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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 20, 2010

MEMORANDUM **D377476**

SUBJECT: EFED Registration Review Problem Formulation for Sodium Fluoroacetate (1080)
PC Code No. 075003; Case No. 62-74-8

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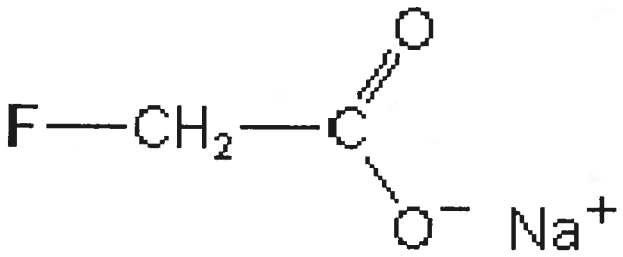
9/21/10

This memo summarizes the draft registration review problem formulation for sodium fluoroacetate (1080). After reviewing the available fate and toxicity data, no changes in risk conclusions are anticipated relevant to the 2009 response to the petition to cancel 1080. However, as outlined in the Agency's response to the petition and addenda (filed January 24,2007, March 20, 2007, July 27,2007 and January 7,2008) requesting that EPA suspend and cancel the registration of the predator control uses of sodium cyanide (1080), the Agency will conduct an endangered species risk assessment for all uses of sodium fluoroacetate. In this assessment, risk to listed species will be re-evaluated in terms of the eighteen use restrictions added to the labels to reduce the risk to listed animals.

Problem Formulation for the Ecological Risk Assessment of Sodium Fluroacetate (1080)



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1 Purpose

The purpose of this problem formulation is to provide the foundation for the ecological risk assessment being conducted for sodium fluoroacetate (1080). Although case number 3073 includes *2*-fluoroacetamide, this pesticide will not be assessed because there are no active labels. As such, it articulates the purpose and objectives of the risk assessment, evaluates the nature of the problem, and provides a plan for analyzing the data and characterizing the risk (EPA, 1998). Additionally, this problem formulation is intended to identify data gaps, uncertainties and potential assumptions needed to address those uncertainties in characterizing the ecological risk associated with the registered uses of sodium fluoroacetate.

2 Problem Formulation

2.1. Nature of Regulatory Action

The Food Quality Protection Act of 1996 mandated the EPA to implement a new program, *i.e.*, registration review (http://www.epa.gov/oppsrrd1/registration_review/). All pesticides distributed or sold in the United States generally must be registered by EPA. The decision to register a pesticide is based on the consideration of scientific data and other factors showing that it will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. The registration review program is intended to ensure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health and the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the new registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely.

As part of the implementation of the new Registration Review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Agency is beginning its evaluation to determine whether sodium fluoroacetate continues to meet the FIFRA standard for registration. This problem formulation for the environmental fate and ecological risk assessment chapter in support of the registration review is intended for the initial docket opening the public phase of the review process.

2.2 Regulatory History

Development and use of sodium fluoroacetate as a predacide and rodenticide in the United States began in the 1940s (e.g., Robinson, 1948) prior to the 1947 enactment of the Federal Insecticide, Fungicide and Rodenticide Act (1947). Products containing sodium fluoroacetate were among those registered shortly after the Act went into effect.

Following the issuance of Executive Order 11643 in 1972, which banned the use of poisons to control predators on Federal lands, EPA issued PR Notice 72-2 which canceled all registered predator control uses of sodium fluoroacetate, sodium cyanide, and strychnine (Ruckelshaus, 1972).

In 1977, the U.S. Department of the Interior (USDI) applied for an Experimental Use Permit (EUP) to investigate the potential risks and benefits associated with the use of sodium fluoroacetate in "toxic collars" to be placed on the necks of sheep and goats. EPA classified all legal uses of sodium fluoroacetate as "Restricted" due to "Acute oral toxicity hazard to non-target organisms, use and accident history" in 1978 (Costle, 1978). In 1981, EPA was petitioned by the USDI and livestock interests to reevaluate the aforementioned 1972 predacide cancellation decision with respect to sodium fluoroacetate.

On July 18, 1985, EPA granted a registration (EPA Registration Number 6704-85) to USDI for the Livestock Protection Collar (LPC) containing sodium fluoroacetate. In 1986, this product was transferred to the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA, Registration No. became 56228-22). Since the registration for USDI, five State-limited registrations have been issued for sodium fluoroacetate beginning in 1987. These products permit use of collars in Montana, New Mexico, South Dakota, Texas, and Wyoming.

Following the receipt of a 1993 Biological Opinion (BO) from the U.S. Fish and Wildlife Service, labels for 1080 products were modified to include language for the protection of endangered species. Specifically, restrictions on use of the LPC in the habitat of endangered species were listed on the labels (Appendix A). Endangered species identified on the label included the California condor, San Joaquin kit fox, black-footed ferret, Louisiana black bear, jaquarundi, ocelot, Northern Rocky Mountain wolf and grizzly bear.

On, January 24, 2007, ten non-governmental organizations, Sinapu, Public Employees for Environmental Responsibility (PEER), Beyond Pesticides, Forest Guardians, Predator Defense, Western Wildlife Conservancy, Sierra Club, The Rewilding Institute, Animal Defense League of Arizona, and Animal Welfare Institute, petitioned the Agency for cancellation of all registered uses of 1080. The request for cancellation was based on purported unreasonable adverse effects on the environment, misuse, inability of the registrant to secure the pesticide (prevent unauthorized access) and harm to endangered species. Following review of this petition, the Agency determined use of 1080 does not create unreasonable adverse effects on the environment under FIFRA and its registration meets the FIFRA eligibility standards as indicated in a memo the may be located on the docket, dated March 6, 2009.

However, as part of this registration review action, the Agency will reconsult with U.S. Fish and Wildlife Services in accordance with Section 7 of the Endangered Species Act (USFWS/NMFS, 1998) based on additional species identified and potential changes in ranges/habitat boundaries for previously identified species. A letter initiating formal

consultation will be delivered to USFWS. In addition, EPA will confirm that the measures in place remain adequate to protect listed species identified from the 1993 BO and recommend additional measures for new listed species identified if necessary.

2.3. Previous Risk Assessments

A Reregistration Eligibility Decision (RED) that included an ecological risk assessment for fish, invertebrates, and plants in aquatic habitats, as well as birds, mammals, invertebrates/honey bees and plants in terrestrial habitats, was issued in May of 1995 for sodium fluoroacetate. The 1995 RED evaluated risks to non-target species of birds and mammals including endangered and non-endangered species via potential exposure through the following mechanisms.

Primary hazard

- Contaminated sheep or goat carcasses with either broken (punctured) or unbroken collars
- Toxicant spilled on the ground or vegetation when a collar is punctured

Secondary hazard

- Carcasses of coyotes killed by the sodium fluoroacetate livestock protection collars and not removed
- Vomitus of poisoned coyotes. (The chemical has emetic properties)

In the 1995 RED, the Agency reviewed a variety of laboratory and field studies that documented the efficacy, fate, toxicity, and secondary poisoning of sodium fluoroacetate on wildlife. References for those studies are found in the Reference section and will be summarized in the registration review assessment. Based on this review, the Agency concluded that the principal source of risk is exposure of scavengers feeding on the head and neck area of dead livestock bearing the sodium fluoroacetate livestock protection collars. The other sources of exposure identified above were identified as not likely to result in unacceptable risk. Several factors were cited that are believed to reduce the risk associated with use of the sodium fluoroacetate livestock protection collars including: include rapid decomposition of carcasses; selective feeding of scavengers from wounds on the carcass rather than contaminated skin surface of the head or neck; and the emetic property of the chemical. The Agency further concluded that the risk concerns for wildlife could be addressed with applicators following environmental hazard statements, special use restrictions, and endangered species protection statements that are required to be placed on the label.

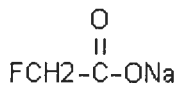
The Agency further concluded that there was low potential risk to aquatic animals, terrestrial insects or plants based on: 1) its low likelihood of exposure as determined from its fate and transport characteristics, and 2) its restricted registered use pattern in the Livestock Protection Collar for sheep and goats, which limits the number of collars to be used. In addition, the Agency concluded that sodium fluoroacetate has the potential for

leaching into groundwater if applied to a soil surface in a sufficient quantity. Regarding spray drift, the Agency concluded that there is a very low potential for exposure via spray drift because sodium fluoroacetate is applied in a collar and its release is not expected to lead to significant spray drift. The data were considered sufficient at the time to allow the Agency to assess the registered uses of sodium fluoroacetate and to determine that sodium fluoroacetate could be used without resulting in unreasonable adverse effects to humans and the environment.

3 Stressor Source and Distribution

Currently, sodium fluoroacetate is a restricted use pesticide in the United States and is registered for use by the U.S. Department of Agriculture and five states (Montana, New Mexico, South Dakota, Texas and Wyoming). Based on the available information from the Material Safety Data Sheet, Center for Disease Control, and the INCHEM web site, sodium fluoroacetate appears to be mobile in soil and is considered as the stressor in this assessment (Table 3.1). 2-fluoroacetamide is not considered to be a stressor in the assessment because they are no active labels.

Table 3.1 Summary of Chemical Information and Physicochemical Properties of Sodium Fluroacetate (1080).

Chemical Formula	FCH_2CO_2Na
Chemical Structure	
Synonyms:	Compound 1080, SFA, Monofluoroacetate
CAS No.:	62-74-8
Appearance:	White Powder
Odor:	Odorless
Molecular Weight:	100.02 g / mol
Solubility in Water	1110 g / L at $25C^{O}$
pH:	10.3
Flash Point:	55.3 °C
Melting Point:	$392^{O}F$, $200^{O}C$ (Decomposes)
Vapor Pressure (mm Hg):	0.828 mmHg at 25°C
Stability:	Chemically stable due to the strong C-F bond. Stable up to 100C under normal storage conditions. The aqueous solution is expected to be stable at any pH. (WHO 1975)
Henry's Law Constant	Non-volatile

Conditions to Avoid:	Explosive about Flash Point
(Material Data Safety Sheet: http://www.sciencelab.com/msds.php) (Centers Disease Control and Prevention: http://www.cdc.gov/niosh/npg/npgd0564.html) (INCHEM: (http://www.inchem.org/documents/pims/chemical/pim494.htm)	

3.1. Mechanism of Action

Although animals vary widely in their sensitivity to sodium fluoroacetate (discussed in the following sections), its basic mode of action is considered the same in all animals. Sodium fluoroacetate acts by disrupting the "Krebs cycle", the metabolic pathway that breaks down food for providing energy for cell function. At sufficiently high doses, this disruption leads to a rapid depletion of energy reserves, which is followed by death usually from cardiac or respiratory failure. Animals that are exposed to sub-lethal doses may show mild signs of poisoning. However, sublethal exposures of sodium fluoroacetate are subject to metabolic transformation and excretion, generally within one to four days, after which the animal recovers. Therefore, sublethal ingestion of sodium fluoroacetate is expected to be eliminated within one week[1].

3.2. Overview of Pesticide Usage

Sodium flouroacetate is a restricted use pesticide in the United States. There is one concentrate product registered to USDA/APHIS (56228-26) that is limited to use in the manufacture of Livestock Protection Collars. There are six use labels currently registered. There is one use label for the USDA/APHIS. Sodium fluoroacetate is also registered for use by five states (Montana, New Mexico, South Dakota, Texas, and Wyoming).

The current labels for sodium fluoroacetate represent the FIFRA regulatory action; therefore, labeled use and application rates specified on the label form the basis of this assessment. The assessment of pesticide use information is critical to the development and selection of appropriate modeling scenarios and inputs.

Uses for sodium fluoroacetate are presented in **Table 3.3** with label maximum application rates. All collars have the same amount of sodium fluoroacetate. For this assessment, one application per year is used. Up to 20 collars may be used in fenced pastures up to 100 acres in size. Up to 50 collars may be used in pastures of 101 to 640 acres. Up to 100 collars may be used in pastures of 641 to 10,000 acres.

A set of 18 label restrictions have been issued for sodium fluoroacetate which greatly restrict the exposure and risk potential of this pesticide (Appendix A). The restrictions that apply to the ecological risk assessment include number of collars that may be used

[1] http://www.doc.govt.nz/ publications/conservation/threats-and-impacts/animal-pests/the-use-of-sodium fluoroacetate-for-pest-control/4-information-about-sodium fluoroacetate/4_1-key-facts/

and use in areas where it is possible to monitor the restrictions (1080 may not be used in open range). Applicators must be trained, and only the registrant or manufacturer, not the applicators may refill the collars. The collars may only be used when evidence of predation has been demonstrated or may be reasonably expected from past attacks. Livestock are required to be monitored for damaged or missing collars every seven days. All use of the collars is required to be discontinued if more than nine collars cannot be accounted for in a 60-day period. Damaged collars and other waste are to be buried under three feet of soil and not to be buried within ½ mile of human habitation and water supplies. No more than 10 collars may be buried in one hole.

Table 3.3. Summary of Sodium Fluoroacetate Uses[1] and Application Information

USE	Max Appl Rate (lb/A)	Number of Collars
Sheep/Lambs/Kids/Goats/Dairy Goats	0.00067-0.0134	1- 20 collars may be used in fenced pastures up to 100 acres in size.
	0.01407-0.0335	21- 50 collars may be used in pastures of 101 to 640 acres
Goats (wool/angora)	0.03417-0.067	51- 100 collars may be used in pastures of 641 to 10,000 acres.

1. Uses assessed based on LUIS report Table 1 and EFED label data report.

3.3. Environmental Fate and Transport

As part of the 1995 RED, the Agency reviewed all submitted environmental fate and transport studies and none were found to be acceptable. Based on available data in the open literature, sodium fluoroacetate does not appear to be persistent in soil. Based on its reported high solubility in water, it has the theoretical potential to move through the soil into groundwater if it reaches to the soil surface in a sufficiently quantity. Selected studies documenting the environmental fate of sodium fluoroacetate are summarized below.

Degradation of Sodium Fluoroacetate in the Environment

Studies show that micro-organisms in New Zealand soils will degrade sodium fluoroacetate. The degradation occurs by enzymes defluorinating fluoroacetate (removing the fluorine atom). Ultimately, enzyme intermediates and non-toxic products are formed, such as glycolate (Eason, C.T., 2002). Common soil fungi can also defluorinate sodium fluoroacetate (Walker, J.R.L., 1994).

In laboratory experiments, the amount of sodium fluoroacetate remaining in soils was reduced to 50% after 10 days at 23°C, 30 days at 10°C and 80 days at 5°C (Parfitt, R.L., Eason, C.T., Morgan, A.J., Wright, G.R.T., Burke, C.M., 1994). Leaching experiments in soil showed that traces of sodium fluoroacetate might be leached through soil, particularly if heavy rainfall occurred shortly after sodium fluoroacetate was applied. The conclusion made by the authors of a range of studies into the fate of sodium fluoroacetate in New Zealand soils is that "most New Zealand soils can be expected to contain micro-organisms with the ability to rapidly develop enzymes capable of degrading sodium fluoroacetate" (Walker, J.R.L., 1994). This suggests that any sodium fluoroacetate that leaches from baits or carcasses should have little persistence in New Zealand soils, at least at temperatures above 5°C.

Biodegradation of sodium fluoroacetate in the environment occurs even more rapidly in water. At 21°C, microorganisms in water degrade sodium fluoroacetate in two to six days (Parfitt, R.L., Eason, C.T., Morgan, A.J., Wright, G.R.T., Burke, C.M., 1994). At lower temperatures, microbial action is slower and degradation might take one to two weeks, or longer, at temperatures below 7°C. Aquatic plants can also significantly affect sodium fluoroacetate degradation rates. In laboratory experiments, the presence of a native aquatic plant (*Myriophyllum triphyllum*) reduced concentrations of sodium fluoroacetate below detectable levels within one day (at 23°C) and within three days (at 7°C) (Ogilvie, S.C., Bowen, L.H., Eason, C.T., 1995).

Monitoring of sodium fluoroacetate in waterways has been conducted in New Zealand where it is reportedly widely used for possum control in the form of baits (Eason 2002). Specifically, Eason (2002) summarized results from multiple monitoring programs between 1990 and 2000 which were undertaken after possum and rabbit control operations using aerially sown 1080. Eason (2002) reported that:

> *"There has been no evidence of 1080 presence in reticulated water and no evidence of significant or prolonged 1080 contamination in surface or ground waters."*

Given the apparent larger scale of 1080 use in these New Zealand control programs, these findings suggest that the highly restricted LTC use in the U.S. is not likely to lead to significant contamination of U.S. surface water resources. Further review of these and other environmental fate studies involving sodium fluoroacetate will be conducted as part of the forthcoming ecological risk assessment for registration review.

4 Receptors

The receptor is the biological entity that is exposed to the stressor (EPA, 1998). The types of terrestrial, non-target receptors that may be exposed include birds, reptiles and terrestrial-phase amphibians. Although toxicity studies for aquatic animals were received, the Agency is not expecting to conduct an aquatic ecological risk assessment due to the very low likelihood of sodium fluoroacetate exposure in aquatic environments. As described previously, exposure in aquatic ecosystems is considered to be highly unlikely given the limited volume of chemical used, its likely environmental degradation and its highly restrictive use pattern as informed by the label use restrictions. Nevertheless, available monitoring data in aquatic systems will be reviewed to confirm this assumption, in particular those in New Zealand where this pesticide has been extensively used and studied.

Consistent with the process described in the Overview Document (EPA, 2004), this risk assessment uses a surrogate species approach in its evaluation of sodium fluoroacetate. Toxicological data generated from surrogate test species, which are intended to be representative of broad taxonomic groups, are used to extrapolate to potential effects on a variety of species (receptors) included under these taxonomic groupings.

Table 4.1 provides a summary of the taxonomic groups and the surrogate species tested to help understand potential ecological effects of pesticides to these non-target taxonomic groups. In addition, the table provides a preliminary overview of the potential acute toxicity of sodium fluoroacetate by providing the acute toxicity classifications. No chronic toxicity studies are available for sodium fluoroacetate because there is a 100% mortality assumption based on acute exposure.

4.1 Terrestrial Receptors

Direct and indirect effects on birds and mammals will be assessed from acceptable submitted studies. Studies reviewed for the RED, as well as any new studies, will be evaluated to determine if there are more sensitive endpoints that are acceptable for use in the assessment.

Birds

No acute, oral toxicity studies have been submitted by the registrant for birds (i.e., LD_{50} data). Data from open literature was previously reviewed for the 1995 RED, indicating sodium fluoroacetate ranges from highly toxic to very highly toxic (e.g., LD_{50} values of 15.0 mg/kg-bw for the Black Vulture, 1.0 mg/kg-bw for the magpie, to 9.1 mg/kg-bw for the mallard duck). Available toxicological studies from the open literature will be reviewed for the forthcoming ecological risk assessment and the most sensitive result that is considered acceptable for quantitative use will be used in this assessment.

An acceptable dietary toxicity test for the Bobwhite quail (MRID 432160-01) resulted in an LC_{50} of 486 mg/kg-diet. However, a more sensitive dietary study for the mallard duck was received. Based on the acceptable LC_{50} of 231 mg/kg-diet for mallard duck (MRID 432160-02), sodium fluoroacetate is classified as being highly toxic to birds on an acute, dietary basis.

Mammals

In addition to evaluating the studies on birds, studies on mammals were also reviewed. An acute rat study (MRID 400169-71) reviewed by HED resulted in an LD_{50} of 0.22 mg/kg-bw and is classified as very highly toxic. Open literature from ECOTOX will be reviewed to determine if there are more sensitive acute and chronic toxicity endpoints that are acceptable for use in the forthcoming risk assessment.

Table 4.1. Test Species Evaluated for Assessing Potential Ecological Effects of Sodium Fluoroacetate and the Associated Acute Toxicity Classification

Taxonomic Group	Example(s) of Surrogate Species	Acute Toxicity Classification
Bird[1]	Bobwhite (*Colinus virginianus*)	LC_{50} = 486 mg/kg (CI of 339-696mg/kg) (MRID 432160-01) Moderately toxic
		An avian reproductive study is not required under Part 158 for indoor uses [4].
	Mallard (*Anas platyrhynchos*)	14d LD_{50}=9.1 mg/kg-bw (5.6-14.6)(Hudson et al, 1984) Very Highly toxic
		LC_{50}=231 mg/kg-diet MRID 432160-02
		An avian reproductive study is not required under Part 158 for indoor uses.
	Rat	LD_{50} = 0.22 mg/kg-bw (MRID 400169-71) Very Highly Toxic
		A rat reproductive study is not required under Part 158 for indoor uses.

Table 4.1. Test Species Evaluated for Assessing Potential Ecological Effects of Sodium Fluoroacetate and the Associated Acute Toxicity Classification		
Taxonomic Group	**Example(s) of Surrogate Species**	**Acute Toxicity Classification**
Insects	Honey bee (*Apis mellifera L.*)	A honey bee study is not required under Part 158 for indoor uses.
Freshwater Fish[2]	BlueGill (*Lepomis macrochirus*)	Bluegill LC_{50}>970 mg/L (MRID 429616-01) Practically nontoxic
	Rainbow trout (*Oncorhynchus mykiss*)	Rainbow trout LC_{50}=54 mg/L (MRID 429616-02) Slightly toxic
	Fathead minnow (*Pimephales promelas*)	A fathead reproductive study is not required under Part 158 for indoor uses.
Aquatic Invertebrates	*Daphnia magna*	Acute EC_{50}=350.6 mg ai/L (MRID 429616-03) Practically non-toxic
		A *Daphnia* life cycle study is not required under Part 158 for indoor uses.
Estuarine/marine fish	Sheepshead minnow *(Cyprinodon variegatues)*	A sheepshead minnow study is not required under Part 158 for indoor uses.
Estuarine/marine invertebrates	Mysid shrimp *(Americamysis bahia)*	A mysid shrimp study is not required under Part 158 for indoor uses.
	Eastern oyster (*Crassostrea virginica)*	An Eastern oyster study is not required under Part 158 for indoor uses.
Terrestrial plants[3]	Vegetative Vigor Monocots – Wheat (*Tritum gestivum*) Dicots – Rape (*Brassica napur*)	Not required if the pesticide is contained. Sodium fluoroacetate is contained in the bladder on the livestock protection collar unless the bladder is punctured. If there is a puncture and the pesticide enters the soil, it is reduced by soil micro-organisms. In the aquatic environment. Micro-organisms also biodegrade sodium flouroacetate.
	Seedling Emegence Monocots – Sorghum (*Sorghum bicolor*) Dicots – Tomato (*Lycopersicon esculentum*)	
Aquatic plants and algae	Duckweed (*Lemna gibba*)	
	Green algae *(Pseudokirchneriella subcapitata*)	
	Blue green Algae (*Anabaena flos-aquae*)	
	Freshwater Diatom (*Navicula pelliculosa)*	

Table 4.1. Test Species Evaluated for Assessing Potential Ecological Effects of Sodium Fluoroacetate and the Associated Acute Toxicity Classification		
Taxonomic Group	**Example(s) of Surrogate Species**	**Acute Toxicity Classification**
	Marine Diatom (*Skeletonema costatum*)	

[1] Birds represent surrogates for terrestrial-phase amphibians and reptiles.-
[2] Freshwater fish may be surrogates for aquatic-phase amphibians.
[3] Four species of two families of monocots, of which one is corn; six species of at least four dicot families, of which one is soybeans.
[4] Toxicity data requirements for sodium fluoroacetate are based on its previous registration as an "indoor" use pesticide.

4.2 Ecological Incidents

Reported incidents to terrestrial species are also considered in determining risk. A preliminary review on April 20, 2010 of the Ecological Incident Information System (EIIS, version 2.1), maintained by the Agency's Office of Pesticide Programs, and the Avian Monitoring Information System (AIMS), maintained by the American Bird Conservancy, indicates eight reported ecological incident associated with the use of 1080. This total excludes incidents classified as 'unlikely' and only includes those incidents with certainty categories of 'highly probable', and 'probable' and 'possible' (for EIIS) and 'certain', 'highly likely', 'likely', 'probable', and 'possible' (for AIMS). In the EIIS and AIMS databases, the "unlikely" category is used when a chemical is not likely to be responsible for the incident. For example, an 'unlikely' classification might be applied in situations where a given chemical is practically nontoxic to the category of organism killed and/ or there is evidence that another pesticide or stressor likely caused the incident. Incidents classified as 'unlikely' for 1080 will not be included in this Problem Formulation or the ecological risk assessment conducted for Registration Review.

Incident reports for non-target organisms typically provide information only on mortality events and plant damage incidents. Except for phytotoxic effects in terrestrial plants, sub-lethal effects for organisms such as reduced growth or impaired reproduction are rarely reported. EPA's changes in the registrant reporting requirements for incidents in 1998 may account for a reduced number of reported incidents. Registrants are now only required to submit detailed information on 'major' fish, wildlife, and plant incidents. Minor fish, wildlife, and plant incidents, as well as all other non-target incidents, are generally reported aggregately and are not included in EIIS.

No aquatic incidents or plant incidents are reported in the EIIS database for sodium fluoroacetate. The EIIS database describes nine terrestrial animal incidents, covering a period from 1984-2003. However, one of those incidents (IO05417-004, in 1989) is classified as unlikely and will not be included in the risk assessment. There are also two incidents from Idaho classified as probable that were determined to be misuses of 1080 (IO19079-007, in 2000 and IO19079-008, in 2003). The two reported bird incidents (IO 013810-019, in 1984 and IO05417-003, in 1989) are also reported in the AIMS database. The 1984 incident (IO013810-019) is classified as probable and reports that three yellow-billed magpie died in California. The 1989 incident (IO05417-003) is classified as

possible and is reported as a registered use. Mortality is reported for fifty-eight ravens in California.

Four incidents classified as highly probable are reported from Idaho (IO19079-003 in 1999, IO19079-005 in 1999, IO19079-006 in 2000 and IO19079-004 in 2000). All four report mortality for one gray wolf per incident.

Table 4.2. Ecological Incidents Reported for Sodium Fluoroacetate in the EIIS and AIMS Databases.

Incident ID	Use Site	Start Date	Species	Legality	Certainty	State	County	Year	Total No.	Appl. Rate	Appl. Method
I013810-019	N/R	4/01/1984	Magpie	Undetermined	Probable	CA	Monterey	1984	3		Bait
I005417-004	N/R	5/16/1989	Rabbit	Undetermined	Unlikely	CA	Kern	1989	12	6 lb/a	Hand application
I005417-003	Rangeland	5/18/1989	Raven	Registered Use	Possible	CA	Kern	1989	58	9.4 lbs/a	
I019079-003		3/31/1999	Gray Wolf	Undetermined	Highly Probable	ID		1999	1		Animal control device
I019079-005		5/16/1999	Gray Wolf	Undetermined	Highly Probable	ID		1999	1		Animal control device
I019079-006		8/29/2000	Gray Wolf	Undetermined	Highly Probable	ID		2000	1		Animal control device
I019079-004		8/29/2000	Gray Wolf	Undetermined	Highly Probable	ID		2000	1		Animal control device
I019079-007		12/2/2000	Gray Wolf	Misuse (intentional)	Probable	ID		2000	1		Animal control device
I019079-008		5/19/2003	Gray Wolf	Misuse (intentional)	Probable	ID		2003	1		Animal control device

In the risk assessment, the incidents will be further evaluated to determine if they represent current patterns of use for 1080. Examples of additional considerations are mitigation (*e.g.*, reduced application rates), product cancellations, and changes in use patterns that have occurred since the date of the reported incidents.

Sodium fluoroacetate is not among the constituents monitored by the National Water Quality Assessment Data Warehouse (NAWQA), maintained by the U.S. Geological Survey.

4.3 Ecosystems Potentially at Risk

Although the current registration review problem formulation develops an ecological risk assessment based on nation-wide use, it may not be possible to identify specific ecosystems at risk. The method of application (livestock collars) and usage restrictions reduces the exposure to ecosystems. Although there are a small number of reports of punctured collars leaking into the environment, the primary exposure is terrestrial from ingestion directly into the mouth or from secondary poisoning from the carcasses.

Based on the restricted use pattern and small number of collars used, significant exposure in aquatic exposure is considered highly unlikely. Although run-off and leaching are

possible routes, the amount of sodium fluoroacetate released into the environment is very low based on current label rates and use restrictions (Appendix A).

5 Assessment Endpoints

Assessment endpoints are defined as "explicit expressions of the actual environmental value that is to be protected." Defining an assessment endpoint involves two steps: 1) identifying the valued attributes of the environment that are considered to be at risk; and 2) operationally defining the assessment endpoint in terms of an ecological entity (i.e., a community of birds, mammals and terrestrial invertebrates) and its attributes (i.e., survival and reproduction). Therefore, selection of the assessment endpoints is based on valued entities (i.e., ecological receptors), the ecosystems potentially at risk, the migration pathways of pesticides, and the routes by which ecological receptors are exposed to pesticide-related contamination. The selection of clearly defined assessment endpoints is important because they provide direction and boundaries in the risk assessment for addressing risk management issues of concern. Changes to assessment endpoints are typically estimated from the available toxicity studies, which are used as the measures of effects to characterize potential ecological risks associated with exposure to pesticides, such as sodium fluoroacetate.

To estimate exposure concentrations, the ecological risk assessment will consider a single application at the maximum application rate from livestock collars. Exposure will be evaluated at 100% of the rate in the collar, which is the most conservative estimate. The most sensitive toxicity endpoints will be used from surrogate test species to estimate treatment-related direct effects on acute mortality assessment endpoints. Toxicity tests are intended to determine effects of pesticide exposure on birds and mammals, as well as terrestrial-phase amphibians and reptiles using birds as surrogates. These tests include short-term acute studies and are typically arranged in a hierarchical or tiered system that progresses from basic laboratory tests to applied field studies. The toxicity studies are used to evaluate the potential of a pesticide to cause adverse effects, to determine whether further testing is required, and to determine the need for precautionary label statements to minimize the potential adverse effects to non-target animals.

An open literature search will be conducted to determine any relevant endpoints. The search will focus on survival, growth and reproductive effects from primary or secondary poisoning as terrestrial effects of sodium fluoroacetate. More sensitive endpoints from acceptable open literature studies will be included in this risk assessment.

6 Conceptual Model

For a pesticide to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a pesticide moves in the environment from a source to an ecological receptor. For an ecological pathway to be complete, it must have a source, a release mechanism, an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure.

A conceptual model provides a written description and visual representation of the predicted relationships between sodium fluoroacetate, potential routes of exposure, and the predicted effects for the assessment endpoint. A conceptual model consists of two major components: risk hypothesis and a conceptual diagram (EPA, 1998).

6.1 Risk Hypothesis

Risk hypotheses are specific assumptions about potential adverse effects (i.e., changes in assessment endpoints) and may be based on theory and logic, empirical data, mathematical models, or probability models (EPA, 1998). For this assessment, the risk is stressor-initiated, where the stressor is the release of sodium fluoroacetate into the environment. For sodium fluoroacetate, the following ecological risk hypothesis is being employed for this risk assessment:

> *Sodium fluoroacetate, when used in accordance with the label, results in exposure of non-target terrestrial vertebrates through direct contact with punctured collars and secondary poisoning via consumption of contaminated carcasses. These exposures have the potential to result in adverse effects on survival, growth and reproduction of non-target terrestrial vertebrates.*

The conceptual model is a generic graphic depiction of the risk hypothesis. It includes the potential pesticide or stressor (sodium fluoroacetate), the source of the pesticide and/or transport pathways, exposure media, exposure point, biological receptor types, and attribute changes.

6.2 Conceptual Diagram

The conceptual site model is a generic graphic depiction of the risk hypothesis, and assumes that sodium fluoroacetate, having indoor nonfood uses, is capable of affecting terrestrial animals provided that environmental concentrations are sufficiently elevated as a result of proposed label uses. Based on an examination of the physico-chemical properties of sodium fluoroacetate, the fate and disposition in the environment, and mode of application, a conceptual model was developed that represents the possible relationships between the stressors, ecological receptors, and the assessment endpoints. Through a preliminary iterative process of examining available data, the conceptual model (i.e., the representation of the risk hypothesis) may be refined to reflect the likely exposure pathways and the organisms that are most relevant and applicable to this assessment (see **Figure 6.1**, below). It includes the potential pesticide or stressor (sodium fluoroacetate), the sources and/ or transport pathways, exposure media, exposure points, biological receptor types and attribute changes.

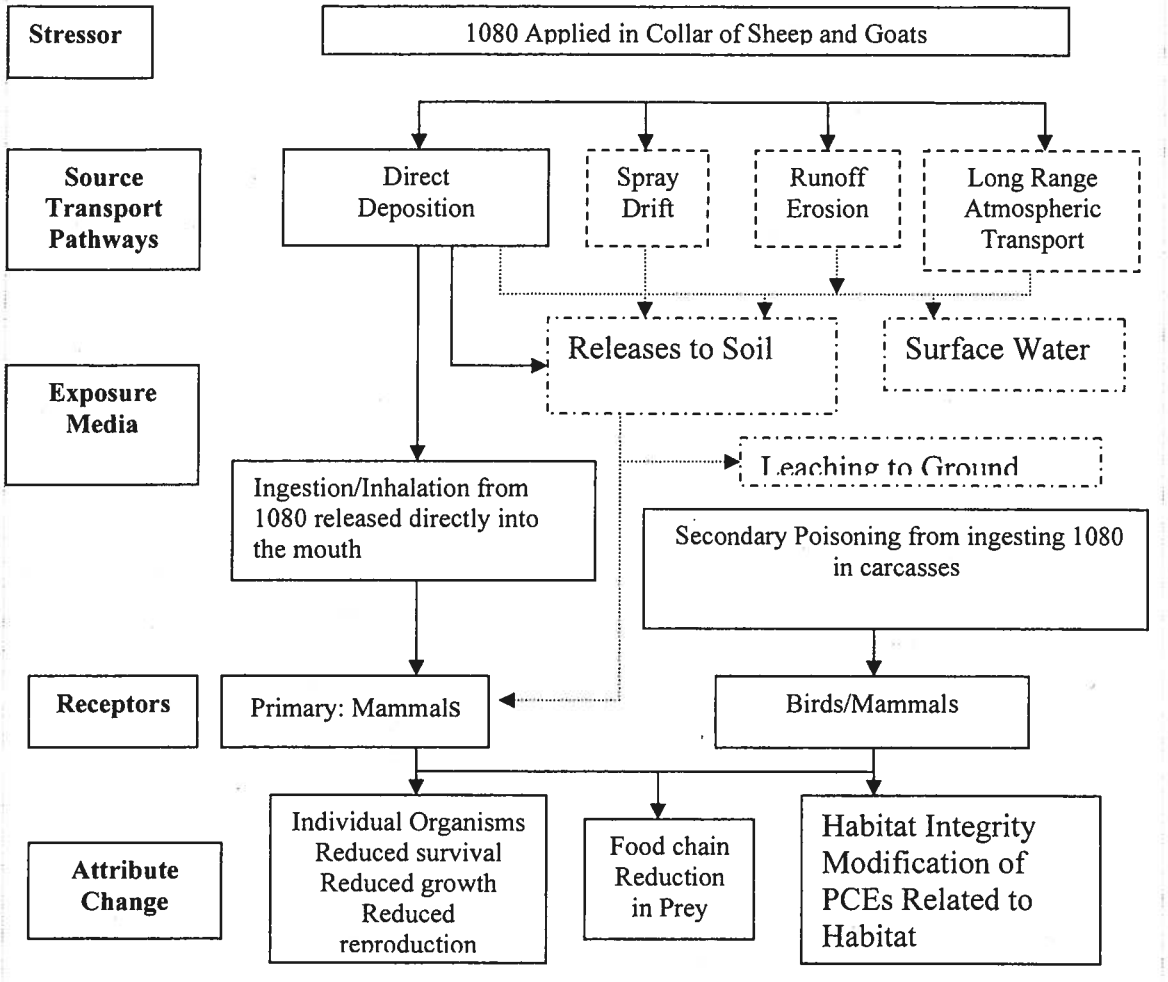
In order for a chemical to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a pesticide moves in the environment from a source to an ecological receptor. For an

ecological exposure pathway to be complete, it must have a source, a release mechanism, an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure. In addition, the potential mechanisms of degradation/ transformation (i.e., which degradation/ transformation products may form in the environment, in which media, and how much) must be understood, especially if for the chemical, its metabolites/ transformation products are of greater toxicological concern than the parent compound. The assessment of ecological exposure pathways, therefore, includes an examination of the source and potential migration pathways for constituents, and the determination of potential exposure routes.

Under the possible uses of sodium fluoroacetate, the sources and mechanisms of release of the compound are from punctures of the collar. There is low risk to non-target species based on the method of application. When a terrestrial species punctures the collar while preying on the protected livestock, sodium fluoroacetate is injected directly into the mouth causing death. There is a possibility of secondary poisoning from the carcasses of predators that have ingested the pesticide, however, number of collars is small and there is a small amount of sodium fluoroacetate per collar. The representative terrestrial receptors are mammals (predatory and scavenging) birds (scavenging), and reptiles (scavenging). The attribute changes used to assess risk to terrestrial receptors depend on the type of test (e.g., reduced survival, growth, or reproduction for animals).

Several potential exposure pathways are not expected to be evaluated in the forthcoming ecological risk assessment. These include direct deposition to soil and subsequent leaching to ground water, runoff to surface water, or direct exposure to terrestrial wildlife (soil ingestion). Based on previous risk assessment conducted in the 1995 RED, these exposure pathways are considered very unlikely due to the chemical properties, use patterns, and label use restrictions. Long-range atmospheric transport is also not expected to be a concern given the chemical properties and use pattern.

Figure 6.1. Ecological Conceptual Exposure Model for Screening Level Risk Assessment of Sodium Fluroacetate/1080 Applied in a Livestock Protection Collar



7 Analysis Plan

In order to address the risk hypothesis, the potential for adverse effects on the environment is estimated. Sodium fluoroacetate and 2-fluoroacetamide are included in Case 3073. However 2-fluoroacetamide does not have any active labels and therefore no assessment of this pesticide will be conducted. Usage, environmental fate and transport, and ecological effects of sodium fluoroacetate are characterized and integrated to assess the risks. This is accomplished using lines of evidence. Open literature references for 1080 are located in Appendix B. Summaries of fate studies to be used in the assessment may be found in Appendix C.

No aquatic exposure is likely based on the highly restricted use pattern and low number of collars in use. The restrictions for the use of sodium fluoroacetate include providing a statement that other alternatives have been used prior to using sodium fluoroacetate. No aquatic or terrestrial exposure from runoff or leaching is expected. Although run-off and leaching are possible routes, the amount of sodium fluoroacetate released into the environment appears to be very low based on field data summarized in the 1995 RED.

The status of actions resulting from a Petition to Cancel 1080 initiated by Sinapu, Public Employees for Environmental Responsibility (PEER), Beyond Pesticides, Forest Guardians, Predator Defense, Western Wildlife Conservancy, Sierra Club, The Rewilding Institute, Animal Defense League of Arizona, and Animal Welfare Institute, (January 24, 2007) will be reviewed for the assessment. Although the petition to cancel 1080 was denied (EPA Response Petition to Cancel Sodium Fluoroacetate, January 16, 2009), the Agency will reconsult with US Fish and Wildlife Services based on additional species identified and potential changes in habitat boundaries for previously identified species. Therefore, a new ecological risk assessment and additional ecological toxicity and environmental fate data are not anticipated as being needed for sodium fluoroacetate in support of registration review. However, as outlined in the Agency's response to the petition and addenda (filed on January 24, 2007, March 20, 2007, July 27, 2007 and January 7, 2008) requesting that EPA suspend and cancel the registration of the predator control uses of sodium cyanide (M-44) and sodium fluoroacetate (Compound 1080), the Agency will conduct an endangered species assessment for the registered use of Compound 1080.

Risk will be re-evaluated in terms of the eighteen use restrictions (Appendix A) added to the labels to reduce the risk to listed animals. One restriction provides provisions for protecting endangered species including the California condor, San Joaquin kit fox, black-footed ferret, Northern Rocky Mountain wolf and grizzly bear based on the 1993 Biological Opinion. Nonetheless, during consultation with the US Fish and Wildlife Service on other species potentially affected, EPA will confirm that the measures in place remain adequate and that the ranges of these species have remained constant since the 1993 BO.

In addition to submitted toxicity studies, open literature will be reviewed for information concerning primary and secondary poisoning from 1080.

Incident reports will be reviewed. No modeling will be conducted due to the conservative assumption of one-hundred percent mortality for terrestrial vertebrates puncturing the collar. Although, the Overview Document (USEPA, 2004) provides for determining the likelihood of effects to individual organisms from particular uses of a chemical by estimating the probit dose-response slope and either the level of concern or the actual calculated risk quotient value, no RQs for primary exposure are estimated for this assessment. RQs for secondary poisoning may be calculated if acceptable data is available to determine tissue residues.

This analysis plan will be revisited and may be revised depending upon the data available in the open literature and the information submitted by the public in response to the opening of the Registration Review docket.

7.1. Stressors of Concern

The focus of this assessment is on the parent material, sodium fluoroacetate. However, the Agency will review open literature to identify metabolite(s) of potential toxicological concern. Toxicity data for environmental mixtures of sodium fluoroacetate with other pesticides (those mixtures occurring in the environment following application), if available, may be presented as part of the ecological risk assessment. It is expected that the toxic effect of sodium fluoroacetate, in combination with other pesticides used in the environment, is likely to be a function of many factors including, but not necessarily limited to: (1) the exposed species, (2) the co-contaminants in the mixture, (3) the ratio of sodium fluoroacetate and co-contaminant concentrations, (4) differences in the pattern and duration of exposure among contaminants, and (5) the differential effects of other physical/ chemical characteristics of the receiving waters (e.g. organic matter present in sediment and suspended water). Quantitatively predicting the combined effects of all these variables on mixture toxicity to any given taxa with confidence is beyond the capabilities of the available data and methodologies. However, a qualitative discussion of implications of the available pesticide mixture effects data on the confidence of risk assessment conclusions will be addressed as part of the uncertainty analysis.

7.2. Measures of Exposure

Terrestrial exposure is expected to occur when the collar is punctured by a predator. A conservative assumption of 100% mortality will be made for any animal puncturing the collar. Secondary poisoning will be evaluated based on estimates of sodium fluoroacetate deposition on, and accumulation in, target and non-target predators. Although this pathway was evaluated in the 1995 RED, it will be re-evaluated with inclusion of current exposure assessment methods for estimating diet and dose-based EECs for terrestrial wildlife. These methods are described in the Agency's TREX model (version 1.4.1).

As indicated previously, exposure of aquatic or terrestrial receptors from runoff or leaching of sodium fluoroacetate is not expected to be a significant contribution to

ecological risk due to its chemical properties, method of use (contained in collars), very small volume of use, and use restrictions.

7.3. Measures of Effect

Ecological effects data are used as measures of direct and indirect effects to biological receptors. Data are typically obtained from registrant-submitted studies or from literature studies identified by ECOTOX. The ECOTOX database provides more ecological effects data in an attempt to bridge existing data gaps. ECOTOX is a source for locating single chemical toxicity data and potential chemical mixture toxicity data for aquatic life, terrestrial plants, and wildlife. ECOTOX was created and is maintained by the USEPA, Office of Research and Development, and the National Health and Environmental Effects Research Laboratory's Mid-Continent Ecology Division. The ECOTOX run has been received. The studies with endpoints for survival for both primary and secondary poisoning will be evaluated in the risk assessment.

Where available, sub-lethal effects observed in both registrant-submitted and open literature studies will be evaluated qualitatively. Such effects may include behavioral changes (e.g., lethargy and changes in coloration). Quantitative assessments of risks, though, are limited to those endpoints that can be directly linked to the Agency's assessment endpoints of impaired survival, growth and reproduction.

The assessment of risk for direct effects to non-target organisms makes the assumption that the toxicity of sodium fluoroacetate to birds is similar to terrestrial-phase amphibians and reptiles. The same assumption is made for fish and aquatic-phase amphibians.

The acute measures of effect used for animals in this assessment are the LD_{50}, LC_{50} and EC_{50}. LD stands for "Lethal Dose", and LD_{50} is the amount of a material, given all at once, that is estimated to cause the death of 50% of the test organisms. LC stands for "Lethal Concentration" and LC_{50} is the concentration of a chemical that is estimated to kill 50% of the test organisms. EC stands for "Effective Concentration" and the EC_{50} is the concentration of a chemical that is estimated to produce a specific effect in 50% of the test organisms. Endpoints for chronic measures of exposure for listed and non-listed animals are the NOAEL/NOAEC and NOEC. NOAEL stands for "No Observed-Adverse-Effect-Level" and refers to the highest tested dose of a substance that has been reported to have no harmful (adverse) effects on test organisms. The NOAEC (i.e., "No-Observed-Adverse-Effect-Concentration") is the highest test concentration at which none of the observed effects were statistically different from the control. The NOEC is the No-Observed-Effects-Concentration.

7.4. Integration of Exposure and Effects

Risk characterization is the integration of exposure and ecological effects characterization to determine the potential ecological risk from the use of pesticides and the likelihood of direct and indirect effects to non-target organisms in terrestrial habitats. The exposure and toxicity effects data are integrated in order to evaluate the risks of adverse ecological effects on non-target species. For the assessment of risks, the risk quotient (RQ) method

is usually used to compare exposure and measured toxicity values. EECs are divided by acute and chronic toxicity values. The resulting RQs are then compared to the Agency's Levels of Concern (LOCs) (USEPA, 2004). Primary exposure from puncturing the collar resulting in ingestion/inhalation is assumed to have a 100% mortality rate. Therefore, no RQs will be estimated for primary exposure. However, toxicity values from open literature for secondary poisoning from ingestion/inhalation from carcasses will be evaluated for use in the RQ for the risk assessment. These criteria will be used to indicate when sodium fluoroacetate's uses, as directed on the label, have the potential to cause adverse direct or indirect effects to non-target organisms. In addition, incident data from the EIIS and AIMS will be considered as part of the risk characterization.

7.5. Endangered Species Assessments

Consistent with the Agency's responsibility under the Endangered Species Act (ESA), the Agency will evaluate risks to Federally-listed threatened and/or endangered (listed) species from registered uses of 1080. This assessment will be conducted in accordance with the Overview Document (USEPA, 2004), provisions of the ESA, and the Services' Endangered Species Consultation Handbook (USFWS/NMFS, 1998).

The assessment of effects associated with the registration of 1080 is based on an action area. The action area is considered to be the area directly or indirectly affected by the federal action, as indicated by the exceedance of Agency Levels of Concern (LOCs) used to evaluate direct or indirect effects. The action area will encompass those areas designated on all labels. It also takes into account the potential for direct and indirect effects and any modification to critical habitat based on ecological effect measures associated with reduction in survival, growth and reproduction as well as sub-lethal effects.

The nationwide action area does not imply that direct and/or indirect effects and critical habitat modification are expected to or are likely to occur over the full extant of the action area, but rather to identify all listed species and critical habitat that may potentially be affected by the action. The agency will use more rigorous analyses, including consideration of available land cover data, toxicity data and exposure information to determine areas where individual listed species and designated critical may be affected or modified via endpoints associated with survival, growth or reproduction.

The Agency's approach to defining the action area under the provisions of the Overview Document (USEPA 2004) considers the results of the risk assessment process to establish boundaries for that action area. For the purposes of this assessment, attention will be focused on the footprint of the action (i.e., the area where 1080 application occurs), plus all areas where offsite transport may result in potential exposure. Specific measures of ecological effect that define the action area for listed species include any direct and indirect effects and/ or potential modification of its critical habitat, including reduction in survival, growth, and reproduction as well as the full suite of sub-lethal effects available in the effects literature. Therefore, the action area extends to a point where environmental exposures are below any measured lethal or sub-lethal effect threshold for any biological entity at the whole organism, organ, tissue, and/ or cellular level of organization.

The 1993 Biological Opinion (BO) provided a list of endangered species and actions to reduce risk to those species resulting from the use of 1080 for control of coyotes. Those species and modification were added to the labels as restrictions to protect endangered species identified in the opinion. Species identified in the opinion include the California condor, San Joaquin kit fox, black-footed ferret, Northern Rocky Mountain wolf and grizzly bear. The document lists no federal agencies using 1080, although USDA does have an active label. States with registrations covered under the BO include Montana, New Mexico, South Dakota, Texas and Wyoming. The opinion resulted in specific restrictions for the grizzly bear and the gray wolf listed on the label. No takes are allowed for either the grizzly bear or the wolves.

Species	Habitat	Used By State Agency
Gray Wolf	Arizona, California, Colorado, Connecticut, Iowa, Idaho, Illinois, Indiana, Kansas, Massachusetts, Maine, Michigan, Minnesota, Missouri, Montana, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, Nevada, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Texas, Utah, Vermont, Washington, Wisconsin and Wyoming	Montana, New Mexico, Texas and Wyoming
Grizzly	Alaska, Idaho, Montana, Washington and Wyoming	Montana and Wyoming

7.6. Drinking Water Assessment

A drinking water assessment will not be conducted for sodium fluoroacetate. Although sodium fluoroacetate is thought to be very mobile, no significant route of exposure to either surface water or ground water has been identified given its use pattern and restrictions which might serve as a potential source of drinking water supply.

7.7 Preliminary Identification of Data Gaps

Environmental Fate

Although there are no acceptable registrant submitted fate studies, the environmental fate database for sodium fluoroacetate is believed to be sufficient for the purposes of the forthcoming ecological risk assessment based on the body of open literature. Open literature sources will be reviewed for persistence properties and for tissue residue to estimate secondary effects.

Ecological Effects

Table 7.1 lists required ecological studies for sodium fluoroacetate. Studies will provide information to reduce uncertainty for non-target and endangered species assessments. Based on the indoor nonfood use pattern, no studies are required to be submitted. There are three studies conditionally required, acute avian oral, acute freshwater fish and acute freshwater invertebrate (*Daphnia*). No plant studies are required under Part 158 because sodium fluoroacetate is a contained pesticide treatment.

Table 7.1 Ecological Effects Data Requirements for Sodium Fluoroacetate

Data Requirement §158.490 WILDLIFE AND AQUATIC ORGANISMS	Use Pattern*	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA 3©(2)(B)?
71-1(a) Acute Avian Oral, Quail or Duck	12	Yes	00073988	No
71-2(a) Acute Avian Diet, Quail	12	Yes	00107878,00072663	No
71-2(b) Acute Avian Diet, Duck	12	Yes	0010498	No
72-1(a) Acute Fish Toxicity Bluegill	12	Yes	429161-01	No
72-1 Acute Fish Toxicity Rainbow Trout	12	Yes	429616-02	No
72-2(a) Acute Aquatic Invertebrate	12	Yes	429616-03	No

8 References

Centers Disease Control and Prevention: http://www.cdc.gov/niosh/npg/npgd0564.html)
INCHEM: (http://www.inchem.org/documents/pims/chemical/pim494.htm)

Material Data Safety Sheet: http://www.sciencelab.com/msds.php?msdsId=9927711)

U.S. Environmental Protection Agency (USEPA). 2004. Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency. Endangered and Threatened Species Effects Determinations. Office of Prevention, Pesticides and Toxic Substances, Office of Pesticide Programs, Washington, D.C. January 23, 2004.

U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS). 1998. Endangered Species Consultation Handbook: Procedures for Conducting Consultation and Conference Activities Under Section 7 of the Endangered Species Act. Final Draft. March 1998.

Appendix A. 1080 Use Restrictions

Restrictions for 1080

The use of sodium fluoroacetate in the animal protection collar is currently registered in five states (Montana, New Mexico, South Dakota, Texas, and Wyoming).

The following list of use restrictions for sodium fluoroacetate represents the USDA/APHIS product. The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

USE RESTRICTIONS

1. Use of livestock protection (LP) collars shall conform to all applicable Federal, State, and local regulations.

2. LP Collars shall be sold or transferred only by registrants or their agents and only to certified Livestock Protection Collar applicators. Collars may be used only by specifically certified Livestock Protection Collar applicators or by persons under their direct supervision. 1 The certified applicator is directly responsible for assuring that all use restrictions are met. The certified applicator will decide, in accordance with label directions, when and under what circumstances collars will be used. The certified applicator will either apply collars or be physically present where collars are applied by a noncertified person. However, a noncertified person who has received adequate instructions from the certified applicator may store collars, check collars in the field, remove collars, repair or dispose of damaged collars in accordance with use restrictions, retrieve collars laying in the field and properly dispose of contaminated material and animal carcasses.

3. Certification of applicators shall be performed by appropriate regulatory agencies. Prior to certification, each applicator shall receive training which will include, but need not be limited to:
(a) Training in safe handling and attachment of LP collars.
(b) Trainig in disposal of punctured or leaking LP collars, and contaminated animal remains, vegetation, soil, and clothing.
(c) Instructions for practical treatment of 1080 poisoning in humans and domestic animals.
(d) Instructions on record keeping.

4. Registrants or their agents shall keep records of all collars sold or transferred at their address of record. Records shall include the name,
address, state where Livestock Protection Collar certification was issued, certification number of each recipient, and dates and numbers of collars sold or transferred.

5. Each applicator shall keep records dealing with the use of LP Collars and the results of such use. Records shall be maintained in accordance with appropriate State or Federal regulations but for not less than two years following disposal or loss of collar. Such records shall include, but need not be limited to:

11. All LP collared livestock must be checked at least once every seven days and collars adjusted if needed. If any LP collared animal is not accounted for in two consecutive checks, an intensive search for it must be made. In addition, if more than three LP collared animals are not accounted for during any one check, an intensive search for these animals is required. If more than nine (9) LP collars are unaccounted for during any 60 day period, remove all collars from animals and terminate their use. Do not resume use until adequate steps have been taken to prevent further, excessive loss of collars.

12. Damaged, punctured, or leaking LP collars shall be removed from the field for repair or proper disposal. Damaged collars shall be placed individually in leakproof containers while awaiting repair or proper disposal. Authorized collar repairs are limited to minor repairs of straps andfastenings. Leaking or punctured collars must be properly disposed.

13. Dispose of 1080 wastes (punctured, leaking, or otherwise unrepairable LP collars; contaminated leather clothing, animal remains, wool, hair, vegetation, water, and soil) under three feet of soil, at a safe location, preferably on property owned or managed by the applicator and at least 1/2 mile from human habitations and water supplies. No more than 10 collars may be buried in any one hole. If buried in a trench, each group of 10 collars must be at least 10 feet apart. Incineration may be used instead of burial for disposal in the field (preferably on property owned or managed by the applicator) at least 1/2 mile from human habitation and water supplies. Place collars and waste (listed above) in an incinerator or refuse hole, saturate with diesel fuel, and ignite. Attend the burn until the contaminated material is completely consumed. Alternatively, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance in disposing of wastes at approved hazardous waste disposal facilities. When snow or frozen ground make on-site disposal impractical, up to one cubic foot of wastes may be stored in a leak-proof container in a dry, locked place for 90 days. Metal Container: Triple rinse contaminated and uncontaminated containers with water. Puncture and dispose of contaminated container and rinsate as above. Plastic Container: Triple rinse with water. Then puncture and dispose of container and rinsate as above.

14. All persons authorized to possess and use LP Collars shall store them under lock and key in a dry place away from food, feed, domestic animals, and corrosive chemicals and in outbuildings, or in outdoor storage areas attached to, but separate from human living quarters.

15. Provisions for the protection of endangered species: The LP Collar may not be used in the following areas due to potential adverse effects to endangered species (California condor). STATE COUNTIES California Fresno, Kern, Kings, Los Angeles, Monterey, San Luis Obispo, Santa Barbara, Tulare, and Ventura The LP collar may not be used in the following areas without written approval from the nearest U.S. Fish and Wildlife Service Office (FWS, Endangered Species Specialists). If FWS or the user determines that the use of collars may adversely impact an endangered species (San Joquin kit fox, black-footed ferret, Northern Rocky Mountain wolf, or Grizzly bear) in the specific areas requested, collars may not be used in these areas. Written approval must be obtained

annually. State Counties or Area NEAREST FWS OFFICE/PHONE California Alameda, Contra Costa, Sacramento, CA Merced, San Joaquin, 916-978-4866 Santa Clara, and Satnislaus Idaho Bonner, Boise (north of Boise, ID State Highway 21), 208-334-1931 Boundry, Clearwater, Custer (north of local road running from Sun Valley to Chilly and a corresponding line northeast from Chilly to Patterson), Fremont, Idaho, Lemhi, Shosshone, and Valley Michigan Keweenaw (Isle Royal) and Twin Cities, MN entire Upper Peninsula 612-725-3276 State Counties or Area NEAREST FWS OFFICE/ PHONE Minnesota Aitkin, Becker, Beltrami, Twin Cities, MN Carlton, Cass, Clearwater, 612-725-3276 Cook, Crow Wing, Hubbard, Itasca, Kittson, Koochiching, Lake, Lake of the Woods, Mahnomen, Marshall, Pennington, PineRoseau, and St. LouisMontana Beaverhead, Carbon, Helena, MTFlathead, Gallatin, Glacier, 406-449-5322 Lake, Lewis and Clark,Lincoln,Madison,Missoula,Park, Pondera,Powell, Sanders,Stillwater, Sweet Grass,and TetonWashington Pend Orielle,Okanogan,Boise,ID (National Park and Forrest 208-334-1931), Skagit, and WhatcomWisconsin Douglas, Florence, Twin Cities, MN, Lincoln, Oneida, and Price 612-725-3276 Wyoming Fremont, Park, and Teton Helena, MT and Yellowstone National 406-449-5322 Parks 16. The number of LP collars used shall be the minimum necessary for effective livestock protection. For pastures of the following size classes, do not use more collars than the number indicated. Size (acres) Number of Collars up to 100 20 101 to 640 50 641 to 10,000 100 38 17. Each applicator will have a one-ounce bottle of syrup of ipecac (to induce vomiting in case of accidental poisoning) available when attaching, inspecting, removing, or disposing of LP collars.

18. No contaminated animal will be used for food or feed. In addition, for State-limited products, additional use restrictions consistent with EPA's regulatory position and legal decisions regarding predacidal uses of sodium fluoroacetate may be added. The organization of restrictions may be altered so as to maintain consistency with applicable State and Federal laws and regulations but no requirements may be dropped or mitigated. Any changes to the use restrictions must be requested through the amendment process and must be accepted by the U.S. Environmental Protection Agency before they may be incorporated into the labeling of product released for shipment in the U.S. Unless the Agency specifically indicates otherwise, the current accepted labeling for registered 1080 Livestock Protection Collar products remains acceptable. The registrants should submit 5 copies of their last accepted labeling (all 3 componets thereof) with their 8-months responses. The Agency will then review the documents to determine whether any changes are needed.

Appendix B. Literature Studies Related to the Fate and Effects of 1080

1. Coleman, J. and Livingstone, P., 2000: Fewer possums less bovine Tb. The Brushtail Possum, Montague, T.L. (Editor), Manaaki Whenua Press, Lincoln: 220–231.

2. Butcher, S., 2000: Impact of possums on primary production. The Brushtail Possum, Montague, T.L. (Editor), Manaaki Whenua Press, Lincoln: 105-110.

3. Payton, I., 2000: Damage to native forests. The Brushtail Possum, Montague, T.L. (Editor), Manaaki Whenua Press, Lincoln: 111–125.

4. Nugent, G., Sweetapple, P., Coleman J., Suisted, P., 2000: Possum feeding patterns: dietary tactics of a reluctant folivore. The Brushtail Possum, Montague, T.L. (Editor), Manaaki Whenua Press, Lincoln: 10–23.

5. Sadleir, R., 2000: Evidence of possums as predators of native animals. The Brushtail Possum, Montague, T.L. (Editor), Manaaki Whenua Press, Lincoln: 126-131.

6. Veltman, C., 2000: Do native wildlife benefit from possum control? The Brushtail Possum, Montague, T.L. (Editor), Manaaki Whenua Press, Lincoln: 241-250.

7. Innes, J. and Barker, G., 1999: Ecological consequences of toxin use for mammalian pest control in New Zealand – an overview. New Zealand Journal of Ecology 23(2): 111–127.

8. Department of Agriculture, Department of Conservation and Land Management, Department of Health, 2002: 1080 Summary information. Miscellaneous Publication No. 011/2002. Australia.

9. Eason, C.T., 2002: Technical Review of Sodium Monofluoroacetate (1080) Toxicology. Animal Health Board and Landcare Research New Zealand Limited.

10. Fagerstone, K.A., Savarie, P.J., Elias, D.J., Schafer, E.W. Jnr., 1994: Recent regulatory requirements for pesticide registration and the status of Compound 1080 studies conducted to meet EPA requirements. In Proceedings of the science workshop on 1080. Seawright, A.A., Eason, C.T. (Editors). The Royal Society of New Zealand, Miscellaneous Series 28.

11. Eason, C.T. and Turck, P., 2002: A 90-day toxicological evaluation of compound 1080 (sodium monofluoroacetate) in Sprague-Dawley rats. Toxicological Sciences 69: 439-447.

12. Tremblay, L.A., Fisher, P., Leusch, D.L., 2002. Evaluation of the potential of sodium monofluoroacetate (1080) and fluorocitrate to bind to mammalian oestrogen receptor. Landcare Research Contract Report: LC0203/044.

13. Eason, C.T., Wickstrom, M., Turck, P., Wright, G.R.G., 1999: A review of recent regulatory and environmental toxicology studies on 1080: Results and implications. New Zealand Journal of Ecology 23(2): 129–137.

14. McIlroy, J.C., 1984: The sensitivity of Australian animals to 1080 poison. VII. Native and introduced birds. Australia Wildlife Research 11: 373-385.

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Appendix C Summaries of Open Literature Reviewed in the RED

Birds, Acute and Subacute

Acute oral toxicity

The acute oral LD value for the technical grade of sodium fluoroacetate for avian species has been reported in the literature. Hudson et al. (1984) reported the acute oral LD values for the ring-necked pheasant, mallard duck and chukar (Alectoris graeca) to be 6.4 (95% C.I. = 3.85-10.8), 9.1 (95% C.I. = 5.6-14.6) and 3.51 (95% C.I. = 2.58-4.78) mg/kg, respectively. Ward and Spencer (1947) determined the acute lethal doses for numerous avian species and reported LD values as low as 3.0, 5.0, and 15 mg/kg for the widgeon (Mareca americana), golden eagle (Aquila chrysaetos), and black vulture (Cartharista urubu), respectively. Atzert (1971) reported the LD for the black-billed magpie (Pica pica) to be 1 mg/kg. In addition, the USDA conducted a series of acute oral LD tests on the magpie to get toxicity data for a species that is likely to scavenge the carcasses of coyotes and/or livestock (Burns and Connolly, 1992). Results of these studies showed that the acute oral LD for the magpie ranged from 1.78 mg/kg to 2.3 mg/kg, depending on temperature and season.

Ward and Spencer (1947) determined the acute lethal doses of sodium fluoroacetate for numerous mammalian species and reported LD values as low as 0.1 mg/kg for both the cotton rat (Sigmodon hispidus) and coyote (Canis latrans). They also reported that the LD for the deer mouse (Peromyces sp.) was 4.0 mg/kg. Beasom (1982) reported that the LD values for the opossum (Didelphis virginiana) and raccoon (Procyon lotor) were 41.6 and 1.1 mg/kg, respectively. Atzert (1971) reported that the LD of sodium fluoroacetate to the striped skunk (Mephitus mephitus) and opossum are 1 and 60 mg/kg, respectively. These data indicate that sodium fluoroacetate can be classified as very highly toxic to mammals on an acute oral basis.

Secondary Poisoning

Knowlton and Ebbert (1991) used radiolabeled sodium fluoroacetate as a physiological marker to determine the amount of toxicant likely to be consumed by a coyote and the amount likely to occur on the necks of collared goats (Capra sp.) when the coyotes attacked the goats and punctured the collars that contained 30 ml of the toxicant. The volume of fluid dispensed from the collar was 19.2 ml on average (range 11.9 to 27.8 ml); the average volume ingested by the coyote was 1.0 ml (0.1 to 2.9 ml). The average amount of toxicant contaminating the neck of the goat was 75 mg (39 to 118 mg). The average amount of toxicant not recovered was 113 mg (0 to 234 mg). Once punctured, the pouches discharged over 85% of their contents within a short time period. Relatively little of the toxicant was actually ingested by the coyotes with 6 of 15 coyotes ingesting less than 5 mg when killing the goat. Savarie et al. 1990 also studied contamination of the necks of collared lambs (Ovis sp.) killed by coyotes. They found that 12 contaminated sheepskins contained an average of 96 mg sodium fluoroacetate with a range of 23 to 200 mg.