Registration Decision RD2026-15

Cholecalciferol, SELONTRA RODENT BAIT, TC 411 Rodent Bait, TC 412 Rodent Bait, TC 413 Rodent Bait, and TC 411 BULK

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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 humans 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 written comments directly related to the proposed decision, such as comments directed to the science evaluation, 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 cholecalciferol

Health Canada, pursuant to subsection 8(1) of the *Pest Control Products Act*, is granting registration for the sale and use of Cholecalciferol Technical, the related end-use products, SELONTRA RODENT BAIT, TC 411 Rodent Bait, TC 412 Rodent Bait, and TC 413 Rodent Bait, and the related manufacturing concentrate, TC 411 BULK, all containing the active ingredient cholecalciferol, to control rodent pests indoors and outdoors.

The Proposed Registration Decision PRD2026-06, *Cholecalciferol, SELONTRA RODENT BAIT, TC 411 Rodent Bait, TC 412 Rodent Bait, TC 413 Rodent Bait, and TC 411 BULK*, containing the detailed evaluation of the information submitted in support of this registration, underwent a 30-day consultation period ending on 26 April 2026. The evaluation found that, under the approved conditions of use, the health and environmental risks and the value of the pest control product(s) are acceptable. Health Canada received written comments relating to the health and environmental assessments during the public consultation period conducted in accordance with section 28 of the *Pest Control Products Act*. Health Canada also received comments that were not directly related to the proposed decision in PRD2026-06, *Cholecalciferol, SELONTRA RODENT BAIT, TC 411 Rodent Bait, TC 412 Rodent Bait, TC 413 Rodent Bait, and TC 411 BULK*.

Comments and responses

Health Canada received comments from two individual members of the public on the health and environmental assessments of cholecalciferol, SELONTRA RODENT BAIT, TC 411 Rodent Bait, TC 412 Rodent Bait, TC 413 Rodent Bait, and TC 411 BULK.

1. Comment related to incident reports

One individual stated that companion animal poisonings from cholecalciferol can occur, as incident reports have been submitted to Health Canada.

[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*.

Health Canada response:

Health Canada considers all available data and scientific information to ensure that pesticides continue to meet modern health and environmental safety standards and continue to have value. As part of this process, Health Canada uses pesticide incident information to identify and characterize any potential risks to health or the environment from the use of pesticides.

A comprehensive analysis of incident information for cholecalciferol was integrated into the scientific risk assessment of all cholecalciferol end-use products. As outlined in PRD2026-06, *Cholecalciferol, SELONTRA RODENT BAIT, TC 411 Rodent Bait, TC 412 Rodent Bait, TC 413 Rodent Bait, and TC 411 BULK*, a small number of serious U.S. incidents involving pet exposure to cholecalciferol were reported to Health Canada; however, detailed information regarding pet access to cholecalciferol products was limited. Based on the available incident information, together with the health and environmental risk assessment outcomes, risk-reduction measures are required for all cholecalciferol end-use products. Specifically, all of the baits contain a bittering agent to deter ingestion by pets, and access is minimized by bait placement in either tamper-resistant bait stations or in inaccessible locations, by the restrictive product packaging, such as the protective wrapper on the bait block, and by the prompt removal of unconsumed bait. With these protective measures in place, the end-use products containing cholecalciferol are not expected to pose unacceptable risks to companion animals when used according to label directions. Health Canada will continue to monitor incident reports as part of its ongoing regulatory oversight, which includes re-assessment of previous conclusions, as necessary.

2. Comments related to exposure and toxicity to non-target species

One individual opposes the use of cholecalciferol rodenticides in Canada, citing concerns related to non-target animal safety and secondary exposure. The commenter claims that cholecalciferol has a narrow margin of safety and is highly toxic to domestic pets and wildlife; that predators may be exposed through consumption of poisoned rodents; and that bioaccumulation is possible due to storage of vitamin D compounds in fat.

Health Canada response:

As discussed in PRD2026-06, an environmental risk assessment was conducted as described in the guidance document, *Health Canada's Approach to Environmental Risk Assessment for Pest Control Products*, to estimate the potential for adverse effects on non-target species. The risk assessment evaluated (1) risks to non-target animals that consume the baits (primary poisoning), and (2) risks to birds and mammals via the consumption of poisoned carcasses (secondary exposure). The risk assessment showed that cholecalciferol poses a limited secondary poisoning risk to birds and mammals. Where toxic symptoms occurred from secondary poisoning, the animals were able to recover when the contaminant source was removed. The use of tamper-resistant weatherproof bait stations, and requirements to retrieve and dispose of unused baits and carcasses reduces risks to non-target mammals and birds from both primary and secondary exposure.

In addition, the end-use products have risk mitigation measures in place to reduce potential ingestion by pets. Specifically, all of the baits contain a bittering agent to deter ingestion, and access is minimized by bait placement in either tamper-resistant bait stations or in inaccessible

locations, by the restrictive product packaging (such as the protective wrapper on the bait block), and by the prompt removal of unconsumed bait. These various measures are intended to help keep pets safe from cholecalciferol products.

Bioaccumulation of cholecalciferol in the food chain is not expected to be a concern. It exists naturally in the tissues and blood of all animals. Cholecalciferol is metabolized in the liver and kidneys, and is essential for maintaining calcium and phosphate absorption. Surplus cholecalciferol is stored in fat or metabolized and excreted in bile. Exposure to a lethal dose of cholecalciferol in bait results in a cessation of feeding usually within 24 hours referred to as a "stop-feeding" effect, which limits body residues of cholecalciferol to the consumed dosage before death occurs. The use of tamper-resistant bait stations and protected bait points will prevent direct access of non-target animals to baits. They will also reduce leaching of cholecalciferol from the baits into the soil or water. If cholecalciferol is released into the environment, it is expected to degrade quickly in soil, and is not expected to reach groundwater and surface water as it is insoluble. Bioaccumulation in terrestrial and aquatic organisms is therefore not anticipated.

Overall, significant environmental exposure is not expected. When cholecalciferol baits are used in accordance with label directions, environmental risks, including risks to non-target species, are acceptable.

Other information

Inspection of confidential test data

The relevant confidential test data on which the decision is based (as referenced in PRD2026-06, *Cholecalciferol, SELONTRA RODENT BAIT, TC 411 Rodent Bait, TC 412 Rodent Bait, TC 413 Rodent Bait, and TC 411 BULK*) are available for public inspection, upon application, in the Pesticides Regulatory Directorate's Reading Room. For more information, please contact the Pesticides Information Service.

Notice of objection

Any person may file a notice of objection,[3] which must be based on scientific grounds, regarding this registration decision on cholecalciferol, SELONTRA RODENT BAIT, TC 411 Rodent Bait, TC 412 Rodent Bait, TC 413 Rodent Bait, and TC 411 BULK within 60 days from the date of publication of this Registration Decision through the Public Engagement Portal (Public Engagement Portal forms – Notice of Objection). The request for reconsideration must include the Notice of Objection form, the scientific explanation of the objection and the supporting scientific evidence in possession of the requestor that wouldn't already be in Health Canada's possession or cite specific Health Canada documentation they wish to rely on as supporting evidence (for example, scientific reports) in the form of electronic copies of cited references. Each of the references provided or cited must be clearly associated with the objection it supports. Failure to provide a complete package may result in the Notice of Objection being considered ineligible for further consideration by Health Canada. For more information regarding the basis

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

for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Canada.ca website or contact the Pesticides Information Service.

Proportional effort

Active ingredients registered in Canada are categorized based on criteria in Health Canada's Policy on Proportional Effort. The categorization is used to inform Health Canada's allocation of resources related to pesticide reviews in alignment with the required level of regulatory effort. Cholecalciferol is categorized as lower proportional effort based on the health criteria and environmental criteria. Information on the risk assessment conclusions that resulted in the categorization is included in the proposed regulatory decision PRD2026-06. The proportional effort categorization will be used to inform the scope and level of effort needed for future reviews.

Continuous Oversight

Health Canada's policy on continuous oversight of pesticides and the associated information note describe the process for monitoring scientific literature of active ingredients registered in Canada, and the criteria used to determine which active ingredients will be monitored when a final regulatory decision is made. The criteria outlined in the information note have been met. However, as with non-conventional active ingredients, the large volume of scientific literature associated with the widespread non-pesticidal uses of cholecalciferol requires a tailored search strategy to effectively identify relevant information. As these tailored search strategies are still under development, scientific literature and regulatory information will not be monitored as part of continuous oversight for this active ingredient at this time.

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.

Pre-market 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 exposure when interacting with treated pets.

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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.

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, pre-harvest 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 post-market assessments, monitoring and surveillance, including incident reporting, all play an essential role to help ensure the continued acceptability of risks and value of registered pesticides.