

May 6, 2024

The Honourable Mark Holland
Minister of Health
Health Canada
70 Colombine Driveway
Ottawa, ON K1A 0K9

Via online form submission

Re: Notice of Objection to RVD2024-04 Re-evaluation Decision “Predacide Uses of Strychnine and Sodium Monofluoroacetate and their Associated End Use Products” (March 7, 2024)

This notice of objection is submitted by Animal Justice, Wolf Awareness, Humane Society International Canada, WeHowl, and Animal Alliance of Canada (“**the Objectors**”) pursuant to s 35(1) of the *Pest Control Products Act*, SC 2002, cs 28 (“**PCPA**”) regarding the Re-evaluation Decision on the continued registration of Sodium Monofluoroacetate (“**Compound 1080**”). Additional organizations which support this notice of objection are listed below.

An additional submission will be made by May 16, 2024, the date for extension granted to some of the Objectors in order to review “confidential test data” provided by the Pest Management Regulatory Agency (“**PMRA**”).

PART I: OVERVIEW

On March 7, 2024, Health Canada’s PMRA released its re-evaluation decision summarizing the results of their cyclical re-evaluation of two predacides: strychnine and Compound 1080 titled “Predacide Uses of Strychnine and Sodium Monofluoroacetate and their Associated End Use Products” (“**RVD2024-04**”). The PMRA reversed its proposed decision to continue the registration of strychnine and canceled all end-use products, given that the significant level of environmental risks were unable to be mitigated. This change in course was due largely to Animal Alliance of Canada having obtained prior use records from the registrant, the Government of Alberta, which they, Wolf Awareness and Animal Justice, provided to the PMRA in both a Special Review Request in 2020, and again in their comments on the proposed re-evaluation decision PRVD2022-18. The records revealed the difficulties in tracking mortality caused by strychnine and in collecting poisoned carcasses. These records also provided further evidence of the extent of non-target poisoning. The Objectors support and commend the PMRA’s decision to cancel the registration of strychnine.

In RVD2024-04, the PMRA declined to cancel Compound 1080, the last remaining predacide in Canada, and continued its registration in Alberta (the only registrant of Compound 1080). The PMRA concluded that the predacide has value and that the environmental and health risks are acceptable.

Any person may file with the Minister a notice of objection to a re-evaluation decision pursuant to s 35(1) of the *PCPA*. The Minister may establish a panel to review the decision and to recommend whether the decision should be confirmed, reversed, or varied (s 35(3)). A review panel is necessary where the notice of objection “raises scientifically founded doubt as to the validity of” the evaluations of the products’ health and environmental risks and their value (*Review Panel Regulations* SOR/2008-22, s 3).

The PMRA did not conduct a full assessment of Compound 1080. RVD2024-04 “was focused on the feasibility of risk management measures rather than a traditional quantitative risk assessment approach” (RVD2024-04, page 27). This approach is contrary to s 19(2) of the *PCPA*, which requires the PMRA to take a scientifically based approach to re-evaluation decisions. It is also contrary to s 19(1)(b) which is clear that the registrant must persuade the Minister that both the health and environmental risks, and the value of products containing Compound 1080, are acceptable.

The PMRA relied on glaringly incomplete registrant use records in its decision to allow the continued registration of Compound 1080. In doing so, the PMRA failed to hold the registrant to its burden under s 19(1)(b) of the *PCPA* to persuade the Minister that the risks and value are acceptable. Rather, the PMRA has rewarded the registrant for its poor record keeping and allowed the continued registration of Compound 1080 without a full appreciation of the extent of the environmental risks at play.

Furthermore, the Objectors are concerned that the PMRA has not addressed the risks of Compound 1080, yet expects the pesticide to replace the use of strychnine, which has been used within the context of caribou recovery in Alberta since 2006. This will undoubtedly exacerbate the risks already caused by Compound 1080 used in livestock areas, which the PMRA found acceptable in part because the chemical is used at rates they consider to be low. The Objectors are also of the view that risk mitigation measures proposed in RVD2024-04 are unlikely to mitigate environmental risk.

Finally, the registrant’s failure to comply with conditions of registration to date not only undermines the PMRA’s decision to continue the registration of products containing Compound 1080 but supports canceling the registration pursuant to s 25 of the *PCPA*.

We object to the assumptions and conclusions made by the PMRA and request that a review panel be instituted pursuant to s 35(3) of the *PCPA*. We request that the Panel cancel the use of Compound 1080 and that its use be phased-out on a 6-month accelerated track to match that of strychnine. In what follows, we present a summary of our concerns, and their scientific bases, with Compound 1080 and the re-evaluation decision at issue. As previously noted, organizations which have received access to “confidential test data” from the PMRA will later submit supplemental information to support our objection based on that information.

PART II: BACKGROUND

Compound 1080 is an extremely lethal chemical with a broad killing spectrum belonging to the “Fluoroacetic Acid” chemical family. It causes intense and prolonged suffering to animals who ingest it, including excruciating pain and distress for hours or even days before a victim finally loses consciousness. Most animals who have been poisoned by Compound 1080 present a variety of signs, including: lethargy, retching and vomiting, anxiety, trembling, fecal and urinary incontinence, severe and prolonged convulsions, unusual vocalizations, hyperactivity, excessive salivation, muscular weakness, incoordination, hypersensitivity to sensory stimuli, and respiratory distress. Compound 1080 creates organ disorders, which can be extremely painful as essential cellular processes break down (Atzert 1971). Compound 1080 eventually causes death as a result of cardiac failure, central nervous system failure, or respiratory arrest (Sherley 2007).

Compound 1080 is believed to be at least partly responsible for the decline of several species at risk in North America, including the burrowing owl (Butts 1973), swift fox (Burnett 1989; Ginsberg and Macdonald 1990; COSEWIC 2009), California condor (Hegdal et al. 1979), and black-footed ferret (Defenders of Wildlife, 1982). Alberta allows the placement of Compound 1080 within the home ranges of several federally listed species at risk that scavenge, including American badger, black-footed ferret, grizzly bear, swift fox, wolverine, burrowing owl, ferruginous hawk, peregrine falcon and short-eared owl. Other scavenging mammals and birds are listed provincially with at-risk status, including long-tailed weasel and Canada lynx, putting their populations at a higher level of risk from primary and secondary poisoning (Parr and Barron 2021).

Like strychnine, Compound 1080 is an indiscriminate poison. It has killed humans and pets, in addition to eagles, badgers, bobcats, raccoons, bears, wolves, coyotes and various other wildlife species in North America (Randall 1981; EPA 1995; CCWHC 1999). Companion dogs have been killed from both legal and illegal use of Compound 1080 in Canada. Animals that ingest non-lethal doses of the poison have reduced survival after being weakened, as individuals depend upon alertness, agility, and coordination to survive (J. Smits pers comm 2017 and see Fry et al. 1986). If they recover, these animals may experience long-term effects of toxicity (Robinson 1953; Randall 1981).

Despite its highly controversial use as a predator control substance and the numerous and varied risks it presents to the environment and the health and safety of Canadians, Compound 1080 is still used in Alberta to kill wolves and coyotes suspected of preying on farmed animals. Though wolves and coyotes are present in areas across the country, Alberta is the last jurisdiction in Canada to use Compound 1080 and is among few jurisdictions in the world to allow its use.

PART III. ENVIRONMENTAL RISK

1. The Test

Under s 16 of the *PCPA*, re-evaluations of registered products are aimed at ensuring products in use in Canada continue to meet current health and environmental standards and continue to have value. The primary objective in the administration of the *PCPA* is to prevent unacceptable risks to individuals and the environment caused by pest control products (s 4(1)).

The risks of pest control products are acceptable if there is “reasonable certainty that no harm to human health, future generations or the environment will result [...]” (*emphasis added*) (s 2(2)). The burden is on the registrant (in this case, the Alberta Government) to persuade the Minister that the health and environmental risks and value of the product are acceptable (s 19(1)(b)). The Objectors submit that the registrant has not done so.

In conducting a re-evaluation, the Minister may cancel the registration of a pest control product if the Minister has reasonable grounds to believe that it is “necessary to deal with a situation that endangers human health or safety or the environment” (s 20(1)). In doing so, the Minister is to take into account the precautionary principle. The precautionary principle is a principle of international and domestic environmental law, defined in the *PCPA* at s 20(2) as:

Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent adverse health impact or environmental degradation.

If the Minister does not consider that the health or environmental risks or value of a pest control product are acceptable, the Minister shall amend the registration if the risks and value would be acceptable after amendment, or cancel the registration (s 21(2)).

Environmental risk is defined in the *PCPA* as “the possibility of harm to the environment”. The environment includes all living organisms (s 2(1)). The Act does not require certainty of the full scope of environmental harm prior to cancellation. Indeed, such a requirement would represent the antithesis of the precautionary principle.

As set out below, the PMRA has not held the registrant to its burden and has misinterpreted the test to be applied, requiring evidence of a certainty of environmental harm. Instead of requiring the registrant to show that there is reasonable certainty that no harm will result, it has in effect required the Objectors to prove a certainty of harm. An analysis on the basis of the proper test which ought to have been undertaken leads to the incontrovertible conclusion that Compound 1080's registration should be canceled.

2. Lack of toxicity data regarding non-target species

In PRVD2022-18 and RVD2024-04, the PMRA concluded that, while Compound 1080 does threaten death of non-target organisms, it is more toxic to canids than to other animals and is less likely than strychnine to result in secondary poisoning. However, the PMRA relied on a lack of data to conclude that the environmental risk caused by Compound 1080 is acceptable, stating that “[r]eliable data for non-target deaths as a result of the use of sodium monofluoroacetate are not available” (RVD2024-04, page 18). In its evaluation, the PMRA did not grapple with the fact that there is a dearth of necessary information because of the nature of the product, the existing use limitations set by PMRA, and the incomplete record-keeping by the registrant. Scientific evidence clearly shows that non-target organisms are killed by Compound 1080. The fact that the registrant does not have data clearly showing the scope of those deaths is reason to cancel registration, not continue it.

In their report to the British Columbia Government regarding predacious Compound 1080, the Canadian Cooperative Wildlife Health Centre noted that “the lethal dose to wild mammals is not precisely known for many species” (1999, page 3). The PMRA did not acknowledge that there is no toxicity data regarding the level at which Compound 1080 causes death to various North American animals such as mustelids (e.g. wolverines and fishers), ursids (grizzly bears, but see non-specific bear toxicity mentioned in USFWS 1993), felids (including cougars and Canada lynx), and several avian raptors. These animals, all of whom live in Alberta and are known to scavenge, are at risk of becoming non-target victims of Compound 1080. Furthermore, these species have not been subject to acute toxicity testing, nor have studies calculated the residue concentrations of Compound 1080 in their tissues following poisoning, precluding risk calculations for these species acting as secondary poisoning vectors.

The PMRA also did not account for existing scientific evidence regarding the risk of Compound 1080 to non-target species and its wide variation in acute oral toxicity. It is not appropriate to extrapolate existing toxicological data to even closely related species for which there is a lack of data. For example, the cotton rat is 40 times more sensitive to Compound 1080 than the deer mouse, both of which belong to the family Cricetidae (RVD2024-04, Table 3, page 43). Even within the Canid genus (to which wolves and coyotes belong), some of the most sensitive species known, dogs, are almost twice as sensitive as coyotes (Environmental Protection Agency 1995,

page 9). Worryingly, there does not seem to be any toxicity data for wolves specifically, only domestic dogs.

The PMRA summarized some toxicity endpoint data but failed to collect the most up-to-date data; for example, golden eagle LD₅₀ toxicity was calculated by Ward and Spencer (1947) to be 5.0mg/kg, updated by Tucker and Crabtree (1974) to be between 1.25-5.00 mg/kg, and updated once again by Hudson to be 3.54mg/kg. Notably, the lowest lethal dose for golden eagle noted by Hudson was a mere 0.498mg/kg. It is possible that the toxicity data varies to this extent simply due to the lack of adequate test subjects; many toxicity tests rely on 5-10 individuals. The Objectors contend that LD₅₀ is not an appropriate endpoint to apply to risk assessment calculations, especially for sensitive (e.g. golden eagle) and at-risk species, when very few mortalities could result in population-level declines. A more conservative endpoint is warranted for these species.

Furthermore, ambient temperature and season have been found to affect toxicity significantly. For example in their 1993 Biological Opinion, the United States Fish and Wildlife Services summarized findings from Fry et al. 1986 which concluded that “[t]urkey vultures are about 2.5 times as sensitive to acute Compound 1080 exposure at 8-9°C then when dosed at 23-28°C” (page II-79). Similarly, in 1982, in a decision whether to register Compound 1080 to control predators, the United States Environmental Protection Agency (“EPA”) referred to a study by doctors Buck and Beasley, which indicated that “a median lethal dose of 1080 at 22°C was 21 mg/kg, while at 8°C, the equivalent dose was 4.5 mg/kg, indicating that temperature had a great effect on the toxicity of the poison. LD₅₀ values are more likely to have been established in laboratories at or near normal room temperatures.” (United States Department of Agriculture, *Statement on Compound 1080*, Freedom of Information 2024). The PMRA has apparently not considered how temperature will impact species’ sensitivity to Compound 1080 in the likely event that the use pattern expands to incorporate wolf poisoning in caribou range, which has to date only occurred during winter months.

Toxicological information for terrestrial arthropods has not been considered by the PMRA, despite the fact that Compound 1080 has known insecticidal properties, unlike other vertebrate toxicants (Eason et al. 2011, page 3). The EPA noted in its recent re-evaluation of Compound 1080 that “[s]odium fluoroacetate is very highly toxic to pollinator insects with LD₅₀ level of 0.8 µg ai/bee after oral exposure (24-hour observation)” (2023, page 10). At-risk arthropods with ranges in Alberta include yellow-banded bumblebee, Western bumblebee, species of yucca moth, Weidemeyer’s admiral, and Verna’s flower moth (Government of Canada 2024). Vomitus containing Compound 1080 emitted by poisoned animals can expose these arthropods to risk. Arthropods can also consume poisoned tissues. Eisler describes other routes of exposures and resulting effects on various invertebrates (1995, pages 14-15).

In 1999, the Canadian Cooperative Wildlife Health Centre (“CCWHC”) referenced research conducted by Hegdal et al. (1979) which supports their conclusion that it “also is possible for insects containing 1080 residues to be consumed by insectivorous animals, with the potential for secondary poisoning by this route.” The CCWHC also referenced their experience with Compound 1080 use in New Zealand, concluding that risks of non-target mortality of or via invertebrates should not be discounted (1999, page 3). While the research on invertebrates was not extensive at that time, the PMRA has seemingly not examined the literature to identify further studies.

The paucity of toxicity data for ungulates is also of particular concern given PMRA’s assumption that Compound 1080 will replace strychnine in at-risk caribou range. Eisler notes that New Zealand successfully poisoned red deer and white-tailed deer, closely related ungulates to caribou, using Compound 1080 (1995). Additionally, Hudson (1984) also concluded that mule deer, a closely related ungulate tested for Compound 1080 sensitivity, have LD₅₀ of 0.33-1.00mg/kg. The average boreal caribou weighs 110-210kg (Environment Canada 2011). Assuming similar toxicity (regarding which actual data is lacking), exposure to between 36.3 and 69.3 mg of Compound 1080 could be fatal, and lesser exposures could negatively impact the behaviour or health of caribou. Baits can have up to 60-90 mg of Compound 1080 per PMRA’s Reg. No. 18300. Caribou could therefore be negatively impacted if consuming vegetation covered in poisoned vomitus, water contaminated by poisoned carcasses, baits rejected by canids, or bait leachate.

Finally, the PMRA’s decision did not evaluate the impact of sublethal doses on non-target species. Such doses of Compound 1080 can result in increased indirect mortality. Disorientation of a non-target species following poisoning can result in death by predation, from vehicle strikes, drowning, dehydration, exposure or being caught in fences.

Chronic sublethal effects of Compound 1080 are generally poorly understood due to a lack of research. While the EPA does not require such evidence, concluding that “long-term exposure is not expected for LPC uses”, this conclusion should not be imported into Canada. American use patterns and end use products of toxic collars are significantly different from the registered use in Canada where tablets are placed into meat baits left on the landscape. In Canada, the PMRA acknowledges that exposure of wildlife to the tablets is likely occurring.

Some scientific studies have made clear that sublethal toxicity can significantly affect animal behaviour. For example, Burns et al. 1991 reported “[t]hree eagles showed no obvious signs, whereas 3 others showed obvious reactions to 1080, including reduced feeding, fluffed feathers, loss of muscular strength and coordination (inability to mount perch), lethargy, and body tremors.” Fry et al. concluded that “the debilitating effects of high sublethal doses would probably result in death of dosed birds in the wild” (1986, page 30). In that study, clinical

symptoms, such as intention tremors, persisted between 3 and 11 days in turkey vultures who consumed Compound 1080 (Abstract).

3. Lack of aquatic risk assessment in small water bodies

In RVD2024-04, the PMRA concluded that risks to aquatic animals were negligible even if the maximum amount of baits permitted were dropped into a 1-acre wetland. However, smaller and differently vegetated water bodies (e.g. irrigation ponds, livestock watering holes and other natural and ephemeral ponds) exist on farms and on public land where Compound 1080 has been and is likely to continue to be deployed in response to livestock depredation.

The EPA has contemplated this issue within the American use context, and prohibits the use of Compound 1080 in open rangeland. There, it can only be used in toxic collars in fenced areas (EPA 2023, page 9) because “significant environmental pressure of sodium fluoroacetate is highly unlikely from its single registered use provided barriers prevent contamination of natural waters” (United States Fish and Wildlife Service 1993, page II-80). Barriers such as fences also serve to prevent predators from entering areas used to raise domestic animals, and thus can help to reduce predation events. While some farms may fence small water bodies, there is no evidence to suggest that all or most water bodies on public lands where predacides are used in Canada are fenced. Again, unlike in the US, Compound 1080 is not used in toxic collar form and is more widely dispersed on the landscape.

4. Mortality cannot be accurately quantified under existing use limitations

Due to the way in which Compound 1080 interacts in animals’ bodies, there is fundamental difficulty, if not impossibility, in studying the extent of the non-target deaths it causes. Those complete records we do have from the registrant show that, similar to strychnine, carcasses poisoned with Compound 1080 are rarely collected, but baits are often consumed (PMRA#3249560).

Depending on the dose of Compound 1080 consumed, symptoms can begin hours after ingestion (Fry et al., 1986) during which time animals can travel significant distances from a bait site (CCWHC 1999, page 5). Scavenging birds can fly away prior to succumbing to death, further spreading this poison, and making the true biological cost of its use on Canada’s landscape difficult to determine. In its toxicity testing for sodium monofluoroacetate, the United States Department of the Interior found that it took up to 1 day for subject species to die, depending on the species (Hudson, page 74, 1984). In the 1982 decision on Compound 1080 the EPA commented the following with respect to the risks associated with large-bait poisoning using Compound 1080, a use pattern now cancelled in the US (Eisler 1995) but similar to carcass baiting in Canada:

The characteristic latency period after the ingestion of Compound 1080 makes it likely that all birds and animals poisoned thereby would not die in the immediate vicinity of the bait. Because of these factors, it is probable that many birds and animals poisoned by 1080 were never located and reported.

Compound 1080 does not readily bioaccumulate in animal tissue, but it can persist in carcasses at hazardous concentrations that remain lethal to various scavengers, both mammalian and avian, for several months (Eisler 1995). Additionally, poison residues vary between species. For instance, research in New Zealand demonstrated that after 75 days, carcasses of possums poisoned with Compound 1080 still posed a serious risk to dogs (APVMA 2008).

The registrant itself accepts this reality as fact. The Government of Alberta's policy entitled "Use of Toxicants for Wildlife Management" acknowledges that it "is very difficult to monitor [Compound 1080's] effectiveness as it is slow acting; animals can travel long distances before succumbing to the toxicity" (AESRD 2012, FOIPP Request E17-G-0418, page 58). Alberta's toxicant policy also states that "retrieval of carcasses is typically impossible and secondary poisoning of other wildlife species feeding on the carcass is a potential concern" (Ibid).

Evidence from the United States further illustrates this issue. Coyote poisoning with lethal doses of Compound 1080 solution in LPCs resulted in coyotes displaying "symptoms within 4 hours of exposure and died an average of 90 minutes following onset of symptoms." (EPA 2023, page 9) In one study by the USDA, the experiment used captive animals fed poisoned coyote carcasses because of anticipated difficulty in finding poisoned coyotes in the wild (Burns et al. 1986, Introduction).

Australian studies have observed similar issues. In Sodium Fluoroacetate Final Review Report and Regulatory Decision, the Australian Pesticides and Veterinary Medicines Authority commented that "[v]ery few non-target carcasses have been recovered following 1080 baiting campaigns. Where radio tracking has been used to facilitate recovery, carcasses have been found in burrows or under cover rather than in open situations" (AVPMA 2008, page 30).

To be clear, the Objectors do not request that the PMRA conduct or permit animal studies to obtain further data about the impacts of Compound 1080 on poisoned animals. Such studies cannot be ethically justified given the low value of Compound 1080, the significant pain and suffering caused to animals who ingest the substance, and the fact that its use is unnecessary. In any event, it would not be feasible to test every single species exposed to Compound 1080 in the ecosystems in which it is placed in Alberta, nor would it be appropriate given the at risk status of several of the species exposed to this toxicant.

5. Limited scope of the re-evaluation and failure to obtain necessary records

In undertaking its re-evaluation of Compound 1080, the PMRA “was focused on the feasibility of risk management measures rather than a traditional quantitative risk assessment approach” (PRVD2022-18, page 10).

There has been a historic and ongoing failure on the part of the PMRA to perform an appropriate science-based environmental risk assessment of Compound 1080. In the previous cyclical re-evaluation of Compound 1080, the PMRA did not perform a science-based environmental risk assessment for the high-concentration tablet form of Compound 1080 (PACR2004-20 and RRD2005-05). Instead, it relied on an EPA re-evaluation that did not even assess the high-concentration tablet form of Compound 1080, only the low-concentration solution LPCs, because that was and continues to be the only formulation of Compound 1080 registered in the US. This contravenes the PMRA’s policy for re-evaluation, DIR2001-03, Program 1, which states that:

- The [review documents] must address the active ingredient itself and its main formulation types registered in Canada, and it must be relevant to Canadian uses.
- The [review documents] must document in sufficient detail the data underlying its main conclusions to which Canadian content can be added, i.e., it must provide sufficient data on which to base Canadian environmental and human exposure assessments when Canadian use situations differ from those of the U.S.

For both the 2005 cyclical re-evaluation and the 2014 Special Review of Compound 1080, “the PMRA did not request use records at the time for REV2013-04/RVD2014-03 or PACR2004-20/RRD2005-05” (PMRA pers. comm. 2024), and conducted only a superficial, qualitative assessment of risk.

To make matters worse, in undertaking the present re-evaluation, the PMRA neglected to obtain all use records from the registrant since the last re-evaluation decision was published in 2005. Instead, they obtained from the registrant only use records from a 10-year period before the re-evaluation began (from 2010-2021). Risk assessments without complete use records are impossible to perform given the paucity of toxicological and experimental studies for predacidal tablets in North America. The use records are the evidence needed to quantify mortality rates. The importance of these records is no better illustrated than the PMRA’s reversal of its proposed decision to maintain the registration for strychnine on the basis of 2005-2010 records provided by Wolf Awareness and Animal Justice.

The PMRA could also have obtained recent use records from prior registrations (e.g. Government of Saskatchewan re: Reg. No. 25857) but did not do so. The use patterns were very similar and could have informed a risk and value assessment.

RVD2024-04 also does not amend the label to provide sufficient recording requirements to ensure future compliance. For example, the PMRA could, but has not, amended the product labels to require the registrant to submit use data on a regular basis to the PMRA. We note that the registrant's internal policy is to keep use records for five years (AESRD 2012), and that the cyclical re-evaluation period is 15 years long which makes loss of records a very real concern. This is especially so given that records older than five years obtained through Freedom of Information requests made in 2010 resulted in the PMRA's cancellation of preadical strychnine. It seems there has been a lack of proper scientific evaluation since initial registration in 1984. Inadequate reviews such as RVD2024-04 merely build limited information onto an already-shaky foundation. The PMRA ought to have carried out a proper scientific evaluation in this instance. Given that they have not, a Review Panel is necessary to review the decision and to recommend whether it should be confirmed, reversed or varied pursuant to s 35(3) of the *PCPA*.

The approach taken by the PMRA was also deferential to the registrant and did not interrogate the registrant's position or the overall environment and health risks and value of the chemical with any scientific rigour.

For example, the PMRA has provided no evidence that risk to non-target organisms can be mitigated by maintaining a 7-day site check requirement, or even that quantification of target mortality is possible using a 7-day site check approach. To the contrary, the label requirements regarding 7-day bait checks seem to have been set to accommodate the registrant, not to prevent risks caused by Compound 1080 (PMRA pers comm. 2024). This displays a lack of a scientific rigour involved in the PMRA's re-evaluation and proposed mitigation measures and again shows that the registrant has not discharged its burden under s 19(1)(b) of the *Act*.

The US Fish and Wildlife Service Biological Opinion from 1993 for Compound 1080 concluded that "prompt disposal of collared livestock carcasses and predators suspected of Compound 1080 poisoning is essential because residual toxicant on livestock and poisoning by secondary exposure from scavenging dead predators has been reported (Rudd and Genelly 1956, Eastland and Beasom 1986, Connolly 1989 as quoted by USFWS 1993)." Poisoned carcasses are likely to be almost completely consumed by scavengers in the 7-day period between bait site checks permitted by the label.

6. Inadequate risk mitigation measures

Existing product labels, along with the amendments now established, and other mitigation measures initiated by RVD2024-04 will not be effective at mitigating environmental risk.

For example, the PMRA has provided no basis to show that additional label requirements will mitigate risk given that the registrant has in many instances not complied with label requirements to date. The PMRA has acknowledged that the registrant has a history of poor record keeping in the context of Compound 1080 use, even though the label already required the registrant to keep records of the use of Compound 1080. The registrant has failed to comply with the law by failing to follow the label requirements to keep complete records. This has resulted, at least in part, in a lack of records surrounding the extent of the environmental harm caused by Compound 1080.

Had the registrant kept such records, there would likely be no basis to continue its registration as the scientific evidence of harm would perhaps be more clear (though difficulties in tracking Compound 1080 mortalities with accuracy remain due to its mechanism of action). The PMRA's decision to continue to register Compound 1080 rewards the registrant for failing to keep proper records rather than canceling the registration due to the registrant's non-compliance pursuant to s 25 of the *PCPA*.

Additionally, the use limitation designed to protect species at risk on the amended product label is too vague to be effective. The amended label directs users not to “apply this product if species at risk (for example the swift fox) that may feed on sodium monofluoroacetate bait or on poisoned carcasses are present in your (local or specific) area”. This use limitation provides insufficient guidance to the product user regarding how to assess whether species at risk may be present and “may” feed on the bait or poisoned carcasses. This use limitation was added following the Special Review Decision for Compound 1080 in 2014. The PMRA has not shown that risks to endangered species have been mitigated by this change. Of additional concern, the PMRA inexplicably did not include this particular use limitation for wolf use (only for coyote use) between 2014 and 2024, which may have resulted in harm to species at risk.

Registrant use data shows that Compound 1080 has been used in the ranges of at least American badger, wolverine, burrowing owl, Grizzly bear and sensitive raptors and amphibian species (Alberta Environment and Parks [2018 E17-G-0418], Alberta Agriculture and Forestry 2017 [AF 2017-G-001], and see maps on pages 22-23 in Wolf Awareness 2018). The US EPA requires that each Compound 1080 applicator have a “species list” created using data from the Fish and Wildlife Service's species at risk online tool (EPA 2023, page 16). This ensures that applicators acknowledge species at risk in each geographic area where Compound 1080 will be used. The list must also be up-to-date at no more than 3 months old. Such a list is critical to ensure that species at risk clauses in pesticide labels function as they should to mitigate exposure to these

sensitive species. The PMRA has required no such list or similar tool, and instead directs users to contact the Government of Alberta for more information. However, the PMRA has not provided any information regarding the Government of Alberta's ability to provide the necessary species at risk occupancy data at a fine enough scale (i.e. "local or specific area") for users to adhere to the use limitation

The PMRA has also failed to institute any search requirement to ensure that those administering Compound 1080 are looking for and keeping track of carcasses. The only mention of carcass searching is on the "Vertebrate Toxicant Use Report" template, where there is a field for users to specify how much time they spent or distance they covered searching. The PMRA has stated throughout the RVD2024-04 that the reporting requirements were previously not specific enough to guide users in how to track their use of Compound 1080. This new label provides some specificity but leaves this critical issue, which would allow better tracking of non-target deaths, unresolved.

The PMRA has also not provided evidence to show that the following label requirements will mitigate risks:

- The PMRA has amended the label to require "placing baits under intact hide or on the underside of the carcass" to reduce non-target poisoning. In the field, carcasses get moved, dragged, carved out, ripped apart, and carried off by birds and mammals who scavenge upon it, further exposing animals to Compound 1080 at the bait site and in surrounding areas (see Incident Report 2018-5366 for an example of carcass scavenging around a strychnine bait site).
- The PMRA has amended the label to clarify that vegetation is no longer considered appropriate for covering carcasses, and instead has replaced this requirement with 15 cm of loose soil or 30 cm of snow. However, this is no better than vegetation. Loose soil and snow can be blown by wind, and snow can melt. These changes can occur within 1 day, let alone within 7 days between site checks.
- The label requires (and previously included as one of two disposal options) that poisoned carcasses must be buried under 60 cm (2 feet) of soil. The PMRA has presented no evidence showing that non-target animals will not dig up carcasses buried at such depth. This disposal requirement is insufficient to mitigate risks. Bears, cougars, badgers, coyotes and wolves all rely on strong olfactory senses for survival and excel at digging. Notably, the EPA requires that damaged livestock collars and other waste is to be buried at three feet (EPA 2023). The Government of Alberta's Livestock Mortality Burial Techniques (no date) requires that deadstock be covered at a minimum of only one metre of soil to deter scavengers.
- Finally, there is a lack of clarity around how users are to decide whether to use "small" or "large" baits to poison wolves. The difference in total amount of poison between these

two approaches is significant (up to 18 tablets can be placed in “small baits”, and up to 12 tablets can be placed in large baits). Without this clarity, users are more likely to apply more poison, resulting in greater risk to non-target species. Overbaiting was a very common type of non-compliance committed by the registrant, as was noted by PMRA in Document # 3249560.

7. Failure to assess expected increase in use of Compound 1080

The PMRA concluded in RVD2024-04 that Compound 1080 was acceptable, in part, because it is used at low rates, at fewer than 3000 tablets per year. The PMRA has not grappled with the fact that Compound 1080 is likely to replace strychnine in Alberta’s caribou recovery program; the last program utilizing strychnine. The registrant is likely to use Compound 1080 in its stead.

PART IV. VALUE

The PMRA has taken the position that their assessment of value is essentially an inquiry into whether or not the chemical has its immediate desired effect, i.e whether it kills animals. The PMRA must approach this issue more expansively in accordance with the definition of “value” in the *PCPA* and must take into account the overall purposes of the *PCPA*. S 2 of the *PCPA* defines value as:

- [...] 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 what it is intended to be used; and
 - (c) health, safety and environmental benefits and social and economic impact.

This is a more expansive definition than that applied by the PMRA. The inquiry must take into account the contribution of the product to pest management and the wider context including its environmental and social impact. It is incumbent upon the PMRA to assess the value of a product in light of the pest management strategy at issue. The current logic applied by the PMRA would result in anything fatal to animals meeting the value assessment, which cannot be what Parliament intended in drafting the *PCPA*.

There is a scarcity of evidence to support the efficacy of lethal intervention against predators with the aim of protecting human interests. However, lethal control of carnivores has many documented drawbacks. Please see Treves et al. 2016 and Animal Justice and Wolf Awareness 2020. In addition, there is a mounting body of scientific evidence to support the advantages of implementing non-lethal, prevention-based methods at reducing future conflicts among livestock

and carnivores and maintaining stable canid families. A proper value assessment should account for the negative impacts of removing native carnivores through poisoning programs.

The amended label states that Compound 1080 can only be used where alternative predation management strategies have failed or are “impractical.” Alternative predation management strategies promoted by the PMRA in this context include hunting and trapping of wolves and coyotes. However, published scientific literature (see Animal Justice and Wolf Awareness 2020) concludes that hunting and trapping¹ can shift predation events spatially on the landscape (i.e. result in livestock predation at nearby farms), or exacerbate it in the future (i.e. long-term livestock losses at the same farm where wolves and coyotes are killed). Researchers have concluded that these counter-intuitive results are due to various factors that can include reduced social cohesion and increased levels of reproduction, which can affect prey selection and predation rates. As such, the PMRA is enabling alternatives to poison that are unlikely to help most farmers and more likely to increase livestock losses to carnivores, resulting in increased reliance on poison. This contravenes Canada’s commitment to the COP 15 Global Biodiversity Framework, in particular Target 7 (Official Convention on Biodiversity 2022).

Both wolves and coyotes have intrinsic value and perform important ecosystem services which also contribute to Canada’s biodiversity. Wolves are apex predators and have cascading impacts on other trophic levels. This includes altering prey behaviour and numbers, impacting herbivory and disease transmission in herbivores, and providing carcasses for many other scavenging species to consume. Coyotes are generalist predators that prey heavily on rodents, benefitting many farmers.

PART V. HUMANENESS

Finally, the Objectors continue to be concerned that the PMRA failed to assess the humaneness of Compound 1080 in its re-evaluation decision. In Consultation Summary - Humane Vertebrate Pest Control (2021), the PMRA declined to add humaneness into the analysis stating that no international standards for such an assessment existed. However, these standards have long since existed. Professional bodies in North America established the humane animal euthanasia standards (e.g. Canadian Veterinary Medical Association, American Veterinary Medical Association, Canadian Council on Animal Care) and have communicated directly with PMRA about these standards (e.g. CVMA 2021). Moreover, international consensus principles for ethical wildlife control were published in 2017, including worldwide expertise from industry, academia, and non-governmental organizations (Dubois et al. 2017).

¹ We note that poisoning is analogous to hunting and trapping, in that they are all lethal control methods, and rarely can they target the individual depredating wolves or coyotes with certainty (except hunting carnivores actively killing livestock). Similarly, poisoning and trapping are indiscriminate (CCWHC 1999).

PART VI: CONCLUSION

In RVD2024-04, the PMRA failed to hold the registrant to its burden of demonstrating that the environmental risks and value of Compound 1080 are acceptable, and that Compound 1080 should continue to be registered for use in Canada. There is no scientific basis to support the PMRA's conclusion that environmental risks can be mitigated by new proposed amendments. The PMRA's conclusions were based on a lack of records, due in part to the registrant's failure to keep such records. An omission of this data should not provide a basis to continue product use. Those records could have been critical to the outcome of the re-evaluation, given the PMRA's own reversal of their proposed decision to continue to register strychnine on the basis of older use records.

Compound 1080 is an indiscriminate and highly toxic chemical for which a full environmental impact cannot readily be calculated. However, the environmental risks are clear, and more than sufficient for the PMRA to have concluded that they were unacceptable. For these reasons, there is scientifically founded doubt as to the validity of the PMRA's evaluation of the environmental risks of Compound 1080 as well as its value and a review panel should be established by the Minister.

Yours truly,

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