

Pest
Management
Regulatory
Agency

Policy on Proportional Effort

PMRA Policy Document



*Protecting human health
and the environment*



*Protéger la santé humaine
et l'environnement*

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Disclaimer

This administrative document does not constitute part of the *Pest Control Products Act* or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence.

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1.0 Purpose

The purpose of this document is to describe Health Canada's Pest Management Regulatory Agency's (PMRA) proportional effort (PE) policy.

The PE policy outlines a systematic categorization process to inform the PMRA's allocation of resources related to the review of pesticides in Canada. Through this PE framework, the PMRA aims to better direct resources as the pesticide category is aligned with the level of regulatory effort. This provides an approach for enhancing efficiency in the PMRA's regulatory activities while maintaining the highest standards for the protection of human health and the environment.

The PE policy and framework also reflects the PMRA's commitment to continuous improvement in its regulatory processes.

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* (the Act) is to prevent unacceptable risks to human health and the environment from the use of pesticides. The Act prescribes both pre-market and post-market assessment of the human health and environmental risks and value of pesticides to determine their initial and continued acceptability in Canada.

Registered pesticides in Canada are subject to re-evaluations as required by the *Pest Control Products Act*. The PMRA's re-evaluation workload continues to grow due to increasing numbers of re-evaluation initiations, the complex nature of re-evaluations and the need to review large volumes of data and extensive use patterns. Similarly, pre-market evaluations are also becoming more complex in nature. The increase in the PMRA's workload necessitates a systematic and predictable approach to workload prioritization and management that will ultimately allow the PMRA to maintain a sustainable and resilient pesticide regulatory system that can adapt to increasing workload and complexity.

To adapt to this shifting context, the PMRA is implementing the *Policy on continuous oversight of pesticides*, which brings together new and improved strategies to proactively identify information that could impact acceptability of a registered pesticide. Building on existing monitoring activities, such as incident reporting and water monitoring, the *Policy on continuous oversight of pesticides* includes ongoing systematic monitoring of scientific literature to quickly and efficiently identify, assess and manage emerging risks; afford registrants more predictability around new information that will be required to support continued registration of their products; and improve the transparency of pesticide regulation for people in Canada. When concerns arise, the PMRA will take timely regulatory action where needed to protect health and the environment.

In addition to the *Policy on continuous oversight of pesticides*, the PMRA is relying on the PE Policy and its systematic framework for categorizing each registered pesticide with the regulatory effort and resources required for that pesticide. The degree of oversight for each active ingredient will be informed by the most recent and relevant science. Coupled with continuous oversight, proportional effort supports a more sustainable approach to managing risks throughout the pesticide regulatory lifecycle.

3.0 Objective

The PE policy will enhance the PMRA's ability to align the regulatory review effort level with the category identified using the systematic categorization framework. Further, incorporating a risk-based approach in the framework and then using this for workload prioritization will allow for better allocation of resources designed to facilitate more timely and efficient regulatory decision-making. In addition, the PMRA anticipates additional benefits of this approach such as increased transparency, predictability, and consistency within the Canadian pesticide regulatory program.

To achieve these goals, the PE policy is supported by a risk-based scientific categorization framework applied to pesticide active ingredients registered in Canada. The categorization provides a mechanism for the PMRA to align its regulatory effort in a manner that considers key elements of the active ingredient's risk profile. The application of the PE policy is expected to result in increased efficiency and reduced complexity of reviews that will allow the PMRA to keep pace with its post-market workload.

The categorization framework establishes two categories for registered active ingredients: lower PE and higher PE. To determine the PE category for any given pesticide, the PMRA applies rigorous scientific criteria. These are described in the following section.

All pesticides registered for use in Canada have been found to pose acceptable risks to human health and the environment. By focusing resources on those pesticides that have the greatest potential for increased risk if their associated conditions of use change over time, the PE categorization directs PMRA efforts to ensure that the risks continue to be acceptable.

The PE policy supports, but does not replace, requirements of the *Pest Control Products Act*, such as for re-evaluations, special reviews, and applications for registration. All requirements of the *Pest Control Products Act* continue to apply irrespective of PE categorization.

For both registration and re-evaluation activities, the PMRA continues to apply existing proportional review approaches. Examples of these approaches include the *Registration of Non-Conventional Pest Control Products*, tiered data requirements depending on how a pesticide is used and the re-evaluation categories as outlined in the *Management of Pesticides Re-evaluation Policy*. The PE policy allows the PMRA to apply and expand the use of these approaches in a more standardized, predictable and transparent manner.

4.0 Proportional effort categorization

4.1 Scope of proportional effort categorization

Categorization is applied to all registered active ingredients. The PE framework does not apply to active ingredients not registered in Canada, nor does it apply to the following products or submission types:

- Authorized products, including those that have a Research Authorization or Notification;
- Contaminants and impurities of concern; or,
- Specification of a maximum residue limit(s) (MRL) for an imported commodity for an unregistered active ingredient in Canada.

4.2 Proportional effort criteria

The PMRA applies the following scientific criteria to active ingredients registered for use in Canada. More detailed descriptions of the criteria are provided in Appendix I.

General criterion:

- G1. Pesticides that require a high level of oversight given the novelty of the pesticide technology(ies) that have very limited regulatory history within Health Canada or internationally.

Human health criteria:

- H1. Pesticides that require a high level of oversight to ensure the sufficiency of scientific information available for the protection of human health, including vulnerable subpopulations.
 - H1.1. *Pest Control Products Act* factor (PCPA factor)
 - H1.2. Uncertainty factors
- H2. Pesticides that have the potential for significant exposure to people in Canada
 - H2.1. High exposure use scenarios
 - H2.2. Restricted class products
- H3. Pesticides that are approaching the limits of acceptability for cancer and/or non-cancer risk for dietary, drinking water, occupational and/or residential scenarios.
 - H3.1. Dietary risk (includes drinking water and imported foods)
 - H3.2. Lifetime cancer risk
 - H3.3. Occupational and residential risk
- H4. Pesticides that require a high level of oversight due to scientific complexities associated with a required cumulative risk assessment.

Environmental criteria:

- E1. Pesticides that have the potential to be present in the surrounding environment.
 - E1.1. Possibility of release to the environment
 - E1.2. Nature of pesticide
 - E1.3. Magnitude of use
- E2. Pesticides that require a high level of oversight, due to their environmental fate characteristics.
 - E2.1. Persistence in the environment
 - E2.2. Potential for bioaccumulation
 - E2.3. Potential to leach through soil or runoff into surface water
 - E2.4. Potential to be transported in surface runoff
- E3. Pesticides that may be highly toxic to one or more non-target organisms.
 - E3.1. Potential for pesticides to affect aquatic and/or terrestrial organisms in their environment

The criteria may be updated to capture any new or changing information relevant to an active ingredient's relative risk or the PMRA risk assessment methodology. As part of a broader strategy to consider Indigenous knowledge related to the effects of pesticides into risk assessment and policies, the PMRA will develop a plan to engage Indigenous partners, and reassess the proportional effort criteria to ensure the categorization approach reflects these evolving strategies.

5.0 Application of proportional effort criteria

5.1 Categorization of active ingredients according to the criteria

Each registered active ingredient is considered against the PE criteria in a step-wise fashion, using information from the PMRA's most recent risk assessment.

First, it is determined if the active ingredient meets the general criterion. If the general criterion is met, the active ingredient will automatically be categorized as higher PE.

The active ingredient is then considered against the human health and environmental criteria and subcriteria based on the most recent risk assessment. Normalized scores, weightings and thresholds are applied, and the active ingredient is categorized as either lower or higher PE for each of health and environment.

Overall, the PMRA considers an active ingredient as higher PE if it meets the general criterion, or is categorized as higher PE against the human health criteria, the environmental criteria, or both. Active ingredients that do not meet the general criterion, and are categorized as lower PE for both human health and the environment are designated as lower PE.

For more detailed descriptions of the criteria, please refer to the appendix. Additionally, descriptions of how the PMRA applies the criteria in determining the PE categorization can be found in the Proportional Effort Information Note.

5.2 Use of categorization results to inform work planning

The categorization of registered active ingredients using standardized scientific criteria will lead to more effective work-planning, resource allocation and management of regulatory review processes by systematically identifying those active ingredients and areas of review where efforts are most needed.

PE categorization, as well as the specific outcomes for each criterion and sub-criterion, inform the scope and level of effort needed for a review. This information guides the PMRA in identifying key areas of focus ahead of time, allowing for the strategic allocation of resources to areas requiring more in-depth assessment. This targeted approach applies to all reviews, regardless of the pesticide's PE categorization.

Active ingredients will continue to be reviewed according to PMRA policies, such as the existing *Management of Submission Policy (MOSP)* and *Management of Pesticide Re-evaluation Policy (MORE)*, which outline timelines, data requirements and assessments. These policies provide the flexibility to target assessments as required to determine the acceptability of risks associated with the use of pesticide products. However, work planning under these policies will be better informed through application of PE categorization, as described above.

The PE categorization is a point-in-time reflection of the most recent risk assessment that serves as a guide for the next update to the risk assessment. However, PE categorization does not limit the PMRA's ability to consider additional information. For example, if new information (for example, new scientific information, advances in assessment methodologies) becomes available prior to the scoping phase of a re-evaluation indicating the PE categorization underestimates the risk of the active ingredient, the PMRA would expand the re-evaluation as appropriate.

5.3 Initial categorization and updates

For new active ingredients, PE categorization will be established once the PMRA has conducted a full assessment and registered the active ingredient and its associated end-use product(s).

To facilitate work planning for active ingredients already registered at the time this policy is implemented, the PMRA has assigned PE categorizations based on the most recent risk assessments.

Since categorization reflects the latest risk assessment, any updates to that assessment may result in a change to the categorization. The PMRA may revise the active ingredient's categorization as appropriate following each risk assessment and regulatory decision. This includes, for example, certain registration amendments, and the outcome of a re-evaluation or special review. The categorization will only be revised if the updated risk

assessment results in changes to the inputs for categorization. It is possible that even if some of the inputs change, the overall categorization remains the same. To enhance public and stakeholder understanding, information describing how the risk assessment conclusions impacted the categorization will be included with the associated regulatory decision.

The PMRA is also implementing the *Policy on continuous oversight of pesticides*, that involves gathering scientific information about pesticides on an ongoing basis. If information collected under continuous oversight identifies new risk information, this will be managed through existing regulatory processes that could lead to an updated risk assessment, and could result in a subsequent change in PE categorization.

6.0 Transparency

The PMRA is committed to improving public and stakeholder confidence in Canada's regulatory system for pesticides by enhancing awareness and understanding of the decision-making process. The PMRA continues to improve the transparency of the pesticide regulatory processes, including through updates to its website and the Public Registry to provide information in a way that is easier to find, and understand, as well as increasing access to the information considered in decision-making.

The PMRA will be transparent with respect to a registered active ingredient's proportional effort categorization, and any changes to that categorization made over time as a result of regulatory decisions.

An active ingredient's initial categorization will be published as part of its registration decision. Pesticide categorizations will be updated throughout the product's lifecycle as new risk information becomes available and risk characterization evolves. Information on the risk assessment conclusions that resulted in the categorization, or changes to the categorization, will be included with the associated regulatory decisions.

As proportional effort is used to enhance PMRA work planning and resource allocation, an active ingredient's proportional effort categorization will also be communicated through the annual publication of the Re-evaluation and Special Review Workplan.

7.0 Evaluation and review

The PMRA is committed to measuring the success of the PE policy, and adjusting it as needed. The PMRA may review the policy, and categorization criteria at any time to respond to emerging issues.

The PMRA will develop metrics, such as those listed below to measure success:

- The proportion of active ingredients that are considered lower PE vs higher PE.
- The number of active ingredients that are recategorized from lower PE to higher PE, and vice-versa.
- The duration of lower PE and higher PE re-evaluations compared to established timelines, and to previous average durations.
- The level of effort (measured in hours worked) on both higher and lower PE re-evaluations compared to previous levels.
- Average number of regulatory re-evaluation decisions completed annually.
- The number of open re-evaluations on-hand.



Appendix I Description of proportional effort criteria and categorization approach

Novelty and regulatory history within Health Canada or internationally

Criteria	Description
G1. Pesticides that require a high level of oversight to monitor for emerging science, given novel pesticide technologies that have very limited regulatory history within Health Canada or internationally	<p>Novelty and regulatory history:</p> <p>Newly registered active ingredients using technology unsimilar to any registered or previously registered active ingredient, and that has not been reviewed by the PMRA previously will be considered higher PE for the first 5 years of registration. Such active ingredients often lack a formalized regulatory testing paradigm or require existing testing paradigms to be significantly adapted to accommodate the novel technology.</p> <p>Examples of novel pesticide technologies include, nanopesticides or double stranded ribonucleic acid (dsRNA) -based pesticides.</p>

Human Health

Criteria	Description
H1. Pesticides that require a high level of oversight to ensure the sufficiency of scientific information available for the protection of human health, including vulnerable subpopulations.	<p>H1.1. <i>Pest control Products Act</i> factor (PCPA factor):</p> <p>The PCPA factor is an additional 10-fold factor that must be applied by default to pesticide risk assessments for protection of fetuses, infants, and children. In some cases, the PCPA factor may be reduced on the basis of reliable scientific data. The impact of the PCPA factor on the categorization increases based on the magnitude of the PCPA factor applied to the risk assessment.</p>
	<p>H1.2. Uncertainty factors:</p> <p>Additional uncertainty factors (beyond the standard 10-fold factors each applied for interspecies extrapolation and intraspecies variability) may be applied during a risk assessment where there may be certain limitations to the scientific data available. The impact of uncertainty factors on the categorization increases based on the magnitude of any additional uncertainty factors that are applied to the risk assessment.</p>
H2. Pesticides that have the potential for significant exposure to people in Canada.	<p>H2.1. High exposure use scenarios:</p> <p>High exposure use scenarios include those with the potential for high human exposure such as, personal insect repellents, metal working fluids and/or paint.</p>

Criteria	Description
	<p>The impact of high exposure use scenarios on the categorization increases if the use pattern includes specific scenarios with potential for high human exposure.</p> <hr/> <p>H2.2. Restricted class products:</p> <p>Products classified as restricted class are those for which the PMRA, out of concern for risks, has set additional requirements, or conditions on the use, for the pesticide. The impact of a products class on the categorization increases if the active ingredient has one or more restricted class products registered</p>
<p>H3. Pesticides that are approaching the limits of acceptability for cancer and/or non-cancer risk for dietary, drinking water, occupational and/or residential scenarios</p>	<p>H3.1. Risk from food and drinking water:</p> <p>The PMRA evaluates acute and chronic dietary exposure from food and drinking water sources. Dietary risk is determined by comparing the estimated human exposure to the dietary reference values. The PMRA often expresses this dietary risk as a percentage of the reference value. This is commonly referred to as a “risk cup”. The impact of the acute and chronic dietary risk on the categorization increases based on the outcome of the dietary risk assessment, the level of refinement applied to the assessment, and the drinking water exposure estimates.</p> <hr/> <p>H3.2. Cancer risk:</p> <p>The PMRA calculates a separate cancer risk when there is evidence of non-threshold carcinogenic effects. Potential cancer risk is calculated for all relevant exposure scenarios based on the use of the pesticide. The impact of cancer risk on the categorization increases as the lifetime cancer risk increases.</p> <hr/> <p>H3.3. Occupational and residential risk:</p> <p>The PMRA calculates risks associated with occupational and residential exposure based on the use of the pesticide. The impact of occupational and residential risk on the categorization is based on the level and amount of risk mitigation required to reduce the exposure to acceptable levels. Impact increases as additional mitigation measures are required in the risk assessment.</p>
<p>H4. Pesticides that require a high level of oversight due to scientific complexities associated with a required cumulative risk assessment</p>	<p>H4. Cumulative risk:</p> <p>Cumulative risk assessments are conducted when potential exists for co-exposure to pesticides that have a common mechanism of toxicity. The impact of the cumulative risk assessment on the categorization is based on the need for a cumulative assessment. Impact increases as the complexity of the required cumulative assessment increases.</p>

Environment

Criteria	Description
<p>E1. Pesticides that have the potential to be present in the environment.</p>	<p>E1.1. Possibility of release to the environment; and</p> <p>E1.2. Nature of pesticide</p> <p>These criteria act as a high-level screen to determine the potential for environmental exposure considering the product type, location of use, the potential for the pesticide to be released into the environment and the contribution of this release compared to other natural or anthropogenic sources</p>
	<p>E1.3. Magnitude of use</p> <p>The magnitude of use is estimated based on the maximum area of application in Canada. This is calculated using the amount of the pesticide that was sold in Canada (5-year average national sales) divided by the lowest application rate registered across all products for that active ingredient. The impact of the magnitude of use on the categorization increases as the maximum area of application increases.</p>
<p>E2. Pesticides that require a high level of oversight, due to their environmental fate characteristics</p>	<p>E2.1. Persistence in the environment:</p> <p>The impact of persistence on the categorization is based on the potential for a pesticide to persist in the environment represented by the aerobic half-life in soil. The impact increases as the persistence increases.</p>
	<p>E2.2. Potential for bioaccumulation:</p> <p>The impact of bioaccumulation on the categorization is based on the potential for a pesticide to bioaccumulate as determined by the octanol-water partition coefficient. The impact increases as the coefficient increases.</p>
	<p>E2.3. Potential to leach: through soil or runoff into surface water:</p> <p>The impact of leaching potential on the categorization is based on the potential for a pesticide to leach or runoff as represented by the soil sorption coefficient. The impact increases as the coefficient decreases.</p>
	<p>E2.4. Water solubility:</p> <p>Water solubility is used as an indicator of the tendency of the pesticide to be removed from crop residues or foliage during rainfall and be transported by surface runoff to the aquatic environment. The impact of water solubility on the categorization increases as the solubility increases.</p>

Criteria	Description
<p>E3. Pesticides that may be highly toxic to one or more non-target organisms.</p>	<p>E3.1. Potential for pesticides to affect aquatic and/or terrestrial organisms in their environment:</p> <p>The criterion measures the toxicity of the active ingredient to different organism groups. The most sensitive (lowest) endpoint used in the PMRA risk assessment is considered for categorization.</p> <hr/> <p>Fish:</p> <p>The impact of toxicity to fish on the categorization is based on the acute and chronic endpoints used in the risk assessment. Acute toxicity endpoint for fish is typically the LC50/EC50. Chronic toxicity endpoint for fish is typically the no observed effect concentration (NOEC). Impact increases as the endpoint decreases.</p> <hr/> <p>Aquatic invertebrates:</p> <p>The impact of toxicity to aquatic invertebrates on the categorization is based on the acute and chronic endpoints used in the risk assessment. Acute toxicity endpoint for aquatic invertebrates is typically the EC50. Chronic toxicity endpoint for aquatic invertebrates is typically the NOEC. Impact increases as the endpoint decreases.</p> <hr/> <p>Aquatic plants:</p> <p>The impact of toxicity to aquatic plants on the categorization is based on the vascular and non-vascular endpoints used in the risk assessment. Typically, this is the EC50 or NOEC. Impact increases as the endpoint decreases.</p> <hr/> <p>Birds and mammals:</p> <p>The impact of toxicity to birds and mammals on the categorization is based on the acute and chronic endpoints used in the risk assessment. The acute toxicity endpoint for birds and mammals is typically the LD50. The chronic toxicity endpoint for birds and mammals is typically the NOEC. Impact increases as the endpoint decreases.</p> <hr/> <p>Pollinators/bees:</p> <p>The impact of toxicity to pollinators/bees on the categorization is based on the acute contact and oral endpoints. Acute contact toxicity for bees is typically the LD50. Oral toxicity for bees is typically the LD50. Impact increases as the endpoint decreases.</p>

Criteria	Description
	<p>Beneficial arthropods:</p> <p>The impact of toxicity to beneficial arthropods on the categorization is based on the toxicity to beneficial worms and toxicity to beneficial arthropods. The toxicity to earth worms is typically the LC50. The toxicity to other beneficial arthropods is typically the LR50, EC50 or NOEC. Impacts increases as the endpoint decreases.</p> <hr/> <p>Terrestrial plants:</p> <p>The impact of toxicity to terrestrial plants on the categorization is based on the Seedling emergence and vegetative vigour endpoints. Seedling emergence in terrestrial plants is typically the EC25 or NOEC. Vegetative vigour in terrestrial plants is typically the EC25 or NOEC. Impact increases as the endpoint decreases.</p>