Re-evaluation Decision RVD2024-04

Predacide Uses of Strychnine and Sodium Monofluoroacetate and their Associated End-use Products

Final Decision

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Table of Contents

Re-evaluation decision for predacide uses of strychnine and sodium monofluoroacetate and their associated end-use products

Under the authority of the *Pest Control Products Act*, all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they meet current health and environmental standards and have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies, as well as comments received during public consultations. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies. More details, on the legislative framework, risk assessment and risk management approach, are provided under the Evaluation Approach section of this document.

Strychnine is a toxicant registered as a restricted class end-use product used to kill predators and skunks in Alberta. It is applied as tablets in meat baits (for example, pieces of animal meat or fish or animal carcasses) to kill wolves, coyotes or bears in order to prevent predation of wildlife populations (for example, woodland caribou populations) threatened with extirpation or those wildlife populations that are economically or ecologically important and to prevent human-predator conflicts (in other words, predation of domestic animals such as livestock and attacks on humans). Only authorized employees of Alberta Fish and Wildlife Division are permitted to sell, store, handle or use the tablet product. Strychnine is also applied as a solution injected into eggs used as baits to kill skunks in rabies control programs. This solution product is restricted for storage, handling and use by employees of the Department of Alberta Agriculture and Food, or municipal employees, authorized under the Alberta *Agricultural Pests Act*, provided that such designated or authorized persons are trained and certified by the Department.

Sodium monofluoroacetate (also known as Compound 1080) is a toxicant registered as a restricted class end-use product used to kill coyotes and wolves in Alberta. It is used to either protect domestic animals (for example, livestock) or wildlife species at risk from predation, when there is a threat to human safety and/or other problems posed by these predators. Sodium monofluoroacetate is applied as tablets in meat baits (for example, chicken heads or animal carcasses). Only persons authorized under the Alberta *Agricultural Pests Act* and by designated Fish and Wildlife Officers of the Government of Alberta are permitted to store, handle or use this product. Note that sodium monofluoroacetate applied as a solution in neck collars worn by livestock prey (in other words, goat or sheep) was discontinued and the product registration expired in July 2022.

Currently registered products containing strychnine or sodium monofluoroacetate used as predacides can be found in the Pesticide Product Information Database and in Appendix I. The Proposed Re-evaluation Decision PRVD2022-18[1] containing the evaluation of the predacide uses of strychnine and sodium monofluoroacetate and proposed decision, underwent a 90 day consultation period ending on 29 November 2022. PRVD2022-18 proposed continued

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

registration of the predacide uses of strychnine and sodium monofluoroacetate and all associated end-use products provided new risk mitigation measures are put in place.

Health Canada received comments (and information) relating to the health, environmental and value assessments. Commenters are listed in Appendix II. These comments are summarized in Appendix III along with the responses by Health Canada. These comments and new data/information resulted in revisions to the environmental risk assessment (see Science evaluation update), and resulted in changes to the proposed re-evaluation decision as described in PRVD2022-18.

A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2022-18, and further information used in the re-evaluation decision is listed in Appendix VI of this RVD. Therefore, the complete reference list of all information used in this final re-evaluation decision includes both the information set out in PRVD2022-18 and the information set out in Appendix VI herein.

This document presents the final re-evaluation decision[2] for the re-evaluation of predacide uses of strychnine and sodium monofluoroacetate, including the required amendments (risk mitigation measures) to protect human health and the environment, as well as label amendments required to bring labels to current standards. All products containing strychnine and sodium monofluoroacetate that are registered in Canada are subject to this re-evaluation decision.

Re-evaluation decision for predacide uses of strychnine and sodium monofluoroacetate

Health Canada has completed the re-evaluation of the predacide uses of strychnine and sodium monofluoroacetate. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing sodium monofluoroacetate is acceptable. An evaluation of available scientific information found that the uses of sodium monofluoroacetate products meet current standards for protection of human health and the environment and have acceptable value when used according to revised conditions of registration which includes new mitigation measures. Label amendments, as summarized below and listed in Appendix V, are required.

All uses of strychnine are cancelled since environmental risks are not shown to be acceptable when used according to the current conditions of registration, or when additional mitigation is considered.

Risk mitigation measures

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. Cancellation and the required amendments, including any revised/updated label statements

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

and/or mitigation measures, as a result of the re-evaluation of the predacide uses of strychnine and sodium monofluoroacetate, are summarized below. Refer to Appendix V for details.

Strychnine

- Cancellation of all uses.

Sodium monofluoroacetate

Product stewardship program – outline of minimum requirements

A registrant-implemented product stewardship program is required for the sodium monofluoroacetate product. The goal of this program is to ensure the proper handling and use of the restricted-class product containing sodium monofluoroacetate.

The registrant is required to:

- Develop and implement a training program for the use of the sodium monofluoroacetate product that (1) emphasizes the requirement to follow the label directions, (2) educates users on appropriate disposal methods, and (3) educates users that predacides are to be used in an Integrated Pest Management (IPM) program and only when other management methods have been attempted and deemed not feasible or effective.

- Keep, monitor and maintain records (in electronic format) relating to the use of sodium monofluoroacetate ("Vertebrate Toxicant Usage Record" – See Appendix V), including tracking that all training requirements have been completed by users prior to accessing this product, and maintaining an inventory of use, return or damage of the product. These records must be available upon request at any time for Health Canada review.

    - Users will be required to submit completed copies of the "Vertebrate Toxicant Usage Record" for each use of sodium monofluoroacetate to the registrant.

- Submit reports of non-target deaths (see "Vertebrate Toxicant Usage Record") and any other relevant incidents conforming to the Incident Reporting Regulations.

- Notify Health Canada within 24 hours when any use record indicates use not in accordance with labelled directions. Cease the use of sodium monofluoroacetate until Health Canada reviews and provides direction.

Human health

Label improvements:

- Updated personal protective equipment (PPE) requirements to meet current labelling standards and to specify that the PPE must be worn when handling the product and when handling poisoned baits and carcasses.

- Clarification of disposal statements for poisoned baits/carcasses.

Risk mitigation:

To protect users from occupational exposure and to reduce exposure to bystanders, the following risk-reduction measures are required for sodium monofluoroacetate:

- Requirement for an inventory on the disposal of poisoned baits and poisoned carcasses to be recorded in the "Vertebrate Toxicant Usage Record".

Environment

Risk mitigation:

To protect the environment and further minimize risk to non-target species, the following risk-reduction measures are required:

- Revisions to the label for Sodium Monofluoroacetate Predacide (Reg. No. 18300):
    - Updated and clarified reporting requirements, including the completion of the "Vertebrate Toxicant Usage Record".
    - A statement prohibiting the use of drop baits in conjunction with poisoned carcasses.
    - Label improvements to harmonize the use limitations for the target animals (coyote and wolf).
    - Use limitations requiring the user to (1) remove and destroy all baits within 15 days of initial placement, (2) monitor and maintain accurate Vertebrate Toxicant Usage Records, and (3) inspect poisoned bait at least every seven days.
    - To prevent access to birds, removal of the option to cover baits with vegetation or other material, which may be displaced by wind leaving baits exposed.

Value

- Label improvements are required to clarify label use directions for sodium monofluoroacetate products:
    - Amendments to vague site claims (for example, change "domestic animal" to "livestock", refinement of "wildlife populations that are economically or ecologically important");
    - Change the claim of "control" to "reduces" or "kill" as the goals are different in these programs; (in other words, reduction in predator population in a localized area or targeting individual animals);
    - Additional IPM statements related to the use of non-lethal and lethal strategies with these products being intended as a last resort in management programs as indicated in the Product Stewardship Program. Alternative strategies used and rationale for toxicant use to be documented in the "Vertebrate Toxicant Usage Record".

Implementation of the re-evaluation decision

Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review* provides general timelines for implementation of post-market decisions.

When a re-evaluation or special review decision requires cancellation of pest control products, consistent with Health Canada's *Information Note: update on implementation of post-market decisions* (2021), Health Canada will immediately cancel pest control product registrations on the date of a decision made under paragraph 21(2)(*b*) of the *Pest Control Products Act*.

If there are no serious and imminent risks to human health or the environment, Health Canada will allow for a phase-out period consistent with DIR2018-01 and will impose any conditions necessary for carrying out the purposes of the *Pest Control Products Act* under the authority of paragraph 21(5)(*a*) of the *Pest Control Products Act.*

When a re-evaluation or special review decision results in an amendment to the label of pest control products, Health Canada will generally allow registrants up to 24 months from the publication date of the decision to implement the required amendments, including updating product labels.

Based on the following considerations, all products containing strychnine are cancelled with a six-month phase-out period and required label amendments to the sodium monofluoroacete product, including a product stewardship program, must be implemented no later than 24 months after the publication date of this decision document.

Strychnine

Based on the current use pattern and approved label conditions, potential and relative risks to health are considered acceptable in the six-month phase-out period.

The environmental risks from the registered uses of strychnine are not shown to be acceptable. No feasible risk mitigation measures have been identified. Considering the current use pattern, the new evidence on the high prevalence of non-target deaths despite existing mitigation measures, and that there are no additional appropriate mitigation measures to permit acceptable risk to the environment from the use of strychnine, strychnine is cancelled with an accelerated phase-out period of six months. Due to the limited nature of the use of strychnine, it is not expected that imminent and serious risk to the environment will occur in the six-month phase-out period. However, such risks may arise if a longer phase-out period is imposed given the potential for non-target deaths and potential threat to species at risk as a result of the use of strychnine.

Taking into consideration the above factors, an accelerated phase-out period of six-months for strychnine is considered appropriate from a human health and environmental perspective.

Sodium monofluoroacetate

Potential and relative health risks are considered acceptable during the general 24-month implementation period unless there is evidence from incident reports or other sources of real-world post-market surveillance data suggesting that there are adverse health effects occurring as a result of the use of the product according to the currently approved label/use conditions. Other considerations may include how widely the product is used, the populations potentially exposed to the product and/or other factors. Taking into consideration these factors, the 24-month implementation timeline for label amendments for sodium monofluoroacetate is considered appropriate from a human health perspective.

The environmental risks from the registered uses of sodium monofluoroacetate have been shown to be acceptable with the implementation of risk mitigation measures. The risks identified are considered acceptable because they are not expected to cause irreversible harm over the label implementation period. Potential effects of sodium monofluoroacetate include death of non-target organisms; however, it is a much more targeted toxicant than strychnine and is generally more toxic to canids than other animals, thus less likely to result in non-target deaths. Affected populations have the potential to recover following implementation of the additional restrictions, which will reduce overall exposure. Recovery is expected because risks to these non-target organisms are geographically limited to areas where sodium monofluoroacetate is applied and areas adjacent to application sites. The presence of unaffected non-target animals in areas where sodium monofluoroacetate is not being used will further facilitate recovery since unaffected organisms can move back into areas where effects may have occurred. Overall, the risk to these animals is considered acceptable over the 24-month period to implement the mitigation measures.

Taking into consideration the above factors, the general 24-month implementation timeline for label amendments for pest control product containing sodium monofluoroacetate is considered appropriate from a human health and environmental perspective.

Next steps

To comply with this decision, the required amendments and cancellation must be implemented within the timelines described below. Refer to Appendix I for details on specific products impacted by this decision.

Amendments to sodium monofluoroacetate product

The required amendments (risk mitigation measures and label updates) must be implemented on the sodium monofluoroacetate product label no later than 24 months after the publication date of this decision document. Accordingly, the registrant/retailers will have up to 24 months from the date of this decision document to transition to selling/distributing the product with the newly amended labels. Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available on the Public Registry.

Product stewardship program for sodium monofluoroacetate product

As part of this re-evaluation decision, a product stewardship program for sodium monofluoroacetate, reviewed by Health Canada, must be implemented no later than 24 months after the publication date of this decision document.

Cancellation of strychnine products

As of the date of this decision document, all strychnine products are cancelled. A 6 month phase-out period is established to deplete existing stocks in Canada.

During this phase-out period, continued possession, handling, storage, and use of existing stock in Canada of these products will be authorized under paragraph 21(5)(a) of the *Pest Control Products Act* as per the timeframe below.

- Authorized use for six (6) months from the publication date of this decision document.

During the six month phase-out period, the manufacture and sale in Canada or import into Canada of these cancelled products are prohibited.

Products that have a phase-out period will be listed as "Phase-out" in the Public Registry for the duration of their authorization.

The registrant is required to continue to provide any incident reports in the manner set out in the Pest Control Product Incident Reporting Regulations and all obligations under those regulations continue to apply during the phase-out period as if the product was registered.

The registrant is required to continue to provide a sales report in a manner consistent with section 3 and for the purposes of section 8 of the Pest Control Products Sales Information Reporting Regulations for each pest control product, as if the product was registered. This condition is in effect until all reports relevant to the 2024 calendar year have been submitted.

Other information

Any person may file a notice of objection[3] regarding this decision on the predacide uses of strychnine and sodium monofluoroacetate within 60 days from the date of publication of this Re-evaluation 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 PMRA's Pest Management Information Service.

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

The relevant confidential test data on which the decision is based (as referenced in PRVD2022-18 and in Appendix VI of this document) are available for public inspection, upon application, in PMRA's Reading Room. For more information, please contact the Pest Management Information Service.

Evaluation approach

Legislative framework

The Minister of Health's primary objective under the *Pest Control Products Act* (the 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 conditions of registration can be established to prevent unacceptable risks to human health and the environment.

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.

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.[4] 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[5].

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.[6]

Assessments estimate potential health risks to defined populations[7] under specific exposure conditions. They are conducted in the context of the 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. 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.

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

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

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

7 Consideration of Sex and Gender in Pesticide Risk Assessment

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.

During re-evaluation, value is examined under current conditions and in light of alternative pest control methods (both chemical and nonchemical) that may have been developed since the pesticide was first registered. An assessment of the benefits associated with the pesticide may also be conducted to demonstrate its value in the current context, and to identify potential alternatives.

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, frequency 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 re-evaluation 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*. Implementation of post-market decisions follow the framework articulated in the *Policy on Cancellations and Amendments Following Re-evaluation and Special Review*.[8]

Following a decision, continuous oversight activities such as post-market review, monitoring and surveillance, including incident reporting, all play an essential role to help ensure the continued acceptability of risks and value of registered pesticides.

[8] PMRA Regulatory Directive DIR2018-01 *Policy on Cancellations and Amendments Following Re-evaluation and Special Review*

Science evaluation update

1.0 Technical grade active ingredient

It was noted in Proposed Re-evaluation Decision PRVD2022-18 *Predacide Uses of Strychnine and Sodium Monofluoroacetate and their Associated End-use Products*, there are no technical grade active ingredient products registered as a source of active ingredient for predacides containing strychnine or sodium monofluoroacetate.

As a result of this re-evaluation decision, the registrations of all strychnine products are cancelled; hence, the requirement to register a technical grade active ingredient product is no longer applicable.

Paragraph 4(1)(a) of the Pest Control Products Regulations provides a grandfathering clause allowing an end-use product to use unregistered active ingredients as long as it was registered, or the application for its registration was received by Health Canada, by 1 January 1984.[9] Based on this, the sodium monofluoroacetate product, Registration Number 18300, is exempt from requiring registration of a technical grade active ingredient under *Pest Control Products Act* subsection 6(1), as the application for its registration was received by Health Canada prior to 1984.

2.0 Revised health assessment

As part of PRVD2022-18, existing labels were assessed for consistency and clarity with respect to risk management of bystander and occupational exposures. The updates to personal protective equipment (PPE) label statements proposed in the PRVD are required and are expanded in the final decision to include handling of poisoned baits and carcasses.

Revision of the disposal statements to include incineration at an approved provincial facility for all carcasses (target and non-target) poisoned with sodium monofluoroacetate was proposed in PRVD2022-18. Considering comments received during the consultation period (See Appendix III), this revision to the disposal requirements for carcasses poisoned with sodium monofluoroacetate is no longer required. Label improvements will be made to clarify disposal of product and product containers versus poisoned baits and carcasses. Additionally, to protect users from occupational exposure and to reduce exposure to bystanders, an inventory of the disposal of poisoned baits and poisoned carcasses is required to be recorded in the "Vertebrate Toxicant Usage Record".

An additional requirement for the registrant-implemented Product Stewardship Program includes an educational component focused on proper disposal of these products and their associated contaminated wastes.

[9] https://laws-lois.justice.gc.ca/eng/regulations/SOR-2006-124/

Occupational and bystander risks are considered acceptable when the required mitigation measures are in place and adhered to.

2.1 Health incident reports

Since the publication of the PRVD2022-18, no human or domestic animal incidents involving strychnine or sodium monofluoroacetate were reported to the PMRA (in other words, from 9 May 2022 to 14 December 2023).

3.0 Revised environmental risk assessment

3.1 New data submitted by Wolf Awareness and Animal Justice

During the consultation on PRVD2022-18, two non-governmental organizations, Wolf Awareness and Animal Justice, provided strychnine and sodium monofluoroacetate use records from 2005–2010 that were acquired from the Government of Alberta via a Freedom of Information and Protection of Privacy request. This information was not reviewed prior to the consultation because Health Canada requested ten years' worth of use records from registrants at the initiation of the re-evaluation and reviewed data from 2010 to 2021 for PRVD2022-18.

The records submitted by Wolf Awareness and Animal Justice generally support the conclusions made by Health Canada in PRVD2022-18. The use records all show high levels of potential non-compliance with label directions, the lack of proper records, and a higher number of non-target animals killed than target animals.

The information provided by Wolf Awareness and Animal Justice also contained information that was not available to Health Canada prior to the consultation: (1) use records from 2006 to 2009 that include both the number of strychnine tablets set out and the number of strychnine tablets recovered from bait sites in the Government of Alberta's caribou recovery program, and (2) field notes in the records reporting that strychnine baits were taken without the recovery of carcasses and that there was evidence of more wolves or other animals at the bait sites than were recovered dead near the bait sites (for example, based on animal tracks or other signs of animal activity in the vicinity of the bait sites). The records submitted by Wolf Awareness and Animal Justice show that between 2006 and 2009, 810 to 1736 tablets of strychnine were used annually to kill a reported total of 62 wolves (11 to 18 wolves per year; Appendix IV, Table 1). Consistent with the registrant submitted use records reviewed by Health Canada, a higher number of non-target animals were killed than target animals. The carcasses of 40 ravens, 25 coyotes (when not the target pest), 23 foxes, 3 lynx, 1 fisher and 1 weasel were recovered during this time. The records consistently note that strychnine-laced baits were missing without the recovery of carcasses of target/non-target animals. Hervieux et al. (2014, supplemental data; PMRA# 3478549) report a similar, but not identical number of non-target animals killed in the Little Smoky woodland caribou range between 2006 and 2009: 39 ravens, 25 coyotes (when not the target pest), 23 foxes, 1 fisher and 1 weasel; no lynx were reported dead in the Hervieux dataset.

The use records submitted by Wolf Awareness and Animal Justice note that strychnine-poisoned baits were frequently taken without the recovery of carcasses and that there was evidence of more wolves or other animals on site than were recovered dead (for example, based on animal

tracks or other signs of animal activity). A limited number of strychnine tablets were recovered from the sites, ranging from 21 to 80 per year, indicating that >90% of strychnine set out was consumed by animals or left on the landscape. Based on the provided data, between 44 and 95 tablets of strychnine were used for each confirmed wolf kill. Given the lack of recovered carcasses, signs of animal activity, and very strong evidence in the ratio of strychnine tablets used per targeted kill, these data indicate that non-target kills are likely significantly higher than reported. This information was considered in the risk assessment for the final re-evaluation decision.

3.2 Risk to terrestrial organisms

Strychnine

Strychnine is an indiscriminate, non-selective toxicant. It is currently only used to control wolves in the Government of Alberta's woodland caribou recovery and livestock protection programs. Strychnine has not been used to control coyotes and black bear in Alberta since at least 2005. According to use records from 2005 to 2021, annual predacide use of strychnine in Government of Alberta programs was generally less than 2000 tablets; however, use peaked at approximately 2800 tablets in 2008. The records show that strychnine use has decreased significantly since 2015. Annual use after 2015 was less than 50% of previous years. The Government of Alberta has not used strychnine to control wolves in its livestock protection program since 2016 to minimize risk to non-target species given that depredation generally occurs in April to November when bears are active on the landscape.

The use of strychnine results in the deaths of many species beyond the target species (in other words, wolves). Use records consistently report a higher number of deaths for non-target animals than wolves. The use records and incident reports also provide evidence of both primary and secondary poisoning of scavenging non-target animals. The animals that consume strychnine or strychnine-poisoned carcasses in turn poison other animals when consumed. As would be expected, the reported target and non-target deaths increase with the amount of strychnine used. For the approximately 16 500 strychnine tablets used between 2005 and 2021, the deaths of at least 490 wolves (target animal), 312 ravens, 127 coyotes (when not the target pest), 83 foxes, 35 magpies, eight lynx, six dogs, four martens, four fishers, three weasels, three golden eagles, two bald eagles, two skunks, two grizzly bears (one reportedly emaciated, near death and out of its den in the winter), one crow, one grey jay, one mink, one ermine and one great gray owl were reported.

Non-target mortalities based on the use records and incident reports are likely significantly underestimated. Studies conducted to evaluate carcass scavenging and search efficiency in the field determined that there was a low probability of finding a carcass despite substantial effort searching (average of 79 minutes per 1 ha site; McKinnon et al., 2002 (PMRA# 3051153), McKinnon and Mineau, 2004 (PMRA# 3051152)). The studies found that only 14–38% of Richardson's ground squirrel, ring-necked pheasant and Japanese quail carcasses placed in the field remained after three days. These searches occurred in agricultural fields. Searching in the Boreal Forest would likely be much less effective due to the terrain and density of trees.

Not all of the toxicants used are ingested by animals. The documents received during the consultation period provided additional information on the number of toxicant tablets consumed, how many were retrieved and disposed of, and how many were left on the landscape. The 2006–2009 use records provided by Wolf Awareness and Animal Justice during the consultation demonstrate that >90% of the strychnine tablets set out were likely consumed by animals. These records frequently note that poisoned baits were taken without the recovery of carcasses and that there was evidence of more wolves or other animals on site than were recovered dead (for example, based on animal tracks or other signs of animal activity). This new data indicates that non-target kills are likely significantly underreported.

The species of non-target animals killed by the predacide use of strychnine in use records as well as in a study providing an overview of gray wolf poisoning programs in northern Ontario in the 1950s and 1960s (Harris and Armstrong, 2021; PMRA# 3478550) are fairly consistent. The majority of non-target animals killed by the predacide uses of strychnine (in other words, coyotes, ravens, foxes and magpies) are carrion eaters that are commonly found across Canada and have stable populations (Appendix IV, Table 2). Harris and Armstrong (2021; PMRA# 3478550) note that the number of gray jay deaths from predator poisoning programs are likely underreported given that they cache food by storing pieces of carrion in trees to be consumed later. As such, it is likely that these birds would die away from the bait sites, making carcass retrieval more difficult. The death of only one gray jay as the result of strychnine use was reported in the use records between 2005 and 2021. Many of the other non-target species found at strychnine bait sites (described above) are also known to either cache food or raid the food caches of other species. This increases the likelihood of primary and secondary poisonings occurring away from the bait sites where the carcasses would not be found during site searches. Additionally, Alberta Environment and Protected Areas reports that coyotes have been observed to dig drop baits out of snow piles and leave the naked strychnine tablets on the snow surface (PMRA# 3248737). The resulting presence of strychnine tablets on the surface increases the likelihood of non-target species being poisoned.

The Government of Alberta's predator and/or rabies control programs have been identified as threats to the following species at risk:

- The American badger (*Taxidea taxus taxus*) in Alberta, which is listed as "Special Concern" on Schedule 1 of the *Species at Risk Act* (SARA). Badgers are managed as furbearers under the Alberta *Wildlife Act*, which allows for year-round hunting. The 2012 Committee on the Status of Endangered Wildlife in Canada (COSEWIC) status report on the American badger (PMRA# 3478551) identifies the rodenticide use of strychnine as a threat to this species. While the report did not specifically identify the predacide use of strychnine as a threat, American badgers feed on carrion. As such, this species would also be at risk of primary and secondary poisoning from consuming strychnine-poisoned baits or the carcasses of animals killed by strychnine.

- The swift fox (*Vulpes velox*), which is listed as "Threatened" on Schedule 1 of SARA. The swift fox currently occurs only in the southernmost portion of the prairies on both sides of the Alberta-Saskatchewan border. The 2021 COSEWIC status report for the swift fox (PMRA# 3478748) identified accidental poisoning from rodenticides and predacides as an important

limiting threat to this species. The COSEWIC report notes that the Alberta Ministry of Agriculture and Forestry (now called Alberta Agriculture and Irrigation) no longer issues toxicants for coyote control in swift fox areas. The report also notes that no swift fox carcasses have been submitted to the provincial Fish and Wildlife Laboratory nor have there been reports of swift fox poisoning. Health Canada has not received any incident reports involving the swift fox. The registered labels for Strychnine Wolf, Coyote and Black Bear Control Predacide (Reg. No. 20410) and Sodium Monofluoroacetate Predacide (Reg. No. 18300) prohibit use of the products if species at risk that may feed on the poisoned bait or poisoned carcasses are present in the area. Strychnine Predacide Skunk Control (Reg. No. 24510) does not currently have a restriction to prohibit use in species at risk territory. PRVD2022-18 proposed including a label statement to prohibit use where species at risk may consume the poisoned bait eggs; however, the registrant has responded that species at risk occur in the areas of historical rabies outbreaks, indicating that the proposed risk mitigation measure for Strychnine Predacide Skunk Control is not feasible.

- Wolverine (*Gulo gulo*), which is listed as "Special Concern" on Schedule 1 of the SARA. The wolverine has a low population density and low reproduction potential. As such, the loss of a few individuals has the potential to negatively affect reproductive success. The Government of Alberta has identified predator and rabies control programs as a threat to Alberta's wolverine population (PMRA# 3478749). The range of the wolverine overlaps with the area that strychnine is used in the caribou recovery program. Wolverine is managed as a fur bearing animal in Alberta.

The Government of Canada has made a international commitment through the Global Biodiversity Framework to contribute to minimizing the loss of biodiversity and reducing the overall risk from pesticides by at least half through integrated pest management based on science and taking into account food security and livelihoods (COP 15 Target 7[10]). While the non-target species reported killed by the predacide use of strychnine are generally common species with stable populations, the number of non-target deaths exceeds the number of target deaths (at least 596 non-target deaths vs. 490 target deaths based on the use records from 2005 to 2021). Additionally, it is possible that other less common non-target species were killed by the use of strychnine but their carcasses were not found. The use of strychnine as a predacide has been identified as a threat to several species at risk and has resulted in the deaths of at least two grizzly bears, which are currently listed as "Special Concern".

The newly reviewed data provide evidence that non-target deaths are likely significantly underreported. There have been thousands of tablets of strychnine used over the years for which associated wolf carcasses were never retrieved. In 2018, an incident report provided evidence of the deaths of at least 18 non-target animals (at least eight ravens, five foxes, two coyotes, a lynx, a grizzly bear and a great gray owl) at strychnine bait sites over the course of June-July when no toxicant was supposed to be present. Fox scat around the carcasses was also observed, without

[10] Official Convention on Biological Diversity (CBD) press release, 2022. By 2030: Protect 30% of Earth's lands, oceans, costal areas, inland water; Reduce by $500 billion annual harmful government subsidies; Cut food waste in half. 19 December 2022, Montreal. https://www.cbd.int/article/cop15-cbd-press-release-final-19dec2022. PMRA# 3475857.

the retrieval of fox carcasses. This indicates that additional animals may have been poisoned but were not found. This incident report also shows that deaths of many non-target organisms can occur for months after the closure of a strychnine bait site if the toxicant and poisoned carcasses are not completely removed. The incident report resulted in enforcement action on the Alberta Government in 2019. Health Canada's subsequent inspections did not identify any instance of non-compliance.

The impact to non-target species as a result of the use of strychnine could be significant and may affect biodiversity and the food chain within localized areas as well as the populations of species with low densities and reproduction rates. Anecdotally, a trapper reported reduced numbers of canids, ravens and other scavengers in the areas of strychnine bait sites over the years. Furthermore, the trapper noted that wolverine, which were once plentiful in the area, appeared to have disappeared in the last decade despite no industrial development in the area.

According to the currently registered labels of strychnine products, bait sites must be checked at least every 7 to 15 days. This provides ample time between site checks for strychnine-poisoned baits to be consumed, resulting in the poisoning of non-target species both at, and away from, bait sites. The registrants have indicated that it is generally not feasible to check the sites more frequently, particularly in remote areas and have requested additional flexibility in the timing of site checks.

When considering the new information as well as the information considered in PRVD2022-18, environmental risks associated with the predacide uses of strychnine are unacceptable due to risks to non-target species, especially for those species with low densities and reproduction rates. The deaths of non-target animals outnumber those of target animal (wolves). The carcasses of many species other than wolf are frequently found at strychnine bait sites. Additionally, strychnine predator control and rabies programs have been identified as threats to several species at risk. No feasible measures to mitigate risk to non-target terrestrial species have been identified.

Sodium monofluoroacetate

Fewer than 3000 tablets of sodium monofluoroacetate are used annually in Alberta. Reliable data for the number of target and non-target deaths as a result of the use of sodium monofluoroacetate are not available; however, non-target deaths are expected to be lower than for strychnine due to a lower risk of secondary poisoning. The Alberta Fish and Wildlife "Use, Storage and Handling of Vertebrate Toxicants for Problem Wildlife Control and Wildlife Management" Procedure (PMRA# 3248740) notes that sodium monofluoroacetate is the preferred toxicant to use in the summer as it is less toxic to non-canid species. The Alberta Coyote Predation Control Manual states that sodium monofluoroacetate has replaced strychnine for coyote removal because it is a more selective poison that is less likely to result in secondary poisoning (PMRA# 3202326).

Sodium monofluoroacetate is classified as highly to very highly toxic to birds and mammals; however, it is much more toxic to canids than other animals. Birds are less sensitive to sodium monofluoroacetate than mammals (Appendix IV, Table 3). There is a risk of death for animals who ingest poisoned baits; however, the risk of secondary poisoning is much lower than for

strychnine. Burns et al. (1986; PMRA# 3478775) report average and maximum sodium monofluoroacetate concentrations of 0.29, 0.30 and 0.31 ppm and 0.66, 0.79 and 0.76 ppm in the muscle, small intestine and stomach tissue, respectively, of coyotes killed with 5–15 mg of sodium monofluoroacetate (equivalent to one to three tablets). Based on these concentrations, most scavengers would need to consume many times their body weight in poisoned tissues to reach their respective LD_{50} values (Appendix IV, Table 4).

Burns et al. (1986) report no mortalities or signs of toxic effects in dogs, coyotes, skunks or magpies fed exclusively on coyotes poisoned with 5–15 mg of sodium monofluoroacetate for 14 to 35 days. Furthermore, no sodium monofluoroacetate residues were detected in muscle samples from the tested animals. Burns et al. (1991; PMRA# 3478551) fed striped skunks and golden eagles diets containing 4.1 and 7.7 ppm sodium monofluoroacetate for five days, which is much higher than the concentrations expected to be found in poisoned animals in the wild. No mortalities were observed in the study although some eagles showed signs of intoxication including loss of strength and coordination, lethargy and tremors. Both species reportedly reduced consumption of the treated diets but resumed normal feeding on untreated diets within a few days. The study authors concluded that the carcasses of coyotes killed by sodium monofluoroacetate posed little hazard to skunks or golden eagles.

Given the limited and restricted use of sodium monofluoroacetate, as well as the low likelihood of significant secondary poisoning risk, environmental risks are considered to be acceptable when used according to the label directions with the required new risk mitigation measures. The new risk mitigation measures include improved label directions, updated reporting requirements and a registrant-implemented product stewardship program to improve user training and compliance.

3.3 Risk to aquatic organisms

PRVD2022-18 addressed aquatic risks from the use of the predacide products qualitatively. Strychnine and sodium monofluoroacetate are not permitted to be used in aquatic systems. Unconsumed baits and poisoned carcasses must be retrieved and disposed of in accordance with label directions. In the event that this does not occur, despite the requirement, it is very unlikely that these products would enter aquatic systems at concentrations that would result in adverse effects.

Health Canada received comments regarding the lack of a quantitative aquatic risk assessment during the consultation. As such, a screening level risk assessment was conducted based on available data for both compounds. Estimated environmental concentrations (EECs) in surface water were calculated assuming that the maximum amount of toxicant permitted at a site based on label directions was dropped into a one-hectare wetland. For strychnine, this was assumed to be 36 tablets (155 mg a.i./tablet; 3 tablets × 12 baits). For sodium monofluoroacetate, this was assumed to be 18 tablets (5 mg a.i./tablet; 3 tablets × 6 baits). Water bodies of two different depths were evaluated: an EEC in surface water 15 cm deep was used to determine risk to amphibians while an EEC at an 80 cm depth was used to evaluate risks to all other aquatic organisms.

Available toxicity endpoints were adjusted to calculate an effects metric. The effects metric accounts for potential differences in species sensitivity as well as varying protection goals (in other words, protection at the community, population, or individual level). For characterizing acute risk, the effects metric was calculated by dividing acute toxicity values (for example, LC_{50} and EC_{50}) by an uncertainty factor (UF; for example, 10 for fish and 2 for aquatic invertebrates). Acute toxicity endpoints for *Daphnia magna*, and freshwater fish were used. Endpoints for aquatic plants are not available; however, these are not required given negligible exposure and risk from the use pattern.

A risk quotient (RQ) was calculated by dividing the EEC by the effects metric and was then compared to the level of concern (LOC). The calculated RQs are many orders of magnitude below the LOC of 1 (Appendix IV, Table 5). As such, potential risks to aquatic organisms from the predacide use of strychnine and sodium monofluoroacetate inadvertently reaching water bodies are negligible.

During the consultation, the International Fund for Animals (IFAW) noted that there is documented evidence that strychnine was being used on waterways in the Little Smoky region during the winter of 2018. IFAW states that it is impossible to tell how many baits have been left behind at the end of the poisoning program to fall into the river system after the ice thaws and expressed concern that the Athabasca River rainbow trout (*Oncorhynchus mykiss*) population may be exposed. The Athabasca River rainbow trout population is listed as "Endangered" on Schedule 1 of SARA and ranked as "Threatened" under the Alberta *Wildlife Act*.

The protocol of the caribou recovery program is to bury drop baits in snow mounds of up to 1.5 meters in height. The snow piles are to be dug up and inspected on a weekly basis. At the end of the program delivery, unconsumed drop baits are recovered and disposed of. It is not expected that a significant amount of strychnine would be left behind at the bait sites at the end of the programs. As shown by the RQs, risks to aquatic organisms are expected to be negligible even if more than the maximum permitted amount of strychnine at a site was to enter water. Additionally, the calculation of the EECs does not consider dilution of the strychnine in the water system. Dilution of the predacide products would be expected to occur in a flowing stream or river, particularly during spring thaw, resulting in even lower exposure for aquatic organisms.

Based on the screening level risk assessment, risks to aquatic organisms from the use of strychnine and sodium monofluoroacetate are negligible when used according to label directions. However, strychnine is cancelled due to unacceptable risks to non-target terrestrial organisms.

3.4 Environmental incident reports

Since the publication of the PRVD2022-18, no environmental incidents involving strychnine or sodium monofluoroacetate were reported to the PMRA (in other words, from 9 May 2022 to 11 October 2023).

4.0 Value assessment

Strychnine

It was determined that the environmental risks associated with the predacide and skunk control uses of strychnine are unacceptable which resulted in the cancellation of all uses.

It is expected that the cancellation of strychnine will have minimal impact in predator and skunk management because both lethal and non-lethal approaches to manage these animals are available. Sodium monofluoroacetate is an alternative bait product that can be used to kill wolves in species-at-risk conservation programs, such as the woodland caribou recovery strategy program. Shooting and trapping of wolves are alternative approaches that can be used in conjunction with non-lethal strategies such as restoration and protection of habitat in conservation programs. Sodium monofluoroacetate baits are the preferred toxicant to kill coyotes and may be used to kill wolves preying on livestock. Shooting, trapping and non-lethal methods (for example, fencing, guardian animals) can be used to prevent livestock predation. Human safety concerns related to predators can be dealt with using alternative approaches (for example, shooting, trapping, public education programs). There are no registered alternative products to strychnine for killing black bears. However, few impacts to end users are expected as alternative non-lethal (for example, keeping food away) and lethal (for example, shooting) approaches are available. Strychnine to kill skunks in rabies control programs has not been used in Alberta since 1993 because there has been no incidence of skunk rabies. Alternative methods of managing skunks are available such as shooting, trapping and vaccination should there be an outbreak of skunk rabies.

Sodium monofluoroacetate

Regarding the value of sodium monofluoroacetate, refer to section 5.2 Value of sodium monofluoroacetate in Proposed Re-evaluation Decision PRVD2022-18, *Predacide Uses of Strychnine and Sodium Monofluoroacetate and their Associated End-use Products*.

5.0 Conclusion of science evaluation

Health

Heath risks associated with the use of strychnine and associated end-use products are shown to be acceptable with additional risk mitigations. However, these products are cancelled since environmental risks from the use of strychnine are not shown to be acceptable.

Health risks associated with the use of sodium monofluoroacetate and associated end-use product are shown to be acceptable with implementation of risk mitigation measures, including a product stewardship program. Label improvement and amendments are required to meet current labelling standards, including updated PPE.

Environment

It has been determined that the environmental risks associated with the use of strychnine and associated end-use products are not shown to be acceptable. Therefore, all predacide and skunk control uses of strychnine are cancelled.

It has been determined that the environmental risks associated with the use of sodium monofluoroacetate and associated end-use product are shown to be acceptable with the implementation of additional risk mitigation measures, including a product stewardship program.

Value

It has been determined that strychnine and its end-use products have acceptable value. However, these products are cancelled due to environmental risk concerns. This will have minimal impact in predator and skunk rabies management programs because there are alternative approaches available for use and/or these products are not in use at this time.

It has been determined that sodium monofluoroacetate and its end-use product has acceptable value. Additional label improvements are also required.

List of abbreviations

a.i.	active ingredient
bw	body weight
cm	centimetre
COP	Conference of the Parties
COSEWIC	Committee on the Status of Endangered Wildlife in Canada
EC_{50}	effective concentration on 25% of the population
EEC	estimated environmental concentration
EPA	Environmental Protection Agency
IFAW	International Fund for Animals
Kg	kilogram
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOC	level of concern
mg	milligram
No.	Number
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
Reg.	Registration
RQ	risk quotient
SARA	*Species at Risk Act*
UF	uncertainty factor

Appendix I Registered products containing strychnine and sodium monofluoroacetate in Canada

Table 1 Products containing sodium monofluoroacetate requiring label amendments[1]

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (%, g/l)
18300	Restricted	Government of Alberta / Alberta Agriculture & Forestry	Sodium Monofluoroacetate Predacide	Tablet	5 mg/tablet

[1] As of 22 December 2023, excluding discontinued products or products with a submission for discontinuation.

Table 2 Products containing strychnine cancelled as a result of re-evaluation[1]

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (%, g/L)
20410	Restricted	Alberta Environment and Protected Areas, Fish and Wildlife Stewardship Branch	Strychnine Wolf, Coyote & Black Bear Control Predacide	Tablet	Strychnine 38.6% (155 mg strychnine/tablet)
24510	Restricted	Government of Alberta / Alberta Agriculture and Forestry	Strychnine Predacide Skunk Control	Solution	Strychnine 35 mg/mL

[1] As of 22 December 2023, excluding discontinued products or products with a submission for discontinuation.

Appendix II List of commenters to PRVD2022-18

List of commenters' affiliations for comments submitted in response to PRVD2022-18

Category	Commenter
Registrant	Government of Alberta / Alberta Agriculture and Irrigation (AGI)
Non-governmental organization	Canadian Veterinary Medical Association (CVMA)
	International Fund for Animal Welfare (IFAW) Canada
	Animal Protection Party of Canada
	Animal Alliance of Canada
	Humane Society International/Canada
	Zoocheck
	Wolf Awareness
	Animal Justice Canada
	Canada Council on Animal Care
	Ontario Wildlife Rescue
	Humane Canada
	Ontario SPCA and Humane Society
	The Fur-Bearers
	Coyote Watch Canada
	David Suzuki Foundation
	Cochrane Ecological Institute
	Campbell Centre for the Study of Animal Welfare
	Animal Environmental Legal Advocacy
	Society of British Columbia Veterinarians
	Ontario Veterinary Medical Association
	Townline Veterinary Hospital
Agricultural association	Canadian Cattle Association
Municipal	Municipal District of Willow Creek
	Municipal District of Greenview
	County of Northern Lights
General	Members of the public

Appendix III Comments and responses

Health Canada received over 1500 written comments during the public consultation for the predacide uses of strychnine and sodium monofluoroacetate proposed re-evaluation decision. Commenters' affiliations are listed in Appendix II. These comments were considered during the final decision phase of this re-evaluation. Summarized comments and Health Canada's responses to them are provided below.

1.0 Comment related to the health assessment

1.1 Comments related to the danger that predacides pose to the health and safety of people, companion animals and livestock

Comments received from non-governmental organizations and the public stated that hundreds of companion animals have been poisoned in Canada after consuming baits or bodies of animals poisoned with strychnine or Compound 1080 (Sodium Monofluoroacetate). The commenters request that action is taken to protect Canada's wildlife as well as the health and safety of people, companion animals and livestock.

Health Canada response

With respect to human health, occupational risks were shown to be acceptable when strychnine and sodium monofluoroacetate are used according to the conditions of registration, including revisions to personal protective equipment requirements for all products. As required by law, users must follow all label directions when using pest control products registered under the Pest Control Products Act. The inclusion of personal protective equipment for workers handling these chemicals provides a level of protection against exposure. Statements for directions of use and proper handling and storage of these chemicals aim to minimize exposure to people and companion animals and livestock. To further reduce the potential for exposure, this re-evaluation decision requires the implementation of a Product Stewardship Program by the registrant to increase user education and awareness regarding disposal methods for unused toxicants, poisoned baits, and poisoned carcasses. The product labels will also include a requirement for users to complete a "Vertebrate Toxicant Usage Record" which includes a requirement for an inventory on the disposal of poisoned baits and poisoned carcasses.

2.0 Comments related to the environmental risk assessment

2.1 Comments related to use records/data considered in re-evaluation

Comments received from non-governmental organizations and the public stated that Health Canada did not consider use records/data that were more than ten years old despite strychnine being in use for decades.

Health Canada response

The re-evaluation of products containing strychnine and sodium monofluoroacetate used as predacides was focused on the feasibility of risk management measures rather than a traditional quantitative risk assessment approach. Ten years was considered to be a suitable timeframe to understand how these products are being used in order to inform the re-evaluation. As such, records from 2010–2021 were reviewed for PRVD2022-18. Comments received from non-governmental organizations included use records for strychnine and sodium monofluoroacetate between 2005–2010 that were acquired through the Government of Alberta's Freedom of Information and Protection of Privacy. The records from 2005–2010 generally support the conclusions made by Health Canada in PRVD2022-18 (for example, high potential for non-compliance with the existing label, lack of proper use records, and a higher number of non-target animals killed than target animals); however, they also included information that was not previously available to Health Canada prior to the public consultation: use records from 2006 and 2009 for the caribou recovery program that included both the number of strychnine cubes set out, as well as the number of strychnine cubes recovered from bait sites. The field notes in these records also reported that baits were taken without the recovery of carcasses and that there was evidence of more wolves or other animals on site than were recovered as carcasses (for example, based on animal tracks or other signs of animal activity). This information was considered in the updated risk assessment for this re-evaluation decision.

2.2 Comments related to the lack of use records/data for sodium monofluoroacetate regarding non-target deaths

Comments received from non-governmental organizations stated that the vast majority of municipalities in Alberta did not collect data on the number of target animals (in other words, coyote) or non-target animals killed as a result of the use of sodium monofluoroacetate, despite this being a requirement under the label use directions.

Health Canada response

The currently registered label for Sodium Monofluoroacetate Predacide (Registration Number 18300) indicates the following under Use Limitations:

> "15. The user of tablets must monitor and keep accurate records on the use of each poisoned bait."

Current use directions do not specify what information must be recorded or if the information is to be submitted by the municipalities. However, as a result of this re-evaluation decision and requirement for a Product Stewardship Program, users are required to complete the Vertebrate Toxicant Usage Record (refer to Appendix V) and submit copies of these records directly to the registrant (Government of Alberta) for monitoring purposes. The requirement for the use of the Vertebrate Toxicant Usage Record is intended to specify record keeping requirements and improve compliance with label uses directions. The registrant is required to monitor records and notify Health Canada within 24 hours when any use record indicates use not in accordance with labelled directions. The use of sodium monofluoroacetate will be ceased until Health Canada reviews and provides direction.

2.3 Comments related to the lack of a quantitative environmental risk assessment

Comments received from non-governmental organizations and the public stated that a quantitative environmental risk assessment was not conducted for these predacide products and that risk quotients were not calculated. Comments noted that it is unfortunate that samples were not collected from carcasses to provide data to evaluate the risk of secondary poisonings.

Health Canada response

Risk quotients are a tool to assist in evaluating environmental risk but they are not the final determinant of risk nor the only way to evaluate risk. A quantitative risk assessment was not conducted because it is acknowledged that exposure of animals to strychnine or sodium monofluoroacetate may result in death via direct and/or secondary poisonings. The predacide products are applied as baits at specific sites (in other words, where predation has been confirmed) and to be used only as a last resort in predator management programs. For this reason, the re-evaluation focused on the feasibility of risk management measures rather than a traditional risk assessment approach.

Samples from carcasses are not considered necessary to evaluate the risk of secondary poisonings. Use records and incident reports considered in the re-evaluation provided evidence that the risk of secondary poisoning as a result of the use of strychnine does exist. While limited field data are available for the use of sodium monofluoroacetate in Alberta, studies evaluating the risk of secondary poisoning have concluded that the risk is considered low. Burns et al. (1986) reported no mortalities or signs of toxic effects in dogs, coyotes, skunks or magpies that fed exclusively on coyote carcasses poisoned by 5 to 15 mg of sodium monofluoroacetate (1 to 3 tablets) for 14 to 35 days. Additionally, Burns et al. (1991) fed striped skunks and golden eagles diets containing 4.1 and 7.7 ppm sodium monofluoroacetate for five days. This is higher than the maximum concentrations observed in coyote carcasses poisoned by 5 to 15 mg of sodium monofluoroacetate (<1 ppm) in Burns et al. (1986). No mortalities were observed in this study although some eagles showed signs of intoxication including loss of strength and coordination, lethargy and tremors. Both species reduced consumption of the treated diets but resumed normal feeding on untreated diets within a few days. The study authors concluded that the carcasses of coyotes killed by sodium monofluoroacetate posed little hazard to skunks or golden eagles. This information was considered in the updated environmental risk assessment for sodium monofluoroacetate.

2.4 Comments related to the lack of an aquatic risk assessment

Comments were received from non-governmental organizations stating that there is documented evidence of strychnine baits being laid on waterways in the Little Smoky region during the winter of 2018. Given the limited data available due to privacy concerns, the inadequacy of reporting and the failure to remove baits noted in PMRA documents, it is impossible to tell how many baits have been left on riverbeds to enter aquatic systems. There are endangered Athabasca rainbow trout in streams where strychnine is used.

Health Canada response

Strychnine and sodium monofluoroacetate are prohibited from use in aquatic systems. Unconsumed baits and poisoned carcasses must be retrieved and disposed of in accordance with label use directions. Despite this requirement, in the event that poisoned baits and carcasses are not disposed of properly, it is very unlikely that these products would enter aquatic systems at concentrations that would result in adverse effects. To support this assumption, a quantitative screening level aquatic risk assessment was conducted for the updated environmental risk assessment (refer to Science evaluation update, Section 3.3).

2.5 Comments related to the environmental risk from the use of the predacide products

Comments received from non-governmental organizations and the public stated that predacide products pose unacceptable environmental risks because they are indiscriminate poisons known to kill more non-target animals than target animals and that many baits are consumed without any carcasses being found/recovered. Additionally, these products have also been shown to kill endangered species.

Health Canada response

Comments and information received during the consultation period regarding non-target poisonings were considered resulting in an updated environmental risk assessment (refer to Science evaluation update, Section 3.2). The strychnine environmental risk assessment was updated to consider use records from 2006 to 2009 that showed that the majority of strychnine tablets used were consumed by animals and included field notes that reported that strychnine baits were frequently taken by animals without the recovery of carcasses. This information was not included in the records previously reviewed, and indicates that deaths of non-target species are likely significantly higher than reported. Based on the revised environmental risk assessment, all uses of strychnine are cancelled.

New data that would affect the environmental risk assessment for sodium monofluoroacetate were not provided during the public consultation.

3.0 Comments related to the value assessment

3.1 Comments related to alternatives that are safer and effective to prevent predation on farmed animals and for the protection of species at risk such as caribou

Comments received from non-governmental organizations and the public state that there are effective and viable alternative control methods that should be used in an Integrated Pest Management (IPM) program. Alternative approaches identified included oral vaccination for rabies in skunks, contraceptives, hunting and trapping. Few critically important mitigation measures to reduce human disturbance and preserve habitat in order to protect the caribou population have been implemented in government run programs.

The use of predacides should not be considered in isolation of other aggressive wolf management approaches and other environmental pressures (for example, habitat loss, climate change) on wolves. Alternative control measures are available should a rabies outbreak occur in skunks in Alberta. Concerns were raised that there is a lack of enforcement that predacides will be used as a last resort.

Health Canada response

Health Canada recognizes that alternative methods exist to prevent predation on farmed animals and to protect species at risk such as caribou and is in agreement that other control methods should be used. The availability of alternative methods does not prevent the registration of a pesticide provided that the potential risk to human health and the environment is acceptable and it has value when it is used as directed on the label. As per the labelled instructions, the use of predacide baits is intended to be used as a last resort when alternative methods have failed or are not practical. As such, the decision to use a predacide bait are better assessed at a site level. When alternative methods are used, it is expected that the use of predacides would be minimal and thus, the exposure to non-target animals would be minimal as well. To ensure that predacides are being used as a last resort, which is a risk mitigation measure, a Product Stewardship Program and additional reporting related to the use of alternative control methods are required when a predacide is used.

3.2 Comments related to value of predacide products in conservation programs and livestock protection programs

Comments received from non-governmental organizations and the public stated that the value of predacide products is unacceptably low given that placing indiscriminate poisons in the environment is not necessary or effective. Additionally, the Agency failed to conduct value assessments for both strychnine and sodium monofluoroacetate (Compound 1080). There is no statistical evidence of an impact of poisoning wolves on caribou population dynamics which is part of an ongoing scientific discussion of caribou conservation in the published literature, none of which were cited in the proposed re-evaluation decision. The years of combined effect of aerial shooting and poisoning of the wolf population as a result of Alberta's caribou management program has not been considered. Additionally, killing predators can cause increased predation as new predators move into control areas. However, other comments received from agricultural associations stated that predation losses are being experienced by livestock producers and that a reduction in availability of predacides would have negative economic, ecological, livestock welfare, and species preservation consequences.

Health Canada response

Before a pesticide is allowed to be used or sold in Canada, it must undergo a rigorous scientific assessment process that provides reasonable certainty that no harm to human health and the environment will result from exposure to it, and that it has value, when the pesticide is used according to label directions.

The value of a pesticide refers to the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration. A weight of evidence approach is used that includes the product's efficacy, effect on the site and the health, safety and environmental benefits derived from use of the product, as well as the social or economic impacts.

Strychnine and sodium monofluoroacetate (Compound 1080) kill target predators when bait is applied at rates indicated on the registered labels. Predators are known to kill livestock, and pose a risk to human safety. Health Canada recognises that there are risks inherent with predacide baiting including potential non-target exposures and secondary poisonings. Bait use is of value when alternative control methods have been ineffective or when they are not feasible. Labelled risk mitigation measures are required to minimize the inherent risks of bait use on non-target and secondary poisonings such as using baits as a last resort only when alternative control methods are ineffective or are not practical.

It is not within the mandate of the *Pest Control Products Act* to evaluate the successfulness of control methods, including lethal ones (for example, shooting, predacides), used in conservation programs such as the Government of Alberta's caribou protection plan. As such, this information was not considered in the re-evaluation of these predacides.

However, considering information received during the public consultation, Health Canada has determined that the environmental risks associated with the predacide use of strychnine are not acceptable due to risks to non-target animals and is now cancelled. Loss of strychnine is expected to have minimal impact as there are both non-lethal and lethal approaches available to manage predator problems. The use of sodium monofluoroacetate is acceptable for continued registration with the implementation of revised risk mitigation measures and Product Stewardship Program.

3.3 Comments related to the value of strychnine use in skunk rabies control program

Comments received from the public stated that strychnine has not been used to poison skunks in Alberta since 1998, therefore it should not remain registered.

Health Canada response

Rabies is a serious disease that has to be reported to the Canadian Food Inspection Agency (CFIA) under the *Health of Animals Act* and Regulations. It impacts the central nervous system of all mammals, including humans. Currently, skunk rabies has not been established in Alberta. It would have serious impacts on the economy, human health, domestic animal health and wildlife health; therefore, strychnine would have value for use to kill skunks in rabies control programs should an outbreak occur in Alberta. However, considering information received during the public consultation, Health Canada has determined that the environmental risks associated with the predacide use of strychnine are not acceptable due to risks to non-target animals and is now cancelled. Loss of this active ingredient is expected to have minimal impact as there are both non-lethal and lethal management methods available.

4.0 Comments related to risk mitigation measures

4.1 Comments on non-compliant use of predacide products

Comments received from non-governmental organizations and the public stated that the Government of Alberta has continuously failed to follow label requirements for predacide products despite being under a high level of scrutiny. These comments also state that there is no evidence that the Government of Alberta has adhered to the risk mitigation measures required as a result of the 2014 special review decision for sodium monofluoroacetate and; therefore, it is not possible to evaluate whether the mitigation measures have been effective. The comments added that amending the labels to tighten and clarify requirements will not ensure compliance and that the only environmentally safe option is to take the products off the market.

Health Canada response

The risk mitigation measures in PRVD2022-18 presented an approach to increase oversight and accountability when predacide products are used. The risk mitigation measures, including clarification of the limited situations in which these products are permitted to be used, and the product stewardship program are intended to improve reporting and proper handling of these products. As a result of this re-evaluation decision, all uses of strychnine are cancelled. The registrant of sodium monofluoroacetate will be required to develop and implement a training program for its use to emphasize the requirement to follow label directions, educate users on appropriate disposal methods, educate users that predacides are to be used in an Integrated Pest Management (IPM) program and only when other management approaches have been attempted and deemed not feasible or effective, and monitor and maintain records on use of predacides via the "Vertebrate Toxicant Usage Record" (Appendix V). For any activity not in accordance with label requirements, registrants are to notify Health Canada within 24 hours and cease any further use of the predacide. Should non-compliance be determined, Health Canada will take enforcement action. Health Canada may request these records at any time for review and will initiate compliance and enforcement action if required.

4.2 Comments on the additional requirement for a pesticide applicator certificate

Comments received from municipalities questioned the additional requirement for a pesticide applicator certificate. Many municipalities do not have the resources to provide the level of service required for staff to apply the sodium monofluoroacetate baits and this would not allow farmers/producers to apply directly. Workplace Hazardous Materials Information System (WHMIS) training should be sufficient. Agricultural producers may receive toxicant specific education through the existing Alberta Farmer Certification Program for restricted use pesticides. Alternative amendment to the label could be: "Only to be sold to and used by individuals holding an appropriate pesticide applicator Certificate, or completion of the Farmers Certification Course, as recognized by the province of Alberta".

Health Canada response

The additional restriction to add label statement, “Only be sold and used by individuals holding an appropriate pesticide applicator certificate or license recognized by the province of Alberta”, is to ensure that users have received the proper training supported by a valid provincially recognized certificate or license that meets the Standard for Pesticide Education, Training and Certification in Canada. Users must be educated to follow the label use directions and that predacides are to be used in an Integrated Pest Management (IPM) program and only when other non-lethal and lethal strategies have failed or are not logistically possible. As a result of this re-evaluation decision, application of a predacide product is not permitted by those who do not possess a valid applicator certificate or licence recognized by the province of Alberta.

4.3 Comments on storage stability of sodium monofluoroacetate tablets

Comments received from non-governmental organizations stated that many use records submitted to the PMRA provide evidence that sodium monofluoroacetate tablets deteriorate (crumbling, melting together) while in storage. This makes safe handling, accurate record keeping of stock and deployment of an appropriate quantity impossible.

Health Canada response

Use records considered in this re-evaluation did report that some tablets showed signs of deterioration; however, they also indicated that these tablets were returned to the registrant for disposal. There were no indications that deteriorated tablets were deployed for use in the field, nor that this would affect the safe use of the product. Additionally, pesticide registrants are required, as per the Pest Control Products Incident Reporting Regulations (IRR), to report all incidents associated with the use of their product to the Pest Management Regulatory Agency. This includes any incidents associated with the packaging of the product either during use or storage.

4.4 Comments on the requirement for incineration of carcasses

Comments received from the registrant and municipalities questioned the requirement for incineration of carcasses, who will pay for the cost of incineration, and whether facilities are aware of this requirement. Additionally, disposal of unconsumed carcasses by incineration would not be feasible as incineration services are not available throughout the province of Alberta.

Health Canada response

Currently registered labels of predacide products require unconsumed poisoned/treated baits to be burned at high temperature or buried to a depth of 46–60 cm. There exist incineration requirements for carcasses (target and non-target) on labels for strychnine; however, this is not specified on labels for sodium monofluoroacetate. As presented in PRVD2022-18, it was proposed that all predacide labels require incineration of unconsumed poisoned baits and all carcasses at an approved provincial treatment facility and in accordance with provincial requirements.

This requirement was intended to reduce the hazard of secondary poisoning of non-target organisms and to minimize human exposure. This method of disposal was consistent with the Alberta Fish and Wildlife Division procedures for the *Use, Storage and Handling of Vertebrate Toxicants for Problem Wildlife Control and Wildlife Management* document.

Considering information received during the public consultation, Health Canada has determined that the environmental risks associated with the predacide use of strychnine are not acceptable due to risks to non-target animals and therefore, strychnine is cancelled.

The use of sodium monofluoroacetate is acceptable for continued registration with the implementation of revised risk mitigation measures and Product Stewardship Program. However, incineration requirements for unconsumed poisoned baits and carcasses are no longer part of the re-evaluation decision. The existing disposal requirements for unconsumed poisoned baits and poisoned carcasses (burning or burial to 60 cm) are considered sufficient to mitigate risks to non-target species and minimize human exposure.

4.5 Comments related to the product stewardship program

The registrant provided information on current training procedures and proposed revisions in order to address required components of the product stewardship program, potential for electronic documentation for a "toxicant use record" and relating to site visits, search time and ability to oversee use across various municipalities in Alberta.

Health Canada response

Health Canada acknowledges the registrant's submission of information regarding the product stewardship program and toxicant use record requirements. As part of the re-evaluation decision, a product stewardship program (PSP) for sodium monofluoracetate product will be required to be implemented within 24 months from the date of the publication of this final decision document. A PSP is not required for strychnine products as they are cancelled.

The registrant of sodium monofluoroacetate product will be required to submit a PSP that details how the minimum requirements and goals of the PSP will be addressed. The PSP must include plans for the development and implementation of a training program for the use of sodium monofluoroacetate that emphasizes the requirement to follow the label directions, educates users on appropriate disposal methods, and that Sodium Monofluoroacete Predacide is to be used in an Integrated Pest Management (IPM) program and only when other management methods have been attempted and deemed not feasible or effective. The PSP must also include information on the implementation of the "Vertebrate Toxicant Usage Record" with clear guidance on how these records will be maintained, monitored and made available to Health Canada upon request. The PSP must also include a mechanism to cease the use of Sodium Monofluoroacete Predacide when use records submitted to the registrant show that the use of the product was not compliant with the label use directions.

The PSP will be reviewed by Health Canada to determine if it meets the goals of the PSP as outlined in this re-evaluation decision. Health Canada will monitor the implementation of the PSP and engage with the registrant if adjustments are required.

5.0 Other comments

5.1 Comments relating to Alberta Ministry staff not complying with their own Act, regulations and policies

Comments were received from non-governmental organizations stating that there is evidence that the Government of Alberta is not complying with their own regulations and policies. The comments noted that, despite Freedom of Information requests, evidence was not received that proper documentation, as required by the Alberta *Agricultural Pests Act*, was completed prior to the use of sodium monofluoroacetate to control wolves by an employee of the Ministry of Justice and Solicitor General of Alberta. For non-governmental organizations, it is questionable whether Alberta Ministry staff are complying with their own Act, regulations and policies.

Health Canada response

In accordance with the PCPA, Health Canada requires that pest control products are used in accordance with their registered labels. It is not the jurisdiction of Health Canada to enforce the Government of Alberta's legislation or policies; however, it should be noted that Fish and Wildlife Officers of the Government of Alberta are permitted to use Sodium Monofluoroacetate Predacide (Reg. No. 18300) to control wolves preying on livestock. They are listed as a separate user from those authorized to use the product under the Alberta *Agricultural Pests Act*.

5.2 Comments related to revised use directions for Compound 1080

A comment was received from the registrant regarding the following existing label statement:

> "For use by Alberta Fish and Wildlife Services personnel on public land where predation of domestic animals or other problems occur requiring coyote removal."

which was proposed to be updated to:

> "On public land this is for use only by designated Fish and Wildlife Officers in the Alberta Government where predation of livestock by coyotes has been confirmed within the past 30 days."

The comment indicated that Fish and Wildlife Officers do not look after coyote control on public land in Alberta. As per the *Agricultural Pest Act* the "occupant" means a person occupying or exercising control or having the right to occupy or exercise control over land or property. For the holders of grazing leases which occur on public land, they are the "occupant" and can control coyotes on this land within the period of their lease.

Health Canada response

The existing label statement indicated that Alberta Fish and Wildlife Services personnel are permitted to use Sodium Monofluoroacetate Predacide on public land where predation has occurred. As per PRVD2022-18, the wording of this statement was improved for clarity. If the reference to Fish and Wildlife Officers is not accurate, the registrant may amend the statement or remove it as part of an application to amend the product label of sodium monofluoroacete submitted to Health Canada's Pest Management Regulatory Agency.

5.3 Comments relating to humaneness

The majority of comments received during the consultation of PRVD2022-18 were part of a letter-writing campaign indicating that predacide use is inhumane, expressing concerns for animal welfare, and that these products should be banned.

Health Canada response

Health Canada's Pest Management Regulatory Agency published a consultation document, Humane Vertebrate Pest Control, in December 2018 seeking input from Canadians on how the humaneness of pesticides to control vertebrate predators could be considered during their approval and use. Consultation Summary – Humane Vertebrate Pest Control was published in January 2021 presenting an overview of the comments received and the Agency's next steps. As a result of the consultation, Health Canada determined that it will not be taking steps towards incorporating humaneness considerations into the pesticide risk assessment framework. There are currently no internationally recognized science-based parameters to evaluate the humaneness of pesticides, and no new information on this topic was brought forward during the consultation process. Note that provincial and territorial governments are responsible for and have measures in place to address both wildlife management and animal welfare. Therefore, an evaluation of humaneness was not part of the re-evaluation on the predacides uses of strychnine and sodium monofluoroacetate.

Appendix IV Revised environmental risk assessment tables

Table 1 Summary of strychnine use in the government of Alberta caribou recovery program between 2006 and 2009

Year	Total number of sites	Total number of strychnine tablets used	Total number of poisoned baits	Total number of strychnine tablets recovered	Number of wolves killed	Non-target animals killed	Number of tablets not recovered (assumed consumed)	% of strychnine assumed consumed	Number of strychnine tablets/wolf confirmed killed
2006	15	810	180	70	17	6 coyotes 8 ravens	740	91.4	43.5
2007	15	1086	183	38	11	3 coyotes 7 ravens 8 foxes 1 fisher	1048	96.5	95.3
2008	22	1736	264	80	18	7 coyotes 17 ravens 9 foxes 3 lynx 1 weasel	1656	95.4	92.0
2009	30	1134	363	21	16	9 coyotes 8 ravens 6 foxes	1113	98.2	69.6

Table 2 Overview of the population status of non-target species found at strychnine bait sites

Species	Reported deaths from:		Estimated population in Canada	Status	Comment
	Use records (2005–2021)	Incident reports			
Common raven (*Corvus corax*)	304	8	500 000 to 5 000 000 in Canada[(1)]	SARA: not listed COSEWIC: no designation Alberta (2020): Secure	Strong and continuing population gains across the country suggest that there is little conservation concern for this species.[(1)]

Species	Reported deaths from:		Estimated population in Canada	Status	Comment
	Use records (2005–2021)	Incident reports			
Coyote (*Canis latrans*)	125	2	Data not found	SARA: not listed COSEWIC: no designation Alberta (2020): Secure	Coyote populations and range appear to be spreading across Canada.
Black-billed magpie (*Pica hudsonia*)	35	0	500 000 to 5 000 000 in Canada[(1)]	SARA: not listed COSEWIC: no designation Alberta (2020): Secure	This species is well monitored by the Breeding Bird Survey and shows little overall population change relative to ~1970. There are no pressing conservation concerns for this species; however, it has been identified as a priority for Bird Conservation Regions 6 (Boreal Taiga Plains)[(2)] and 11 (Prairie Potholes)[(3)] in Alberta. The population objectives are to maintain the current population (stable) via regional stewardship.
Red fox (*Vulpes vulpes*)	83	0	Data not found	SARA: not listed COSEWIC: no designation Alberta (2020): Secure	The red fox is one of Canada's most widespread mammals.[(4)] The Government of Alberta allows red foxes to be hunted year-round by residents without a license on properties for which they have right of access.[(5)]
Fisher (*Martes pennanti*)	4	0	Data not found	SARA: not listed COSEWIC: no designation Alberta (2020): Sensitive	According to the Government of Alberta,[(6)] the species is considered uncommon to rare. The population status is unknown, and trends in population and distribution are uncertain. Current forestry practices may reduce availability of preferred habitat. The fisher harvest has declined since 1985.
Canada lynx (*Lynx canadensis*	7	1	Data not found	SARA: not listed COSEWIC: Not at Risk Alberta (2020): Sensitive	According to the Government of Alberta,[(6)] the lynx is a cyclic species, with fewer than an estimated 8000 individuals in Alberta at the bottom of the cycle. The population has decreased in recent years and some concern exists over habitat loss and fragmentation.

Species	Reported deaths from:		Estimated population in Canada	Status	Comment
	Use records (2005–2021)	Incident reports			
Bald eagle (*Haliaeetus leucocephalus*)	2	0	500 000 to 5 000 000 in Canada[1]	SARA: not listed COSEWIC: Not at Risk Alberta (2020): Sensitive	According to the Government of Alberta,[6] this species was once at risk throughout its North American range but is now recovering. It has a low density in Alberta and its nests are vulnerable to human disturbance.
Golden eagle (*Aquila chrysaetos*)	3	0	500 000 to 5 000 000 in Canada[1]	SARA: not listed COSEWIC: Not at Risk Alberta (2020): Sensitive	According to the most recent estimate by the Government of Alberta,[6] there are 100-250 breeding pairs in Alberta. Disturbance from human-related activities is the greatest threat.
Weasel (species not reported)	3	0	The weasel species found was not reported. There are two species of weasel in Alberta. The least weasel (*Mustela nivalis*) is designated as "Secure" in Alberta while the long-tailed weasel (*Mutela frenata*) is designated as "May be at Risk". COSEWIC has designated the long-tailed weasel as "Not at Risk" (last assessed in 1993).		
Ermine (*Mustela erminea*)	1	0	Data not found	SARA: not listed COSEWIC: no designation Alberta (2020): Secure	The ermine population in Alberta is considered to be secure.
Striped skunk (*Mephitis mephitis*)	2	0	Data not found	SARA: not listed COSEWIC: no designation Alberta (2020): Secure	The striped skunk population in Alberta is considered to be secure.
Grizzly bear (*Ursus arctos*)	1	1	20 000 (691 in western Alberta)[7]	SARA: Special Concern COSEWIC: Special Concern Alberta (2020): At Risk	According to the Government of Alberta[7], population estimates are currently underway. Greatest threat is loss and degradation of wilderness habitats through resource extraction and recreational development.

Species	Reported deaths from:		Estimated population in Canada	Status	Comment
	Use records (2005–2021)	Incident reports			
American crow (*Corvus brachyrhynchos*)	1	0	5 000 000 to 50 000 000 adults[(1)]	SARA: not listed COSEWIC: no designation Alberta (2020): Secure	Little change in the population relative to ~1970.[(1)]
Gray jay (*Perisoreus canadensis*)	1	0	500 000 to 5 000 000[(1)]	SARA: not listed COSEWIC: no designation Alberta (2020): Secure	Both the Christmas Bird Count and Breeding Bird Survey suggest little overall change in abundance since the 1970s; however, the northern portion of the population is not well covered by either survey. The gray jay has been identified as a priority for conservation and/or stewardship in several Bird Conservation Region Strategies in Canada; however, none of these are in Alberta.[(1)]
American mink (*Neovison vison*)	1	0	Data not found	SARA: not listed COSEWIC: no designation Alberta (2020): Secure	The American mink population in Alberta is considered to be secure.
Great grey owl	0	1	50 000 to 500 000 adults[(1)]	SARA: not listed COSEWIC: Not at Risk Alberta (2020): Sensitive	According to the Government of Alberta[(6)], this is a naturally scarce species that is widely distributed in foothills and boreal habitats. It is vulnerable to harvest of mature forests as it requires stands of mature forest for nesting.
Marten (*Martes americana*)	4	0	Data outside of the Newfoundland and Labrador population not found	SARA: Newfoundland and Labrador population "Threatened"; Alberta population not listed COSEWIC: Newfoundland and Labrador population	The marten population in Alberta is considered to be secure.

Species	Reported deaths from:		Estimated population in Canada	Status	Comment
	Use records (2005–2021)	Incident reports			
				"Threatened"; Alberta population not listed Alberta (2020): Secure	
Wolverine (*Gulo gulo*)	0	0	Western subpopulation (Canada to the west of Ontario): 15 688–23 830 adults[8]	SARA: Special concern COSEWIC: Special concern Alberta (2020): May Be at Risk	The population estimate presented assumes that trapping effort is constant and that wolverine densities are relatively uniform across the range. According to the Government of Alberta,[6] an uncertain provincial estimate of <1000 has been proposed. Trends in distribution and population unknown but the populations may be declining. The PMRA has not received reports of wolverine deaths due to strychnine; however, Alberta has identified its predator and/or rabies control programs as a threat to this species (PMRA No. 3478749). An incident report submitted to Health Canada by a trapper notes that wolverine, which were once plentiful in their area, appear to have disappeared in the last decade.
Swift fox (*Vulpes velox*)	0	0	445 adults[9]	SARA: Threatened COSEWIC: Threatened Alberta (2020): At Risk	According to the Government of Alberta,[6] this species was extirpated. The ability to maintain reintroduced population is uncertain, but recent census data are encouraging. It is designated as "Endangered" under the Alberta *Wildlife Act*. The current population of swift fox in Canada is the result of reintroductions. Predacides have been identified as an important limiting threat for the species. No reports of swift fox poisonings by strychnine have been reported to Health Canada.
American badger (*Taxidea taxus taxus*)	0	0	17,700 to 43,900 (Alberta, Saskatchewan and Manitoba)[10]	SARA: Special concern COSEWIC: Special concern	According to the Government of Alberta,[6] badgers have likely declined on a provincial scale but have increased at smaller scales around the

Species	Reported deaths from:		Estimated population in Canada	Status	Comment
	Use records (2005–2021)	Incident reports			
				Alberta (2020): Sensitive	province. The population is dependent on fluctuating ground squirrel populations. Health Canada has not received reports of badger poisonings by strychnine; however, as a carrion-consuming animal, the badger would be at risk of primary and secondary poisoning when feeding on strychnine-poisoned carcasses.

SARA: *Species at Risk Act*

(1) Environment and Climate Change Canada, 2019. The status of Birds in Canada Website, Data-version 2019. Environment and Climate Change Canada, Gatineau, Quebec, K1A 0H3. https://wildlife-species.canada.ca/bird-status/com-com-eng.aspx?sY=2019&sL=e. PMRA No. 3478749.
(2) Environment Canada, 2013. Bird Conservation Strategy for Bird Conservation Region 6: Boreal Taiga Plains. Abridged Version. August 2013. PMRA No. 3478755.
(3) Environment Canada, 2013. Bird Conservation Strategy for Bird Conservation Region 11 in the Prairie and Northern Region: Prairie Potholes. Abridged Version. August 2013. PMRA No. 3478760.
(4) Environment and Climate Change Canada. Hinterland Who's Who. 1993. https://www.hww.ca/en/wildlife/mammals/red-fox.html . Accessed April 6, 2023. PMRA No. 3478764.
(5) Government of Alberta, 2023. Foxes. https://www.alberta.ca/foxes.aspx. Accessed April 6, 2023. PMRA No. 3478765.
(6) Government of Alberta, 2022. Alberta wild species status. November 7, 2022. https://www.alberta.ca/lookup/wild-species-status-search.aspx . PMRA No. 3478768.
(7) Parks Canada, 2023. Bears in the mountain national parks. Grizzly bears. Accessed June 22, 2023. https://parks.canada.ca/pn-np/mtn/ours-bears/generaux-basics/grizzli-grizzly. PMRA No. 3478769.
(8) COSEWIC. 2014. COSEWIC assessment and status report on the Wolverine *Gulo gulo* in Canada. Committee on the Status of Endangered Wildlife in Canada. Ottawa. xi + 76 pp. PMRA No. 3478771.
(9) COSEWIC. 2021. COSEWIC assessment and status report on the Swift Fox *Vulpes velox* in Canada. Committee on the Status of Endangered Wildlife in Canada. Ottawa. xii + 61 pp. PMRA No. 3478748.
(10) COSEWIC. 2012. COSEWIC assessment and status report on the American Badger Taxidea taxus in Canada. Committee on the Status of Endangered Wildlife in Canada. Ottawa. iv + 63 pp. PMRA No. 3478551.

Table 3 Sodium monofluoroacetate acute oral LD_{50} values for bird and mammals

Species	LD_{50} value (mg a.i./kg bw)	Toxicity classification[a]
Mammalian endpoints		
Rats	0.1–0.22	Very highly toxic
Coyotes	0.12	Very highly toxic
Dogs	0.066	Very highly toxic
Mice	0.50	Very highly toxic

Rabbits	0.34	Very highly toxic
Cotton rat	0.1	Very highly toxic
Deer mouse	4.0	Very highly toxic
Raccoon	1.1	Very highly toxic
Opossum	41.6	Highly toxic
Skunk	1.0	Very highly toxic
Avian endpoints		
Mallard	9.1	Very highly toxic
Chukar	3.5	Very highly toxic
Ring-neck pheasant	6.4	Very highly toxic
Widgeon	3.0	Very highly toxic
Golden eagle	5.0	Very highly toxic
Black vulture	15.0	Highly toxic
Black-billed magpie	1.0 - 2.3	Very highly toxic
Data from the USEPA RED for sodium monofluoroacetate (Compound 1080) (USEPA 738-R-95-025; PMRA No. 2223915). [a]According to the USEPA toxicity classification		

Table 4 Estimated amount of tissue that a scavenger would need to eat to reach its LD_{50} for sodium monofluoroacetate

Species	Weight (kg)	LD_{50} (mg a.i./kg)	LD_{50} dose (mg)	Amount of tissue (kg) a scavenger would need to eat to reach the LD_{50}					
				Muscle (0.29 ppm a.i.) (1)	Small Intestine (0.30 ppm a.i.) (1)	Stomach (0.31 ppm a.i.) (1)	Muscle (0.66 ppm a.i.) (2)	Small Intestine (0.79 ppm a.i.) (2)	Stomach (0.76 ppm a.i.) (2)
Coyote(3)	11.4	0.1	1.14	3.93	3.80	3.68	1.7	1.4	1.5
Dog	1.4	0.066	0.09	0.31	0.30	0.29	0.14	0.11	0.12
Raccoon	3.5	1.1	3.85	13	13	12	5.8	4.9	5.1
Skunk(3)	3.18	1	3.18	11	11	10	4.8	4.0	4.2

Species	Weight (kg)	LD_{50} (mg a.i./kg)	LD_{50} dose (mg)	Amount of tissue (kg) a scavenger would need to eat to reach the LD_{50}					
				Muscle (0.29 ppm a.i.) (1)	Small Intestine (0.30 ppm a.i.) (1)	Stomach (0.31 ppm a.i.) (1)	Muscle (0.66 ppm a.i.) (2)	Small Intestine (0.79 ppm a.i.) (2)	Stomach (0.76 ppm a.i.) (2)
Black vulture(3)	2	15	30	103	100	97	45	38	39
Golden eagle(3)	4.54	5	22.7	78	76	73	34	29	30
Black-billed magpie(3)	0.18	1	0.18	0.62	0.60	0.58	0.27	0.23	0.24

(1) Average sodium monofluoroacetate residue concentrations in tissues from coyotes poisoned by 5 to 15 mg of sodium monofluoroacetate from Burns et al., (1986; PMRA No. 3478775), as determined for PACR2004-20 (PMRA No. 901191).

(2) Maximum sodium monofluoroacetate residue concentrations in tissues from coyotes poisoned by 5 to 15 mg of sodium monofluoroacetate, reported in Burns et al., (1986; PMRA No. 3478775).

(3) For animals with this footnote, the amount of tissue a scavenger would need to eat to reach the LD_{50} based on average tissue concentration (footnote 2) was determined for PACR2004-20 (PMRA No. 901191). Values for animals without these footnotes were calculated for this submission; the weight for these animals was based on the low end of the typical range for the species.

Table 5 Screening level risk assessment for aquatic organisms

Species	EEC (mg a.i./L)	Endpoint	Uncertainty factor	Effects metric (mg a.i./L)	RQ	LOC	RQ > LOC?
Strychnine(1)							
Daphnia magna	0.0007	48-h EC_{50} = 10 mg a.i./L	2	5	0.00014	1	No
Rainbow trout	0.0007	96-h LC_{50} = 2.3 mg a.i./L	10	0.23	0.0030	1	No

Species	EEC (mg a.i./L)	Endpoint	Uncertainty factor	Effects metric (mg a.i./L)	RQ	LOC	RQ > LOC?
Bluegill sunfish	0.0007	96-h EC_{50} = 0.76 mg a.i./L	10	0.076	0.0092	1	No
Amphibian (bluegill surrogate)	0.0037	96-h EC_{50} = 0.76 mg a.i./L	10	0.076	0.049	1	No
Sodium monofluoroacetate(2)							
Daphnia magna	0.00001125	48-h EC_{50} = 350 mg a.i./L	2	175	6.43E-08	1	No
Rainbow trout	0.00001125	96-h LC_{50} = 54 mg a.i./L	10	5.4	2.08E-06	1	No
Bluegill sunfish	0.00001125	96-h LC_{50} = 970 mg a.i./L	10	97	1.16E-07	1	No
Amphibian (rainbow trout surrogate)	0.00006	96-h LC_{50} = 54 mg a.i./L	10	5.4	1.11E-05	1	No

(1) Strychnine endpoints were used in PACR2005-08 (PMRA No. 2771750) and were originally obtained from the USEPA RED for strychnine (PMRA No. 3203172).

(2) Sodium monofluoroacetate endpoints were used in PACR2004-20 (PMRA No. 901191) and were originally obtained from the USEPA RED for sodium monofluoroacetate (PMRA No. 2223915).

Appendix V Label amendments for Sodium Monofluoroacetate Predacide (Registration Number 18300)

Information on approved labels of currently registered products should not be removed unless it contradicts the label statements provided below.

1) PRIMARY DISPLAY PANEL

Replace:

> COYOTE CONTROL AND WOLF CONTROL

With:

> FOR USE IN LIMITED SITUATIONS AS DESCRIBED UNDER RESTRICTED USES TO KILL COYOTES AND WOLVES

The principal display panel must prominently show the statement "READ THE LABEL AND ACCOMPANYING BROCHURE (or LEAFLET) BEFORE USING." and the brochure or leaflet must contain all of the information that is to be shown on the principal and secondary display panels in addition to the specified information.

Replace:

> READ THE LABEL BEFORE USING

With:

> READ THE LABEL AND ACCOMPANYING BROCHURE (or LEAFLET) BEFORE USING

Add the following statements:

> STORE THIS PRODUCT UNDER LOCK AND KEY
>
> A VERTEBRATE TOXICANT USAGE RECORD MUST BE WRITTEN AND COMPLETED WITH THE USE OF THIS PRODUCT

Under NET CONTENTS, text must be revised to specify the total weight and number of tablets per container using the following format: *Total weight* (*Number of tablets* at 5 mg per tablet).

Following NET CONTENTS, revise the currently labelled registrant contact information in accordance with label requirements:

- the registrant's name; and
- the name, postal address and telephone number of a contact person in Canada to which public inquiries may be directed.

2) SECONDARY DISPLAY PANEL

For all restricted class products, the NOTICE TO USER section must appear prominently at the top of the secondary display panel, followed by these sections: "NATURE OF RESTRICTION", "RESTRICTED USES" and "DIRECTIONS FOR USE". All of these sections must be placed in a box to set the information apart from all other information that is required to be shown on the secondary display panel.

Under NOTICE TO USER

Replace:

> This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label. The user assumes the risk to persons or property that arises from any such use of this product.

With:

> This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label.

Under NATURE OF RESTRICTION

Add the following:

> Only to be sold to and used by individuals holding an appropriate pesticide applicator certificate or license recognized by the province of Alberta.
>
> Applicators must complete all required training under the registrant's Product Stewardship Program relating to the handling and use of this product, disposal methods, and an Integrated Predator Management Program.
>
> Replace:
>
> This product is for storage, use and handling only by persons authorized under the Alberta Agricultural Pests Act and by designated Fish and Wildlife Officers of the Government of Alberta.
>
> With:
>
> For coyote uses:
>
> On public land, Sodium Monofluoroacetate Predacide is for storage, use and handling only by designated Fish and Wildlife Officers of the Alberta Government. On private land, this product is for storage, use and handling by persons authorized under the Alberta *Agricultural Pests Act*.

For wolf uses:

Sodium Monofluoroacetate Predacide is for storage, use and handling only by designated Fish and Wildlife Officers of the Alberta Government.

Under RESTRICTED USE

Immediately following RESTRICTED USES, add the following revised text for **Use Limitations**, delete old text from label:

Use Limitations

Use Limitations Applicable to Both Coyote and Wolf Uses

1. For use only after alternative predator management strategies have failed or when there are no other practical alternative predator management strategies as outlined in an Integrated Predator Management Program. For additional details, refer to the Vertebrate Toxicant Usage Record included in this label/brochure (or leaflet).
2. DO NOT apply this product if species at risk (for example the swift fox) that may feed on sodium monofluoroacetate baits or on poisoned carcasses are present in your (local or specific) area. For information on species at risk in your area, contact the Fish and Wildlife Division of Alberta Environment and Protected Areas.
3. At the time of application, the applicator must post warning signs at all normal access points to and where poisoned baits are set. Signs must include as a minimum the following information: the signal word DANGER, the statement "DO NOT ENTER. TOXIC BAITING IN PROGRESS. Keep children, dogs, and other domestic animals out of the area.", the date and time baiting began and when baits will be removed, the product name, active ingredient, registration number, registrant name, and the contact information for the responsible applicator.
4. Signs must remain in place for the entire duration that the baits remain in the treatment area. Signs are to be removed only at the end of the treatment (i.e., once all baits and carcasses are removed from the area for disposal).
5. The applicator must provide a copy of this label and accompanying brochure (or leaflet) to the landholder on whose land Sodium Monofluoroacetate Predacide tablets are being used.
6. For each use of Sodium Monofluoroacetate Predacide, the applicator must complete the Vertebrate Toxicant Usage Record at each visit to a baiting site.
7. The applicator must inspect poisoned baits at least every 7 days, or require the landholder to inspect and report back to the applicator accordingly. If any sodium monofluoroacetate baits are found exposed and are to remain in place during treatment, baits must be recovered with loose soil or snow in accordance with the use directions on this label/brochure (or leaflet).
8. At the end of treatment, the applicator must provide a completed copy of the Vertebrate Toxicant Usage Record to the landholder (if applicable) and submit completed copies of the Vertebrate Toxicant Usage Record to the registrant.
9. The applicator must remove and destroy all poisoned baits within 15 days of initial placement.

10. To prevent poisoning of non-target animals, all unconsumed poisoned baits removed from use and carcasses of poisoned animals must be burned or buried to a depth of 60 cm (2 feet). Unused, damaged or unusable Sodium Monofluoroacetate Predacide product and empty product containers must be disposed of at an approved provincial treatment facility and in accordance with provincial requirements.

Additional Use Limitations Specific to Coyote Uses

1. For use only to kill offending problem coyotes in livestock (including game) production where herd or flock management is practiced and coyote predation has been confirmed within the last 30 days. An Integrated Predator Management Program for Livestock that includes the use of alternative management approaches must be available and employed at the treatment site prior to the use of this product. Sodium Monofluoroacetate Predacide tablets must be used as a last resort when all other livestock protection approaches have failed or are not practical. Refer to the Vertebrate Toxicant Usage Record in this label/brochure (or leaflet) for more details.
2. Sodium Monofluoroacetate Predacide tablets must not be set within 800 metres from the boundary of a hamlet, village, town or city, nor closer than 400 metres to a residence except that of the landholder who has approved the use of Sodium Monofluoroacetate Predacide tablets.

Additional Use Limitations Specific to Wolf Uses

1. For use as a last resort when all other alternative management approaches have failed or are not practical in the following situations:
    a. to kill offending problem wolves in livestock (including game) where wolf predation has been confirmed within the last 30 days.
    b. where predation has been identified as one of the primary factors impacting a wildlife population designated as a Species at Risk under Canada's *Species At Risk Act* or Alberta's *Wildlife Act* as outlined in a Species at Risk Conservation Program under official approval by the Minister responsible for wildlife.
    c. where a serious threat to human safety from wolves exists.
2. An Integrated Predator Management Program tailored to the use pattern (i.e., Livestock Protection, Conservation, Human Safety) that includes the use of alternative management approaches must be available and employed at the treatment site prior to the use of this product. Sodium Monofluoroacetate Predacide tablets must be used as a last resort when all other approaches have failed or are not practical. Refer to the Vertebrate Toxicant Usage Record for more details.
3. DO NOT set baits within 800 metres of an inhabited dwelling.

Following the Use Limitations section, add section title **DIRECTIONS FOR USE**.

Under **DIRECTIONS FOR USE**, replace application instructions for COYOTE and WOLF with the following:

COYOTE

DO NOT use single dose baits in conjunction with multi dose baits. Apply either as:

Single Dose Bait:

Place one Sodium Monofluroacetate Predacide tablet into a meat bait of about 100 g (e.g., chicken head). Place up to three of these poisoned baits at a site where livestock has been killed by a coyote within the past 30 days. Cover the sodium monofluroacetate bait with 15 cm of loose soil or 30 cm of snow at the treatment site.

OR

Multi Dose Bait:

For targeting specific coyotes, place up to three Sodium Monofluroacetate Predacide tablets into a carcass of an animal killed by a coyote at the predation site within the last 30 days. For targeting multiple coyotes, place up to six Sodium Monofluroacetate Predacide tablets into a carcass of an animal killed by coyotes at the predation site within the last 30 days. To prevent exposure and minimize hazard to birds, place Sodium Monofluroacetate Predacide tablets in the carcass in a manner that is protected by intact hide or on the underside of the carcass and then cover sodium monofluroacetate baits with 15 cm of loose soil or 30 cm of snow at the treatment site

WOLF

DO NOT use small baits in conjunction with large baits. Apply either as:

Small Bait:

Place three Sodium Monofluroacetate Predacide tablets into a meat bait of about 100 g. Conceal up to six of these sodium monofluroacetate baits either along trails leading to an unpoisoned carcass or in a circle around an unpoisoned carcass. Cover sodium monofluroacetate baits with 15 cm of loose soil or 30 cm of snow at the treatment site.

OR

Large Bait:

Place up to twelve Sodium Monofluroacetate Predacide tablets into a carcass that is securely anchored. To prevent exposure and minimize hazard to birds, place Sodium Monofluroacetate Predacide tablets in the carcass in a manner that is protected by intact hide or on the underside of the carcass and then cover the sodium monofluroacetate baits with 15 cm of loose soil or 30 cm of snow at the treatment site.

3) PRECAUTIONS

Replace:

Wear gloves when handling tablets.

With:

> Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes when handling the product, or when handling poisoned baits and poisoned carcasses.

4) DISPOSAL

Replace:

> Burn unconsumed poisoned baits, toxicant containers and damaged or unusable tablets at high temperature or bury to a depth of 60 cm. For information on the disposal of unused, unwanted product and the cleanup of spills contact the provincial regulatory agency or the manufacturer.

With:

> Unused, damaged or unusable Sodium Monofluoroacetate Predacide product and empty product containers must be disposed of at an approved provincial treatment facility and in accordance with provincial requirements. Contact the registrant and the provincial regulatory agency in case of a spill, and for clean-up of spills.
>
> All unconsumed poisoned baits removed from use and carcasses of poisoned animals must be burned or buried to a depth of 60 cm (2 feet). An inventory of the disposal of poisoned baits and carcasses of poisoned animals must be recorded in the Vertebrate Toxicant Usage Record.

5) VERTEBRATE TOXICANT USAGE RECORD

Add new section **VERTEBRATE TOXICANT USAGE RECORD** at the end of the label/brochure (or leaflet).

Add the following table:

Vertebrate Toxicant Usage Record[1, 2]	
Applicator information (Name / Title / Role / Organization)	
Provincial Applicator Certification Number	
Type of Applicator (One of the following: Government employee, Landholder or Other – specify)	
Toxicant used including Pest Control Product Registration Number	SODIUM MONOFLUOROACETATE PREDACIDE (Reg. No. 18300)
Type of land ownership (i.e., Private or Public)	
Site location. Please include landholder name (if applicable), address, lot number, township identifying information and other identifying information (for example, directions and distance from a permanent landmark and/or GPS coordinates).	

Vertebrate Toxicant Usage Record[1, 2]						
Target predator species (i.e., coyote or wolf)						
Reason for using this product (i.e., Livestock protection; Conservation program; Human safety)						
What alternative pest management approaches were used at the site?						
Rationale as to why this product was used rather than alternative predator management practices.[3]						
Are species at risk that could be exposed to the toxicant known to be present in the area? If so, what species?						
Rationale as to why the use of this toxicant will not affect species at risk.						
SITE VISIT RECORD SECTION						
Site visit (to be conducted at least every 7 days)	**Bait placement**	**Site visit #1**	**Site visit #2**	**Site visit #3**	**Site visit #n**	**Site closure**
Date:						
Days elapsed since the last site visit						
Number of tablets used						
Method of poisoned-bait placement (For coyotes – single or multi-dose bait. For wolves – small or large bait.						
Amount of poisoned-bait consumed/missing						
Amount of poisoned-bait retrieved						
Amount of poisoned-bait disposed of						
Method of poisoned-bait disposal						
Amount of time spent searching for carcasses/distance (area) searched						
Target species: species and number of carcasses retrieved						
Non-target organisms: species and number of carcasses retrieved. Also, submit a Mandatory Incident Reporting Form as per the requirements prescribed in the Incident Reporting Regulations[4].						
Date of carcass disposal						
Method of carcass disposal						
Additional notes						
APPLICATOR ATTESTATION SECTION						
I confirm that I am authorized to use this product as per the product label, and that I have read and understood the label and brochure (or leaflet) before use.	**Initials:**					
I confirm that I have completed all required training under the registrant's Product Stewardship Program relating to this product.	**Initials:**					
I confirm that I provided a copy of the label and brochure (or leaflet) to the landholder and provided	**Initials (if applicable, otherwise indicate N/A):**					

Vertebrate Toxicant Usage Record[1, 2]	
them additional guidance on the location and monitoring of the bait (if applicable).	
I confirm that alternative methods were used and that they were ineffective or impractical.	**Initials:**
I confirm that the information above is accurate and complete.	**Signature:** **Date:**

Notes:

(1) The Vertebrate Toxicant Usage Record is to be filled in at every site visit.

(2) An electronic version of this information (in spreadsheet format, such as Microsoft Excel) must be maintained and made available to Health Canada upon request. At the end of treatment, the applicator must provide a copy to the landholder (if applicable) and submit completed copies of the Vertebrate Toxicant Usage Record to the registrant of the toxicant product.

(3) (a) For Livestock Protection (coyotes and wolves): Other livestock management practices that must be considered include: elimination of alternate attractive food sources (for example, secured garbage, proper carrion disposal); proper flock or herd management (for example, short birthing season, regular surveillance, protection of vulnerable animals such as young using confinement methods, maintaining healthy animals, keeping livestock away from forested areas); maintaining fencing designed to keep predators out; use of guardian animals (for example, dogs, donkeys); hiring a shepherd or herdsperson; practice night confinement; frightening devices or registered repellents for that use; and alternative lethal controls (for example, shooting).

(b) For Conservation Program Use (wolves only): Other conservation safety practices that must be considered include: habitat restoration and habitat protection of the species-at-risk; reducing impacts on species-at-risk due to humans; fencing; trapping and alternative lethal controls of wolves (for example, shooting).

(c) For Human Safety (wolves only): Other human-predator safety practices that must be considered include: a public education program; elimination of alternate attractive food sources (for example, secured garbage, remove pet food); do not feed wildlife including wolves, their prey and birds; confining pets indoors or secure outdoor runs; leashing of pets during walks; trapping and alternative lethal controls (for example, shooting).

(4) Pesticide registrants are required to report to the PMRA all incidents associated with their products. For details on the reporting requirements, such as the type of incidents that must be reported and the timeframes for reporting, please refer to the Incident Reporting Regulations and related Guidance Document provided in the web link: https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/registrants-applicants/reporting/mandatory-incident.html

Appendix VI References considered following publication of PRVD2022-18

Information considered in the updated environmental assessment

Additional information considered

Published information

Strychnine

PMRA Document Number	Title
3478549	Hervieux et al., 2014, Canadian Journal of Zoology. 92(12): 1029-1037. Supplemental information., Managing wolves (*Canis lupus*) to recover threatened woodland caribou (*Rangifer tarandus caribou*) in Alberta, DACO: 9.9
3478550	Harris and Armstrong, 2021, The Canadian Field-Naturalist. 135(2): 142-152., An overview of experimental Gray Wolf (*Canis lupus*) poisoning programs in northern Ontario, 1956 to 1964, DACO: 9.9
3478551	COSEWIC, 2012, Committee on the Status of Endangered Wildlife in Canada, COSEWIC assessment and status report on the American Badger *Taxidea taxus* in Canada, DACO: 9.9
3478748	COSEWIC, 2021, Committee on the Status of Endangered Wildlife in Canada, Swift Fox (*Vulpes velox*): COSEWIC assessment and status report 2021, DACO: 9.9
3478749	Alberta Fish and Wildlife, 2023, Alberta's Species at Risk website: https://open.alberta.ca/dataset/c0bb7ebe-b2a2-4d50-a0d0-bba15ac5c10d/resource/3f9f02ae-6173-4438-ae4e-a3a8f7be02b8/download/sar-wolverine-factsheet-may2003.pdf, Alberta's Wolverine (*Gulo gulo*) Factsheet, DACO: 9.9
3478750	Environment and Climate Change Canada, 2019, Website: https://wildlife-species.canada.ca/bird-status/com-com-eng.aspx?sY=2019&sL=e, The status of Birds in Canada Website, Data-version 2019., DACO: 9.9
3478755	Environment Canada, 2013, Environment Canada, Bird Conservation Strategy for Bird Conservation Region 6: Boreal Taiga Plains., DACO: 9.9
3478760	Environment Canada, 2013, Environment Canada, Bird Conservation Strategy for Bird Conservation Region 11 in the Prairie and Northern Region: Prairie Potholes., DACO: 9.9
3478764	Environment and Climate Change Canada, 1993, Environment Canada, Hinterland Who's Who., DACO: 9.9
3478765	Government of Alberta, 2023, www.Alberta.ca, Human-wildlife conflict - foxes, DACO: 9.9
3478768	Government of Alberta, 2022, Alberta website: https://www.alberta.ca/lookup/wild-species-status-search.aspx, Alberta wild species status, DACO: 9.9

3478769	Parks Canada, 2023, Parks Canada website: https://parks.canada.ca/pn-np/mtn/ours-bears/generaux-basics/grizzli-grizzly, Alberta wild Bears in the mountain national parks. Grizzly bears status, DACO: 9.9
3478771	COSEWIC, 2014, Committee on the Status of Endangered Wildlife in Canada, Wolverine (*Gulo gulo*): COSEWIC assessment and status report 2014, DACO: 9.9

Sodium monofluoroacetate

PMRA Document Number	Title
3478775	Burns et al, 1986, Proceedings of the Vertebrate Pest Conference, 12(12), Secondary toxicity of coyotes killed by 1080 single-dose baits, DACO: 9.9
3478776	Burns et al, 1991, Proceedings of the Vertebrate Pest Conference, 12(12), Secondary Hazard of Livestock Protection Collars to Skunks and Eagles (Abstract), DACO: 9.9

Unpublished Information

Strychnine

PMRA Document Number	Title
3051153	2002. Potential for secondary poisoning from the use of 2% strychnine-treated wheat bait to control Richardson's Ground Squirrels. DACO 9.9.
3051152	2004. Effectiveness and non-target impact of zinc phosphide and various concentrations of strychnine in controlling Richardson's Ground Squirrels in Saskatchewan. DACO 9.9.