

May 16, 2024

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

Via email submission to pmra.docs.arla@hc-sc.gc.ca

Re: Supplemental information to support Notice of Objection (Sub. No. 7004-1715027871456) to RVD2024-04 Re-evaluation Decision “Predicide Uses of Strychnine and Sodium Monofluoroacetate and their Associated End Use Products” (March 7, 2024)

PART I: OVERVIEW

Herein is additional information to support Submission Number 7005-1715027871456, a Notice of Objection submitted on May 6, 2024 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”). This additional information is submitted following receipt of “confidential test data” (“**CTD**”) provided by the Pest Management Regulatory Agency (“**PMRA**”) to the signed representatives of Animal Justice, Wolf Awareness, Humane Society International Canada, and Animal Alliance of Canada (“**the Objectors**”).

Following the PMRA’s publication of RVD2024-04, the Objectors each requested and received from the PMRA Reading Room access to the monograph(s) and all evaluation reports for RVD2024-04. The Objectors each received eight documents:

PMRA #2201761
PMRA #3261308
PMRA #3265735
PMRA #3478633
PMRA #3489117
PMRA #3492403
PMRA #3500633
PMRA #3561174

A review of the CTD does not assuage the Objectors’ concerns articulated in the Notice of Objection regarding the scientific validity of the PMRA’s assessments underlying RVD2024-04. In fact, it heightens the Objectors’ concerns as it makes clear that the PMRA did not conduct a detailed assessment of the environmental risks at issue nor the product’s value. The CTD also shows that the PMRA conducted an insufficient literature review to draw the conclusions on which the re-evaluation decision relies. The Objectors reiterate that the registrant has not discharged its burden of convincing the Minister that Compound 1080’s environmental risks and values are acceptable (*PCPA*, s 19(1)(b)). There is scientific founded doubt as to the validity of the environmental risk and value assessments underlying RVD2024-04. As such, the Objectors

urge the Minister to institute a panel to review the decision to continue the registration of Compound 1080 (*PCPA* s 35(3); *Review Panel Regulations* SOR/2008-22, s 3(a)).

PART II: The Confidential Test Data Does not Address Concerns with the Environmental Risks at Issue and Compound 1080's Value

i. The CTD contains virtually no additional information to support RVD2024-04

According to the PMRA itself, “[b]efore a pesticide is allowed to be used or sold in Canada, it must undergo a rigorous scientific assessment” to assess whether the *PCPA* requirements are met. That is that there is a “reasonable certainty that no harm” to the to the environment or human health will result and the product has value (PMRA #3500633; *PCPA* ss 2(2) and 19(1)(b)). Upon review of the CTD, the Objectors conclude that the environmental risk and value assessments conducted were limited wholly to the information presented in the RVD2024-04. The PMRA did not conduct a sufficient assessment and should not have concluded that there was a reasonable certainty that no harm will result in the use of Compound 1080.

RVD2024-04 states “[n]ew data that would affect the environmental risk assessment for sodium monofluoroacetate were not provided during the public consultation.” However, registrant use records (Government of Alberta 2010) supplied by some of the Objectors during the public consultation period for the proposed decision – the same records that resulted in PMRA’s cancellation of strychnine – did contain use record summaries for Compound 1080. This appears not to have been evaluated by PMRA as they are not referenced in the final decision or the CTD. These records show further examples from 2005 to 2009 of no carcasses (target or non-target) being recovered when Compound 1080 was used. The complete lack of mortality observations do not support PMRA’s conclusion that environmental harm is acceptable for the reasons described in the Notice of Objection. The PMRA ought to have taken these data into account.

ii. There is insufficient information regarding the rarity of Compound 1080 use

The PMRA concluded in RVD2024-04 that the environmental risks posed by Compound 1080 were acceptable because, at least in part, the use of Compound 1080 is expected to be minimal if used in accordance with the label requirements. It appears that the PMRA has not attempted to quantify the amount of Compound 1080 that will be used and has thus not properly assessed the product’s environmental risks and value.

Prior to RVD2024-04 Compound 1080 users were already required to utilize the poison cautiously. The label provided that Compound 1080 could only be used “where proper herd management is practiced to discourage predation.” Changes made to the product label and the newly required Product Stewardship Program are meant to emphasize that Compound 1080 should not be used unless other predator management strategies have failed or there are no practical alternatives. Indeed, PMRA#3500633 (“**the Value Assessment**”) received as part of the CTD states that “[c]ases where alternative measures are not viable or ineffective are expected to be extremely rare”. However, in finding the environmental risks and value of Compound 1080 acceptable, the PMRA has not defined what is “rare” and seems not to have acknowledged Compound 1080’s expected increase in use to replace strychnine to kill wolves in caribou range in assessing the environmental impacts and value of the product.

Unfortunately even with prior label requirements and Alberta policies requiring poison to be used sparingly, records show that the registrant has not used such restraint. Neither the Value Assessment nor any other CTD document provides an evaluation of the use records that PMRA possessed and summarized in #3249560 and #3249390, which were provided to the Objectors during the proposed re-evaluation consultation period. Those documents showed that most of the registrant's use records for Compound 1080 were so incomplete that PMRA concluded "[t]he Alberta Coyote Predation Control Manual (2017; PMRA #3202326) indicates that lethal control should only be used as a last resort and provides information on herd management; however, data to determine if this is occurring prior to issuing sodium monofluoroacetate to landowners are not available."

Strychnine use records show obvious non-compliance with the limitation of poison being used only as a last resort. For example, in #3249390, PMRA states that in 2012 and 2015, "[r]ecords for two winter wolf control programs were provided. These programs do not appear to have followed the label directions. These programs appear to have been used as a pre-emptive measure to reduce wolf populations and do not appear to have been implemented as a direct response to predation." The registrant's repeated non-compliance with this limitation, which is set out in both the product label and their own provincial policy for toxicants, indicate that Compound 1080 use is unlikely to be "rare", at least as it relates to areas where it is expected to replace strychnine.

The Objectors are also concerned that the PMRA drew the conclusion that use will be infrequent despite their lack of fulsome consideration of poison alternatives or focus on sustainable control of predators. The registrant already compiles records of wolf depredation on livestock as per their livestock loss compensation program. The PMRA could have obtained such records to assess the extent and context of reliance on poison and whether reliance on the poison has been appropriate to date. It does not seem that the PMRA obtained or assessed those records. Previously, the PMRA prioritized working to "identify, develop and promote the use of products other than strychnine as well as viable non-chemical integrated pest management-compatible control methods" as a member of the Richardson's Ground Squirrel Integrated Pest Management Steering Committee, consisting of experts from producers, industry, researchers, provincial governments and the PMRA (RVD2007-03). A similar steering committee focusing on the lethal control of predators prior to the final decision for predacides would have been helpful to address concerns around frequency of application and help reduce pesticide use as per Canada's commitment to the COP 15 Global Biodiversity Framework.

iii. No basis has been provided to support the seven day bait check requirement

The Objectors have been provided with no data to support the requirement that bait sites be checked every seven days, which leads to scientifically founded doubt as to whether this requirement is sufficient to mitigate risk to non-target species. Indeed, the Objectors reiterate that the seven day bait check requirement directly hinders quantification of non-target mortality and carcass collection, both of which have been almost always impossible to document thus far (see #3249560).

iv. Environmental risks have not adequately addressed in determining the proper disposal methods

Prior to RVD2024-24, the product label required carcasses and unused baits to be buried or incinerated. According to PMRA #3561174 (the “**Health Evaluation Memo**”) in the CTD, during the re-evaluation process, the PMRA proposed changing the label to require that all disposal be done by way of incineration (PRVD 2022-18). The purpose of this update was, in part, “to reduce the hazard of secondary poisoning of non-target organisms and to minimize human exposure [...]” (Health Evaluation Memo).

However, the Health Evaluation Memo explains that the PMRA then received information from the registrant and municipal users of Compound 1080 expressing that this requirement would not be feasible. This is despite the fact that, according to the PMRA, incineration was already required per Alberta’s own toxicant policy. The Health Evaluation Memo illustrates that, following internal communication within the PMRA, the Environmental Assessment Directorate “should now lead the update of the disposal statement.” It then refers to a Science Committee discussion document which the Objectors have not received. The Objectors have not been provided with any quantitative risk assessment supporting the reversal of the proposed decision to limit the means of destroying unused baits and carcasses, and how that might impact non-target species through primary and secondary poisoning, respectively.

v. The Objectors are concerned with the use of Compound 1080 as population reduction

The Objectors also wish to draw the reader’s attention to the PMRA’s comment in PMRA #324878 that Compound 1080 “cannot be used for general population reductions”. This restriction did not make it into the new label requirements which is not explained in the materials provided to the Objectors. Communications within the Government of Alberta illustrate that Compound 1080 is used in bounty areas and their expectation is that illegal use of toxicants will increase in such areas (Lamont 2010, in Government of Alberta 2011). It is unknown how many animals will be killed in those areas.

vii. The PMRA did not acknowledge available toxicity information

The CTD suggests that the PMRA did not review toxicity research that does exist for animals living in the wild in Alberta. In RVD2024-04 the PMRA refers to materials summarized by the US Environmental Protection Agency and not the underlying research compendia in their entirety nor any other available studies regarding the toxicity of animals who reside in Alberta. The Objectors direct the reader to the research at Appendix A which shows the toxicity data available regarding some of these animals. This further illustrates the risk of non-target deaths by Compound 1080 which cast scientifically founded doubt on the PMRA’s environmental and value assessments.

PART III: The PMRA Did Not Conduct a Sufficient Literature Review

The Environmental Assessment Monograph (PMRA #3478633) provided in the CTD summarizes the publications that were included in comments provided to the PMRA during the comment period for PRVD2022-18. The studies listed are foundational documents that should have been obtained by PMRA before that proposed decision was published. Moreover, the Environmental Assessment Monograph does not include any indication that PMRA conducted further literature searches to identify any new scientific findings published since the proposed

decision, or to explore context around the issues raised in the comments on the proposed re-evaluation decision. This document illustrates a lack of sufficient literature review by the PMRA and raises scientifically founded doubt in the assessments RVD2024-04 relies on.

For instance, the PMRA reviewed a mere three studies in any detail. Of these studies, the Objectors note the following, which the PMRA did not appear to appreciate:

- Harris and Armstrong (2021) substantiates the trend that carcasses poisoned with Compound 1080 are very rarely recovered.
- Burns et al. (1986) evaluated primary poisoning of coyotes and secondary poisoning of skunks, dogs, coyotes and black-billed magpies, but did not test the vast majority of species who are exposed to sodium monofluoroacetate in Alberta. It also did not evaluate residues from primary poisoning victims other than coyotes, and residues are known to vary by species. Finally, this research did not discuss temperature's impact on toxicity, which may account for two dogs, who are very sensitive to Compound 1080, not dying from secondary poisoning. The findings of the study are therefore questionable.
- The PMRA commented on Burns et al. 1991 only to the extent of its abstract. The PMRA justified this decision by explaining that "Health Canada does not have access to this journal". This journal article is available for free on JSTOR and otherwise for a fee. The Objectors have obtained the journal article, which raised the following concerns:
 - The research took place in Utah in September and October, where temperatures were likely warm. The article contains no information on temperature, a factor that impacts toxicity.
 - The subjects included only skunks and golden eagles. Skunks ate less when they were fed poisoned food, and half the eagles were visibly unwell when consuming poisoned food, indicating that sublethal doses can have significant impacts on behaviour and health values, as the Objectors discussed in the Notice of Objection.
 - Fasting and stomach contents impact sensitivity to Compound 1080. The animals used in the research were fed unnatural pretreatment meals (pet food for the eagles, and commercial mink food for the skunks). These diets may not represent wild food intake in terms of type of food, quantity, or frequency, which could result in the test subjects being less sensitive to the poisoned food they were fed later. It should be noted that the author stated that the skunks used had a quantity of Compound 1080 at the upper "confidence limit" but "did not die, probably because the 1080 came in food instead of in a lone dose on an empty stomach." Therefore, in addition to considering temperature at bait sites, the feeding habits of scavenging wildlife should have been considered by PMRA when setting bait composition and site use maximums on the product label.
 - The study illustrates that there is significant variation in toxicity between individual animals in the same species, for example in golden eagles.

PART IV: CONCLUSION

The CDT on which the RVD2024-04 relied demonstrate the paucity of information that the PMRA considered, and the lack of analyses behind setting use limitations, label changes, and assessing risk and value. This material heightens the Objectors' concerns raised in the Notice of Objection. The registrant has failed to discharge its burden of proving that the risks to the environment and value of Compound 1080 are acceptable and there is scientifically founded doubt as to the evaluations carried out in the re-evaluation of Compound 1080. As such, a panel

ought to be instituted to review the PMRA's decision to continue the registration of Compound 1080 pursuant to s 35(3) of the *PCPA*.

Yours truly,

Hannah Barron
Conservation Director
Wolf Awareness

Lia Laskaris
Chief Executive Officer
Animal Alliance of Canada

Kelly Butler
Wildlife Campaign Manager
Humane Society International Canada

Kaitlyn Mitchell
Director of Legal Advocacy
Animal Justice

Alexandra Pester
Staff Lawyer
Animal Justice

REFERENCES

- Atzert, S. 1971. A review of sodium monofluoroacetate (Compound 1080): its properties, toxicology, and use in predator and rodent control. United States Department of the Interior, Fish and Wildlife Service, Special Scientific Report Wildlife No. 146. Accessed May 15, and available online at [https://books.google.ca/books?hl=en&lr=&id=XnsDrUdpMyMC&oi=fnd&pg=PA1&dq=Atzert,+1971.+S.P.+Atzert.+A+review+of+sodium+monofluoroacetate+\(Compound+1080\):+its+properties,+toxicology,+and+use+in+predator&ots=z8zJ5BryKP&sig=wXPwyfN7XmF566kEwjewgej4PvA&redir_esc=y#v=onepage&q&f=false](https://books.google.ca/books?hl=en&lr=&id=XnsDrUdpMyMC&oi=fnd&pg=PA1&dq=Atzert,+1971.+S.P.+Atzert.+A+review+of+sodium+monofluoroacetate+(Compound+1080):+its+properties,+toxicology,+and+use+in+predator&ots=z8zJ5BryKP&sig=wXPwyfN7XmF566kEwjewgej4PvA&redir_esc=y#v=onepage&q&f=false).
- Burns, R., G. Connolly and I. Okuno. 1986. Secondary toxicity of coyotes killed by 1080 single-dose baits. *Proceedings of the Vertebrate Pest Conference*. 12: 324-329.
- Burns, R., H. Tietjen, and G. Connolly. 1991. Secondary hazard of livestock protection collars to skunks and eagles. *The Journal of Wildlife Management*. 55: 701-704.
- Government of Alberta. 2010. Freedom of Information and Protection of Privacy Act Request 2010-G-0057.
- Lamont, R. 2010. Personal communication with S. Cotteril, Alberta Sustainable Resource Development. In: Government of Alberta. 2011. Freedom of Information and Protection of Privacy Act Request No. 2011-G-0046.
- Harris, A. and T. Armstrong. 2021. An overview of experimental Gray Wolf (*Canis lupus*) poisoning programs in northern Ontario, 1956 to 1964. *Canadian Field-Naturalist* 135(2): 142–152.

APPENDIX A: Relevant Toxicological Data Not Evaluated by PMRA

Table 1. Select species toxicity summarized in Atzert's *A review of sodium monofluoroacetate (Compound 1080): its properties, toxicology, and use in predator and rodent control*. United States Department of the Interior, Fish and Wildlife Service (1971)

Species	Lethal dose (LD50, unless "<", then LD100; all mg/kg)	Reference	Route of administration
Mule deer	0.3-1.00	Tucker and Crabtree 1970	Oral
Bear (species not identified)	0.5-1.0	Robinson 1953	Oral
Bobcat	<0.66	Ward and Spencer 1947	Intraperitoneal
Domestic cat	0.2	Ward and Spencer 1947	Intravenous
Grey fox	<0.3	Ward and Spencer 1947	Intraperitoneal
Badger	1-1.5	Ward and Spencer 1947	Intraperitoneal
Domestic ferret	1.41	Tucker and Crabtree 1970	Oral (stomach tube)
Marten	~1.0	Robinson 1953	Oral
Mink	~1.0	Robinson 1953	Oral
Porcupine	<1.0	Ward and Spencer 1947	Intraperitoneal
Golden eagle	1.25-5.00	Tucker and Crabtree 1970	Oral

Full reference information:

Robinson, W. 1953. Coyote control with Compound 1080 stations in national forests. *Journal of Forestry* 51:880-885.

Tucker, R and F. Crabtree. 1970. Handbook of toxicity of pesticides to wildlife. Bureau of Sport Fisheries and Wildlife, Denver Wildlife Research Center, Resource Publications No. 84. 131pp.

Ward, J and D. Spencer. 1947. Notes on the pharmacology of sodium monofluoroacetate-Compound 1080. *Journal of American Pharmaceutical Association*, 36:59-62.