced transparency, all stakeholders (including registrants) and the public are given 90 days to submit comments to PMRA.

f. Registrants and stakeholders should be consulted after the risk assessments are completed and before issuing the proposed decision. This will ensure alignment with the United States Environmental Protection Agency re-evaluation process, where the public can provide comments at two points during the re-evaluation process.

PMRA Response
In the past, the exchange of information with technical registrants on preliminary risk assessments led to extensive scientific debates that created significant internal workload. This resulted in PMRA missing re-evaluation targets and in many cases arriving at the same regulatory decisions originally proposed. Sharing preliminary risk assessments with registrants exclusively does not support PMRA’s commitment to openness and transparency.

Pursuant to Health Canada’s commitment to transparency, risk assessments will not be shared with registrants and users exclusively. The proposed decisions will have a 90 day consultation period during which all stakeholders can provide comments and additional information. However, registrants are encouraged to be engaged throughout the process. PMRA will provide

technical briefings open to all stakeholders to explain the basis of the proposed and final regulatory decisions, prior to publishing, in instances where substantial mitigation is required. All proposed and final decisions will be disclosed openly via the Health Canada website to all interested stakeholders and the public.

6. Comment related to use expansions

Some use expansions should be permitted during re-evaluation.

PMRA Response
The introduction of new data or changes in the pesticide use pattern during the re-evaluation review phase can significantly change the scientific assessment (for example, toxicology endpoints). This can result in PMRA having to repeat work completed in the previous steps, and would result in delaying the re-evaluation. The final version of the regulatory directive provides more flexibility indicating that PMRA will process concurrently with re-evaluations any applications for emergency registrations, and minor label changes and amendments. In other cases involving more substantive amendments, PMRA will coordinate the review of the pre-market submission with the science review component of the re-evaluation. Thus, if during the re-evaluation review phase new scientific findings are established, the PMRA will apply these to all subsequent pre-market and post-market decisions.

7. Comments related to incident reports

Clarify whether studies submitted through incident reporting will be considered in the re-evaluation, including studies that demonstrate both increased and decreased risk, and that studies submitted through incident reporting will be compensable if the information is used during a re-evaluation.

PMRA Response
According to paragraph 2(f) of the Pest Control Products Incident Reporting Regulations, registrants are required to submit scientific studies if the study demonstrates any new hazard or any risk that may be greater than the risk determined at the time of registration of if the presence of a previously undetected component or derivative of a pest control product is detected. Studies demonstrating decreased risk should not be submitted as an incident report.

All incident reports received by the PMRA are evaluated, regardless of whether there is a scheduled re-evaluation. Priority is given to incidents that are serious in nature, that involved multiple people or animals, or that indicate a recurring problem. Evaluations can vary in scope, depending on a variety of factors, such as the amount of information that is available and the complexity of the issue. The PMRA evaluates the information provided in the incident report in conjunction with other relevant information that is available in the scientific literature or the PMRA database. Of the studies submitted through the incident reporting program, only those studies that demonstrate increased risk (adverse effects) will be taken into account during the re-evaluation.

Information submitted under section 13 of the *Pest Control Products Act* (that is, incident report data) is not considered compensable data under section 17.1 of the Pest Control Products Regulations.

8. Comments related to performance measurement

a. Re-evaluation timelines should be communicated in the re-evaluation work plans and the results of timelines being met should be reported (for example, in the annual report) and shared with stakeholders.

PMRA Response
As described in Section 4.3 Information Gathering, PMRA commits to publishing a project plan outlining the areas of focus, and timelines for all category 1 and 2 re-evaluations. Timelines for category 3 re-evaluations will be provided in the multi-year work plan. PMRA also commits to reporting to stakeholders on re-evaluation performance against these timelines.

b. 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. What is the basis for setting the performance standard at 80%?

PMRA Response
This performance standard is new. Once PMRA has some experience with the new process, the performance standard will be reviewed and potentially revised.

9. Other comments

a. The data protection/compensation aspects of re-evaluation need to be considered.

PMRA Response
PMRA is currently developing an approach for re-evaluation data. A separate guideline on the administration of the regulations in the context of re-evaluations and special reviews is being developed.

b. PMRA needs to ensure that the re-evaluation process uses reasonable assumptions in the risk assessment.

PMRA Response
PMRA will seek opportunities to engage interested stakeholders on pertinent science policy discussions. PMRA recognizes that these types of discussions should take place outside the specific re-evaluation public consultations so that they can be more objective and strategic. Topics could include the interpretation and use of water / soil monitoring data in its re-evaluations, the use of modelling data, and assumptions in risk assessment.

c. PMRA should have an internal review (across sections/science groups) after the risk assessment is complete and before proposed decision is published.

PMRA Response
A robust internal process for ensuring that PMRA makes integrated science-based decisions using the agreed-upon principles of risk assessment and risk management is a key component of the Review phase. Science teams prepare and present peer-reviewed evaluations of health and environmental risk and value to an interdisciplinary science subcommittee, in order to integrate and coordinate the preliminary science recommendations from the various science review teams. Regulatory decisions are then made by consensus of PMRA's Science Management Committee, consisting of senior managers from each of PMRA's directorates.