Health Canada Santé Canada

Canada

Pest Management Regulatory Agency

Health Canada's Approach to Environmental Risk Assessment for Pest Control Products

PMRA Guidance Document

Protecting human health and the environment

Protéger la santé humaine et l'environnement

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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.

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1 Purpose and scope

This guidance document provides an overview of Health Canada's decision framework for assessing the environmental risks from the use of pest control products (pesticides) in Canada.

The decision framework for assessing risks is described in *PMRA Guidance Document: A Framework for Risk Assessment and Risk Management of Pest Control Products*. The decision framework's environmental risk assessment component is the subject of this document, which includes general details about the process and the science-based approaches used to assess environmental risk.

The assessments are carried out by Health Canada's Pest Management Regulatory Agency (PMRA) Environmental Assessment Directorate (EAD). We will not discuss the roles of other PMRA directorates, advisory bodies, and other federal policies (except for the Toxic Substances Management Policy (TSMP) in the registration of pesticides.

2 Regulatory process

Health Canada's PMRA regulates pesticide use and sales under the authority of the *Pest Control Products Act* and its regulations. The primary objective of our mandate is to prevent unacceptable risks to individuals and the environment from the use of pesticides. The Act is the primary federal legislation by which all pesticides must be registered or authorized for use before they can be manufactured, imported, sold, or used in Canada.

We use a decision-making framework founded on the assessment and management of risk. All new pesticides must undergo a pre-market assessment before being approved for use in Canada. Once pesticides are in use in Canada, they are subject to continued monitoring and periodic re-evaluations to ensure their use remains acceptable.

3 Environmental risk assessment

The environmental risk assessment is a scientific evaluation of the likelihood that exposure to a pesticide can cause adverse effects on individual organisms, populations, or ecological systems.

We conduct an environmental risk assessment for the registration of new pesticides, a change or expansion in the use pattern for an existing registered pesticide, or the re-evaluation or special review of registered pesticides that are already in use.

Pre-market assessments

The assessment for the registration of a new pesticide or for a change or expansion in the use pattern for an existing registered pesticide is also referred to as a pre-market assessment.

Before a new pesticide is granted registration for use in Canada, the applicant must submit detailed scientific information about the pesticide's active ingredient and its formulations. Information includes the environmental fate, behaviour and ecotoxicity of the pesticide active ingredient and of any other components of interest—such as transformation products, formulants, and impurities.

The applicant must also submit a product label, which defines the use of a pesticide, and includes information such as:

- application method
- application rate and frequency
- type of application equipment
- targeted pest species
- crops or sites to which it is applied

A change or expansion in use pattern can refer to modifications to where or how the pesticide is applied (for example, increasing the application rate or adding targeted pest species or crops). If there are proposed changes to the uses indicated on the product label that increase the potential for environmental exposure or result in an exposure route that was not previously assessed, we will either update the existing risk assessment or conduct a new assessment. Depending on the changes, we may require additional information from the registrant.

Once we've completed the new or expanded assessment, we will set out the standards and conditions for pesticide use and registration. A pesticide or new use for a pesticide product is registered if there is reasonable certainty from the scientific evaluation that no harm to human health or the environment will result.

Post-market assessments

The assessment for a registered pesticide already in use is called a post-market assessment.

Registered pesticides are typically re-evaluated every fifteen years. They can be re-evaluated earlier if new information indicates the need for re-evaluation. We also initiate special reviews to respond to emerging issues on an as-needed basis (for example, a special review would be initiated if new information indicates a potential increase in risk or identifies a new risk of concern from the current use(s) of a pesticide). A special review is focused on a specific aspect of concern identified. The re-evaluation process ensures that the body of information and risk assessment for each active ingredient and its associated end-use product(s) are up-to-date and meet current scientific standards.

Our business processes also reflect a continuous oversight approach that proactively identifies emerging risks and allows for decision-making that is better informed and timelier when new risks are identified. This approach includes proactively identifying and reviewing new information that could reveal the need for further investigation. Our transformation process is described on the PMRA transformation page on the Canada.ca website.

The re-evaluation of registered pesticides incorporates all pesticide use patterns and any additional scientific information obtained since the original registration. We gather additional information for the pesticide product or active ingredient through the following:

- scientific reviews conducted by other regulatory agencies, such as the United States Environmental Protection Agency (USEPA) and the European Food Safety Authority (EFSA)
- peer-reviewed scientific literature
- field monitoring data in media such as water, air, soil and biota
- incident reports from sources such as the Canadian Pesticide Incident Reporting Program and the USEPA Ecological Incident Information System Database

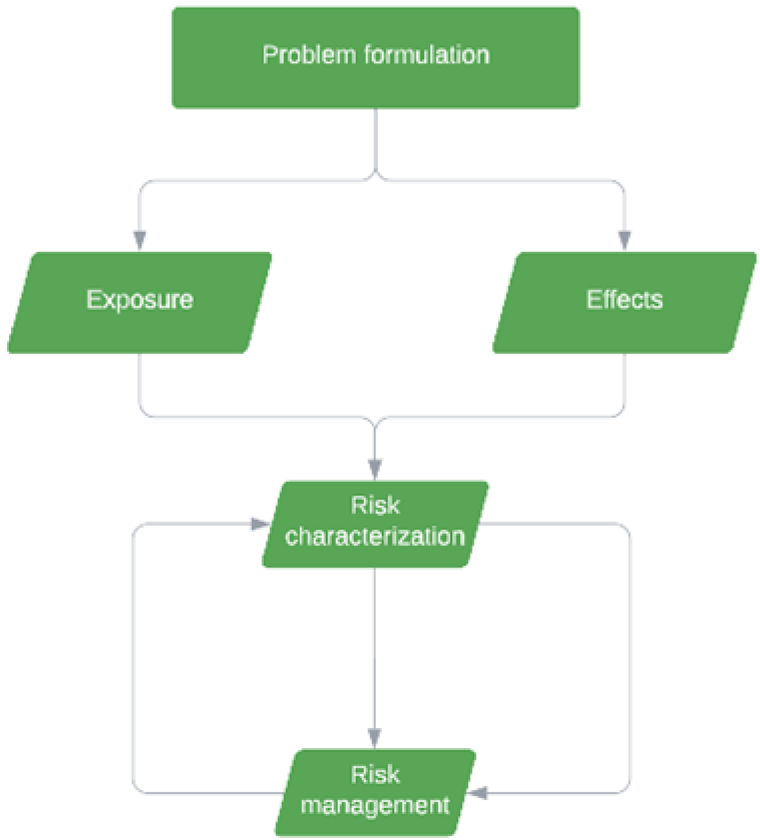
The information from the above sources is more readily available for our post-market assessments; it is often not available when we conduct our assessments for new pesticides or for changes or expansions in the use pattern of existing registered pesticides. However, when available, we consider information from scientific reviews, scientific literature, monitoring data, and incident reports in our pre-market assessments.

Environmental risk assessment approach

We take a tiered approach to environmental risk assessment. The first tier (known as a screening-level risk assessment) identifies pesticides that pose a negligible environmental risk. During the screening-level risk assessment, we use scientific data (for example, standard studies describing fate, behaviour, and hazards) and conservative assumptions to identify pesticides that are not likely to pose a risk to the environment. If a potential risk is identified, we move to higher-tier assessments. Compared to the screening level, higher tiers of the environmental risk assessment incorporate more realistic information on exposure and toxicity.

These include exposure scenarios to evaluate the potential for the pesticide to move into sensitive terrestrial and aquatic environmental compartments, such as lakes and rivers. Refinements may use computer-based modelling techniques, monitoring data, more realistic toxicity studies or field research. We may also include qualitative information in higher tiers to further characterize the risk. As part of the higher-tier assessments, we will also evaluate measures to reduce or mitigate expected risks.

Risk assessment framework



The risk assessment framework consists of the following phases:

Problem formulation	This phase involves a process in which we identify the objectives and scope of the risk assessment (for example, how the environment will be exposed to a pesticide, the information we need to determine any adverse effects, the areas of possible concern and how we plan to do the analysis).
Exposure assessment	This phase involves the analysis and characterization of the fate of the pesticide active ingredient and its transformation products and their movement in the environment.
Effects assessment	This phase involves the analysis and characterization of ecotoxicity.

Risk characterization	This phase involves the integration of the environmental exposure and effects information to characterize the risk (for example, we could use a risk quotient (RQ) or other, more refined techniques) using an iterative process with a tiered approach. Risk management options are considered when characterizing risks.
Risk management	This phase involves the development of recommendations for the mitigation of any identified risks, the standards and conditions for the use of the pesticide, and the recommendation for registration. Risk management options are also considered during risk characterization.

3.1 Problem formulation

This phase involves a preliminary look at the available data to identify data gaps and focus the risk assessment on the areas of possible concern. In this phase, we also develop an analysis plan.

The following summarizes critical parameters we incorporate into developing the pesticide problem formulation and analysis plan. These are the basis for the environmental risk assessment:

3.1.1 Protection goals

3.1.2 Assessment endpoints

3.1.3 Scope of the problem

3.1.4 Sources of information

3.1.5 Data gaps

3.1.1 Protection goals

Under the *Pest Control Products Act* (4(1)), our primary objective is to prevent unacceptable risks to people and the environment from the use of pesticides. The health or environmental risks of a pesticide are acceptable only if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product. We determine this by considering the pesticide's conditions or proposed conditions of registration.

In conducting environmental risk assessments for pesticides, we look at protecting non-target plants and animals in the environment. Organisms considered include:

- Terrestrial organisms such as:
  - earthworms and other soil-dwelling invertebrates
  - pollinators such as bees

- predators and parasitoids (beneficial arthropods such as predatory and parasitic insects, spiders, and mites)
- birds
- small wild mammals
- terrestrial plants

- Aquatic organisms from freshwater and marine systems such as:
  - aquatic invertebrates
  - fish
  - amphibians
  - algae
  - aquatic vascular plants

We incorporate biodiversity protection in our assessment by protecting these groups of non-target organisms. This approach also considers food chain effects (for example, protecting aquatic invertebrates protects the fish and bird species that may use aquatic invertebrates as a food source).

3.1.2 Assessment endpoints

Assessment endpoints are more specific descriptions of taxonomic groups and their attributes (for example, survival and growth of birds, rather than just birds) that need to be protected and, for pesticides, are defined based on the broader, over-arching protection goals as described under the *Pest Control Products Act*. Assessment endpoints are developed to be measurable and meaningful and are, therefore, more clearly related to measures of effects that can be studied and determined in toxicity studies.

Table 1 presents the assessment endpoints we use in our environmental risk assessments for various taxonomic groups present in the environment.

Table 1: Assessment endpoints for environmental risk assessment of pesticides[1]

Taxonomic group	Generic attributes of interest[2]	Primary entity to be protected[3]
Terrestrial plants	Species richness, species diversity, species assemblage/composition, structure and function	Community
Aquatic plants and algae	Species richness, species diversity, species assemblage/composition, structure and function	Community

Taxonomic group	Generic attributes of interest[2]	Primary entity to be protected[3]
Aquatic invertebrates	Species richness, species diversity, species assemblage/composition, structure and function at the community level, and survival, growth, reproduction, abundance at the population level	Community
Terrestrial invertebrates	Changes in species diversity, changes within functional groups, local extirpation, changes in distribution pattern, altered patterns of occupancy, abundance, biomass, survival, growth/development, reproduction	Functional group
Fish	Survival, growth, reproduction, abundance	Population
Amphibians and reptiles	Survival, growth, reproduction, abundance	Population
Birds	Survival, growth, reproduction, abundance	Population
Small wild mammals	Survival, growth, reproduction, abundance	Population

Notes to Table 1:

1 To identify the assessment endpoints to use for pesticide environmental risk assessments, we met with scientists from outside the PMRA to review the various taxonomic groups present in the environment and identify the attributes (such as growth, reproduction and survival) and levels of ecological organization (such as individual, population and community) for each group that should be assessed and protected to meet the overall protection goals.

2 While some attributes like growth were not explicitly identified as a general attribute of interest for some taxonomic groups during meetings with scientists from outside the PMRA, we consider survival (mortality), reproduction, growth and other sub-lethal effects that are expected to lead to effects on growth, reproduction and survival as important attributes of interest for all taxonomic groups.

3 Individuals of threatened or endangered species can be the desired entity to protect under certain circumstances.

In toxicity studies, measurement endpoints (measures of effects) are determined by exposing representative test organisms to a pesticidal substance and recording the effects on the attributes of interest identified for that taxonomic group. In most studies, effects are measured in individual organisms, even if the entity to be protected is at the population or community level. The ecotoxicity endpoints we require for pesticide risk assessments are measures of reduced growth, reproduction, survival, and other sub-lethal effects expected to affect growth, reproduction and survival. Reproductive success is one of the indicators we use to measure the protection of populations (for example, we can assess the reproductive success of birds by analyzing changes in parameters such as clutch size or survival of chicks). For terrestrial plants, we use effects on seed germination and plant growth to assess community-level effects—or, more broadly—effects on habitats. The underlying assumption is that if we protect lower levels of ecological organization—such as organisms—from effects, then by extension, higher levels of organization, such as populations and communities, are also protected.

We use the effects information and information about the use of pesticides to identify the main sensitive taxonomic groups (such as plants, vertebrates, and invertebrates) that can be exposed and the areas of potential environmental risk. Together, this information is the basis for the problem formulation.

3.1.3 Scope of the problem

To establish the scope of the environmental risk assessment, we need to understand the environmental routes of exposure for a pesticide, such as through soil, water, the food chain or air. The use pattern and the nature of the pesticide inform the potential routes for environmental exposure and guide the development of the problem formulation. We also need to consider the toxicity of the pesticide to non-target organisms in the environment.

The product label

We use the product label (based on the proposed (or registered) uses of the pesticide) to determine routes of exposure. The application to register a pesticide requires the submission of use instructions for each end-use product that will be marketed for sale and use in Canada. Labels for end-use products are an essential source of information regarding the nature and use of the pesticide being evaluated. The label indicates the relevant exposure scenarios we need to assess and informs how we conduct the risk assessment.

The product label includes information such as the following:

- functional class of pesticide (such as herbicide, insecticide or fungicide)
- pesticide formulation (such as granular, wettable powder or emulsifiable concentrate)
- type of application equipment and method(s) that are used (such as aerial or ground-applied foliar spray, soil incorporated, or seed treatment)
- application target (such as plants, seeds, soil, structures, or forests)
- active ingredient(s) in the product
- rates, frequency, and timing of application(s)

Pesticide formulation specifications

A Statement of Product Specification Form (SPSF) is required for each pesticide registration in Canada. SPSFs identify the composition of the technical grade product and the end-use product(s) consumers will use. Regulated parties must identify the active ingredient(s), any formulants in the product and their proportions. Impurities[1] in the technical grade product must also be identified and monitored during the production process and indicated in the form.

We screen formulants and impurities to determine the potential for toxicity to non-target organisms. Results from our screening could indicate the need to include an analysis of these components in the environmental risk assessment.

Use-site categories and data requirements

Once we identify the pesticide's uses, we can determine the environmental exposure routes. To formulate the problem for pesticide risk assessment, we define it through use-site categories (Table 2) and formalized data requirements corresponding to each use-site category. Each use-site category is defined by the crops, organisms or sites being treated and where the treatment occurs (as indicated in product labels). Environmental data requirements have been described for each use-site category based on the potential exposure pathways and are published in use-site data code (DACO) tables.

Use-site DACO tables

Each defined use-site category has a corresponding DACO table which indicates the fate and toxicity data that we need to conduct an environmental risk assessment for that type of exposure scenario. In the DACO tables, each data element has been assigned a numerical data code (DACO number). The definitions and DACO tables are used to inform pesticide companies about the information required for us to conduct a scientifically sound environmental risk assessment for a given use-site category. The DACO numbers allow the information to be submitted, identified, and categorized in a database for efficient storage and retrieval.

Data requirements are categorized as either "required" (R), "conditionally required" (CR) (which are needed when specific criteria apply), or "not required" (NR). An example of this categorization would be a pesticide application to protect a food or feed crop that requires (R) data regarding the fate of the substance in soil and water. Data to address the fate of the substance in the air are CR and are based on the potential for the substance to volatilize from soil or plant surfaces after it has been applied.

In most cases, studies are conducted with the technical grade active ingredient; in other cases, an end-use formulation is used. We use the data requirements outlined in Revised Environmental Data Requirements in our assessments.

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[1] *Impurities are identified through the analysis of technical grade product from several production runs (batch data) at production facilities.*

Each use site has an identified set of exposures that determines the type of fate and effects data required. We may request both acute and chronic data depending on the nature of the pesticide's active ingredient.

The DACO tables were developed primarily for conventional (synthesized) chemical pesticides. However, data requirements have been adapted for active ingredients and their associated products that comprise natural substances such as biopesticides (microbial and pheromone pesticides), plant extracts or other naturally derived substances. These data requirements have been published in separate guidance documents, such as Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals and Guidance for the Registration of Non-Conventional Pest Control Products.

For a subset of use-site categories, the environmental release of pesticides is minimal under most circumstances. Therefore, little or no environmental data are required, and we don't typically conduct an environmental risk assessment. Table 2 indicates whether environmental data are required for each use-site category.

Table 2: Use-site categories

Use-site category number	Use-site category descriptions	Environmental data required?
1	Aquaculture and aquatic food sites	Yes
2	Aquatic non-food sites	Yes
3	Empty food and feed storage structures and areas	No
4	Forests and woodlots	Yes
5	Food crops grown indoors in greenhouses or other enclosed structures	Yes
6	Non-food crops grown indoors in greenhouses or other enclosed structures	Yes
7	Terrestrial non-food and non-feed seed, fibre and industrial crops	Yes
8	Terrestrial animals for food production	Yes
9	Terrestrial animals for the production of non-food commodities	Yes
10	Seed and plant propagation materials: food and feed	Yes
11	Seed and plant propagation materials: non-food and non-feed	Yes
12	Food and feed processing and storage	No
13	Terrestrial feed crops	Yes
14	Terrestrial food crops	Yes
15	Indoor hard surfaces: antimicrobials	No

Use-site category number	Use-site category descriptions	Environmental data required?
16	Other terrestrial non-food and non-feed sites: limited public access	Yes
17	Industrial process fluids: antimicrobials	Yes
18	Materials: antimicrobials	Yes
19	Other indoor surfaces, water and air: antimicrobials	No
20	Structures	Yes
21	Structures and surrounding soil for termites	Yes
22	Underwater structures and materials	Yes
23	Wood	Yes
24	Companion animals	No
25	Outdoor human habitat and recreational areas: residential and public access	Yes
26	Human skin, clothing and proximal sites	No
27	Outdoor ornamentals	Yes
28	Indoor ornamentals and plantscapes	No
29	Swimming pools: algicides and bactericides	No
30	Turf	Yes
31	Terrestrial vertebrate attractants and repellents	Yes
32	Terrestrial vertebrate toxicants	Yes

Active ingredient and its transformation products

The environmental risk assessment primarily focuses on the pesticide active ingredient, but as a pesticide breaks down in the soil, water, or air, other chemicals may be formed. These are called transformation products or breakdown products. If transformation products of environmental relevance are identified, we may expand the risk assessment to include additional characterization of the breakdown products.

We recommend that regulated parties submit study reports that include proposed degradation pathways. This is helpful information for us to have when it's available because it illustrates the pathway by which the pesticide active ingredient can degrade to form the transformation products. Fate studies, where the active ingredient is the test substance, report the detection and quantification of any potential major transformation products (> 10% of the applied parent substance). Depending on the situation, we could require further studies with transformation products to assess their potential levels and persistence in different media or potential toxicity to non-target organisms. Our environmental risk assessment must consider any major transformation products that are expected to be present in the environment. The level of investigation potentially required to characterize any transformation products in the environmental risk assessment is identified in the problem formulation phase.

3.1.4 Sources of information

Once we identify the required data elements, we compile the available information. Studies conducted using scientifically valid protocols are the primary source of information used to evaluate pesticide risks. This can be data generated under controlled conditions in the laboratory or under field or semi-field conditions. Typically, the laboratory and field studies are submitted by the registrant.

The problem formulation process also involves a search for information available from a broad range of other sources, including:

- the public domain (such as peer-reviewed scientific literature from academic researchers)
- federal and provincial scientists
- reviews and data evaluation records from foreign regulatory authorities (such as the USEPA, EFSA and the Australian Pesticides and Veterinary Medicines Authority (APVMA))
- the PMRA's database of mandatory and voluntary pesticide incident reports
- reports collected by other groups or jurisdictions (such as the USEPA Environmental Incident Information System (EIIS), American Bird Conservancy Avian Incident Monitoring System (AIMS), provincial and territorial environment or fishery ministries, or wildlife health centres throughout Canada, or other similar databases)

Pesticide incident reports

A pesticide incident is a negative effect on humans, animals or the environment that can result from being exposed to a pesticide.

Registrants must report to the PMRA any information about incidents involving their pesticide as it relates to human health, the environment or value. Canadians can also voluntarily report pesticide incidents to the PMRA. A collection of incident information allows for the monitoring of pesticide effects under realistic conditions. Information received through this program can be used as further evidence in the environmental risk assessment and regulatory decisions.

3.1.5 Data gaps

We look for potential gaps in the available information to complete the problem formulation. If the gaps are critical, more data are required to fully characterize the fate and toxicity of the pesticide before the assessment phase can begin. If the assessment can proceed, the requirement for further information can still be an iterative part of the assessment process. The regulatory process can be paused or halted to allow for the generation of new data or the submission of other information from registrants. We will request additional information if questions or issues arise at any point during the assessment process.

Once we have gathered the required information and identified the major exposure pathways, the main sensitive receptors and the areas of focus for the environmental risk assessment, the problem formulation phase is complete, and the assessment phase begins.

3.2 Exposure and effects assessment

The purpose of the assessment phase is to review, evaluate, analyze, and verify the information that is available regarding the environmental fate, behaviour and ecotoxicity of the pesticide active ingredient. This includes analyzing other components of interest, such as transformation products, formulants, and impurities.

Although the exposure and effects assessments are presented as two distinct phases of the risk assessment framework, both can be done simultaneously in the assessment phase of the process.

The exposure assessment consists of characterizing the potential for exposure of environmental habitats and organisms to pesticides. We estimate pesticide concentrations in the environment by considering several factors:

- information on the intended use pattern of the pesticide
- environmental fate and behaviour data
- water modelling and monitoring information
- the duration of exposure

The effects assessment consists of characterizing the ecotoxicity effects that can be expected for different organisms. Characterization of the effects includes:

- how toxic a pesticide is to different organisms
- what effects can result from exposure
- how the effects relate to the assessment endpoints
- how the effects change with varying levels of pesticide exposure

During this phase of the review, the available data and information must undergo a critical evaluation. This can include the calculation of fate parameters and effects endpoints and a discussion of the variability and uncertainties related to the results. Assessments should indicate if study protocols followed Good Laboratory Practices, identify deviations from standard study guidelines, and assess the suitability of the data for use in the risk characterization (including any limitations). For more detailed information on assessing study acceptability, see Information Note: Determining Study Acceptability for use in Pesticide Risk Assessments (2019).

3.2.1 Evaluation of exposure

To assess exposure for the risk assessment, we need all data regarding the fate and behaviour of the pesticide in the environment described in detail. The information we look for is:

- the physicochemical properties of the pesticide that can affect its fate and behaviour in the environment
- the fate in soil, water, and air that characterizes all processes and provides an overall picture of the processes that are likely to be the most important
- the persistence measured by the half-lives or dissipation times of pesticide active ingredients and any transformation products in the soil and water (this includes levels likely to be found in the environment over time and from one growing season to the next)
- the mobility that determines potential movement into the air, through the soil, or into surface water

Physicochemical properties

Physicochemical properties are determined through laboratory studies. They show a substance's tendency or potential to persist or move in the environment. The principal physicochemical properties that we consider are:

- vapour pressure to predict volatility and the probability of a substance to move into the atmosphere
- solubility in water (which indicates the potential for movement and distribution of a substance in the environment)
- Henry's law constant (which expresses the relationship between solubility in water and the vapour pressure for a given compound and indicates its potential to volatilize from moist soil or a water surface)
- octanol-water partition coefficient (which indicates a compound's potential to bioaccumulate in biota)
- UV/visible absorption spectrum (which indicates the potential to photo-transform)
- dissociation constant (which indicates the potential for dissociation or ionization, which affects its mobility characteristics)

Transformation, degradation, and dissipation

Transformation and degradation studies

We look at laboratory studies of abiotic (hydrolysis and photolysis) and biotic (facilitated by microorganisms) transformation in soil, water, sediment, or air to evaluate transformation or degradation in the environment. We look to see that processes are investigated under aerobic and anaerobic conditions. The results of these studies provide us with the rate of decline of pesticide active ingredients and the formation/decline of their transformation products.

From these studies, we use numerical test data to determine the representative half-life ($t_{1/2}$) and the dissipation times, DT_{50} and DT_{90} (time until 50% and 90% of the chemical has dissipated or transformed, respectively) of the pesticide active ingredient and of its major transformation products when possible. We use the DT_{50} to characterize the persistence of a substance.

Dissipation studies

We require field dissipation studies conducted on land (terrestrial field dissipation) or in water (aquatic field dissipation). These studies help substantiate the transformation and mobility data generated by laboratory studies and can characterize dissipation routes such as leaching. We require that registrants conduct field dissipation studies with the end-use product intended for use in Canada or similar formulation.

To determine the amount of the pesticide likely to carry over to subsequent growing seasons, we review the analysis of soil samples from terrestrial field dissipation studies. A concentration in soil at the end of the growing season greater than or equal to 30% of the amount of active ingredient that was applied shows that the active ingredient has the potential to be carried over to subsequent growing seasons.

Field dissipation studies characterize the dissipation of a pesticide from all chemical and biological processes and routes. They do not provide individual measures of fate parameters, such as rates of transformation or degree of partitioning. Those fate parameters are determined in laboratory studies that focus on one or two processes in isolation.

The number, size, location, and duration of field dissipation studies we need for review will depend on the proposed scale of use of the pesticide.

For a pesticide to be eligible for registration in Canada, field dissipation studies must be conducted within Canadian ecozones or an equivalent ecozone. Field studies conducted in Canadian equivalent ecozones of the United States and Europe can be used to characterize the fate and behaviour of pesticides for Canadian uses. We use a tool called the Ecoregion Crosswalk, which consists of a geographic information system (GIS)-based model called the Europe-North America Soil Geographic Information for Pesticide Studies (ENASGIPS), to identify ecozones comparable to Canada.

Field studies can also be designed to focus on more specific aspects of environmental fate and behaviour under ambient environmental conditions, such as volatilization or leaching. Examples of these field studies include lysimeter studies and prospective groundwater monitoring studies.

Both laboratory and field data can be incorporated into the fate and behaviour assessment using a weight-of-evidence approach.[2]

Mobility

We assess the mobility of a pesticide to describe how it moves through and over the soil and its tendency to bind to soils and sediments. To do this, we require various types of studies—such as adsorption/desorption or soil column leaching. This information indicates how strongly a pesticide can be bound to soil/sediment particles or if the compound will tend to associate more with the water (aqueous) component of the system being assessed.

We determine the leaching potential of a pesticide active ingredient or its transformation products in our mobility assessments. This is the potential for a substance to move downward through the soil and reach groundwater. The potential for leaching depends on many factors, and we use a weight-of-evidence approach considering all available information. This includes results of groundwater modelling, terrestrial field dissipation studies, leaching studies conducted in the laboratory or in the field, mobility information from studies like adsorption/desorption, transformation studies conducted in the laboratory, chemical properties such as water solubility, a set of criteria for leaching potential developed by researchers Cohen et al. (1984)[3], scores developed by Gustafson (1989)[4] and available groundwater monitoring data.

When assessing studies conducted in water-sediment systems, we consider how strongly a pesticide can be bound to sediment. We consider this information as relevant to bioavailability—the degree to which a chemical is absorbed by an organism—in our assessments. This depends on whether pesticide residues remain bound to organic matter or re-enter the water column after moving to substrates. In addition, transformation processes can occur in sediment leading to the release of transformation products (other chemicals) into the water.

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2 A weight-of-evidence approach means that a combination of information from various sources is used to give sufficient evidence to support a conclusion. This approach requires scientific judgement as the "weight" given to each piece of evidence will depend on factors such as the quality of the data, consistency of results, nature and severity of effects, and relevance of the information. In August 2018, Health Canada published guiding principles for using a weight-of-evidence approach. https://www.canada.ca/en/health-canada/services/publications/science-research-data/weight-evidence-general-principles-current-applications.html

3 Cohen, S.Z., S.M. Creeger, R.F. Carsel and C.G. Enfield, 1984, Potential for pesticide contamination of groundwater resulting from agricultural uses. Pages 297–325 In R.F. Krugger and J.N. Seiber, eds., Treatment and Disposal of Pesticide Wastes. ACS Symposium Series No. 259. American Chemical Society, Washington, DC, pp. 297–325.

4 Gustafson, D.I., 1989, Groundwater ubiquity score: a simple method for assessing pesticide leachability. Environmental Toxicology and Chemistry, v. 8, no. 4, p. 339–357.

Additionally, as part of the mobility assessment, we use studies of bioconcentration to measure or estimate the amount of pesticide residues that can accumulate within animal tissue (bioaccumulation). Bioconcentration refers to the partitioning of a pesticide active ingredient or its transformation products from water into the tissue of aquatic organisms. Bioaccumulation refers more generally to the accumulation of a pesticide active ingredient or its transformation products in an organism via contaminated food and water, including transfer through the food chain. For pesticide risk assessment, the studies typically available to assess bioaccumulation are conducted with fish.

Estimated environmental concentrations

Estimated environmental concentrations (EECs) are an estimate of the amount of pesticide to which an organism could be exposed. EECs of pesticides are calculated in various environmental media such as water, soil, and air and on food items for non-target organisms. These estimations are based on the pesticide's application rates, the application timing, and environmental fate information such as dissipation times.

Exposure estimates are tiered to match a stepwise approach to the environmental risk assessment.

For the initial tier, or screening-level of the risk assessment, we review concentrations based on conservative exposure scenarios.

For higher tiers of the risk assessment, exposure estimates can be refined to consider more realistic exposure scenarios. We can also refine exposure estimates based on other factors, such as various application parameters like:

- droplet size
- application method
- the timing of application

For pesticides applied as an aqueous solution, refinement of the exposure concentrations will include considering the off-target movement of the pesticide via spray drift and runoff separately. Since not all pesticides are applied in solutions or using the same application equipment, we review information such as the formulation of the pesticide and where it is being used to determine the potential for exposure.

For pesticides applied outdoors as a solution, granule, a surface coating for seeds, or as a wood preservative, to name a few, the method for determining EECs is different for each.

We also look at the monitoring data for pesticide active ingredient concentrations in waterbodies located in areas of pesticide use available from various jurisdictions across Canada. We can also look at available water monitoring data from the United States given the extensive monitoring programs that exist in that country. We frequently consider surface water monitoring data in the environmental risk assessment for aquatic organisms. We consider available groundwater monitoring data as part of our assessment of the leaching potential of a pesticide active ingredient or its transformation products. Occasionally, we receive pesticide monitoring data for environmental matrices other than water, such as biota, sediment and air. When such data are received, we review them and decide if they are suitable for integration into the environmental risk assessment.

For additional information on estimated environmental concentrations and their use in environmental risk assessment for aquatic and terrestrial organisms, please see the Risk characterization section in this guidance and Appendix A.

3.2.2 Evaluation of effects

While the exposure characterization looks at fate and behaviour data to estimate concentrations of pesticides in various environmental compartments, the assessment of the effects looks at the consequences of exposure of organisms to the active ingredient and transformation products of the pesticide.

We evaluate the toxicity or hazard of a given pesticide by reviewing standard toxicity studies following scientifically acceptable protocols with a range of test organisms. We use surrogate species for each taxonomic group since it isn't feasible or practical to test all organisms in every major taxonomic group in laboratory or field studies.

Depending on the nature of the active ingredient and the use scenario, we may require studies to determine acute or chronic effects. For acute toxicity studies, we use effects endpoints (LC_{50}, LD_{50}, LR_{50}, EC_{50} or IC_{50}) for concentrations, rates or doses causing 50% mortality or sub-lethal effects in the test. For chronic exposures, we use a NOEC (no-observed-effect concentration) or NOEL (no-observed-effect level).

Ecologically relevant endpoints for chronic exposure include, but are not limited to:

- mortality
- growth reduction or inhibition
- reproductive impairment, such as reduced fecundity (number of young)
- reduction of community species richness

The fate and behaviour of a pesticide, its chemistry and its use pattern will determine where the pesticide will end up in the environment and for how long. This, in turn, allows us to decide what types of organisms will most likely be exposed to the chemical and over what period of time. This information helps us to decide what organisms require toxicity testing and whether we need short-term studies (acute) or both acute and chronic (long-term) studies. For instance, if a pesticide is likely to enter the water and then move to sediments where it will persist, we could require a chronic toxicity study with a benthic (sediment-dwelling) organism.

The types of data we routinely require for pesticide risk assessments are summarized in Table 3.

We can also request higher-tier, more complex toxicity studies, such as those conducted outdoors in a terrestrial or aquatic habitat on a case-by-case basis. For example, microcosm or mesocosm studies could be useful to determine community-level effects in aquatic systems. The results from these studies are often challenging to interpret because of the multiple processes that vary throughout the study and season to season. We analyze the data from these studies for quality and reliability. The benefit of including these studies as part of the risk assessment under certain circumstances is additional, more realistic data to support decision-making.

As with fate and behaviour studies, both laboratory and field toxicity data are incorporated in the effects assessment using a weight-of-evidence approach.

In most cases, laboratory toxicological studies are conducted with the technical grade active ingredient. We will request studies with the end-use product as the test substance if we have concerns (for example, the inclusion of a formulant with known toxicological properties). We also consider studies with transformation products in the risk assessment. Field studies are most often conducted with end-use products.

Consult the Revised Environmental Data Requirements to find the environmental toxicology data required to support the pesticide risk assessment for a particular use. Other guidelines exist for the evaluation of pheromones (Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals) and other non-conventional pesticides (Guidance for the Registration of Non-Conventional Pest Control Products).

Table 3: Data for characterizing the effects of pesticides on non-target organism groups

Taxonomic group	Test organism[1]	Test type[1]	Endpoint[1,2]	Toxicity value[3]
Terrestrial				
Earthworms	Earthworm (such as *Eisenia foetida*)	Acute[4]	Mortality	LC_{50}
		Chronic	Mortality, reproductive effects	NOEC
Pollinators	Honeybee (*Apis mellifera*)	Acute oral	Mortality	LD_{50}
		Acute contact	Mortality	LD_{50}
		Chronic adult	Mortality	NOED
		Chronic larva	Mortality	NOEC / NOED
		Colony effects; semi-field, field, end-use product	Mortality, growth, reproductive effects, colony condition	NOEC
Predators and parasitoids	Predators (such as *Typhlodromus pyri*);	Glass plate, laboratory, semi-field,	Mortality, reproductive effects,	LR_{50}, NOER

Taxonomic group	Test organism[1]	Test type[1]	Endpoint[1,2]	Toxicity value[3]
	Parasitoids (such as *Aphidius rhopalosiphi*)	field, end-use product	parasitization ability	
Other soil invertebrates	Examples include collembolans (springtails), nematodes or enchytraeids (potworms)	Acute	Mortality	LC_{50}
		Chronic	Mortality, reproductive effects	NOEC
Birds[5]	Mallard (*Anas platyrhynchos*); Bobwhite quail (*Colinus virginianus*); Other bird species, such as passerine species	Single-dose oral, short-term dietary	Mortality	LD_{50} / LC_{50}
		Reproduction	Sub-lethal effects, reproductive effects	NOEC / NOEL
Small wild mammals[6]	Rat; Mouse	Single-dose oral, short-term dietary	Mortality	LD_{50}
		Reproduction	Sub-lethal effects, reproductive effects	NOEC / NOEL
Vascular plants[7]	Six dicot and four monocot species	Tier I: maximum challenge, end-use product, Tier II: definitive testing, end-use product	Seedling emergence, vegetative vigour	ER_{25} or ER_{50} / EC_{25} or EC_{50}
Aquatic – freshwater				
Invertebrates	Pelagic (Water flea, *Daphnia magna*); Benthic (such as chironomids, *Chironomus* species)	Acute	Immobilization, mortality	EC_{50} or LC_{50}
		Chronic, reproduction	Reproductive effects	NOEC
Fish	Cold water species (Rainbow trout, *Oncorhynchus mykiss*); Warm water species (Bluegill sunfish, *Lepomis macrochirus*)	Acute	Mortality	LC_{50}
		Early life-stage (ELS), lifecycle	Sub-lethal effects, reproductive effects	NOEC
Amphibians	Various species[8]	Acute	Mortality	LC_{50}
		Early life-stage (ELS), lifecycle	Reproductive effects	NOEC

Taxonomic group	Test organism[1]	Test type[1]	Endpoint[1,2]	Toxicity value[3]
Algae	Green (such as *Rhaphidocelis subcapitata*); Cyanobacteria (such as *Anabaena flos-aquae*); Diatom (such as *Navicula pelliculosa*)	Acute	Growth inhibition	IC_{50} or EC_{50}
Vascular plants	Floating (duckweed, such as *Lemna gibba*; Rooted (such as *Myriophyllum spicatum*)	Acute	Growth inhibition, changes in morphology, other	EC_{50}
Aquatic – Estuarine/Marine				
Invertebrates (Crustacean)	Mysid shrimp (*Americamysis bahia*)	Acute	Immobilization, mortality	EC_{50} or LC_{50}
Invertebrates (Mollusk)	Eastern oyster (*Crassostrea virginica*)	Acute	Shell deposition	EC_{50}
Fish	Sheepshead minnow (*Cyprinodon variegatus*)	Acute	Mortality	LC_{50}
		Early life-stage (ELS), lifecycle	Sub-lethal effects, reproductive effects	NOEC
Algae	Diatom (such as *Skeletonema costatum*)	Acute	Growth inhibition	IC_{50} or EC_{50}

Notes to Table 3:

1 These are examples. Studies reporting other test protocols, test organisms and endpoints can also be available (for example, for re-evaluations) or can be requested. Tests to be conducted with an end-use product are indicated under "Test Type".

2 Various sub-lethal effects can be targeted or noted for these studies.

3 In some instances, toxicity values/test results are expressed using different terminology that is acceptable.

4 We no longer require acute studies with earthworms but will consider the data if they are available.

5 Generally, and in line with global practices, we consider bird endpoints as a surrogate for terrestrial-phase amphibian and reptile toxicity data. We use the risk assessment for birds as a surrogate for terrestrial-phase amphibian and reptile risk assessments. The risk assessment for birds is considered protective of risks to terrestrial phase amphibians and reptiles (see section A.2.6 in Appendix A).

6 Data from the mammalian studies submitted for the human health risk assessment are used as a surrogate for non-target wild mammals in the environmental risk assessment.

7 Usually ten crop species; representing a total of nine plant families.

8 When aquatic-phase amphibian data are not available, the most sensitive freshwater fish species is used as a surrogate.

Species sensitivity distribution

In general, the risk assessment is based on single-species toxicity tests measuring effects on individuals. When adequate data are available, we can use a species sensitivity distribution (SSD) to determine a hazardous concentration (HC_p) at which a percentage (p) of all species is assumed to be affected. When available, we use SSDs and HC_p values to represent effects at the community level.

3.3 Risk characterization

The environmental risk characterization integrates exposure and effects information to characterize risk to non-target species. Toxicity endpoints used in risk assessments can be adjusted to account for potential differences in species sensitivity as well as different protection goals (for example, protection at the community, population, or individual level). This adjustment is made by dividing the toxicity endpoint with an uncertainty factor.

The term "endpoint" refers to toxicity values resulting from statistical analyses of individual ecotoxicology studies such as a NOEC or EC_{50}. We use the term "effects metric" to identify effects-based values used to assess risk. An effects metric can be an individual endpoint value from a toxicity study, a geometric mean of multiple endpoints, an HC_p derived from an SSD or a mesocosm, semi-field, or field-based endpoint. The uncertainty factors we apply to the toxicity values are presented in Table 4.

The most widely used method of evaluating environmental risk for chemicals is the quotient method, which is calculated by dividing the EEC of a given pesticide active ingredient or its transformation product by the effects metric.

Risk quotient (RQ) = EEC ÷ effects metric

Where the effects metric is divided by an uncertainty factor:

Effects metric = toxicity endpoint or value ÷ uncertainty factor

In a risk assessment, we compare the RQ to the level of concern (LOC). Exceedance of the LOC indicates a potential for risk and that we may need to refine the risk assessment or implement mitigation measures. Table 4 summarizes the LOC values we use for the different taxonomic groups based on the toxicity information available.

Table 4: Toxicity endpoints, uncertainty factors and levels of concern used in the environmental risk assessment

Organism group	Exposure	Toxicity endpoint or value	Uncertainty factor used to divide the toxicity endpoint or value	Level of concern
Earthworms	Acute[1]	LC_{50}	2	1
	Chronic	NOEC	1	1
Adult bees	Acute contact	LD_{50}	1	0.4
	Acute oral	LD_{50}	1	0.4

Organism group	Exposure	Toxicity endpoint or value	Uncertainty factor used to divide the toxicity endpoint or value	Level of concern
	Chronic oral	NOED	1	1
Bee larvae	Acute oral	LD_{50}	1	0.4
	Chronic oral	NOEC or NOED	1	1
Predators and parasitoids	Acute (glass plate)	LR_{50} (*T. pyri* and *A. rhopalosiphi* only)	1	2
	Extended	LR_{50}	1	1
Other soil invertebrates	Acute	LC_{50}	2	1
	Chronic	NOEC	1	1
Birds/small wild mammals	Acute oral	LD_{50}	10	1
	Acute dietary	LD_{50} (LC_{50} converted to dose)	10	1
	Chronic	NOEL or NOED (NOEC converted to dose)	1	1
Terrestrial vascular plants	Seedling emergence	ER_{25} or EC_{25}; ER_{50} or EC_{50} ÷ 2	1	1
		HC_5 from an SSD[2]	1	1
	Vegetative vigour	ER_{25} or EC_{25}; ER_{50} or EC_{50} ÷ 2	1	1
		HC_5 from an SSD[2]	1	1
Freshwater invertebrates (pelagic and sediment-dwelling)	Acute	EC_{50} or LC_{50}	2	1
		HC_5 from an SSD[2]	1	1
	Chronic	NOEC	1	1
	Mesocosm[2]	NOEC	1	1
Freshwater fish (aquatic-phase amphibian surrogate)	Acute	LC_{50}	10	1
	Chronic (ELS; Lifecycle)	NOEC	1	1
	Mesocosm[2]	NOEC	1	1

Organism group	Exposure	Toxicity endpoint or value	Uncertainty factor used to divide the toxicity endpoint or value	Level of concern
Aquatic vascular plants (floating and rooted)	Acute	EC_{50}	2	1
	Mesocosm[2]	NOEC	1	1
Freshwater algae	Acute	IC_{50} or EC_{50}	2	1
		HC_5 from an SSD[2]	1	1
	Mesocosm[2]	NOEC	1	1
Marine/estuarine invertebrates (crustaceans and mollusks)	Acute	EC_{50} or LC_{50}	2	1
		HC_5 from an SSD[2]	1	1
	Chronic	NOEC	1	1
	Mesocosm[2]	NOEC	1	1
Marine/estuarine fish	Acute	LC_{50}	10	1
	Chronic (ELS; Lifecycle)	NOEC	1	1
	Mesocosm[2]	NOEC	1	1
Marine/estuarine algae	Acute	IC_{50} or EC_{50}	2	1
		HC_5 from an SSD[2]	1	1
	Mesocosm[2]	NOEC	1	1

Notes to Table 4:

1 We no longer require acute studies with earthworms but will consider the data if they are available.

2 When enough data are available, the toxicity value we use in our risk assessments may be an HC_p (typically an HC_5) from a species sensitivity distribution. These are most often derived for terrestrial plants or aquatic organisms. In some cases where data are available, we use a toxicity value from a higher-tier mesocosm study in our aquatic risk assessment. Most of the mesocosm studies used in our assessments are with freshwater invertebrates. The uncertainty factor for HC_p values and for mesocosm endpoints is equal to 1. When data are available, we may also use effects information from higher-tier semi-field or field studies for terrestrial organisms such as bees, predators and parasitoids, earthworms or birds in our risk assessment. We typically do not calculate risk quotients; however, we use this information to refine our risk characterization.

Screening level and refined assessments

The environmental risk characterization integrates the effects and exposure information using a tiered approach. A screening level assessment is followed by a refined assessment if necessary.

Screening-level assessment

We perform a screening-level risk assessment to identify pesticides and specific uses that do not pose a risk to non-target organisms. At this step, we also identify those groups of organisms for which there can be a potential risk. During the screening-level risk assessment, we use simple methods, conservative exposure scenarios such as direct application at a maximum cumulative application rate, and sensitive toxicity effects metrics.

We quantify risks at the screening level using the RQ approach. If the screening level RQ is below the LOC, the risk is considered negligible, and no further risk characterization is necessary. If the screening level RQ is higher than the LOC, we perform a refined risk assessment to further characterize the risk.

Refined assessment

During the refined assessment, we consider additional and more realistic exposure scenarios. Depending on the circumstances, we could also consider different toxicity effects metrics. Refinements can include further characterization of risk based on:

- exposure modelling
- monitoring data
- results from field or mesocosm studies
- probabilistic risk assessment methods

Refinements can be both quantitative and qualitative. They can continue until the risk is adequately characterized or the available data do not permit further refinements.

Example scenario

In the higher-tier aquatic assessment, we consider more realistic exposures through pesticide runoff and spray drift. The EEC for spray drift is the amount of deposition that can occur at the edge of an agricultural field adjacent to a non-target habitat instead of the full application rate. In this situation, we would base the EEC on some fraction of the application rate, which represents the exposure to spray drift. This fraction or percent spray drift depends on the spray quality and application equipment. For runoff, concentrations in a standard body of water are established using fate information and computer-based models. In conjunction with the modelled concentrations, we also consider available monitoring data reporting measured concentrations of the pesticide active ingredient or its transformation products in waterbodies in our runoff assessment. The EECs from spray drift and runoff will be lower than those used in the screening level, which was based on direct applicationin a water body at the full application rate, thus reducing the magnitude of the RQs while representing a more realistic exposure scenario.

3.4 Risk management

The final phase of the risk assessment framework is the determination of risk management options. When we identify potential environmental risks from pesticides, we consider different measures to reduce or mitigate the risks.

Mitigation measures generally aim to reduce the potential for exposure to non-target organisms. There are a limited number of circumstances where mitigation is targeted at reducing toxicity (for example, through changes to a formulation resulting in lower toxicity to non-target organisms). These situations are uncommon.

Various measures can be employed to reduce risks depending on the type and magnitude of concern. Based on the environmental risk assessment for a pesticide, measures can include:

- label statements to identify hazards and mitigate risks
- changes to how the pesticide is used, such as application rates, intervals, equipment and timing
- elimination/cancellation of some or all uses for the pesticide

The risk management and risk characterization phases are an iterative loop; we consider the various risk mitigation options when we characterize the risks.

Pesticide labels

Label statements that impose restrictions or limitations on how or where the pesticide can be applied will reduce environmental exposure.

Changes to directions for use can include reducing the application rate, reducing the number of applications per year, and restricting the timing of application based on crop type or growth stage. Some examples include:

- pesticides with bee toxicity can have restrictions on during-bloom application to bee-attractive crops
- pesticides that are toxic to beneficial arthropods, which are often used in integrated pest management, can have a hazard statement and instructions for minimizing spray drift to off-field areas
- pesticides toxic to aquatic organisms or terrestrial plants can require hazard statements and spray buffer zones for the protection of sensitive aquatic and terrestrial habitats downwind of the application area
- vegetative filter strips can be required to reduce runoff entering sensitive aquatic habitats next to agricultural fields

We consider the degree of effectiveness and the practicality of the proposed mitigation measures when determining risk management options.

If we find that the risk mitigation measures we propose are not feasible considering common operational standards or if identified risks cannot be mitigated to an acceptable level, some or all uses of the pesticide will be rejected or cancelled.

The label we approve contains the registration conditions that govern the pesticide's use. The label is a legal document that can be enforced by law. The use of a pesticide that is inconsistent with the directions or limitations on the label is prohibited.

The label is a pertinent line of communication between the PMRA, registrant, and consumer regarding all aspects of the pesticide. It must clearly state what the pesticide is intended to do and how to use it safely.

For registration of a new pesticide, the applicant provides a draft label which we assess and modify as appropriate based on the conclusions of the risk assessment and proposed mitigation.

The types and uses of pesticides currently registered in Canada vary widely. We have made a concerted effort to develop and implement technical guidance for environmental label statements with a view to their standardization.

4 Toxic Substances Management Policy

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP is part of an overall initiative for the designation and lifecycle management of persistent organic pollutants. The policy puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm it or human health. The policy applies to all substances subject to federal regulation, including those used as pesticides. We apply this policy within our regulatory framework according to the Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy.

Toxic substances that result predominantly from human activity and that are persistent and bio-accumulative are known as Track 1 substances. Substances are designated as Track 1 substances if they meet all the following four criteria:

- toxic or equivalent as defined by the *Canadian Environmental Protection Act* (CEPA) or CEPA-toxic
- predominantly anthropogenic in origin
- persistent
- bio-accumulative

The TSMP calls for the virtual elimination of Track 1 substances.

Toxic substances and other substances of concern may be identified as Track 2 substances if they do not meet all of the four criteria. The TSMP calls for full lifecycle management to prevent or minimize releases of Track 2 substances.

The four TSMP criteria are addressed for pesticide active ingredients, major transformation products, formulants and other compounds of concern to human health or the environment. During our initial review, new pesticide active ingredients and transformation products of concern are screened against the four TSMP criteria.

5 Registration decisions

We use a risk-based strategy to decide on the acceptability of, and terms and conditions for pesticide registrations for use in Canada. Once all the components for chemistry, environment, human health, and value/sustainability have been adequately addressed, pesticides will be registered if the:

- data requirements for assessing value and safety have been adequately addressed
- evaluation indicates that the pesticide has merit and value
- human health and environmental risks associated with its proposed use(s) are acceptable

For a completed pesticide risk assessment, a large amount of scientific data is considered. The risk assessment documents and conclusions go through a rigorous scientific review by a team of evaluators and experts. Once finalized, we publish the risk assessment outcomes and proposed registration decisions for consultation.

For more information about the registration process of pesticides, published decisions or other supporting documentation for pesticide use in Canada, consult the Pesticides section of Canada.ca.

Glossary

Acronyms

AIMS Avian Incident Monitoring System

APVMA Australian Pesticides and Veterinary Medicines Authority

CEPA *Canadian Environmental Protection Act*

cm Centimetre

CR Conditionally required

DACO Data code

DT_{50} Dissipation time for 50% of a substance

DT_{90} Dissipation time for 90% of a substance

EAD Environmental Assessment Directorate

EC_{25} Effective concentration causing 25% effect

EC_{50} Effective concentration causing 50% effect

EDE Estimated daily exposure

EEC Estimated environmental concentration

EFSA European Food and Safety Authority

EIIS Environmental Incident Information System

ELS Early-life stage

ENASGIPS Europe-North America soil geographic information for pesticide studies

ER_{25} Effective rate causing 25% effect

ER_{50} Effective rate causing 50% effect

g Gram

GIS Geographic information system

HC_5 Hazardous concentration for 5% of species in a species sensitivity distribution

HC_p Hazardous concentration

IC_{50} Inhibition concentration causing 50% inhibition

LC_{50} Lethal concentration causing 50% mortality

LD_{50} Lethal dose causing 50% mortality

LOC Level of concern

LR_{50} Median lethal application rate causing 50% effect

NOEC No-observed-effect concentration

NOED No-observed-effect dose

NOEL No-observed-effect level

NOER No-observed-effect rate

NR	Not required
OECD	Organisation for Economic Co-operation and Development
PMRA	Pest Management Regulatory Agency
R	Required
RQ	Risk quotient
SPSF	Statement of Product Specification Form
SSD	Species sensitivity distribution
$t_{1/2}$	Half-life
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	Ultraviolet

Appendix A – Types of exposure assessment

This appendix outlines the various approaches we use to estimate the exposure of aquatic and terrestrial organisms to pesticides in our risk assessments.

A.1 Aquatic

To assess the risk of pesticides to aquatic organisms (plants and animals), exposure is generally measured as the concentration of the pesticide active ingredient (or its transformation products) in water.

For the screening-level risk assessment of aquatic organisms, we calculate estimated environmental concentrations (EECs) in water based on the maximum yearly application rate of the pesticide being applied directly to a waterbody. We assume the pesticide is instantly and homogeneously mixed in the waterbody. If multiple applications are to occur within a growing season, we calculate the EEC based on the sum of concentrations of the pesticide in water from subsequent applications and consider dissipation that would occur between the application events. We use a representative half-life in water/sediment systems with the minimum application interval to make this adjustment.

We calculate EECs in water based on a standing body of water with a specified depth of 80 cm (permanent water bodies) and 15 cm (seasonal water bodies used by amphibians; forestry water bodies). If we need to refine the risk characterization, we recalculate exposure in water as two separate components: concentrations resulting from spray drift and runoff.

For pesticides that are sprayed, the estimated concentration in a body of water adjacent to a site being treated considers the portion of the applied spray that deposits one metre from the downwind edge of the spray equipment during an application. This estimate represents the potential exposure to an area and its inhabitants that are present next to the field being sprayed. The downwind deposition depends on the spray quality (droplet size) and the type of spray equipment used, such as ground versus aerial application equipment.

Regarding potential inputs from overland runoff, we use a series of representative eco-scenarios from across Canada to characterize the potential exposure on a national scale. We consider a 10-ha area draining into a 1-ha pond in our assessment. Using established computer models, our water modelling team calculates EECs in water from overland runoff. The modelling procedure considers multiple parameters that contribute to the movement of pesticide residues into surface water bodies (biotransformation in soil and water, adsorption/desorption), as well as application timing, rates and intervals between pesticide applications. The modelling provides estimates of peak and longer-term average concentrations, which we use to assess risk to aquatic organisms. We select the EECs for the most appropriate timeframe based on the duration of exposure. Water modelling considers specific crop and use-pattern information. For example, modelling parameters for a pesticide used on potatoes can include eco-scenarios in the Prairies, Eastern Canada and Prince Edward Island, where most potatoes are grown in Canada. The application methods, such as foliar, soil or seed piece treatment application, may affect the model parameters.

Refinement of the aquatic risk assessment can include the use of environmental monitoring data. We strive to compile and consider as much water monitoring data collected from across Canada and from the United States for our aquatic risk assessments. This includes data from various surface water sources (reported pesticide active ingredient or transformation product concentrations in bodies of water, such as rivers, lakes, wetlands and reservoirs). We also compile groundwater monitoring data to assess leaching potential as part of the environmental fate assessment. Other jurisdictions—such as federal and provincial authorities—typically collect monitoring data. We are working to establish a national-scale water monitoring program for pesticides to collect more water monitoring data in collaboration with sampling partners across Canada.

Where relevant, we can incorporate alternate measures of exposure in our aquatic assessments. For example, in the case of aquatic macrophytes (duckweed), pesticide exposure can occur through either dissolution in water or direct spray onto plants floating in the water. The testing protocol of toxicity studies conducted with duckweed, which typically involves exposing plants through dissolved pesticide concentrations in water, could be modified to expose the floating plants by spraying the pesticide directly on them. We can consider the exposure based on an application rate (for example, grams per hectare sprayed on the plants) rather than the typical EECs based on water concentrations.

A.2 Terrestrial

We use various approaches to estimate exposure of terrestrial organisms to pesticides in our risk assessment. The approaches differ depending on the organisms' modes of living and potential routes of exposure, such as through feeding or dermal contact, direct or indirect (see Table 5 below).

A.2.1 Earthworms

We consider exposure of earthworms to pesticides for pesticide products that are used outdoors and where contact with the soil, directly or indirectly, is possible. Exposure for earthworms occurs via dermal routes but can also occur through ingestion of contaminated soil, plant matter or detritus.

We determine the EEC for earthworms as the concentration of pesticide in the soil after a direct application. We assume 100% of the application rate of the pesticide is deposited on a soil that has a density of 1.5 g/cm^3 and that residues from the application are evenly mixed in the soil to a depth of 15 cm. The depth of 15 cm was historically used based on the typical depth of the plow layer and remains as convention in environmental risk assessments. We calculate the cumulative EEC for multiple applications by adjusting the sum of the applications for dissipation between applications using the appropriate representative soil half-life and the application interval.

For sprayed plant protection products, we can modify the EEC by considering the interception of pesticide spray by the crop canopy depending on the typical stage of crop growth expected to be present at the time of application.

A.2.2 Pollinators

Bees can be exposed directly or indirectly to pesticides when they are foraging. This occurs through direct contact with a pesticide spray, sprayed foliage and flowers, or ingesting contaminated nectar and pollen. For seed treatments, exposure of bees to pesticides has been documented via drift of abraded seed coat dust when planting under certain conditions; however, multiple factors determine the extent to which dust-off occurs. Foraging bees can also indirectly expose the brood or other adults in a hive to pesticide residues by bringing back contaminated pollen and nectar.

We assess both dermal (contact with the bee's body) and oral (contact through feeding on pollen and nectar) exposure to pesticides for pollinators. We typically estimate exposure for spray applications using the maximum single application rate of the pesticide. This is because individual flowers generally only bloom for a short period of time. Therefore, it is unlikely that a forager bee would be exposed to a flower that was sprayed multiple times. We also consider whether the pesticide is systemic and can be transported through the plant into pollen and nectar. We consider exposure through systemic transport to pollen and nectar when we assess risk from foliar, soil and seed treatment applications. Additionally, we assess the potential for pollinator exposure considering agronomic practices (such as whether a crop is harvested before bloom) and the attractiveness of pollen and nectar of a crop to bees.

The assessment is a tiered approach, from the most conservative at lower tiers to more realistic at higher tiers. At the lowest tier (Tier I), we estimate pesticide exposures based on honey bee castes with known high-end consumption rates. For chemicals with no empirical data to represent the concentration of the chemical in pollen and nectar, we estimate dietary exposure for Tier I risk assessment using generic residue data generated from other chemicals as well as other plant parts. We may refine estimates of exposure using measured pesticide concentrations in pollen and nectar of treated crops and using food consumption rates for different castes of bees.

More details of the exposure assessment for pollinators are outlined in Health Canada's risk assessment framework for bees, which was developed and published in 2014 in cooperation with the USEPA and the California Department of Pesticide Regulation. The guidance can be accessed at Pollinator Risk Assessment Guidance, USEPA.

A.2.3 Predators and parasitoids

The main route of exposure to pesticides for predators and parasitoids, also referred to as beneficial arthropods, which may include predatory and parasitic insects, spiders and mites, is through contaminated plant material and contact with soil for some ground-dwelling species. We can also consider direct exposure via a pesticide spray application. The type and degree of exposure depend on the species and its life habits, with a focus on those which inhabit plant foliage. Our assessment for other non-target arthropods involves estimating both in-field and off-field exposure.

We generally estimate on-field exposure for predators and parasitoids using the cumulative yearly application rate, which is adjusted for dissipation between applications. For indicator species *Typhlodromus pyri* (a predatory mite) and *Aphidius rhopalosiphi* (a parasitoid wasp), and foliage-dwelling arthropods, we use a foliar half-life to calculate the cumulative yearly application rate. If no data are available for foliar dissipation specific to an active ingredient, we use a default foliar half-life of 10 days. For ground-dwelling arthropods, we calculate the cumulative yearly application rate using the appropriate representative soil half-life.

Refinement options for in-field exposure estimates can include the use of foliar and soil deposition factors to take into account that a certain fraction of the application is intercepted by the crop.

Spray drift is the most relevant exposure route for predators and parasitoids in off-field areas. We calculate the off-field exposure of these organisms based on a percentage of the cumulative yearly application rate expected to drift one metre downwind from the site of application.

We can refine off-field exposure estimates by considering options such as using a vegetation distribution factor of 0.10 because the drift values overestimate drift to the lower or interior portions of a three-dimensional habitat structure. Most of the drift would be intercepted by the top or side portions of the off-field vegetation.

A.2.4 Other soil invertebrates

Examples of other terrestrial invertebrates could include collembolans (springtails), nematodes or enchytraeids (potworms). We consider exposure of these organisms to pesticides for pesticide products that are used outdoors and where contact with the soil, directly or indirectly, is possible. Exposure for these invertebrates occurs via dermal routes but can also occur through ingestion of contaminated soil, plant matter or detritus.

As we do for earthworms, we determine the EEC for these other terrestrial invertebrates as the concentration of pesticide in the soil after a direct application. We assume 100% of the application rate of the pesticide is deposited on a soil that has a density of 1.5 g/cm^3 and that residues from the application are evenly mixed in the soil to a depth of 15 cm. The depth of 15 cm was historically used based on the typical depth of the plow layer and remains as convention in environmental risk assessments. We calculate the cumulative EEC for multiple applications by adjusting the sum of the applications for dissipation between applications using the appropriate representative soil half-life and the application interval.

For sprayed plant protection products, we can modify the EEC by considering the interception of pesticide spray by the crop canopy depending on the typical stage of crop growth expected to be present at the time of application.

A.2.5 Birds and small wild mammals

In our risk assessment, we consider ingesting pesticide residues through the direct consumption of contaminated food items as the principal route of exposure for birds and small wild mammals. Food items of birds and small wild mammals, such as plant foliage, seeds or insect prey, can become contaminated by pesticide residues when they are treated directly or have been sprayed indirectly due to pesticide spray drift. This includes pesticides that are field sprayed in liquid formulations, applied to seeds for planting, spread as granules or used in baits.

For the screening-level risk assessment (sprayed pesticide formulations), on-field estimated concentrations in food items are based on the pesticide application rate and maximum residue profiles. For pesticides that are used multiple times in a growing season, we use a cumulative EEC, which sums inputs from all applications within a season, but factors in the dissipation of the pesticide between applications. If no data are available for foliar dissipation specific to an active ingredient, we use a default foliar half-life of 10 days. Subsequently, we determine the concentration of pesticide residues in the diet, an estimated daily exposure (EDE) for a standard set of bird and mammal species based on set categories of animal weights and specialized food guilds: herbivore, fructivore, insectivore, and granivore.

We also calculate EECs for treated seed and granular pesticides. These types of products may be directly consumed, either intentionally or incidentally, by birds or small wild mammals as sources of food or, in the case of birds and granules, as grit. We need additional parameters, such as seeding rates and the amount of pesticide residue per seed, in an assessment of treated seed and granule sizes for an assessment of granular pesticides. Other routes of exposure can also be significant, such as dermal contact and inhalation, and we consider them on a case-by-case basis.

We can further characterize the risks to birds and small wild mammals considering off-field exposure (residues in food items adjacent to the treated field which have received deposits from spray drift). We calculate off-field residues based on a percentage of the maximum application rate expected to drift one metre downwind from the site of application. Other modifications can include using mean pesticide residue concentrations instead of maximum values.

A.2.6 Terrestrial-phase amphibians and reptiles

We do not explicitly characterize exposure and risks to pesticides for terrestrial-phase amphibians and reptiles; we use the exposure and risk assessments for birds as a surrogate. The food ingestion rate for terrestrial-phase amphibians and reptiles is generally lower compared to birds on a per unit mass basis. The EDE for birds, therefore, overestimates terrestrial-phase amphibian and reptile exposure to pesticides, and the risk assessment for birds is considered protective of terrestrial-phase amphibians and reptiles.

A.2.7 Non-target vascular plants

We characterize exposure of non-target terrestrial vascular plants (for example, trees, shrubs and herbaceous plants) to pesticides for both emerging seedlings and established plants. Exposure is via the deposition of pesticide spray on soil or plant surfaces, respectively. The screening-level EEC we calculate for terrestrial vascular plants is based on a direct overspray of the soil (on-site) or of non-target plants using the maximum application rate. We use the cumulative seasonal application rate to assess the risk to emerging seedlings and established plants if more than one application occurs during a growing season. In this case, we use either a foliar half-life (established plants) or a representative soil half-life (seedling emergence) in the calculation to account for dissipation between applications. If a foliar half-life specific to the active ingredient of interest is not available, we use a default foliar half-life of 10 days at the screening level. We can further characterize the exposure by conducting an off-field/off-site assessment in which the application rate used is equivalent to the deposition rate of sprayed pesticide one metre downwind from the site of application. This will vary depending on the type of spray equipment and the timing of the application.

A.2.8 Summary of exposure parameters for terrestrial organisms

The following table describes the exposure parameters for terrestrial organisms based on the application rate of the pesticide.

Table 5: Exposure parameters for terrestrial organisms based on the application rate

Organism	Route of exposure	Parameters for estimating exposure
Earthworms	Contact	Soil concentration; based on the cumulative application rate calculated using the representative soil half-life
Bees	Oral, contact	Amount per bee/day; based on the single application rate for foliar sprays; there are additional pollen and nectar oral exposure considerations for foliar sprays, soil applications

Organism	Route of exposure	Parameters for estimating exposure
		and seed treatments when the pesticide is systemic
Predators and parasitoids: indicator species and foliage-dwelling arthropods	Contact	Cumulative application rate calculated using the foliar half-life
Predators and parasitoids: ground-dwelling arthropods	Contact	Cumulative application rate calculated using the representative soil half-life
Other soil invertebrates	Contact	Soil concentration; based on the cumulative application rate calculated using the representative soil half-life
Birds and small wild mammals	Oral	Daily dose per kilogram of body weight of the animal; based on residues in food items from cumulative application rate calculated using the foliar half-life
Non-target vascular plants	Vegetative vigour: contact	Cumulative application rate calculated adjusted using the foliar half-life
	Seedling emergence: contact	Cumulative application rate calculated using the representative soil half-life