Regulatory Proposal PRO2024-01

Proposed Policy on Continuous Oversight of Pesticides

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1.0 Purpose

The purpose of this document is to describe Health Canada's Pest Management Regulatory Agency's (PMRA) proposed continuous oversight policy for pesticides registered in Canada.

2.0 Background

In Canada, pest control products, or pesticides, are regulated by the PMRA under the authority of the *Pest Control Products Act*.

The primary objective of the *Pest Control Products Act* is to prevent unacceptable risks to individuals and the environment from the use of pesticides. The Act prescribes both pre-market and post-market assessment of the health and environmental risks and value of pesticides to determine the acceptability, or continued acceptability, in Canada.

The *Pest Control Products Act* defines acceptable risk as reasonable certainty of no harm to human health, future generations or the environment resulting from exposure to, or use of, the product, taking into account its conditions, or proposed conditions, of registration. A pesticide's conditions of registration are the mandatory restrictions, or parameters, imposed by the PMRA in order for that pesticide to be manufactured, sold and used safely.

For each pesticide application for registration, the PMRA conducts a scientific review of the available data, including data submitted by applicants and the publicly available scientific information on the pesticide. The PMRA assesses the health and environmental risks and the value of the pesticide under the proposed conditions for use, to determine if the risks and value are acceptable. If the PMRA assessment finds – under the proposed conditions, including any additional risk mitigation measures imposed by the PMRA – that there is reasonable certainty the pesticide will not cause harm to human health or the environment, and has value, the pesticide will be approved for sale and use in Canada.

The *Pest Control Products Act* further requires that all registered pesticides are re-evaluated at least every 15 years to ensure that the risks continue to be acceptable according to current standards.

If at any time during the registration lifecycle the PMRA has reasonable grounds to believe that health or environmental risks, or the value, of a pesticide may no longer be acceptable, PMRA will evaluate the aspect of concern by initiating a special review.[1] The special review will consider relevant information and may amend or cancel the registration if necessary to address the aspect of concern that prompted the special review.

In general, the PMRA has reasonable grounds to believe that the risks are unacceptable when there is compelling and credible evidence that gives rise to a serious possibility that the pesticide may cause an unacceptable health or environmental risk with the existing conditions of use. Upon completion of the special review, the PMRA will issue a proposed decision for

[1] Unless the aspect of concern is included as part of an ongoing special review or re-evaluation. See section 17(7), section 17.1(1) and 17.1(2) of the *Pest Control Products Act*.

consultation that outlines the scientific findings and any changes to the conditions of use that are required. During the course of a special review, the PMRA can take immediate steps to amend or cancel a registration, if such action is necessary, to deal with a situation that endangers human health or safety or the environment.

3.0 Modernizing the pesticide program in Canada

The PMRA is highly regarded as an international leader in science assessment and protection from pesticide risks. However, with the pace of research related to pesticides increasing, and the extent of new scientific information and monitoring data that are continually generated, a more continuous and proactive approach to identifying and considering new science information would further increase the protection of health and the environment.

The objective of the PMRA's continuous oversight policy is to enhance the PMRA's ability to protect human health and the environment in the federal regulation of pesticides in Canada.

Implementation of the continuous oversight policy will move the PMRA pesticide program from a point-in-time model to a continuous life-cycle model that identifies and considers new science information throughout the pesticide lifecycle. The policy will add new oversight processes, building upon existing activities, to create a modern regulatory program with improved capacity to help ensure that risks from pesticides to the people who live in Canada, and the environment, continue to be acceptable.

Implementation of this policy will increase the health and environmental protection of the pesticide regulatory program through:

- Ongoing systematic collection and consideration of science information related to pesticides in Canada;
- Keeping pace with the evolving science of pesticides, including science literature and indigenous knowledge;
- Implementation of timely regulatory action(s), as necessary, in response to a newly identified aspect of concern with a registered pesticide; and
- Supporting the PMRA's science reviews and decision making with up-to-date science and regulatory information on pesticide active ingredients and associated products.

4.0 Continuous oversight of pesticides

Continuous oversight activities would begin after the initial registration of a new pesticide active ingredient and continue throughout the regulatory lifecycle of the pesticide. Continuous oversight would be a complementary process that supports, but does not replace, other review programs outlined in the *Pest Control Products Act* including applications for registration, re-evaluation and special review.

When a potential risk is identified through continuous oversight, the PMRA will leverage existing mechanisms outlined in the *Pest Control Products Act*, such as initiating a special review, or requiring registrants to submit additional information with respect to the pesticide's effects on human health and safety or the environment, and, where necessary, take the

appropriate actions to protect human health and/or the environment. Refer to the Management of Submissions policy, Management of Pesticide Re-evaluation policy and Approach to Special Reviews of Pesticides guidance documents for more information on the PMRA's review programs. In the course of a science review of information collected through continuous oversight, PMRA may also consider any available pesticide use information as part of the risk assessment, risk refinement, or in developing risk management options.

5.0 Monitoring and consideration of pesticides and pesticide information

As part of Continuous Oversight, the PMRA would expand and formalize the information collected on registered pesticides throughout the pesticide regulatory lifecycle and consider this information to identify any emerging risks.

Continuous oversight (or continuous monitoring) would be ongoing throughout the registration of a pesticide (including during major reviews such as re-evaluation or special review) to ensure that new information is being considered between, and during, review activities.

The PMRA will continue to develop and expand the use of automation and innovative tools to support continuous oversight. Actions that result from continuous oversight, such as when a special review is initiated, or where a notice is issued to registrants for more information, would be posted to the PMRA Public Registry, consistent with existing practices. The PMRA continues to improve the transparency of its pesticide review process, including updates to our website and the public registry to provide information in a way that is easier to find, and understand, as well as increase access to the information considered in decision-making.

5.1 Scientific literature and regulatory information

As part of continuous oversight, the PMRA will enhance monitoring of available science literature and regulatory information for new findings related to pesticides that may warrant further assessment or action, including:

- Studies and reports from academic institutions and researchers published in peer-reviewed science journals;
- Scientific databases, also known as grey literature, such as government science journals, monographs and programs that routinely update and release science information, pesticide monitoring, biomonitoring and draft/preliminary risk assessments on pesticides;
- Final decisions and associated documentation (including reference lists) related to a pesticide issued by a regulatory authority from an Organisation for Economic Cooperation and Development (OECD) country; or
- Indigenous knowledge related to the effects of pesticides, where available.

The PMRA will search available sources to identify studies or information on pesticides and their effects or properties. Search methodology and criteria will be transparently documented and made available to the public and regularly updated as required. Searches will be conducted using various methods and innovative tools, such as database alerts, automated searches, weekly digests, or the use of the Health Canada Library services. Studies or information that meet the search criteria will be screened to determine if the study or information is relevant.

Relevance refers to determining if the study is applicable to the assessment of health and environmental effects or risks of a pesticide. Studies related to pesticide economic factors, cost/benefit analysis or agricultural production information are not considered relevant in context of the continuous oversight framework. In screening for study relevance, the PMRA will consider various factors, including:

- Does the study or information pertain to the assessment of health and/or environmental risks of a pesticide;
- Is the study or information applicable to the risk assessment of a pesticide registered in Canada or related to a pesticide that is not registered in Canada but is used on foods imported to Canada;
- Is the study or information reported in a credible, peer-reviewed scientific journal, issued by a reputable scientific organization;
- Are the study design, methodology and/or results sufficiently reported, or otherwise available, to allow for risk characterization and/or conclusions to be drawn from the information; and/or
- Where applicable, are the chemical purity, dose concentrations, durations, controls, test species and/or test model sufficiently reported.

Studies and information that are determined to be relevant will be further triaged to determine what actions, if any, are required. The triage process considers the findings of the study or information and compares it to the existing PMRA risk assessment conclusions, and current understanding of the pesticide, to determine the appropriate action.

Triage of relevant study	Action
Information suggestive of: • greater health or environmental hazard than that determined at the last science review; • an increase or new health or environmental risk relative to what had been determined at the last science review; **Example:** A study that suggests the pesticide is more toxic than was considered in the PMRA risk assessment.	If the study or information provides reasonable grounds to believe that the risks are unacceptable, the PMRA will initiate a special review to conduct a full review of the study or information for the aspect of concern.[2]
Information where the results are equivalent, or already accounted for in, the existing risk assessment. Information is not expected to change the outcome of the PMRA risk assessment. **Example:** A study that describes an effect at a dose that is higher than the level already used in	Summarize study findings and retain the study for further assessment at the next science review point (for example, the next re-evaluation).

[2] Unless the aspect of concern is included as part of an ongoing special review or re-evaluation. See section 17(7), section 17.1(1) and 17.1(2) of the *Pest Control Products Act*.

Triage of relevant study	Action
the PMRA risk assessment.	
Information is not currently appliable to the risk assessment framework or registered use pattern in Canada. Study does not impact the outcome of the current PMRA risk assessment. **Example:** A worker exposure study related to a use that is not applicable in Canada.	Summarize study findings and retain the study for future consideration, if necessary.

Determination of study relevance refers to whether the information is suitable for consideration by PMRA in a pesticide regulatory context. The triage assessment determines if the study, or information, needs to undergo a detailed science review immediately, or be retained for further consideration at the time of the next review. Based on the outcome of the triage assessment, a detailed review of the study or information may be conducted to determine if, and how, the study may be used to support the PMRA risk assessment. Studies and information that are used in the context of a regulatory decision will be referenced in the decision document when it is issued. PMRA continues to work on improving the transparency of information used in regulatory decisions including the proactive disclosure of evidentiary sources and PMRA evaluation reports.

The PMRA is continuing to engage and seek advice from the independent Science Advisory Committee on Pest Control Products on the development a framework for how relevant published studies are evaluated and assessed for use in regulatory decisions. Separate from this consultation and proposed policy, the PMRA will be issuing for consultation a framework on how relevant published studies, including those gathered and screened through the continuous oversight framework, are evaluated and used in risk assessments.

The PMRA will be transparent about the outcomes of the relevance and triage assessments for all studies and regulatory information collected through continuous oversight. This will include a public listing of all information collected through continuous oversight and the outcome of the relevance determination and triage assessment for this information. Consistent with existing practices, where a special review is initiated as a result of science monitoring, the PMRA will post a notice to the Public Registry.

As part of continuous oversight, the PMRA will continue to leverage innovative tools and improve its processes to monitor for trends across relevant studies as well as for new assessment methodology, new assays or new science areas.

In addition to considering foreign decisions for relevant science information, section 17 of the *Pest Control Products Act* also requires that the PMRA initiate a special review when a member country of the Organisation for Economic Co-operation and Development (OECD) prohibits all uses of a pesticide active ingredient for health or environmental reasons.

If a decision is identified that meets the requirements of section 17 of the *Pest Control Products Act*, the PMRA will initiate a special review to consider the aspect of concern that forms the basis of the foreign decision.[3]

5.2 Pesticide incident reporting program

The *Pest Control Products Act* requires registrants to report to the PMRA incidents of adverse effects, or scientific studies indicating a potential new hazard or risk, that involve their registered pesticides. The Pest Control Products Incident Reporting Regulations specify the specific reporting requirements, including the types of information to be reported and the time frames for reporting the information. Registrants are required to report information concerning pesticide incidents that occur in Canada as well as a subset of more serious incidents that occur in the United States.

Incidents include effects on humans, domestic pets, plants and animals (both terrestrial and aquatic), as well as packaging failure that could result in human exposure or injury. Incident reports provide the PMRA with valuable real-world information regarding potential risks to humans or the environment from the use of registered pesticides.

Registrants are also required to provide the PMRA with any scientific study they have sponsored if it indicates either a new health or environmental hazard, increased health or environmental risk or the presence of a component or derivative that has not been previously detected. Registrants must report on a discontinued study or a study that is in progress, if the study has demonstrated adverse effects.

Consistent with existing practices, the PMRA will continually review the information received through the incident reporting program for all pesticide active ingredients and pest control products. Refer to the PMRA Guidance Document for the Incident Report Program for more information.

The *Pest Control Products Act* requires that information received through the incident reporting program be considered to determine if a special review is warranted. Considerations for determining if the information received through incident reporting program require a special review are outlined in the Approach to Special Reviews of Pesticides guidance document. Information received through the incident reporting program that, upon initial review, does not warrant a special review is retained for further consideration at the next application, re-evaluation or other PMRA review.

5.3 Pesticide water monitoring

The PMRA is working to establish a long-term collaborative national-scale water monitoring program for pesticides and develop a framework to ensure consistency in data collected across Canada.

[3] Unless the aspect of concern is included as part of an ongoing special review or re-evaluation. See section 17(7), section 17.1(1) and 17.1(2) of the *Pest Control Products Act*.

Together with federal and provincial governments and local partners, the PMRA is collaborating to increase and enhance pesticide water monitoring on a national-scale. Increasing the data available will support more informed and timely regulatory decisions and allow for the identification of areas where potential risks to human health and aquatic organisms may be present.

Information and data, collected under the PMRA's current water monitoring pilot program, on concentrations of pesticides from a network of Canadian freshwater sampling locations is available through the water monitoring for pesticides dashboard. Additional data on pesticide concentrations in water are available through other relevant sources including data generated by other federal departments, provinces and territories, researchers and pesticide companies.

Using data from all available sources, the PMRA will screen the detected concentrations of pesticides in water against Aquatic Life Reference Values (ALRV) and Human Health Reference Values (HHRV). Reference values are pesticide concentrations in water below which risks to aquatic life and human health are not expected. Where levels of a pesticide found in the Canadian environment exceed the reference values, the PMRA will determine whether a special review is warranted.

5.4 Chemistry information for technical grade active ingredient products

As part of Continuous Oversight, the PMRA will update the existing approach to verify the product chemistry information for individual sources of technical grade active ingredients to be separate from re-evaluation and more frequent. Technical grade active ingredient products are used as the source material for formulating pesticide end-use products. Changes to the manufacturing process or specifications of the active ingredient can have implications for the health or environmental risk assessment of the pesticide.

Registrants of technical grade active ingredient products will be required to submit updated chemistry information in order to verify that the chemical composition has not changed and check impurities against current standards. The PMRA will establish a transparent and predictable work plan outlining the schedule to submit chemistry information for all registered technical grade active ingredients.

The chemistry information to support verification will include:

- Up-to-date product specification form including the concentration of the active ingredient, impurities and/or contaminants;
- Detailed description of the current manufacturing method;
- Recent commercial production data, such as quality control data, indicating the active ingredient concentration, manufacturing location and date as well as impurities or contaminants monitored during the production process.

If upon review of the submitted information, there is evidence that the chemical composition may have changed, or the PMRA identifies a new impurity of concern, the registrant will be required to submit additional data for the PMRA to assess the products chemistry.

Verification of chemistry information as part of continuous oversight does not replace the requirement for registrants to submit an application to report any changes to product chemistry or manufacturing methods. If through continuous oversight, it is identified that the chemistry formulation is no longer within the approved specifications, or if that the manufacturing process has changed from what was initially approved, Health Canada will take action to cancel the registrationof the product and/or initiate compliance actions.

6.0 Application of continuous oversight in supporting PMRA science assessments and decision making

Continuous oversight will support the PMRA's science reviews and decision making through ongoing collection and consideration of science and regulatory information. Maintaining up-to-date information ensures that decisions to change or expand the use of a pesticide in Canada, or to initiate a post-market assessment, are fully informed with the latest science information available for the pesticide active ingredient and associated products.

6.1 Supporting new applications to register or amend the registration of a pesticide

Following the initial registration of a pesticide active ingredient and the associated end-use products, the registrant may submit additional applications over the course of the pesticide lifecycle to amend the registration of the pesticide in Canada. Registrants seeking to amend the registration of a pesticide must submit an application, with the required scientific information, to allow the PMRA to conduct any necessary assessments. Upon reviewing the application, and conducting the necessary risk, and value, assessments, the PMRA issues a decision on the proposed amendment. PMRA's Management of Submissions Policy outlines the approach and associated timelines for the consideration of applications to amend the registration that are received by the PMRA.

Information submitted by applicants in support of a new application is limited to the assessment of the new or amended uses. Implementation of continuous oversight will support the PMRA to efficiently consider the implications of the broader science information available for the pesticide active ingredient and products already registered in Canada when considering a specific application.

For new applications that involve health and environmental assessments, in addition to the submitted data and information from the applicant, the PMRA will consider the information collected through continuous oversight (for example, information from scientific literature, foreign regulator decisions). Application types for which PMRA will consider continuous oversight information include:

- Category A.2.0 – Major new use
- Category B.3.1 – Application rate increase
- Category B.3.2 – Change to application timing
- Category B.3.12 – Label use expansion (new use)
- Category D.3.2 – User requested minor use label expansion

If the assessment of the submitted information and the information collected as part of continuous oversight trigger the need for additional information from the applicant, the submission will be put on hold to request the information as per the Management of Submissions Policy. Where risk acceptability cannot be established, based on the available information, the PMRA would reject the application.

Having continuous oversight information identified and considered will allow the PMRA to efficiently consider the broader science information during applications than would otherwise be feasible. At this time, there are no changes anticipated to the Management of Submissions Policy as a result of considering continuous oversight information during the above noted application types.

6.2 Supporting re-evaluation and special review processes

Continuous oversight supports but does not replace the requirement for re-evaluation as outlined in the *Pest Control Products Act*.

When a re-evaluation is initiated, the PMRA conducts a scoping assessment to determine the review requirements and timelines for the re-evaluation. The scoping assessment considers the previously completed PMRA assessments against current standards as well as what other information is available in the public literature, incident reports, and any reviews and conclusions from other international pesticide regulators.

Implementation of continuous oversight will support the PMRA through ongoing scoping throughout the pesticide lifecycle such that when a re-evaluation is initiated the consideration of available information and identification of re-evaluation requirements are already well established. The PMRA intends to be more transparent with stakeholders about the re-evaluation requirements identified through continuous oversight, including anticipated data needs.

Transitioning to a continuous oversight model will result in less reliance on re-evaluation to identify issues and update assessments while minimizing duplication and over-lap. While re-evaluation will still occur, continuous oversight will work on an ongoing basis to identify and address major risks in advance of the 15-year re-evaluation initiation requirement. This will enable the PMRA to maximize the risk-based approach applied to re-evaluations as outlined in the Management of Pesticides Re-evaluation Policy to improve the timeliness of re-evaluation decisions while increasing the overall level of health and environmental protection.

Through continuous oversight the PMRA will also standardize and make transparent the considerations and decisions on initiating a special review.

7.0 Transparency of continuous oversight

The PMRA is committed to building awareness, knowledge and confidence in the pesticide regulatory system with impacted stakeholders and the people who live in Canada.

The PMRA intends to be transparent with respect to the findings and conclusions of continuous oversight. This will include a public listing of all information collected through continuous oversight and the outcome of the relevance determination and triage assessment for this information. The PMRA is continuing to explore solutions, including digital tools, to expand and improve access to information and conclusions reached as part of continuous oversight.

In all cases, when a special review is initiated, or where a requirement is imposed as a condition of registration, a notice will be posted to the public registry outlining, as applicable, the action taken, requirements the registrant must fulfill and associated timelines.

8.0 Next steps

The PMRA is currently seeking public views and feedback on the proposed Continuous Oversight of Pesticides Policy.

The PMRA will accept comments on this document up to 60 days from the date of publication.

All comments will be considered before finalization and implementation of the policy.

Please forward your comments to PMRA Publications, and include:

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