Registration Decision RD2023-13

Pentachlorophenol Treated Poles and Cross-Arms

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Under the authority of the *Pest Control Products Act*, pesticides must be assessed before they are sold or used in Canada in order to determine that they do not pose unacceptable risks to human health or the environment and have value when used according to the label instructions. The pre-market assessment considers available data and information[1] from pesticide registrants, published scientific reports, other governments, and international regulatory agencies, as well as comments if received during public consultations. Health Canada applies internationally accepted current risk assessment methods as well as risk management approaches and policies. More details, on the legislative requirements, risk assessment and risk management approach, are provided under the section of Evaluation approach of this document.

Registration decision statement[2] for Pentachlorophenol Treated Poles and Cross-Arms

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is granting registration for the sale and use of Pentachlorophenol Treated Poles and Cross-Arms for a finite period of three years (until 4 October 2026), for use in new line construction and replacement of damaged utility poles and/or cross-arms used in the transmission and distribution of electricity and telecommunications. These treated wood products contain the active ingredient pentachlorophenol (plus related active chlorophenols) to prevent deterioration of the wood by wood-boring insects and fungi.

The Proposed Registration Decision PRD2023-06, *Pentachlorophenol Treated Poles and Cross-Arms,* containing the detailed evaluation of the information submitted in support of this registration, underwent a 45-day consultation period ending on 23 July 2023. The evaluation found that, under the approved conditions of use, the health and environmental risks and the value of the pest control product are acceptable. Health Canada received comments (and information) relating to the assessments during the public consultation period conducted in accordance with section 28 of the *Pest Control Products Act*. In addition, comments in support of this registration were received from the Chemistry Industry Association of Canada and the Canadian Paint and Coatings Association, the Canadian Wood Council, the Western Wood Preservers Institute, the Treated Wood Council, Thurlow Law, and Innergex Renewable Energy.

Addition to the conditions pertaining to the registration of Pentachlorophenol Treated Poles and Cross-Arms

As result of a comment provided by the applicant during the public consultation period indicating instances where Canadian electrical companies are providing electrical services to regions in the United States, Health Canada will allow import of treated poles from these regions during the registration period for the purpose of disposal in the conditions pertaining to the registration of this treated product.

[1] Information Note – *Determining Study Acceptability for use in Pesticide Risk Assessments.*

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

Below are the conditions pertaining to the registration of this treated product:

- After 4 October 2023, treatment of wood with pentachlorophenol products is prohibited.
- After 4 October 2023, import of pentachlorophenol-treated wood is prohibited, with the exception of import by Canadian electrical companies for the purpose of disposal of damaged/end-of-life pentachlorophenol-treated utility poles and cross-arms, which is permitted until 4 October 2026, in cases where they provide electrical services to a region in the United States.
- During the registration period, from 4 October 2023 to 4 October 2026, possession, handling, transportation, storage, distribution, use and disposal of existing pentachlorophenol-treated utility poles and cross-arms in Canada is permitted. It is important to define that "use" for this product refers to the installation (including re-installation/relocation) of pentachlorophenol-treated poles and cross-arms by utility companies for the specific purpose of transmitting and distributing electricity and telecommunications. Sale or use of the pentachlorophenol-treated poles and cross-arms for any other purpose is prohibited.
- Once the registration period ends (in other words, after 4 October 2026), distribution, including sale for the purpose of installation (use), and use (in other words, installation) of pentachlorophenol-treated poles and cross-arms is prohibited.
- After 4 October 2026, possession of installed pentachlorophenol-treated poles and cross-arms is permitted.
- After 4 October 2026, transfer of ownership of installed pentachlorophenol-treated poles and cross-arms is permitted. No other form of distribution is permitted.
- After 4 October 2026, handling, transportation, and storage of end-of-life/damaged pentachlorophenol-treated poles and cross-arms is permitted for the purpose of disposal (in accordance with provincial/territorial regulations).
- After 4 October 2026, all unused pentachlorophenol-treated poles and cross-arms must be disposed of in accordance with provincial/territorial regulations.
- The pentachlorophenol-treated poles and cross-arms installed during this registration period (or prior) will not be required to be replaced/removed after 4 October 2026.
- Any installed/in service pentachlorophenol-treated poles and cross-arms that need to be replaced/removed at any time must be disposed of in accordance with provincial/territorial regulations.

Comments and responses

1.0 Comment requesting Health Canada to phase out the use of all wood products treated with pentachlorophenol

A member of the public asked Health Canada to phase out the use of all wood products treated with pentachlorophenol.

Health Canada response

Health Canada's Pest Management Regulatory Agency cancelled all pentachlorophenol products on 4 October 2022 with a one-year phase-out period to allow wood treatment facilities to deplete existing stocks of these cancelled products to treat wood until 4 October 2023 (REV2022-02, *Update on the Special Review of Pentachlorophenol*).

The current registration of Pentachlorophenol Treated Poles and Cross-Arms (from 4 October 2023 to 4 October 2026) allows utility companies to deplete the existing stock of pentachlorophenol-treated utility poles and cross-arms, ensuring people and essential services in Canada continue to have access to reliable electricity and telecommunications.

Before registering a pest control product, Health Canada's Pest Management Regulatory Agency thoroughly assesses the value of the product as well as the risks to human health and the environment. Only products with demonstrated value as well as acceptable health and environmental risks are registered. The risk assessment (summarized in PRD2023-06, *Pentachlorophenol Treated Poles and Cross-Arms*) concludes that the installation of pentachlorophenol-treated utility poles and cross-arms, to be used in new line construction and replacement of damaged or end of service life utility poles and/or cross-arms used in the transmission and distribution of electricity, is acceptable for a period of three years when the product is used according to the label directions.

2.0 Comments on the supply chain of utility poles and available alternatives to pentachlorophenol

The Chemistry Industry Association of Canada (CIAC) and the Canadian Paint and Coatings Association (CPCA) expressed concern that removing a major preservative from the market, would result in a significant shock to the supply chain.

They recommend that to ensure grid reliability, an adequate stock of treated wood products is needed on both sides of the border to ensure electricity suppliers can quickly respond to emergency situations and replace fallen or damaged poles. Thurlow Law provided a similar comment.

The CIAC and CPCA commented that the United States Environmental Protection Agency has approved viable alternatives, like copper naphthenate, while also ensuring an acceptable path forward for pentachlorophenol phase out. They noted that the lack of available alternatives (in contrast to the United States) will harm the availability and supply of poles in the immediate term.

They recommend that, while they respect the registration process is different for all products and uses, a viable alternative should be brought to market quickly. The use of a registration focused on a specific use could be part of the solution in the alternative market. Thurlow Law provided a similar comment, as did the Western Wood Preservers Institute who urges the PMRA to approve alternate oil-borne preservatives to protect the stability and continued access to necessary wood utility poles and cross-arms and to preserve Canada's electrical grid infrastructure.

Health Canada response

With the registration of Pentachlorophenol Treated Poles and Cross-Arms, utility companies are permitted to deplete the existing stock of pentachlorophenol-treated utility poles and cross-arms, until 4 October 2026, thereby ensuring people and essential services in Canada have access to reliable electricity following the phase-out of the use of pentachlorophenol, while allowing utility companies time to acquire stock of new utility poles and cross-arms using registered alternatives.

There are four registered alternatives to pentachlorophenol for the pressure treatment of utility poles and cross-arms in Canada: copper azole (CA)-type preservatives, chromated copper arsenate (CCA)-type preservatives, ammoniacal copper zinc arsenate (ACZA)-type preservatives, and creosote. Of these, three are water-borne (CA, CCA and ACZA) and one is oil-borne (creosote).

In order to approve any pesticide product, Health Canada's PMRA conducts a rigorous assessment to ensure that the risk to health and the environment as well as the value of the product is acceptable. The PMRA does provide industry with guidance to facilitate the timely review of products, including presubmission consultations to advise applicants of what is required for a complete data package.

3.0 Comments on the risk to the reliability of the electrical grid and the need for continued flexibility and cooperation throughout the registration period

The applicant, Electricity Canada, expressed the importance of wood utility poles and cross-arms to the reliability of the Canadian electricity grid pointing out that a shortage of usable wood utility poles and cross-arms could pose a significant public safety risk if electricity companies could not promptly replace damaged or destroyed poles during severe weather events and power outages. They stated that collaborative efforts between regulatory agencies and the electricity sector are vital to ensure a balance between phasing-out pentachlorophenol and upholding the safety and reliability of the electricity grid.

Electricity Canada stated that their members generate and distribute electricity to residential, commercial, industrial and institutional customers in every region of Canada and that their diverse consumer base also means that the sector and its challenges are uniquely complex.

Electricity Canada recommends that the PMRA prioritize the continued reliability of the electricity grid and its role in maintaining public safety and requests continued flexibility and cooperation throughout the remainder of the registration process and as future issues may emerge during the registration period.

Electricity Canada also recommends that the PMRA and Health Canada establish a dispute resolution mechanism to constructively address issues that have reliability and public safety implications.

Health Canada response

Health Canada's PMRA acknowledges the importance of pentachlorophenol-treated utility poles and cross-arms to the electrical grid infrastructure.

Stakeholders may provide additional information to the PMRA regarding any future issues that may emerge during and after the registration period. Stakeholders can contact the PMRA through the Pest Management Information Service.

4.0 Comment requesting the expansion of the registration to ensure "generation" is captured in the description

Electricity Canada commented that the proposed registration of pentachlorophenol-treated utility poles for the **purposes of transmitting and distributing electricity and telecommunications** may not clearly indicate that it covers the full electricity value chain (generation, transmission and distribution). The comment highlighted that there are no handling or operational differences between generation plants and their transmission and distribution counterparts. Therefore, Electricity Canada recommends the inclusion of "generation" where the purposes and uses of pentachlorophenol-treated utility poles and cross-arms are listed.

Innergex Renewable Energy sent a similar comment, stating that the independent power production industry has pentachlorophenol-treated poles and cross-arms in stock in order to replace downed poles and restore service to the power grid in the event of an emergency. They note that independent power producers who sell electricity to the grid and maintain transmission lines across Canada should be included in the registration.

Health Canada response

Health Canada clarifies that the use of pentachlorophenol-treated utility poles and cross-arms at generation plants falls within the purpose of transmitting and distributing electricity. Health Canada also clarifies that the current registration of pentachlorophenol-treated poles and cross-arms is applicable to the independent electrical power production industry.

5.0 Comment requesting clarity on the temporary use of poles and cross-arms during the registration period

Electricity Canada is requesting clarity regarding the temporary use and reinstallation of treated wood utility poles during the registration period. In many instances, treated wood utility poles and cross-arms are moved around due to construction or to provide support for other infrastructure during installation (for example, "rider poles" protecting public safety during wire installation).

Health Canada response

"Use" for this product refers to the installation of pentachlorophenol-treated poles and cross-arms by utility companies for the specific purpose of transmitting and distributing electricity and telecommunications. During the registration period, from 4 October 2023 to 4 October 2026, possession, handling, transportation, storage, distribution, use and disposal of existing

pentachlorophenol-treated utility poles and cross-arms in Canada is permitted regardless of the period of time the poles are to be in use.

6.0 Comment requesting clarity regarding relocation/reinstallation of installed poles and cross-arms beyond the registration period

Electricity Canada stated that useable wood utility poles are frequently relocated for reasons such as changes to transmission corridors, construction, or changes in government zoning or regulations.

Given that pentachlorophenol-treated wood utility poles and cross-arms can have a useful life of up to 70 years, the re-installation/relocation of a pole may occur following the registration period. They noted that the current proposed registration decision is unclear on the handling of non-end-of-life/damaged poles and cross-arms beyond 4 October 2026.

They indicated that if re-installation/relocation of useable pentachlorophenol-treated wood utility poles and cross-arms is prohibited following the registration period, this will result in premature disposal and significant waste. A requirement to dispose of useable (non-end-of-life/damaged) pentachlorophenol-treated wood utility poles and cross-arms will have negative environmental, reliability, and affordability consequences.

Health Canada response

Health Canada acknowledges Electricity Canada's concerns regarding the relocation of useable pentachlorophenol-treated utility poles and cross-arms after the registration period. The registration of Pentachlorophenol Treated Poles and Cross-Arms allows for the installation of pentachlorophenol-treated utility poles and cross-arms existing already in Canada for a finite period of three years (until 4 October 2026). During this time, relocation of already installed poles and cross-arms is also permitted.

Stakeholders may provide additional information to the PMRA regarding this issue or any other specific issues they anticipate after the registration period. Stakeholders can contact the PMRA through the Pest Management Information Service.

7.0 Comment on import for purposes of disposal

Electricity Canada and BC Hydro commented that the proposed registration decision (PRD2023-06) prohibits import to Canada following 4 October 2023. In specific instances, import is necessary for the disposal of treated wood utility poles, particularly for islanded areas of the United States.

An example of this instance would be for Hyder, Alaska. Hyder is not connected by road to the rest of Alaska and their electrical utility is operated by BC Hydro. As poles are replaced, they are imported into Canada for disposal as there are no viable disposal options in Hyder.

The comment stated that, in accordance with existing provincial and territorial practices and regulations, the import of pentachlorophenol-treated wood utility poles should be granted for purposes of end-of-life pole disposal. BC Hydro requested that PMRA permit Canadian utilities,

and their wholly-owned US subsidiaries operating in the islanded areas of the US, to import end-of-life pentachlorophenol-treated poles/cross-arms into Canada for the purpose of disposal.

Health Canada response

Given that specific instances exist where Canadian electrical companies are providing electrical services to regions in the United States, Health Canada agrees that import for the purpose of disposal will be permitted during the registration period until 4 October 2026. Records of disposal, by Canadian electrical companies only, of the pentachlorophenol-treated utility poles must be maintained and provided to Health Canada upon request.

8.0 Comment on storage and possession

Electricity Canada commented that the proposed registration decision (PRD2023-06) does not clarify what is considered a "secured designated area" as outlined under the required label statements. Electricity Canada proposed that members and their contracted partners be included under this designation. All areas where treated products for electricity companies are currently stored are licensed by their respective provincial and regional government bodies to handle, transport and distribute.

Due to the size of pole reserves and utility coverage area (in other words, spanning full provinces and territories), the comment explained that electricity companies often store their pole stocks at the manufacturing site or on contracted third-party land. This is necessary to ensure the adequate quantity of utility poles are available to respond to major weather events that damage and/or destroy large quantities of utility poles. Many electricity companies do not have the land necessary to store all treated poles themselves nor is this a feasible option.

Electricity Canada requested that the PMRA clarify that treated wood utility poles and cross-arms are permitted to be stored at contracted sites (including supplier sites), so long as they were purchased prior to 4 October 2023.

Health Canada response

Language on the label is meant for all who may use pentachlorophenol-treated utility poles and cross-arms and is not meant to be exclusive to the registrant. Under Directions for Use, the label describes that storage of treated poles and cross-arms must be in accordance with applicable federal, provincial, territorial, and municipal legislation, including for environmental protection such as preventing contamination of soil and surface waters. The label further describes under Directions for Use that users should follow any additional industry guidelines for the protection of human health and the environment.

In order to clarify storage requirements and ensure that the label is consistent with applicable legislation, the label statement is revised as follows:

> "Subject to any applicable federal, provincial, territorial and municipal legislation, store treated poles and cross-arms on pole storage or pole racking in a secured designated area."

9.0 Comment that poles and cross-arms treated with pentachlorophenol before 4 October 2023 should not be subject to registration

Hydro-Québec submitted an opinion that poles and cross-arms that were treated with pentachlorophenol before 4 October 2023 should not be subject to registration, since pentachlorophenol was registered or otherwise authorized by the *Pest Control Products Act* until that date. The comment stated that since the *Pest Control Products Act* does not have a retroactive scope, poles and cross-arms treated with pentachlorophenol before the cancellation of the pentachlorophenol registration do not become a pest control product on the day of this revocation.

Health Canada response

Information Note – Treated Articles (1 September 2022) outlines the regulatory requirements for articles that have been treated with pesticides. Treated articles are pest control products under the *Pest Control Products Act*, and as defined under the Pest Control Products Regulations. The antimicrobial preservative (such as pentachlorophenol) used to treat the article, is required to be registered or otherwise authorized under the *Pest Control Products Act*; however, registration of the treated article will not be required if they meet certain criteria:

1. the antimicrobial preservative used to treat the article is registered or otherwise authorized under the *Pest Control Products Act*;
2. the article is treated according to the antimicrobial preservative's approved or authorized uses (in other words, the same use specified on the label of the registered or otherwise authorized end-use product) and within the approved range of rates; and
3. the use is limited to preventing degradation or damage to the product from microorganisms.

Since the authorization period of the pentachlorophenol products expires on 4 October 2023, the sale, import and installation of the pentachlorophenol-treated wood after that date is prohibited. The current registration of the treated poles and cross-arms will allow for the continued distribution and use (in other words, installation) of existing stocks of already-treated utility poles and cross-arms in Canada for the specific purpose of transmitting and distributing electricity and telecommunications until 4 October 2026.

10.0 Comment on the limited registration period and stringent criteria for the use of pentachlorophenol treated poles and cross-arms

Although Hydro-Québec maintained that pentachlorophenol-treated utility poles and cross-arms should not be subject to registration, they feel the registration of Pentachlorophenol Treated Poles and Cross-Arms should at the very least not be limited until 4 October 2026, but rather apply until the end of their useful life. Nor should it add stringent criteria for the use of pentachlorophenol-treated utility poles and cross-arms, particularly in terms of storage and labelling, especially in a context where treated wood is already regulated by the Ministère de l’Environnement, de la Lutte contre les changements climatiques, de la Faune et des Parcs.

Hydro-Québec explained that their distribution grid comprises over 1.8 million poles, of which more than 1.5 million are pentachlorophenol-treated. They maintain and reuse (reinstall) pentachlorophenol-treated utility poles and cross-arms to extend the lifespan of the poles and ensure the continuity of electrical service as well as the sustainability of Hydro-Québec's electrical energy transmission, distribution and generation facilities and to promote the circular economy and sustainable development. Disposal of the pentachlorophenol-treated utility poles and cross-arms currently stored by Hydro-Québec, and those which will be removed from the grid without being damaged or at their end of life as of 4 October 2026, would not only have an impact on the structures supplying electricity to the population, but would also have a significant undesirable environmental impact, by prohibiting their reuse.

Finally, the proposed registration decision should not only refer to "transmission line" poles, but rather to "transmission and distribution lines".

Health Canada response

Health Canada reviewed available scientific information and found that under the conditions of use, for a period of three years, the health and environmental risks and value of the pentachlorophenol-treated utility poles and cross-arms for use in the transmission and distribution of electricity and telecommunications were acceptable.

Time-limited access to pentachlorophenol-treated utility poles and cross-arms was identified as a critical need (per DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*) for an emergency response to power outages, to help ensure reliable communication and restoration of power quickly for people in Canada in times of crisis, such as natural disasters. The three-year registration period will allow for the installation of the already-treated utility poles and cross-arms in new line construction and disposal or replacement of damaged utility poles and/or cross-arms used in the transmission and distribution of electricity and telecommunications across Canada. It will also provide time for industry to transition from using pentachlorophenol to using registered alternatives.

Stakeholders may provide additional information to the PMRA regarding this issue or any other specific issues they anticipate after the registration period.

With regard to the use of "transmission and distribution lines" instead of only "transmission lines", the English version of the proposed registration decision (PRD2023-06) it states "transmission and distribution". However, the French version inadvertently omitted reference to "distribution". This has been corrected in this document.

11.0 Comment on the need for new or amended policy

The CIAC and the CPCA commented that this proposed registration decision was necessary due to a policy difference between the risk-based cancellation process and the lack of such a process for voluntary withdrawals from the Canadian market. The comment noted that the outcome of the proposed decision is appropriate; however, policy gaps must be filled to avoid the recurrence of short-term registrations of this nature.

The CIAC and the CPCA recommend that a new policy be developed to deal with voluntary withdrawals from the market by an existing registrant, or alternatively, a modest amendment to the existing cancellation policy could capture voluntary market exits and ensure the responsibilities of a registrant are continued. Thurlow Law provided a similar comment.

Health Canada response

Health Canada will be reviewing its current policy relating to Regulatory Directive DIR2018-01, *Policy on Cancellation and Amendments Following Re-evaluation and Special Review* and associated Information Note: Update on implementation of post-market decisions. The comments submitted will be taken into consideration as part of this policy review.

12.0 Comment on the use of animal testing to examine the toxicity of pest control products

A member of the public expressed a general concern about potential animal cruelty involved in the testing of pest control products.

Health Canada response

Health Canada requires information on the potential toxic effects of pesticides to determine the potential hazards and risk to human health and the environment from pesticide exposure. Toxicity information typically includes, in part, animal testing data generated by pesticide manufacturers. These studies are conducted according to international testing protocols, which include requirements to ensure protection of the welfare of laboratory animals.

While animal toxicity testing currently plays a critical role in assessing human health and environmental risks from exposure to pesticides, Health Canada supports the reduction of unnecessary animal testing where scientifically justified. To this end, Health Canada does consider requests from pesticide manufacturers to waive requirements for animal studies or to consider validated non-animal alternatives in hazard assessment when feasible and supported scientifically. Health Canada issued guidance for industry on the waiving of mammalian acute toxicity studies in 2013.

Health Canada is also an active participant in various international activities aimed at reducing animal testing while ensuring the protection of human health and the environment. Continued analysis of international trends and approaches is important to ensure continued alignment and harmonization.

While non-animal alternatives exist for certain types of tests (for example, in-vitro tests for irritation), animal testing continues to provide a more accurate assessment of a variety of other potential effects, and more importantly, at what dose level effects may occur, so that this information can then be used to protect human health and the environment.

13.0 Comments in support of this registration were received from the Chemistry Industry Association of Canada and the Canadian Paint and Coatings Association, the Canadian Wood Council, the Western Wood Preservers Institute, the Treated Wood Council, Thurlow Law, and Innergex Renewable Energy

Organizations from material preservative, wood and energy industries expressed support for the three-year registration of Pentachlorophenol Treated Poles and Cross-Arms.

Other information

The relevant confidential test data on which the decision is based (as referenced in PRD2023-06) are available for public inspection, upon application, in the PMRA's Reading Room. For more information, please contact the PMRA's Pest Management Information Service.

Any person may file a notice of objection[3] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act.*

Evaluation approach

Legislative framework

The Minister of Health's primary objective under the *Pest Control Products Act* subsection 4(1) is to prevent unacceptable risks to individuals and the environment from the use of pest control products.

As noted in the preamble of the Act, it is in the national interest that the attainment of the objectives of the federal regulatory system continue to be pursued through a scientifically-based national registration system that addresses risks to human health, the environment and value both before and after registration and applies to the regulation of pest control products throughout Canada; and that pest control products with acceptable risk and value be registered for use only if it is shown that their use would be efficacious and if there is acceptable risk to human health and the environment, taking into account the conditions of registration.

For the purposes of the Act, the health or environmental risks of a pest control product are acceptable 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, taking into account its conditions of registration as per subsection 2(2) of the *Pest Control Products Act*.

Risk for the human health and environment, and value are defined under the Act subsection 2(1) as follows:

> **Health risk**, in respect of a pest control product, means the possibility of harm to human health resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.
>
> **Environmental risk**, in respect of a pest control product, means the possibility of harm to the environment, including its biological diversity, resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.
>
> **Value**, in respect of a pest control product, means the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact.

When evaluating the health and environmental risks of a pesticide and determining whether those risks are acceptable, subsection 19(2) of the *Pest Control Products Act* requires Health Canada to apply a scientifically-based approach. The science-based approach to assessing pesticides considers both the toxicity and the level of exposure of a pesticide in order to fully characterize risk.

Premarket assessments are based on a required set of scientific data that must be provided by the applicants for pesticide registrations. Additional information from published scientific reports, other government departments and international regulatory agencies are also considered.[4]

Risk and value assessment framework

Health Canada uses a comprehensive body of modern scientific methods and evidence to determine the nature as well as the magnitude of potential risks posed by pesticides. This approach allows for the protection of human health and the environment through the application of appropriate and effective risk management strategies, consistent with the purpose described in the preambular text set out above.

Health Canada's approach to risk and value assessment is outlined in A Framework for Risk Assessment and Risk Management of Pest Control Products.[5] A high-level overview is provided below.

i) Assessing potential health risks

With respect to the evaluation and management of potential health risks, Health Canada's risk assessments follow a structured, predictable process that is consistent with international approaches and the Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks.[6]

The evaluation of potential health risks begins with a consideration of the toxicological profile of a pesticide to establish reference doses at which no adverse effect is expected and against which the expected exposure is assessed. This includes, where appropriate, the use of uncertainty (protection) factors to provide additional protection that accounts for the variation in sensitivity among members of human population and the uncertainty in extrapolating animal test data to humans. Under certain conditions, the *Pest Control Products Act* requires the use of another factor to provide additional protection to pregnant women, infants, and children. Other uncertainty factors, such as a database deficiency factor, are considered in specific cases. More details related to the application of the uncertainty factors are provided in SPN2008-01.[7]

Assessments estimate potential health risks to defined populations[8] under specific exposure conditions. They are conducted in the context of the proposed or registered conditions of use, such as the use of a pesticide on a particular field crop using specified application rates, methods and equipment. Potential exposure scenarios consider exposures during and after application of the pesticide in occupational or residential settings, food and drinking water exposure, or

4 Information Note – *Determining Study Acceptability for use in Pesticide Risk Assessments*

5 PMRA Guidance Document, *A Framework for Risk Assessment and Risk Management of Pest Control Products*

6 Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks - August 1, 2000

7 Science Policy Note: *The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides*

8 Consideration of Sex and Gender in Pesticide Risk Assessment

exposure when interacting with treated pets. Also considered are the anticipated durations (short-, intermediate- or long-term) and routes of exposure (oral, inhalation, or skin contact). In addition, an assessment of health risks must consider available information on aggregate exposure and cumulative effects.

ii) Assessing risks to the environment

With respect to the evaluation of environmental risks, Health Canada's environmental risk assessments follow a structured, tiered approach to determine the likelihood that exposure to a pesticide can cause adverse effects on individual organisms, populations, or ecological systems. This involves screening assessments starting with simple methods, conservative exposure scenarios and sensitive toxicity effects metrics, then moving on, where required, to more refined assessments that can include exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods.

The environmental assessment considers both the exposure (environmental fate, chemistry, and behaviour, along with the application rates and methods) and hazard (toxic effects on organisms) of a pesticide. The exposure assessment examines the movement of the pesticide in soil, water, sediments and air, as well as the potential for uptake by plants or animals and transfer through the food web. The possibility for the pesticide to move into sensitive environmental compartments such as groundwater or lakes and rivers, as well as the potential for atmospheric transport, is also examined. The hazard assessment examines effects on a large number of internationally recognized indicator species of plants and animals (terrestrial organisms include invertebrates such as bees, beneficial arthropods, and earthworms, birds, mammals, plants; aquatic organisms include invertebrates, amphibians, fish, plants and algae), and includes considering effects on biodiversity and the food chain. Acute and chronic effects endpoints are derived from laboratory and field studies that characterize the toxic response and the dose–effect relationship of the pesticide.

The characterization of environmental risk requires the integration of information on environmental exposure and effects to identify which, if any, organisms or environmental compartments may be at risk, as well as any uncertainties in characterizing the risk.

iii) Value assessment

Value assessments consist of two components: an assessment of the performance of a pest control product and its benefits.

Assessing pesticide performance involves an evaluation of the pesticide’s efficacy in controlling the target pest and the potential for the pesticide to damage host crops or use-sites. Where the efficacy of a pesticide is acceptable, the assessment serves to establish appropriate label claims and directions and an application rate (or rate range) that is effective without being excessive, and with no unacceptable damage to the use-site or host organism/crop (and subsequent hosts or crops) under normal use conditions.

In many cases, proof of performance alone is sufficient to establish the value of the pesticide, so that an in-depth or extensive evaluation of benefits may not be required. However, a more thorough assessment of benefits may be undertaken in particular cases where performance alone does not sufficiently demonstrate value, or while developing risk management options.

Risk management

The outcomes of the assessments of risks to human health and the environment, and the assessment of value, form the basis for identifying risk management strategies. These include appropriate risk mitigation measures and are a key part of decision-making on whether health and environmental risks are acceptable. The development of risk management strategies take place within the context of the pesticide's conditions of registration. Conditions can relate to, among other things, the specific use (for example, application rates, timing and frequency of application, and method of application), personal protective equipment, preharvest intervals, restricted-entry intervals, buffer zones, spray drift and runoff mitigation measures, handling, manufacture, storage or distribution of a pesticide. If feasible conditions of use that have acceptable risk and value cannot be identified, the pesticide use will not be eligible for registration.

The selected risk management strategy is then implemented as part of the registration decision. The pesticide registration conditions include legally-binding use directions on the label. Any use in contravention of the label or other specified conditions is illegal under the *Pest Control Products Act*.

Following a decision, continuous oversight activities such as postmarket assessments, incident reporting, and compliance and enforcement, all play an essential role to help ensure the continued acceptability of risks and value of registered pesticides.