Health Canada's Pest Management Regulatory Agency
PMRA Information Note – 16 December 2025

Health Canada's approach to proportional effort for pest control products

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Canada

Document history (revision/update)

Updated	Update/Rationale:
16 December 2025	Initial Publication

Disclaimer

This 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. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

Introduction

Through the Policy on Proportional Effort (PE), Health Canada's Pest Management Regulatory Agency (PMRA) is implementing a systematic categorization to inform the allocation of review resources for pesticides in Canada. By adopting this framework, Health Canada aims to better allocate resources based on the level of effort required, thereby enhancing efficiency in its regulatory activities while maintaining the highest standards for human health and environmental protection. The primary use of the proportional effort framework is as a workload management tool.

All pesticides registered in Canada have been found to have acceptable risk, as defined in the *Pest Control Products Act*. It is acknowledged that registered pesticides and their uses pose different risks and may require different levels of regulatory effort to be confident that those risks continue to be acceptable. The PE policy provides a framework to systematically categorize and identify which active ingredients may require greater or fewer evaluation resources at the next update to the risk assessment, and the specific areas of assessment which may be required.

While the Policy on Proportional Effort provides a high-level overview of how the PMRA categorizes registered pesticide active ingredients, this information note provides additional guidance and details. It supplements the policy, focusing on how the PMRA applies the scientific categorization criteria, descriptions of the criteria, including ranges and weightings, and when and how the categorization of a pesticide could change.

Initially, use of the categorization results is being phased in as new re-evaluations are initiated. This approach allows the PMRA to test, monitor and adjust the processes and criteria as needed. This document will be revised as updates are made to provide full transparency to stakeholders.

Part A Categorization

1.0 Categorization of active ingredients

To determine an active ingredient's categorization, the PMRA uses a systematic approach, where each registered active ingredient is assessed against the PE criteria:

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 sub-populations.
  - H1.1. *Pest Control Products Act* 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

As a first step, the PMRA recognizes that certain types of active ingredients, such as biopesticides, microbial pest control agents, non-conventional pesticides and adjuvants are eligible for reduced data requirements and streamlined review processes. These active ingredients often have unique information requirements and risk assessments, making direct comparison with conventional pest control products inappropriate. Therefore, these active ingredients are automatically considered as lower PE.

Secondly, the general criterion (G1) that relates to the novelty of the pesticide technology is considered. A newly registered active ingredient with a mode of action (how it kills the pest) that is different from any registered or previously registered active ingredient would meet this criterion. Pesticides based on novel technologies (for example, nanopesticides, double stranded ribonucleic acid (dsRNA)), would also meet this criterion. Active ingredients that meet this criterion are considered as higher PE and are not subject to further categorization. However, the appropriate data to categorize the pesticide against the other criteria will be retained for future categorization purposes. Once registered, a novel active ingredient will be considered "novel" for 5 years. After 5 years, the pesticide would no longer be considered novel and would be considered against the human health and environmental criteria to determine its designation as part of the full PE framework. Categorization based on the general criterion will be explored further when the PMRA develops an approach to support integrating PE categorization into pre-market assessments.

Finally, the remaining active ingredients are considered against both the human health and environmental criteria. Each active ingredient is categorized as either lower or higher PE for each of health and environment. Detailed descriptions of these criteria are provided in the sections that follow. The categorization approaches for human health and environment differ, reflecting the distinct data requirements and risk assessment methodologies applied to each discipline.

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.

1.1 Categorization against human health criteria

For the purpose of categorization, the four human health PE criteria described above are organized into four equally weighted groups. Each group contributes 25% to the overall categorization:

- Group 1: Dietary risk (H3.1, acute and chronic (food and drinking water), additional drinking water considerations are also included in group 4)
- Group 2: Lifetime cancer risk (H3.2)
- Group 3: Occupational and residential risk (H3.3)
- Group 4: Other key factors related to hazard, exposure, or cumulative risk (H1.1, H1.2, H2.1, H2.2, H3.1 - drinking water, H4)

By grouping this way, 75% of the overall weighting is based on health risk outcomes (in other words, Groups 1–3). The remaining 25% (in other words, Group 4) incorporates key factors that inform risk and relate to the PMRA's role in protecting vulnerable populations (for example, the *Pest Control Products Act* (PCPA) factor).

Based on the most recent risk assessment, each criterion is assigned a score, with higher scores indicating a greater potential need for regulatory oversight and review resources. The score increases, for example, as the calculated risk approaches the acceptable threshold. For active ingredients where the PCPA factor has not yet been characterized, an additional multiplication factor is applied to the dietary risk (Group 1) and occupational and residential risk (Group 3) scores to estimate the potential resources that will be required during the next evaluation.

For each active ingredient, data are sourced from PMRA risk assessments. The indicator for any given criterion or sub-criterion will correspond to a score, which is then weighted as indicated in the table in Appendix I. The weighted scores are added together to generate a normalized score from 0 to 100. Active ingredients with higher normalized scores are expected to require greater regulatory oversight and higher effort during future updates to risk assessments.

Some information may be considered in more than one sub-criterion, such as the *Pest Control Products Act* and the uncertainty factors, which have specific criteria but also contribute to the risk criteria (for example, dietary risk) total. This is by design and to specifically highlight to the PMRA when additional effort for review may be required.

In terms of the human health criteria, active ingredients with normalized scores of 40 or greater are categorized as higher PE. This approach identifies pesticides that may require substantial updates to the risk assessment or increased mitigation measures, while also considering the resources available to conduct these assessments. This threshold allows the PMRA to appropriately anticipate and allocate the amount of resources that would be required to complete reviews that reflect a higher level of complexity.

1.2 Categorization against environmental criteria

For the purposes of categorization, the environmental criteria and the associated sub-criteria are subdivided into those that are used for screening and those that are used for scoring.

Sub-criterion E1.1 Possibility of release to the environment, is used to screen out active ingredients that are not used outdoors or that are unlikely to result in environmental exposure when used according to the product labels. Sub-criterion E1.2, Nature of pesticide, is used to screen out active ingredients for the environment based on knowledge of physical and chemical properties (for example, an active ingredient found to occur naturally is considered lower PE).

All other active ingredients are considered against the remaining environmental criteria as organized into three groups, with the associated weighting indicated below:

- Group 1: Magnitude of use (E1.3)(15% of total score)
- Group 2: Environmental fate characteristics (E2.1, E2.2, E2.3, E2.4)(30% of total score)
- Group 3: Ecotoxicity to non-target organisms (E3.1)(55% of total score)

The PE categorization approach includes the following eight terrestrial and freshwater organism groups as defined in the PMRA's environmental risk assessment framework: birds, mammals, bees, beneficial arthropods and earthworms (terrestrial invertebrates), terrestrial plants, fish, aquatic invertebrates, and aquatic plants (vascular and non-vascular).

Each organism group is considered against the environmental PE criteria using the most recent risk assessment and other key data sources (for example, sales information). Each criterion or sub-criterion is assigned a score, which is then weighted according to the methodology outlined in Appendix I. The weighted scores are summed to produce a normalized score ranging from 0 to 100 for each organism group. The normalized score for each organism group is then compared against a threshold value. These thresholds vary by organism group:

- Birds, mammals, pollinators, terrestrial invertebrates, aquatic invertebrates, and fish: 50
- Terrestrial and aquatic plants: 65

Plants have slightly higher thresholds because plants, especially many common terrestrial and aquatic species, tend to be more resilient and adaptable to environmental changes compared to many animal species. The vast diversity and reproductive strategies of plants can allow some species to recover more easily compared to the more vulnerable animal taxa. The environmental thresholds were validated by comparing PE categorization against historical re-evaluation categorizations.

The thresholds for the eight organism groups inform the overall PE categorization for environment, and the depth of review required for each group. The categorization of an active ingredient as either higher or lower PE is determined as follows:

- Higher PE: If five or more organism groups exceed their individual thresholds, the active ingredient is categorized as higher PE.
- Lower PE: If four or fewer organism groups exceed their individual thresholds, the active ingredient is categorized as lower PE.

However, a lower PE categorization is automatically elevated to higher PE if any of the following conditions apply, as they indicate a need for greater regulatory effort:

- The pesticide is an insecticide or acaracide and the most recent pollinator review predates 2016 (as identified by publication of a final decision involving a pollinator assessment)
- The aquatic invertebrate score or fish score exceeds 60
- The pesticide is a fish toxicant
- The bird or mammal score exceeds 60

These considerations were selected to account for active ingredients where previous assessments used older methodology that requires updating to current standards, or for groups of active ingredients that are anticipated to require more oversight for environmental review (for example, rodenticides).

This PE approach identifies active ingredients that may require substantial regulatory oversight and effort, particularly when updates across multiple organism groups are anticipated in future risk assessments or where there could be significant effort required for one organism group if the conditions of use or methods of assessment have changed.

Part B Application of proportional effort

1.0 When and how the categorization is applied

Proportional Effort categorization of registered active ingredients reflects the most recent risk assessment. Following any subsequent final risk assessment decision, the scores associated with the human health or environmental criteria will be confirmed and may be updated. The resulting new scores for human health and the environment will be compared against the thresholds described above, and the active ingredient's PE categorization will be confirmed or updated as appropriate.

1.1 Use of categorization results to inform re-evaluation work planning

Proportional Effort categorization will be used to guide and inform the scope of re-evaluations. By looking at each active ingredient's health and environmental categorization in advance of a re-evaluation, the PMRA can identify the aspects of the review that require more regulatory effort and focus review resources on assessing those areas.

Under the PE framework, when initiating a re-evaluation, the PE categorization will guide the initial triage step to identify the appropriate re-evaluation category. Higher PE active ingredients will undergo Category 1 re-evaluations (as described in the Management of Pesticides Re-evaluation (MORE) policy), with the scope of the review focussed as directed by the PE categorization process.

For lower PE active ingredients, the PMRA will apply specific considerations during the re-evaluation scoping process. These re-evaluation scoping considerations are used to identify pesticides for which the PE categorization may underestimate the effort required for the next re-evaluation—particularly in cases where risk assessment methodologies have evolved since the last major review or where new findings have emerged from foreign assessments.

Scenarios that may expand the scope of the re-evaluation include:

- Foreign reviews or incident reports that indicate:
    - Effects of concern on vulnerable populations including infants and children that were not previously considered in PMRA assessments
    - Cancer effects that have not yet been included in PMRA assessments
    - Incidents or concerns identified through incident reports that would indicate the need for more extensive review
    - Lower toxicology reference values or endpoints for non-target organisms that are more protective of human health or the environment, which need to be considered in the context of the existing Canadian risk picture

- Drinking water residue estimates have never been modelled, or drinking water metabolites were not included in the residue definition and the dietary risk cup is almost full, which underestimates the dietary risk
- When the registered use pattern includes a high occupational/residential exposure scenario (as indicated under the H.2 criteria), and the previous assessment used methodologies that may underestimate exposure, which may impact the risk outcomes
- Significant changes in the sales of an active ingredient in Canada

Some scoping considerations are time limited, and will not be applicable once all assessments are updated to modern standards. The scoping considerations allow the PMRA to identify active ingredients that require more regulatory effort upon their next review, and to identify those areas where a targeted review is required. It should be noted that some considerations relating to updating risk assessments to modern standards have already been incorporated in the environmental categorization process (for example, the requirement to update the pollinator assessment).

Active ingredients with a lower PE designation that do not meet these scoping considerations will undergo a Category 3 re-evaluation. If any of the above scenarios apply, the re-evaluation of a lower PE active ingredient may shift from a Category 3 re-evaluation to a Category 1 or 2 (meaning that a more in-depth, targeted review is required). In these cases, the scope of the re-evaluation changes; the PE categorization will be confirmed or updated pending the final re-evaluation decision.

1.2 Use of categorization results to inform pre-market assessments

The use of proportional effort categorization to inform pre-market amendments to a pesticide's registration is under consideration. The PMRA will consult with stakeholders on these new approaches and update this document prior to implementation.

2.0 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. As proportional effort is primarily a workload management framework, the PMRA will be taking a phased approach to the implementation of transparency measures. At the time of initial implementation of this framework, proportional effort categorization will only be used to inform re-evaluations. Without the Continuous Oversight of Pesticides Policy fully implemented to provide on-going monitoring, many of the initial PE categorizations will be revisited during the scoping stage of a re-evaluation, and the re-evaluation may be broader in scope than the PE categorization would have indicated.

The PMRA will initially communicate PE categorization alongside any new final registration or re-evaluation decisions in the associated regulatory decision document, as well as through the Re-evaluation and Special Review Workplan. The information communicated in the workplan may vary depending on the extent to which the scoping considerations described above have been incorporated. For new re-evaluation initiations, the information shared will focus on the PE categorization.

Appendix I Definition of criteria, rationales, and weightings

Descriptions of the PE criteria with associated definitions, rationales, and weighting details are found below. For those criteria used for scoring, a list of indicators or values is provided. The indicators or values at the top of the list are associated with the lowest score; those at the bottom of the list are associated with the highest score.

General criteria

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.

Definition and rationale

Novel pesticide technology is defined as a newly registered active ingredient with a mode of action (how it kills the pest) that is both unsimilar to any registered or previously registered active ingredient, and that has not been reviewed by the PMRA previously. Additionally, the active ingredient is not used or is relatively new (available on the market for up to but less than 5 years), in other jurisdictions.

Once registered, a novel active ingredient will be considered "novel" for 5 years and will be assigned automatically to Higher PE. After 5 years, the pesticide would no longer be considered novel and would be considered against the criteria to determine its designation as part of the full PE framework.

Examples of this include, but are not limited to, dsRNA and nanopesticides.

Human health criteria

Group 1: Dietary risk

- Criterion: H3.1 Dietary risk (includes drinking water and imported foods)
- Acute and chronic dietary risk are scored separately
- Group weight: 25% of the total human health score (sum of acute and chronic scores)

Definition and Rationale:

The PMRA evaluates both acute and chronic dietary exposure. Dietary risk is determined by comparing the estimated human exposure to the dietary toxicology reference values. The PMRA often expresses this as a percentage of the reference value. This is commonly referred to as a "risk cup". When the

PMRA calculates the dietary risk, it considers drinking water (DW) and all potential foods treated with a given pesticide in a person's diet. For example, a risk cup that is 85% "full" (example only) may require additional regulatory effort.

Additional considerations include:

- Level of refinement to the assessment
- Drinking water estimates for conventional pesticides
- Maximum residue limit (MRL) status for conventional pesticides

Indicators:

- No acute or chronic dietary assessment required (for example, in cases where there are no relevant acute toxicological effects on which to base an acute dietary risk assessment), or, No food uses or potential for exposure from drinking water (DW) sources.
- Basic assessment (aggregate with DW, if applicable) and Risk ≤20% of the toxicology reference value, or, Refined assessment (aggregate with DW, if applicable) and Risk ≤10% of the toxicology reference value
- Basic assessment (aggregate with DW, if applicable) and Risk >20% of the toxicology reference value,, or, Refined assessment (aggregate with DW, if applicable) and Risk >10 to ≤50% of the toxicology reference value
- Refined assessment (aggregate with DW, if applicable) and Risk >50 to ≤75% of the toxicology reference value
- Refined assessment (aggregate with DW, if applicable) and Risk > 75% to ≤ 95% of the toxicology reference value or, Risk from food only, as no estimated environmental concentration (EEC) has been modelled
- Refined assessment (aggregate with DW, if applicable) and Risk ≥ 95% of the toxicology reference value, or, Highly refined or Probabilistic assessment, or, Risk-based MRLs established

Group 2: Lifetime cancer risk

- Criterion: H3.2 Lifetime cancer risk
- Group weight: 25% of the total human health score

Definition and rationale

The PMRA will calculate a separate cancer risk when there is evidence of non-threshold carcinogenic effects. The PMRA uses a linearized multistage model and will calculate a potential cancer risk for any relevant exposure scenario based on the use of the pesticide. Pesticides with a non-threshold cancer risk that is, for example, at the target limit of 1E-05 for occupational workers scenarios or 1E-06 for non-occupational scenarios (including dietary exposure), require greater regulatory effort.

Indicators:

- Cancer not identified as an endpoint of concern
- Threshold-based approach to cancer risk assessment. Cancer risks addressed by the margin of safety approach.
- Non-threshold effect. Lifetime cancer risk is below level of concern (for example, risks <1E-06)
- Non-threshold effect. Lifetime cancer risk is approaching level of acceptability (for example., risks at 1E-06)
- Non-threshold effect. Lifetime cancer risk is at the level of acceptability (for example, risks slightly above 1E-06, but acceptable due to conservatisms in the assessment)

Group 3: Occupational and residential risk

- Criterion: H3.3 Occupational and residential risk
- Group weight: 25% of the total human health score

Definition and rationale

The PMRA evaluates occupational and residential exposure, as appropriate based on the registered use of the pesticide. Occupational and residential risk is determined by comparing the estimated human exposure to the toxicological reference values. If potential risks are identified, the PMRA first considers refinement of the risk assessment and basic risk mitigation before advancing to more intensive risk mitigation. The selection of risk mitigation and management options is guided by a thorough understanding of the use situation, use practices, application technology, extent of use, and geographical location. Some risk mitigation measures are applied only after all other feasible options are explored. Since mitigation is determined from the risk assessment and implemented when required by the risk assessment, the extent of mitigation was used as an indicator of risk in the framework.

For example, the requirement for workers to wear a long-sleeved shirt and pants is considered a minimum level of mitigation, but if risks are not acceptable at that minimum level, the PMRA might require the user to wear coveralls. Chemicals that require more extensive mitigation measures for risks to be acceptable may require additional regulatory effort.

Indicators:

- No mitigation measures beyond minimum levels required based on the risk assessment (for example, single layer personal protective equipment, minimum restricted-entry interval)
- Mitigation measures that are greater than minimum, but less than extensive
- Proposed use pattern modified prior to registration to reduce exposure to achieve acceptable risk (for example, only the lowest application rate within the proposed rate range was supported)
- Only one extensive mitigation measure required to achieve acceptable risk (for example, reduced number of applications)
- Multiple extensive mitigation measures required to achieve acceptable risk (for example, reduced number of applications and limit amount handled per day)
- Very extensive mitigation measures required to achieve acceptable risk (for example, cancellation of uses/products, product stewardship plan)

Group 4: Other key factors related to hazard, exposure, or cumulative risk

- Criteria: H1.1, H1.2, H2.1 (A and B), H2.2, H3.1 (drinking water), H4
- Group weight: 25% of the total human health score; each criterion in this group is equally weighted in the group score (~3.6% each)

H1.1. *Pest Control Products Act* Factor

Definition and Rationale

The PCPA Factor is an additional 10-fold factor the PMRA applies by default to pesticide risk assessments for the protection of fetuses, infants and children. In some cases, the PCPA Factor can be reduced on the basis of reliable scientific data. Pesticides for which the full 10-fold factor has been maintained require more regulatory effort to ensure health protection.

Indicators:

- Toxicology reference values (TRVs) not established and qualitative risk assessment conducted
- Onefold PCPA factor
- Threefold PCPA factor
- Tenfold PCPA factor

H1.2. Uncertainty factors

Definition and rationale

Additional uncertainty factors beyond the standard 100-fold may be applied to pesticide risk assessments to address uncertainties that may result from situations including the following:

- A no observed adverse effect level (NOAEL) cannot be identified in a toxicology study, necessitating extrapolation from the lowest observed adverse effect level (LOAEL).
- A long-term toxicology study is not available, and therefore extrapolation from a short-term study is required when assessing long-term risks.
- Key toxicology data are missing to adequately characterize the hazards to vulnerable populations, for example.

More regulatory effort will be required for pesticide assessments where additional uncertainty factors are applied.

Indicators:

- TRVs not established and qualitative risk assessment conducted
- Standard 100-fold uncertainty factor (UF) applied
- Application of additional threefold UF
- Application of additional ≥10-fold UF
- TRVs not established and quantitative risk assessment required

H2.1. High exposure use scenarios

Definition and rationale

A) The PMRA reviews the registered use-site categories to determine if a pesticide is registered for use in certain scenarios that have high potential for exposure (for example, personal insect repellents, conventional swimming pool products)

Indicators:

- Registered use pattern does not include one of the significant exposure scenarios
- Registered use pattern includes certain high exposure scenarios which are assessed qualitatively (for example, brine curing)
- Registered use pattern includes certain high exposure scenarios that are assessed quantitatively (for example, personal insect repellents).

Definition and rationale

B) The PMRA considers scenarios where new data that indicate greater exposure than previously assessed have not yet been incorporated in the risk assessment, for example:

- Indoor applications for bed bugs, carpet beetles and fleas
- High exposure agricultural uses (such as orchards [non-herbicide], ornamentals [cut flowers] and greenhouses)
- Paint

Indicators:

- A recent exposure assessment has been conducted or registered use pattern does not include the indicated specific exposure scenarios with potential for high human exposure
- Registered use pattern includes certain high exposure scenarios (for example, mosquito perimeter treatment) where incorporation of new data is less likely to impact the current level of risk mitigation
- Registered use pattern includes certain high exposure scenarios (for example, cleaning products) where incorporation of new data may impact the current level of risk mitigation
- Registered use pattern includes certain high exposure scenarios (for example, indoor bed bugs, paint) where incorporation of new data will likely impact the current level of risk mitigation

H2.2. Restricted class products

Definitions and rationale

Pesticides that have been classified as restricted, for which additional regulatory effort is required due to the level of current risk mitigation measures.

Indicators:

- No registered restricted-class products
- At least one restricted-class product is registered

H3.1. Dietary risk (includes drinking water and imported foods) - Drinking Water

Definitions and rationale

When the PMRA calculates the dietary risk, it considers drinking water (DW) and all potential foods treated with a given pesticide in a person's diet. The PMRA often uses modelling information to determine drinking water exposure. Scores based on drinking water considerations, including situations where new

data/model that indicate potentially greater drinking water levels have not yet been incorporated in the risk assessment.

Indicators:

- Drinking water (DW) estimates are not required as not relevant to the use scenario (for example for indoor uses), or a qualitative risk assessment was conducted
- Modelled DW estimated environmental concentrations (EECs) according to the most recent data/model.
- When a quantitative risk assessment is required: where EECs were modelled prior to new data/model being implemented
- When a quantitative risk assessment is required: where EECs were assessed using the Drinking Water Level of Concern (DWLOC) or EEC not previously modelled when relevant to the use scenario

H4. Cumulative risk assessment

Definition and rationale

Cumulative risk assessments (CRA) are legally mandated when potential exists for co-exposure to pesticides that have a common mechanism of toxicity. This includes pesticides and metabolites that have similar structure to a class of pesticides that may undergo, will undergo, or has already undergone, a cumulative risk assessment or special review for potential health concerns.

Indicators:

- CRA not required (for example, based on use pattern or no common mechanism of toxicity)
- The PMRA has not yet determined whether a CRA is required for an active ingredient with an individual qualitative risk assessment
- CRA assessed qualitatively or in a straight forward quantitative CRA as part of the individual active ingredient's risk assessment
- The PMRA has not yet determined whether a CRA is required for an active ingredient with an individual quantitative risk assessment
- Complex stand-alone quantitative CRA is required or has been conducted (for example, organophosphate or triazole pesticides)

Environmental criteria

Release to the environment screening criteria

E1.1.Possibility of release to the environment screening criteria

Definition and rationale

The site of application is an important factor in determining environmental exposure of pesticides. In the case of both the terrestrial and aquatic environments, outdoor uses of pesticides are expected to result in the highest exposure scenario.

Active ingredients that are used outdoors or that are likely to result in environmental exposure, that is, active ingredients that are screened in by product type, location of use (Use-site Category and description) and their inherent nature are scored in the PE framework to characterize the level of PE for environmental assessment. Active ingredients that are screened out are considered lower PE and do not require scoring for environmental assessment.

NOTE: if registered active ingredients have multiple product types and/or locations of use associated with them, the active ingredient cannot be screened out if one of those characteristics is on the list of criteria to be screened in.

Table 1 Screening criteria for active ingredients requiring PE scoring: Possibility of release to the environment by product type

Screened in (to be scored)	Screened out (lower PE)
• acaricide • algaecide, agricultural • antifouling paint • animal repellent or toxicant • bird chemosterilant • bird repellent • bird toxicant • crop bactericide • fish toxicant • fumigant • fungicide • herbicide • insect growth regulator • insecticide • insect repellent • molluscicide	• air sanitizer • adjuvant, surfactant • biological control product • device • hard surface disinfectant • laundry additive • material preservative • non-parasitic plant disease control • pheromone • plant growth regulator • pruning paint • safener • sanitizer • slimicide • swimming pool algaecide or bactericide

Screened in (to be scored)	Screened out (lower PE)
• nematicide • rodenticide • wood preservatives: antisapstain, heavy-duty, remedial	• wood preservatives, including joinery and stain

Table 2 Screening criteria for actives requiring PE scoring: Possibility of release to the environment by location of use by use-site category

Screened in (to be scored)	Screened out (lower PE)
• 1 - Aquaculture and Aquatic Food Sites • 2 - Aquatic Non-Food Sites • 4 - Forests and Woodlots • 7 - Terrestrial Non-food and Non-feed Seed and Fibre Crops • 10 - Seed and Plant Propagation Material Food and Feed • 11 - Seed and Plant Propagation Materials Non-food and Non-feed • 13 - Terrestrial Feed Crops • 14 - Terrestrial Food Crops • 16 - Non-agricultural, Industrial and Residential Pest Management for Non-food Sites • 20 - Structures • 21 - Structures and Surrounding Soil • 22 - Underwater Structures and Materials • 23 - Wood • 25 - Human Habitat and Recreational Areas	• 3 - Empty Food and Feed Storage Structures and Areas • 5 - Greenhouse Food Crops • 6 - Greenhouse Non-Food Crops • 8 - Animals for Food Production • 9 - Animals Production of Non-food Commodities • 12 - Stored Food and Feed • 15 - Indoor Hard Surfaces • 17 - Industrial Process Fluids • 18 - Materials • 19 - Other Indoor Surfaces, Water and Air • 24 - Companion Animals • 28 - Indoor Plants and Plantscapes • 29 - Swimming Pools

Screened in (to be scored)	Screened out (lower PE)
• 26 - Human Skin, Clothing and Proximal Sites • 27 - Outdoor Ornamentals • 30 - Turf • 31 - Various Indoor and Outdoor Sites • 32 - Various Outdoor Sites • 33 - Residential Outdoors	

Table 3 Screening criteria for actives requiring PE scoring: Possibility of release to the environment by location of use by product location of use description

Screened in (to be scored)	Screened out (lower PE)
• dry formulations • fallowland • food/feed crops (field) • forestry • irrigation canals • non-cropland • non-food/non-feed crops (field) • ornamentals (field) • outdoor living areas • outdoors: large-scale biting-fly control • pastures, rangelands • sewers • shelterbelts • turf • urban areas • water • wood and wood products • woodlands	• air conditioners and air washers • aqueous systems • beehives • domestic pets • dwellings • fabrics/fibres • farm buildings • farm livestock • food/feed establishments • food/feed/seed (stored) • greenhouse • hospitals • industrial establishments • non-fabric/non-food commodities (stored) • nursery stock containers (and/or domestic) • oil field injection waters; oil and gas activities • ornamentals (greenhouse) • outdoor surfaces of buildings • paints • products for reformulation • pulp and paper mill systems

Screened in (to be scored)	Screened out (lower PE)
	• soap and detergents • vehicles • vinyls and other polymers • water (ornamental ponds/pools) • zoos

E1.2. Nature of pesticide

Definition and rationale

Some pesticides are screened out of scoring for the environment based on knowledge of the physical and chemical properties and are considered lower PE without the requirement to score them; these include pesticides such as food grade active ingredients, oils, certain biologicals (that is, pheromones, and microbial or viral products), and those chemicals that occur naturally in the environment.

Group 1: Magnitude of use

- Criterion: E1.3 Magnitude of use
- Group weight: 15% of the total environmental score

Definitions and rationale

Pesticide sales and use data provide an indication of the potential for active ingredients to be found in the environment based on the assumption that the more end-use products that are sold or used, the more potential for environmental exposure. Based on the assumption that pesticides that are sold will be used, sales data can be used as a surrogate for pesticides use.

Sales data is used as an estimate of the magnitude of use (average sales of relevant products per active ingredient normalized by the minimum relevant application rate to calculate a maximum potential area of application in Canada). The 5-year average national sales (kg of active ingredient) is normalized by dividing by the single minimum rate (for example, mg a.i./ha). For new products: estimate “potential” sales by using the most recent 5-year average sales based on product type. The scoring metric organizes the values for the maximum potential area of application in Canada into 6 tiers ranging from 0 to >1 000 000 ha with the score increasing for each tier.

Values (maximum potential area of application in Canada in ha):

- 0
- >0 – 1000
- 1000 – 10 000
- 10 000 – 100 000
- 100 000 – 1 000 000
- > 1 000 000

Group 2: Environmental fate characteristics

- Criteria: E2.1, E2.2, E2.3, E2.4
- Weight of fate characteristics out of total score: 30% (individual criterion weightings: E2.1 = 8.2%, E2.2 = 6.8%, E2.3 = 6.8%, E2.4 = 8.2%)

Note that the fate of pesticides in air is not considered for categorization purposes. Although some physiochemical properties related to the fate of pesticides in air may be submitted to the PMRA, these data do not typically produce quantitative endpoints that are usable in the risk assessment. As such they may not always be suitable or available for categorization purposes. Persistence criteria for pesticides in air are typically a modelled value, thus subject to conservatisms and not suitable for categorization purposes.

E2.1. Persistence in the environment

Definition and rationale

Given that the majority of pesticides used in Canada are applied to vegetation, the initial environmental compartment receiving the active ingredient is soil and, therefore, the half-life in soil is used as an estimate of persistence in the environment. The greater the half-life, the longer the active ingredient will persist in the environment, and, therefore, increase the potential for exposure. This is represented by the aerobic half-life in soil (t1/2 or DT_{50}) in days (d).

Note that the persistence of pesticides in water is not considered for categorization purposes. The majority of the pesticides used in Canada are applied to vegetation and, as such, the initial environmental compartment receiving the active ingredient is soil. The use of the soil half-life as an indication of persistence gives an idea of the potential of a chemical compound to end up in water systems. The greater the soil half-life, the greater the chance it will end up in groundwater or surface water. Once the chemical reaches surface water, it is assumed there could be both acute and chronic exposure to aquatic organisms. The aerobic water-sediment (total system) half-life is not necessary for inclusion as soil persistence is sufficient for the PE categorization system. Additionally, there have been jurisdictional differences over time in endpoint reporting (whole system, water compartment, sediment compartment) which

could lead to inconsistencies within the framework. The scoring metric organizes the values for the half-life in soil (t1/2 or DT_{50}) into 3 tiers ranging from <30 to >100 days with the score increasing for each tier.

Values (half-life in soil as t1/2 or DT_{50} in days):

- < 30
- 30 – 100
- > 100

E2.2. Potential for bioaccumulation

Definition and rationale

The octanol-water partition coefficient (K_{ow}) is a property of a chemical related to its tendency to remain in water (hydrophilic compounds) or fat (lipophilic compounds) and is widely used as a measure of the tendency of an active ingredient to bioaccumulate. The greater the coefficient, the greater the tendency for the chemical to bioaccumulate in tissues. When available, the bioaccumulation factor (BAF) and the bioconcentration factor (BCF) are considered, as they represent accumulation in tissues of aquatic organisms. Both the BAF and BCF are not always reported in the primary literature or physical/chemical properties databases. For the purposes of determining the PE for an active, the log K_{ow} is considered sufficient as an indicator of the tendency of an active ingredient to bioaccumulate. The scoring metric organizes the values for log K_{ow} into 5 tiers ranging from <2 to >5 with the score increasing for each tier.

Values (log K_{ow}):

- < 2
- 2 – 3
- 3 – 4
- 4 – 5
- > 5

E2.3. Potential to leach through soil or runoff into surface water

Rationale and definition

The organic carbon soil sorption coefficient (K_{oc}) is a measure of the potential of a chemical to bind to soil particles. The higher the coefficient K_{oc}, the more it binds to soil particles, and the longer the chemical will remain trapped in the soil. Chemicals with a low coefficient demonstrate high leaching and high run-off, which could result in contamination of groundwater or watersheds. The scoring metric organizes the values for K_{oc} into 5 tiers ranging from 0 to ≥1000 to <100 (L/kg or mL/g) with the score increasing for each tier.

Values (K_{oc} in L/kg or mL/g):

- ≥ 1000
- 500 – 1000
- 300 – 500
- 100 – 300
- < 100

E2.4. Potential to be transported in surface runoff

Definition and rationale

A key consideration related to environmental fate is the tendency of the pesticide to move from the site of application and be transported by surface runoff to the aquatic environment. Water solubility is considered one of the factors in estimating fate and transport of a compound in the environment, and the potential for exposure to aquatic organisms by indicating 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 scoring metric organizes the values for water solubility into 6 tiers ranging from <0.5 to ≥ 3000 mg/L with the score increasing for each tier.

Values (water solubility in mg/L):

- < 0.5
- 0.5 – 2
- 2 – 30
- 30 – 300
- 300 – 3000
- ≥ 3000

Group 3: Ecotoxicity to non-target organisms

- Criterion: E3.1
- Weight of organism group ecotoxicity value in total score: 55%

E3.1. Potential for pesticides to affect aquatic and/or terrestrial organisms in their environment

Definition and Rationale

An important consideration for the environmental criteria is the toxicity and potential effects on non-target terrestrial and aquatic organisms. Therefore, the categorization approach includes acute and/or chronic ecotoxicity endpoints for terrestrial organisms (birds, mammals, plants, beneficial arthropods, earthworms, and bees) and aquatic organisms (fish, plants, algae, vascular plants and invertebrates). Endpoints include effects to mortality/survival, growth, and reproduction, or population effects. These endpoints are typically expressed as LC_{50}/LD_{50} values (lethal concentration or dose to elicit 50% mortality), HC_5/HD_5 (hazard concentration or dose to elicit 50% mortality), EC_{50} (effective concentration to elicit an effect in 50% of the population) or NOECs (no observable effects concentrations). The lowest, most sensitive endpoints considered in the risk assessment for each ecotoxicity sub-group are selected.

Toxicity to aquatic organisms

Includes fish, aquatic invertebrates and aquatic plants. For both fish and invertebrates an acute and chronic endpoint are scored. For aquatic plants, vascular and non-vascular endpoints are scored.

Note that marine organisms are not considered for inclusion in the PE framework as the freshwater organisms can act as a surrogate for the marine ecosystem for categorization purposes. The dataset for freshwater organisms is more complete for active ingredients as marine species studies are conditionally required depending on the potential for exposure in the marine environment. Exposure of marine organisms to pesticides is typically low when the Directions for Use are followed due to tidal dilution. Marine organisms are assessed in the risk assessment for pest control products that may result in marine organism exposure.

Additionally, amphibians are not considered as a stand-alone organism as there are limited data on the effects of pesticides on amphibians; there are not currently enough data across the registered active ingredients to function as a criterion for the PE framework. The standard procedure is to use fish endpoints as a surrogate for amphibians.

The following endpoints are most commonly used: Fish Acute: LC_{50}/EC_{50}, Fish chronic: NOEC, Aquatic invertebrates acute: EC_{50}, Aquatic invertebrates chronic: NOEC, aquatic plants vascular: EC_{50}/NOEC, aquatic plants non-vascular: EC_{50}/NOEC. The scoring metric organizes the values for the toxicity to aquatic organisms (using the acute or chronic endpoint) into 6 tiers ranging from 100 000 to <10 µg a.i./L with the score increasing for each tier.

Values – toxicity to aquatic organisms (acute or chronic toxicity endpoint in µg a.i./L):

- > 100 000
- 10 001 – 100 000
- 1001 – 10 000
- 101 – 1000
- 10 – 100
- < 10

Toxicity to birds and mammals

Acute toxicity endpoints are scored for both birds and mammals. For both endpoints the LD_{50} is most commonly used. The scoring metric organizes the values for the toxicity to birds and mammals for acute endpoints into 6 tiers ranging from 2000 to <10 mg a.i./kg body weight with the score increasing for each tier. Chronic toxicity endpoints are scored for both birds and mammals. For both endpoints the NOEC is most commonly used. The scoring metric organizes the values for the toxicity to birds and mammals for chronic endpoints into 6 tiers ranging from 250 to <10 mg a.i./kg body weight/day with the score increasing for each tier.

Values (acute toxicity endpoint in mg a.i./kg bw):

- > 2000
- 1001 – 2000
- 501 – 1000
- 51 – 500
- 10 – 50
- < 10

Values (chronic toxicity endpoint in mg a.i./kg bw/day):

- > 250
- 101 – 250
- 51 – 100
- 26 – 50
- 10 – 25
- < 10

Toxicity to pollinators

Acute contact and oral toxicity is currently scored for pollinators/bees. For both endpoints the LD_{50} is most commonly used. The scoring metric organizes the values for the toxicity to pollinators (using the acute contact or acute oral

endpoint) into 6 tiers ranging from 100 to <0.1 µg a.i./bee with the score increasing for each tier.

Values (acute contact/acute oral toxicity endpoint in µg a.i./bee):

- > 100
- 51 – 100
- 12 – 50
- 3 – 11
- 0.1 – 2
- < 0.1

Terrestrial invertebrates

Acute toxicity to earthworms and toxicity to beneficial arthropods is scored. For earthworms the LC_{50} is most commonly used. For arthropods the LR_{50}, EC_{50} or NOEC is commonly used. The scoring metric organizes the values for the toxicity to terrestrial invertebrates (using the acute earthworm endpoint in mg a.i./kg dry weight soil or the beneficial arthropod endpoint in a.i./ha) into 6 tiers ranging from 2000 to <10 with the score increasing for each tier.

Values (Acute earthworm toxicity endpoint in mg a.i./kg dw soil, or beneficial arthropod toxicity endpoint in g a.i./ha):

- > 2000
- 1001 – 2000
- 501 – 1000
- 51 – 500
- 10 – 50
- < 10

Terrestrial plants

Both seedling emergence and vegetative vigour are scored for terrestrial plants. For both the EC_{25} or NOEC are most commonly used. The scoring metric organizes the values for the toxicity to terrestrial plants (using the seedling emergence or vegetative vigour endpoint) into 6 tiers ranging from 2000 to <10 g a.i./ha with the score increasing for each tier..

Values (Seedling emergence or vegetative vigour endpoint in g a.i./ha):

- > 2000
- 1001 – 2000
- 501 – 1000
- 51 – 500
- 10 – 50
- < 10

Appendix II List of abbreviations

µg	Microgram
a.i.	Active ingredient
BAF	Bioaccumulation factor
BCF	Bioconcentration factor
CRA	Cumulative risk assessment
d	Days
dsRNA	Double stranded ribonucleic acid
DT_{50}	Dissipation time 50% (the time required to observe a 50% decline in concentration)
DW	Drinking water
DWLOC	Drinking water level of concern
EC25	Effective concentration on 25% of the test population
EC_{50}	Effective concentration on 50% of the test population
EEC	Estimated environmental concentration
g	Grams
ha	Hectares
HC_5	Hazard concentration estimated to be lethal to 5% of the test population
HD_5	Hazard dose estimated to be lethal to 5% of the test population
kg	Kilogram
K_{oc}	Organic carbon-soil sorption coefficient
K_{ow}	Octanol-water partition coefficient
L	Litres
LC_{50}	Concentration estimated to be lethal to 50% of the test population
LD_{50}	Dose estimated to be lethal to 50% of the test population
LOAEL	Lowest observed adverse effect level
LR_{50}	Lethal rate to 50% of the test population
mg	Milligram
MORE	Management of Pesticides Re-evaluation Policy
MRL	Maximum Residue Limit
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
PCPA	*Pest Control Products Act*
PE	Proportional Effort
PMRA	Pest Management Regulatory Agency
t1/2	Half-life
TRV	Toxicology reference value
UF	Uncertainty factor