Human Health and Ecological Risk Assessment For the Use of Wildlife Damage Management Methods by APHIS-Wildlife Services

Chapter XX

THE USE OF SODIUM FLUOROACETATE IN WILDLIFE DAMAGE MANAGEMENT

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EXECUTIVE SUMMARY

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Wildlife Services (WS) uses sodium fluoroacetate, also known as Compound 1080 or sodium monofluoroacetate, in livestock protection collars (LPCs) to protect sheep and goats from coyote predation. An LPC consists of a neck strap that attaches to a sheep or goat with rubber bladders containing a 1% solution of sodium fluoroacetate. A coyote that attacks a sheep or goat tends to kill them by grabbing their throat and, if that animal has an LPC, would usually bite through the rubber bladders and receive an oral dose of sodium fluoroacetate. In the United States, sodium fluoroacetate applied within LPCs to target coyotes is classified as a restricted-use pesticide.

Sodium fluoroacetate is highly toxic to humans and many nontarget species, including mammal and bird species. However, the potential for public exposure to sodium fluoroacetate through WS use of LPCs is negligible. Applicators and those that fill the LPCs have a potential risk of exposure, primarily through dermal contact. This risk is reduced when the label and bulletin are carefully followed and all personal protective equipment is worn.

Exposure of sodium fluoroacetate in the environment and to nontarget species only occurs when the LPC is punctured. Based on the WS use pattern and the environmental fate characteristics of sodium fluoroacetate, soil, water, air, and vegetation contaminated with sodium fluoroacetate are not expected exposure pathways for nontarget species. Exposure of nontarget species could occur if the species 1) prey on the living sheep or goat, puncture the LPC, and ingest sodium fluoroacetate, 2) feed on the head or neck area of the carcass bearing an LPC or ingests wool or parts of the livestock contaminated with sodium fluoroacetate, or 3) feeds on the carcass of a predator or other nontarget species poisoned by sodium fluoroacetate. There is a low risk of exposure to nontarget species, with a possible exception of scavengers. Several factors reduce the exposure risk to scavengers, including the low use by WS and the label requirements, including the technical bulletin. This includes checking the integrity of LPCs and searching for and removing livestock, coyote, and nontarget species carcasses.

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1 INTRODUCTION

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Wildlife Services (WS) use the toxicant sodium fluoroacetate to protect sheep and goats from coyote predation. Sodium fluoroacetate, also known as sodium monofluoroacetate or Compound 1080, is a white powder with currently only one use as a toxicant for coyotes. It was used much more broadly in the past, including as a rodenticide. In the United States, WS uses sodium fluoroacetate in livestock protection collars (LPCs) to target coyotes that specifically prey upon sheep or goats.

An LPC filled with sodium fluoroacetate is one of several options that livestock producers have available for predation management to reduce the loss of livestock. Livestock protection collars are not practical or effective in all predation situations (e.g., free-ranging livestock). Other control methods that are less expensive than LPCs and the labor to install and monitor them may be available. Other control methods may also be more effective or safer to use where potential hazards of LPCs to humans, domestic livestock, pets, and nontarget wildlife are higher or where predation events are frequent and severe (U.S. Environmental Protection Agency (USEPA 2022b). An advantage to using LPCs is they target the depredating individual, or local depredating population, as opposed to the general removal of predators in the area with other methods, such as recreational hunting and trapping, which are not as individual-specific.

Sheep and goat producers experience predation losses. In 2014, predation caused 28.1% (61,712 animals) of adult sheep death losses and 36.4% (132,683 lambs) of lamb death losses (USDA 2015b). The estimated loss value from predation is just over $12 million and $20 million for sheep and lambs, respectively. Coyotes accounted for 54.3% of these predation deaths. In 2014, the number of adult sheep and lambs injured by predators was 14,828 and 16,387, respectively (USDA 2015b). In 2015, 38,880 goats were lost to predation at a value loss of $6.8 million. Pre-weaned and post-weaned kid goat loss to predation was 63,823 and 19,930 animals, respectively. The value of kids lost to predation was over $8.7 million. Predation was the cause of 2.1% of goat inventory loss and 5% of kid loss. Coyotes accounted for about half of goat and kid deaths, about 40,000 animals (USDA 2015a). Thus, as illustrated, damage by coyotes can be substantial, primarily locally, and the removal of individual(s) predating sheep and goats can reduce damage.

This human health and ecological risk assessment provides an evaluation of potential risks and hazards to human health and the environment, including nontarget fish and wildlife, from exposure to sodium fluoroacetate for the proposed use by WS. The methods used to assess potential human health effects follow standard regulatory guidance and methodologies (National Research Council 1983) and generally conform to other Federal agencies such as the U.S. Environmental Protection Agency (USEPA 2022a). The methods used to assess potential ecological risks to nontarget fish and wildlife generally follow USEPA (2022a) methodologies.

This risk assessment starts with problem formulation (identifying hazards) and then evaluates toxicity (dose-response assessment) and exposure (identifying potentially exposed populations and determining potential exposure pathways for these populations). Finally, integrating the toxicity and exposure assessments provides a characterization of risks (determining if adverse human health or ecological risks are present and their significance). This risk assessment also includes a discussion of the uncertainties associated with the risk assessment and cumulative effects.

1.2 Coyote Damage Management with Livestock Protection Collars

The LPC is a toxicant delivery method and targets the depredating coyote. It is a very target-specific method, but the sheep or goat wearing the LPC is usually killed in the attack. The LPC consists of two small rubber bladders, each containing 15 milliliters (mL) (30 mL per LPC) of 1% sodium fluoroacetate in a solution placed under the throat of a sheep or goat and held in place with Velcro™ straps (Figures 1 and 2). Coyotes mostly attack sheep and goats by biting the neck area of the animal (Connolly and Burns 1990). Usually, coyotes that attack a sheep or goat with an LPC bite through the rubber bladder on one or both sides of the LPC. When a coyote attacks a collared animal and bites the throat where the LPC bladders are positioned, the coyote punctures the bladder and receives an oral dose of sodium fluoroacetate. Therefore, correctly positioning the LPC on the animal's neck is required for effective use. The presence of an LPC does not appear to change the way coyotes attack and kill animals, which is not typical of other predators. When appropriately used, coyotes puncture the rubber bladder containing sodium fluoroacetate during an attack 75% or more of the time.

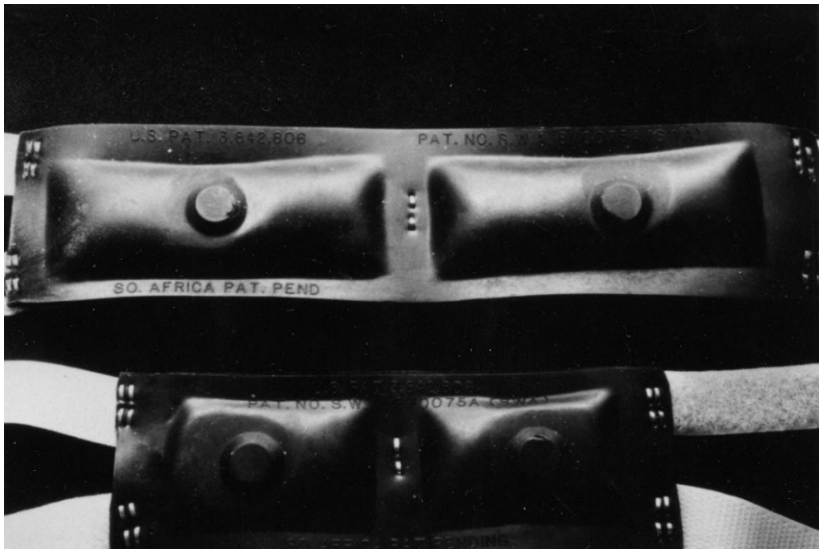

Figure 1. Livestock protection collars filled with 15 ml 1% sodium fluoroacetate in each bladder with two sizes, one for sheep and goats over 50 pounds (above) and lambs and kids between 25 and 50 pounds (below).

Figure 2. Lamb wearing a livestock protection collar.

Livestock protection collars are especially useful where losses are substantial (usually more than once a week), and the sheep or goats are in fenced pastures where they can be gathered and monitored easily (APHIS 2017). Livestock protection collars must be put on a substantial proportion of the lambs/kids or adults if only they are what is present in a pasture. About 20% of the flock should be collared (the labeling restricts LPCs to 20 for up to 100 acres, 50 for 101 to 640 acres, and 100 for 641 to 10,000 acres). Collared livestock must be inspected at least weekly or more often to ensure LPCs are intact, not damaged or missing, and properly on the animals. LPCs that are damaged should be removed, repaired if the bladder is not leaking, and found if

missing. Some lambs and kids are carried away from the pastures by predators or scavengers, and the LPC may not be found.

Applicators of sodium fluoroacetate must be state certified to use LPCs in that state, typically through a pesticide program within a state's agricultural department. When appropriate, WS personnel determine the best location to target a depredating coyote within a fenced pasture. If too many sheep or goats are present, WS personnel generally have the owner pen all but 20-30 animals for the night to limit the number available to predators. WS personnel also inspect fences of pastures where LPCs are to be used to ensure the animals do not escape. If necessary, WS personnel or the livestock owner may repair the fence to prevent sheep or goats from escaping. The applicator determines the number of sheep in the pasture (e.g., 50 ewes and 50 lambs) to determine the number of LPCs to deploy. While using waterproof gloves, the LPCs are inspected prior to placement, ensuring that bladders are not leaking and enough LPCs are available for a project. WS personnel will post signs at entrances to properties to notify the public that may access the property that LPCs are in use. Additionally, neighbors are notified of the deployment of LPCs, so they do not allow their pets or guests' pets to run free. Applicators try to limit use by the landowner and public in the area where the LPCs are in use. Applicators must abide by any threatened and endangered species notifications and avoid areas where they cannot be used. After handling LPCs and animals, WS personnel are required to wash their hands (APHIS 2017).

When a collar is discovered missing (e.g., locate only 19 out of 20 on lambs), WS personnel must attempt to locate the LPC, animal, or carcass. If the sheep or goat was killed, the applicator tries to establish what killed the animal, either by finding the carcass of the predator or looking at tooth marks and sign (tracks, scat, and hair) around the carcass. With waterproof gloves, the carcass, damaged LPC, contaminated clothing (especially leather), and any contaminated soil, brush, or grass (the sodium fluoroacetate solution has a bright yellow dye, so contaminated surfaces can be found) are collected for disposal. While burial three feet below the surface a half mile from residences or water sources, along with incineration, has been an accepted disposal method, new regulations will only allow removal and disposal at an acute hazardous waste disposal service. The applicator has the service pick up the refuse to be disposed of at a hazardous waste site or deliver it to the site.

Accidents and nontarget take are recorded on different forms. Applicators must fill out a form if any accident occurs involving themselves, the landowner, or the public and when a nontarget animal is taken. WS has an incident reporting system that allows the recording of these data, which are submitted to USEPA. These forms do not record incidents involving common predators (e.g., feral dogs) similar to the target species.

1.3 Use Pattern

WS personnel record the species taken with LPC uses and LPC fate in the field in the computer-based Management Information System (MIS[1]). Between fiscal year (FY[2]) 2011 and FY 2020, WS placed an annual average of 397 LPCs at 23 project sites. WS lethally removed an annual average of 12 coyotes a year using sodium fluoroacetate in LPCs (Table 1). LPCs were used in five states (New Mexico, Texas, Utah, Virginia, and West Virginia). Utah, Virginia, and West Virginia have not used them since FY15. From FY11 to FY20, WS found an annual average of 4

[1] MIS - Computer-based Management Information System used for tracking WDM activities. Throughout the text, data for a year (e.g., FY16 to FY20) will be given and is from the MIS. MIS reports will not be referenced in the text or Literature Cited Section because MIS reports are not kept on file. A database is kept that allows queries to be made to retrieve the information needed.

[2] Fiscal year (FY) is October 1 – September 30. For example, FY21 is October 1, 2020 – September 30, 2021.

LPCs punctured without confirmation of the predator that punctured it, 12 LPCs damaged or torn, which likely caught on barbed wire or cacti, and 17 LPCs missing, likely the sheep or goat or the LPC carried off by the predator to an area where it was not found or torn from the sheep or goat in the brush. From FY11-FY20, no nontarget animals were taken. WS personnel often locate carcasses of animals killed by scanning the area and watching for vultures or other scavengers to reduce time searching. The yellow dye marker helps ensure the animal was killed with sodium fluoroacetate.

Table 1. WS observations of outcomes for livestock protection collars used from FY11 through FY20 to manage coyote predation on sheep and goats.

ANNUAL AVERAGE TAKE AND LPC FATE FOR FY11-FY20			
USE AND FATE OF LPCs	**FY11 – FY15**	**FY16 – FY20**	**10-Yr. Annual Average**
Coyotes Killed	11.2	13.4	12.3
Unknown Punctures	3.6	4.0	3.8
LPCs Damaged/Torn	15.4	9.4	12.4
LPCs Missing	23.8	9.8	16.8
# LPCs Placed on Animals	479	314	397
LPC Projects	26.4	19.6	23.0
States Where Applied	NM TX UT VA WV	NM TX	5 States Total

From FY96 to FY10, five nontarget bobcats (0.3 annually) were taken that were depredating lambs wearing LPCs. This has been the only nontarget wildlife known to be taken from FY96 to FY20. The only known incident with a domestic animal from FY96 to FY20 was with a rancher's dog that was killed accidentally in FY00. A WS employee stopped to talk to a rancher with the carcasses of a predated collared sheep and the coyote that killed it in the pickup truck bed. The rancher's dog jumped into the pickup bed unnoticed and was licking the sheep with sodium fluoroacetate on its wool. No antidote exists for sodium fluoroacetate, and the dog died from accidental exposure. Another dog was killed in FY22. In this instance, the rancher and WS employee were driving into a pasture where goats were collared. The rancher's dog jumped out of the pickup and began working goats. The dog grabbed a goat by the LPC, puncturing it. The rancher retrieved the dog and got sodium fluoroacetate on his hand. The dog was kenneled, and the rancher and WS employee rinsed the rancher's hand. The dog received a sodium fluoroacetate dose and died three hours later. The rancher exhibited no symptoms of exposure.

2 PROBLEM FORMULATION

Sodium fluoroacetate has been used as a predacide and rodenticide in the United States and was first authorized for use in 1946 (Connolly 2004). Though it is a natural plant compound, it was first synthesized in the late 1800s (Chenoweth 1949). Connolly (2004) describes the history of sodium fluoroacetate and its uses. The name Compound 1080 came from its cataloged number at Patuxent Wildlife Research Center 1080-44 (1080 was the chemical number and 44 for 1944, the year it was logged). The primary use was as a rodenticide with very little use for predators (i.e., as of 1972, 98% of the use had been for rodents and only 2% for predators). It is used in several areas of the world, with the highest use in New Zealand for invasive mammals where no native mammals, except for bats, exist. Their goal has been to rid islands of invasive species. Native wildlife, primarily birds, are responding well to their eradication. In 1972, uses of sodium fluoroacetate were halted in the United States but were reregistered for use in the LPC in 1990.

2.2 Chemical Description and Product Use

Livestock protection collars consist of two rubber bladders, each containing 15 mL of a 1% solution of sodium fluoroacetate and about 150 mg of the active ingredient in each bladder (APHIS 2017, USEPA 2022b). Therefore, each LPC contains 30 mL of solution or 300 mg of sodium fluoroacetate active ingredient. The bladders also contain a yellow dye (tartrazine) as a safety marker. The bladders are attached to an LPC placed around the neck of the sheep or goat so the bladders lay beneath the throat, just behind the jaw (USEPA 2009, 2022b). WS uses the LPCs mostly on lambs or kids but can use them on adult sheep or goats. When the predator bites at the neck, it punctures the LPC and releases the dose of sodium fluoroacetate into its mouth, which causes death within a few hours (time to death ranges from 2 to 7 hours with an average of 4 hours, 20 minutes; (USEPA 2017)). Coyotes most commonly kill sheep or goats by biting their throats. The selectivity of this method is in the target animal (predator) initiating an attack on the livestock animal (Fagerstone et al. 1994). Often, the sheep or goat wearing the LPC dies from the attack.

WS primarily uses sodium fluoroacetate in areas where predation is already occurring and focuses on depredating coyotes. WS evaluates local conditions to determine if LPCs will be effective. WS considers the severity of predation, the availability and effectiveness of other control methods, the costs of the LPCs, the effort to attach LPCs to livestock and monitor them, and the potential hazards of sodium fluoroacetate to humans, domestic animals, including pets, and nontarget wildlife in determining the need to use LPCs (USEPA 2022b).

Sodium fluoroacetate interrupts the metabolic pathway that breaks down food, which leads to the depletion of energy reserves necessary for cell function (International Programme on Chemical Safety (IPCS) 2001, USEPA 2010). Following exposure, the target organs in animals include the heart, lungs, liver, kidney, testes, and central nervous system (IPCS 2001, Eason 2002). At sufficiently high doses, cardiac or respiratory failure causes death (USEPA 2010).

Sodium fluoroacetate applied in LPCs to target coyotes preying on sheep and goats is a restricted-use pesticide (APHIS 2017). The label requires that LPCs are only used on the necks of sheep and goats in fenced pastures where coyote predation is occurring or is expected to occur (APHIS 2017, USEPA 2022b).

APHIS is the registrant of the sodium fluoroacetate LPC with the product name Sodium Fluoroacetate (Compound 1080) Livestock Protection Collar (EPA Reg. No. 56228-22), which contains 1% sodium fluoroacetate and 99% other ingredients (USEPA 2022b), which can be registered and used in any state. As of 2022, there are two other registrants of LPCs with sodium fluoroacetate, New Mexico Department of Agriculture (USEPA Reg. No. 39508-2) and Rancher's Supply Inc. (USEPA Reg. No. 46779-1). WS also uses these products. All three LPC registrations have the same amount of sodium fluoroacetate and are manufactured and pre-filled by Rancher's Supply Inc. before sale and distribution. APHIS also holds the registration for a manufacturing-use product for sodium fluoroacetate (Compound 1080 (LPC) (EPA Reg. No. 56228-26)), which contains 90% sodium fluoroacetate and 10% other ingredients. The manufacturing-use product is only used for formulation and repackaging of sodium fluoroacetate for the three registered LPCs and not in the field.

Only certified applicators with training in predator control and the use of LPCs or persons under their direct supervision may use LPCs. WS conducts its operational activities in response to requests for assistance. The APHIS LPC is registered for use in six states, including New Mexico, Ohio, Pennsylvania, and West Virginia. WS only uses the Rancher's Supply registration in Texas.

WS in New Mexico currently uses the registration held by the New Mexico Department of Agriculture.

The LPC labels limit the maximum application rate to 20 LPCs for fenced pastures up to 100 acres in size (USEPA 2022b). Up to 50 LPCs may be used in pastures of 101 to 640 acres, and up to 100 LPCs may be used in pastures of 641 to 10,000 acres if these occur in areas where the average annual precipitation does not exceed 20 inches and the vegetation is sparse (APHIS 2017, USEPA 2022b). The labels do not allow LPC usage in fenced pastures greater than 10,000 acres or in open rangeland.

WS follows the labels, including the labels' technical bulletins, to reduce exposure and risk to humans and nontarget species, including federally listed threatened and endangered (T&E) species (APHIS 2017). The LPC labels require applicators to check the collars for damage every 7 days at a minimum. However, it may not be possible to account for every collared animal in large, brushy pastures. The labels require the use of LPCs to be discontinued if more than 9 LPCs or collared animals are unaccounted for during a 60-day period (USEPA 2010, 2022b). Disposal of damaged LPCs is through deep burial, incineration, contacting the state pesticide or environmental control agency, or the hazard waste representative at the nearest USEPA Regional Office for guidance in disposing of wastes at approved hazardous waste disposal facilities (USEPA 2010, 2022b). The current labels allow deep burial in soil; however, this disposal method is not compliant with USEPA's regulations under the Resource Conservation and Recovery Act for acute hazardous waste in discarded chemical products (including unused materials and residues in or on containers) having the sole active ingredient found on the USEPA "P List" in 40 CFR 261.33 (WS 2021). As such, WS personnel generally do not use deep burial to dispose of LPCs or contaminated material and are working with the USEPA to update the APHIS registration to remove deep burial as an option for disposal.

2.3 Physical and Chemical Properties

Technical sodium fluoroacetate ($C_2H_2FO_2Na$, CAS No. 62-74-8, Figure 3), also called sodium monofluoroacetate, is a white, odorless powder with a molecular weight of 100.02 g/mol. It is highly soluble in water (1,110 g/Liter (L) at 25°C) and has a pH of 10.3 (USEPA 2010). It has a low vapor pressure (0.828 mm Hg at 25°C) and is non-volatile. It has a melting point of 200°Celcius (°C) and is considered stable up to 100°C under normal storage conditions (USEPA 2010). The pKa (dissociation constant) of sodium fluoroacetate is 2.72 (IPCS 2001, APHIS 2015, National Center for Biotechnology Information 2022).

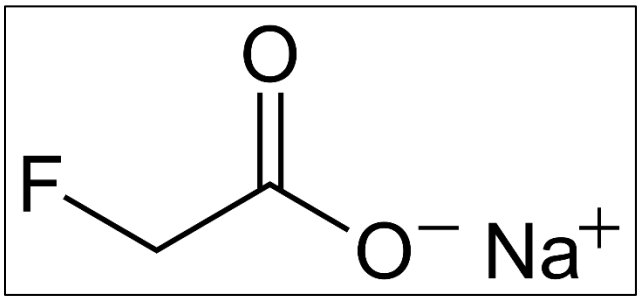

Figure 1. Chemical structure of sodium fluoroacetate ($NaFC_2H_2O_2$, from Sigmaaldrich.com).

2.4 Environmental Fate

Sodium fluoroacetate is highly soluble in water and is mobile in soil. Studies indicate sodium fluoroacetate can leach through soil, particularly after heavy rain (Srinivasan et al. 2012, USEPA 2010); however, it does not persist in soil (Parfitt et al. 1993, 1995, USEPA 2010). Soil microorganisms and fungi will degrade sodium fluoroacetate to nontoxic products (Walker and Lien 1981, King et al. 1994, Eason 2002, USEPA 2010). Sodium fluoroacetate leached from LPCs

or carcasses is unlikely to persist in soils, based on soil degradation studies where 50% degraded after 10 days at 23°C, 30 days at 10°C, and 80 days at 5°C (Parfitt et al. 1993, 1995, USEPA 2010).

In New Zealand, sodium fluoroacetate was not detected in surface and groundwater samples following aerial baiting with sodium fluoroacetate (Parfitt et al. 1993, 1995, IPCS 2001, Eason 2002). In studies simulating New Zealand aquatic conditions, 0.1 parts per million (ppm) sodium fluoroacetate was degraded by 70% within one day and below detectable levels after 100 hours (IPCS 2001). Sodium fluoroacetate biodegrades in water more rapidly than in soil. At 21°C, sodium fluoroacetate biodegrades in two to six days in water; however, at lower temperatures, degradation takes longer, as summarized in USEPA (2010). WS uses sodium fluoroacetate prepackaged in LPCs and does not apply sodium fluoroacetate with any baits.

Plants can take up sodium fluoroacetate from soil or water, and some plant species are sensitive to sodium fluoroacetate. In laboratory experiments, the aquatic plant water milfoil (*Myriophyllum triphyllum*) reduced sodium fluoroacetate concentrations to below detectible levels within one day at 23°C and three days at 7°C as summarized in USEPA (2010). In a laboratory study using the aquatic plant duckweed (*Spirodela oligorrhiza*), growth was reduced at concentrations as low as 5 micrometers (µM) of sodium fluoroacetate (Lien et al. 1979).

2.5 Hazard Identification

Sodium fluoroacetate at high enough concentrations is poisonous to humans. One LPC "contains approximately two to six lethal doses for a 150-pound man" (APHIS 2017, USEPA 2022b).

Ingestion of sodium fluoroacetate does not cause immediate poisoning symptoms. There is a latency period of ½-hour to 2 hours or longer. Symptoms include nausea, vomiting, diarrhea, respiratory distress, convulsions, coma, and cyanosis (IPCS 2001, APHIS 2017, USEPA 2022b). Early symptoms include weak contractions, tingling of the nose, numbness of the face, and alteration in heart sound (IPCS 2001, APHIS 2017, USEPA 2022b). IPCS (2001) cited information that sodium fluoroacetate can cause blurred vision, involuntary eye movement, and pain if it gets into the eye.

2.5.1 Metabolism

Eason (2002) summarized studies that found sodium fluoroacetate was distributed throughout rats' soft tissues and organs. The highest concentration occurred in the blood, then muscle and kidneys, and the lowest concentration in the liver. In mice, the elimination half-life, the time required for the concentration or amount of drug in the body to be reduced by one-half, of sodium fluoroacetate in plasma, muscle, and liver is around 1.6-1.7 hours, but the dose of sodium fluoroacetate given to mice is not provided in the report (IPCS 2001). Rats that received 0.25 mg/kilogram (mg/kg) body weight (bw) of 14C-labelled fluoroacetate excreted 32% at 24 hours and 45% at 72 hours (Tecle and Casida 1989).

The plasma half-life of sodium fluoroacetate was 3.6-6.9 hours and 6.6-13.3 hours in goats and sheep, respectively, given 0.1 mg/kg sodium fluoroacetate (a sublethal dose) through a stomach tube (Eason et al. 1994). The range of sodium fluoroacetate excreted unchanged in sheep was 7.5% to 33.9%, primarily within 48 hours through urine (Eason et al. 1994).

At sublethal exposures in animals, sodium fluoroacetate undergoes metabolic transformation and excretion within one to four days (USEPA 2010). Sodium fluoroacetate is excreted unchanged or

as a nontoxic metabolite. Bioaccumulation is unlikely, given sodium fluoroacetate's rapid metabolism and excretion (Eason 2002).

2.5.2 Acute Toxicity

The USEPA has four categories (toxicity categories I – IV) for acute toxicity based on the LD_{50} or LC_{50}, the median lethal dose or concentration estimated to cause the death of 50% of the test organisms. The toxicity categories determine pesticide labels' signal words, symbols, and hazard statements. Sodium fluoroacetate is considered very highly toxic to mammals (toxicity category I) based on an acute oral LD_{50} of 0.22 mg/kg bw in rats (USEPA 2018a). In rabbits, the acute dermal LD_{50} for sodium fluoroacetate is 324 mg/kg in females and 277 mg/kg in males (toxicity category II) (Savarie and Tietjen 1985, Fagerstone et al. 1994). The calculated oral and dermal toxicity for a 1% sodium fluoroacetate formulation are toxicity categories II and IV, respectively (APHIS 2015). Sodium fluoroacetate is classified as a mild ocular irritant (toxicity category III) based on a study in rabbits that were treated with a 1% solution placed in the conjunctival sac of the eye (Cerven 1987b, Fagerstone et al. 1994). A 1% sodium fluoroacetate formulation is not a dermal irritant (toxicity category IV) based on a study in rabbits (Cerven 1987a, Fagerstone et al. 1994).

2.5.3 Sublethal and Chronic Toxicity

Sodium fluoroacetate is not mutagenic or genotoxic and likely not carcinogenic based on the Ames test, mouse lymphoma assay, and mouse micronucleus assay (Eason et al. 1999). It may have developmental toxicity effects. Sublethal doses of 0.33 and 0.75 mg/kg in female rats during 30% of their gestation caused skeletal effects in offspring; sodium fluoroacetate was teratogenic at 0.75 mg/kg/day (Eason et al. 1999). Rats given 0.75 mg/kg had decreased body weight and food consumption (Eason et al. 1999). A no-observed-effect-level (NOEL) for maternal toxicity is 0.33 mg/kg/day, and for developmental effects is 0.1 mg/kg/day (Eason et al. 1999). Based on a 90-day oral gavage study in Sprague-Dawley rats, sodium fluoroacetate has a NOEL of 0.075 mg/kg/day (Eason and Turck 2002).

In chronic toxicity studies, sodium fluoroacetate at 26 mg/kg-diet given over four months caused growth retardation in rats, damage to the testes, and loss of sperm (Smith et al. 1977). Chronic doses as low as 0.11 mg/kg/day in sheep caused myocardial damage; otherwise, sheep appeared healthy (IPCS 2001).

3 DOSE-RESPONSE ASSESSMENT

3.2 Human Health Dose-Response

In human adults, the LD_{50} for sodium fluoroacetate is approximately 2-10 mg/kg (IPCS 2001).

The American Council of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) is 0.05 mg/m3 (skin) sodium fluoroacetate (IPCS 2001, APHIS 2015). The short-term exposure limit is 0.15 mg/m3 sodium fluoroacetate (IPCS 2001, APHIS 2015). There is no acceptable daily intake (IPCS 2001, APHIS 2015). Specific mutagenicity studies have not been done; however, rats given 5 mg/kg bw sodium fluoroacetate intraperitoneally had a decrease of 40-60% in DNA synthesis rates (IPCS 2001).

A study conducted to estimate the potential for a person to receive a lethal dose of sodium fluoroacetate through the ingestion of meat found a 30 kg child would have to eat 500 kg of meat

from a sheep that had eaten toxic baits within the previous 2.5 hours (Eason et al. 1994). In that study, researchers gave sheep and goats a sublethal dose of 0.1 mg/kg bw sodium fluoroacetate through a gastric cannula and found the animals rapidly cleared the compound (Eason et al. 1994). They concluded the presence of sodium fluoroacetate in meat for human consumption was unlikely. A review of the literature on the effects of sodium fluoroacetate bait on nontarget animals and its fate in animals, including livestock, suggests a minimum withholding period of 5-10 days for livestock to allow for excretion (Eason 2002). WS uses LPCs, not baits, which minimizes the exposure of animals to sodium fluoroacetate through ingestion. Also, livestock contaminated with sodium fluoroacetate from an LPC activated during an attack do not enter the commercial food supply (these animals are usually killed during the attack).

3.3 Ecological Dose-Response

Several mammal and bird species have been tested to evaluate the toxicity of sodium fluoroacetate. Below is a summary of some of the available data with a range for the more sensitive and tolerant species.

Sodium fluoroacetate has high acute oral toxicity in mammals. The acute oral LD_{50} values for coyote and cotton rats are 0.1 mg/kg bw and 41.61 mg/kg bw for Virginia opossum (Table 2) (USEPA 1995).

Sodium fluoroacetate is highly toxic to very highly toxic to birds, with an acute LD_{50} of 15 mg/kg bw for the black vulture, 1.0 mg/kg bw for the black-billed magpie, and 9.1 mg/kg bw for the mallard (Table 2) (USEPA 1995). In dietary exposures, sodium fluoroacetate is moderately toxic to highly toxic to birds; the northern bobwhite has an LC_{50} of 486 mg/kg-diet (Campbell et al. 1994b, USEPA 2018b), and the mallard has an LC_{50} of 231 mg/kg-diet (Campbell et al. 1994a, USEPA 2018b).

Table 2. Sodium fluoroacetate acute toxicity studies on wildlife.

ANIMAL	TEST	DOSE[1]
Mammals		
Cotton Rat	Oral LD_{50}	0.1 mg/kg
Coyote	Oral LD_{50}	0.1 mg/kg
Striped Skunk	Oral LD_{50}	1 mg/kg
Raccoon	Oral LD_{50}	1.1 mg/kg
Deermouse sp.	Oral LD_{50}	4 mg/kg
Virginia Opossum	Oral LD_{50}	41.61 mg/kg
Birds		
Black-billed Magpie	Oral LD_{50}	1 mg/kg; 1.78 mg/kg
American Wigeon	Oral LD_{50}	3 mg/kg
Chukar	Oral LD_{50}	3.51 mg/kg
Golden Eagle	Oral LD_{50}	5 mg/kg
Ring-necked Pheasant	Oral LD_{50}	6.4 mg/kg
Mallard	Oral LD_{50}	9.1 mg/kg
American Rough-legged Hawk[2]	Oral LD_{50}	10 mg/kg
Great-horned Owl	Oral LD_{50}	10 mg/kg
Black Vulture	Oral LD_{50}	15 mg/kg
Mallard	Dietary LC_{50}	231 mg/kg-diet
Northern Bobwhite	Dietary LC_{50}	486 mg/kg-diet

[1]Studies summarized in USEPA (1995, 2010, 2018b)
[2]Subsp. *B. l. sancti-johannis*

Cold-blooded species appear more resistant to sodium fluoroacetate than warm-blooded species (IPCS 2001). In species of adult frogs, the LD_{50} values range from 54.4 mg/kg to greater than 500 mg/kg (Perfect and Bell 2005).

Sodium fluoroacetate is very highly toxic to pollinator insects with an LD_{50} of 0.8 micrograms (μg) active ingredient (a.i.)/bee after oral exposure (24-hour observation) (USEPA 2018b).

In freshwater fish, sodium fluoroacetate is practically nontoxic to slightly toxic in acute exposures. The 96-hour LC_{50} for bluegill is 970 mg/L (practically nontoxic) (Collins 1993a, USEPA 2010), and for rainbow trout, 54 mg/L (slightly toxic) (Collins 1993c, USEPA 2010). In the 96-hour exposure study on bluegill, the no-observed-effect-concentration (NOEC) was 970 mg/L, the highest dose tested, based on no mortality or sublethal effects (Collins 1993a). In rainbow trout, the NOEC was 13 mg/L (Collins 1993c). In the aquatic invertebrate water flea (*Daphnia magna*), sodium fluoroacetate is practically nontoxic, with a 48-hour EC50 (the median effective concentration in dilution water that causes immobilization in the test organism) of 350 mg a.i./L and a NOEC of 130 mg/L (Collins 1993b).

4 EXPOSURE ASSESSMENT AND RISK CHARACTERIZATION

4.2 Human Health Exposure and Risk

Exposure of the public through WS use of sodium fluoroacetate in LPCs is unlikely. WS uses LPCs mostly in areas with limited public access and in accordance with label instructions, including all pertinent WS Policies and Directives[3]. WS personnel follow label instructions, including the label's technical bulletin, which provides safeguards to prevent access to non-certified users. LPC labels require the posting of bilingual warning signs at each access point to notify the public of the hazard and minimize encounters with an LPC. The warning signs remain in place while LPCs are in use. The label advises notifying neighbors that LPCs can be hazardous to free-ranging pets. LPCs must be removed when predation has stopped or is not expected to occur.

Disposed of LPCs and contaminated materials are not expected exposure routes for the public. Disposal of punctured LPCs and materials contaminated with sodium fluoroacetate is through approved hazardous waste disposal facilities (WS 2021). Sodium fluoroacetate is mobile in soil, but WS use pattern and the label requirements suggest that surface and groundwater is not a significant exposure pathway for the public. The label allows deep burial in soil, but WS generally avoids this practice because APHIS, the Environmental Risk and Analysis Services and WS Pesticide Registration Unit recommends against deep burial and is working with the USEPA Office of Pesticide Programs (OPP) to update labels and the APHIS registration.

Individuals that fill the LPCs with sodium fluoroacetate at the manufacturing facility (Rancher's Supply Inc.) are at the greatest risk of exposure because they handle sodium fluoroacetate during the production of LPCs. LPCs are provided to certified applicators pre-filled with sodium fluoroacetate; applicators do not fill the LPCs themselves. The LPC labels only authorize the registrant or the LPC manufacturer to fill LPCs, reducing exposure to applicators. The most likely exposure pathway is through dermal contact. Absorption through the skin is normally low, but

[3] WS' Directive 2.420 discusses the use of LPCs, WS Directives 2.401 discusses the use of pesticides, and WS Directive 1.101 the WS Policy Manual. WS Policy Directives referenced can be found @ http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/wildlifedamage and then under Wildlife Damage – WS Program Directives.

absorption may increase through open wounds (USEPA 2018a). The LPC labels have personal protection equipment (PPE) requirements for applicators to wear waterproof gloves, which would minimize dermal exposure.

Other routes of human exposure are unlikely. Sodium fluoroacetate is non-volatile and is administered in liquid form, indicating inhalation is unlikely. Sodium fluoroacetate is adsorbed rapidly from the gastrointestinal tract. The LPC label prohibits people from using contaminated animals for food or feed. Although it is possible people could eat livestock tainted with sodium fluoroacetate, ingestion of cooked meat is unlikely to cause harm due to the low concentration of sodium fluoroacetate in muscle tissue and the breakdown of sodium fluoroacetate at cooking temperatures (Eason et al. 1994, Temple and Edwards 1985). Consumption of water tainted with sodium fluoroacetate is unlikely. Although it is possible for an LPC to rupture in a water source or for an animal with an LPC or poisoned with sodium fluoroacetate to die near or in a water source, WS does not consider this a likely route of exposure because the combination is unlikely to occur.

The USEPA did not find any pesticide incident cases on the active ingredient fluoroacetate acid derivatives reported in the OPP Incident Data System or the Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health Sentinel Event Notification System for Occupational Risk-Pesticides databases from 1998-2014 (USEPA 2018a). There have been no human fatalities or significant adverse effects of human exposure associated with WS use of sodium fluoroacetate. WS did report another minor incident of human exposure under Section 6(a)2 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in FY 2022. Section 6(a)2 of the FIFRA requires pesticide registrants to report any adverse effects to the USEPA. The incident involved a rancher trying to prevent a dog from lunging at collared goats. The dog punctured one of the LPCs, and when the rancher removed the punctured LPC, there was dermal exposure of the LPC contents to one of the rancher's thumbs. No significant adverse effects were reported from the incident. WS had an incident in FY12 where sodium fluoroacetate squirted out of a bladder for unknown reasons when a WS specialist and rancher were taking LPCs off lambs (the LPC may have been almost torn by a cactus or sharp point on a fence, and pressure may have been applied to make it squirt). The liquid sprayed both men, and they quickly removed contaminated clothing and flushed areas of their skin with water for 10-15 minutes that had been exposed. They then drove to a nearby hospital, showered, and were monitored. No observed reactions occurred, and they were released eight hours later. A 6(a)2 was not completed for this incident since no adverse effects occurred to either person. USEPA was notified of the incident. The National Institute for Occupational Safety and Health (2019) found that sodium fluoroacetate could be a skin hazard based on a calculated skin-inhalation ratio. However, WS did not observe any skin maladies in either of the human incidents that occurred in FY12 or FY22.

4.2 Ecological Exposure and Risk

WS uses sodium fluoroacetate contained within LPCs; therefore, exposure to the environment and nontarget species can only occur when an LPC is punctured. Based on WS use pattern and the environmental fate characteristics of sodium fluoroacetate, soil, water, air, or vegetation contaminated with sodium fluoroacetate are not expected exposure pathways for nontarget species. Sodium fluoroacetate is mobile in soil, but the WS use pattern and the labels' requirements indicate that exposure to surface and groundwater is not a significant exposure pathway for wildlife.

Exposure of nontarget species could occur if the species 1) preys on the living sheep or goat, punctures the LPC and ingests sodium fluoroacetate, 2) feeds on the head or neck area of the carcass bearing an LPC or ingests wool or parts of the livestock contaminated with sodium

fluoroacetate, or 3) feeds on the carcass of a predator or other nontarget species poisoned by sodium fluoroacetate. Acute or chronic exposure to non-scavenging birds is not expected with the use of the LPC.

LPCs containing sodium fluoroacetate are selective for target species because they are designed to kill the coyote attacking the sheep or goat. Coyotes characteristically attack sheep and goats by grabbing the throat (Connolly and Burns 1990); other wildlife and dogs typically attack the animals elsewhere on the body. However, WS has recorded the unintentional killing of nontarget animals from using LPCs. LPCs used by WS resulted in the unintentional killing of seven nontarget animals (five bobcats and two pet dogs, both the ranchers' dogs) from FY96 to mid-year FY22, representing less than 1% of the total number of coyotes taken with this method. A dog in FY22 was the first nontarget animal taken since FY08 when two bobcats were taken. The dog belonged to a rancher working with WS, who was using the LPCs to protect goats. The operator's dog jumped out of a truck and bit a collared goat, dying from sodium fluoroacetate exposure. This incident was reported to USEPA under FIFRA 6(a)2 adverse incident reporting requirements.

The USEPA reviewed the Incident Data System and found other incidents recorded in the system from 1984 to 2016 were related to the misuse of sodium fluoroacetate as bait. No incidents involved WS or the use of the LPC (USEPA 2018b). Several examples of the use of sodium fluoroacetate included the take of wolves and other nontarget animals with the product, but not as used in the LPC. Use was likely from stockpiles of the chemical remaining prior to the ban of sodium fluoroacetate in 1972.

Scavengers are at the greatest risk of exposure to sodium fluoroacetate. Scavengers may feed on the neck region of the sheep or goat carcass that is contaminated with sodium fluoroacetate or may feed on the carcass or vomitus of the poisoned predator. In one field study, coyotes punctured 32 LPCs on sheep, and the authors expect the coyotes that punctured LPCs died. However, only 3 coyote carcasses were recovered, indicating a low recovery of coyote carcasses (Connolly and Burns 1990). More than 3 coyotes were likely involved in the attacks on sheep, or it is possible they were attacking multiple sheep. This low recovery rate is likely due to the latent period between when the LPC is punctured and the onset of poison symptoms—on average, the time to death of coyotes in a pen study occurred 270 minutes after puncturing LPCs (Connolly and Burns 1990). Two studies looked at the amount of toxicant remaining on a sheep (96 mg toxicant) or goat (average 75 mg toxicant) carcass after a coyote attack and the amount of sodium fluoroacetate left on the carcass would be toxic to most birds and mammals (Savarie et al. 1990, Knowlton and Ebbert 1991).

Several factors reduce the risk of scavengers being exposed to toxic amounts of sodium fluoroacetate, including the decomposition rate of the carcass and the feeding behavior of scavengers. The rate of decomposition of the carcass varies depending on environmental factors such as temperature and moisture. Advanced decay is unpalatable to many scavengers (USEPA 1995). The persistence of sodium fluoroacetate in a poisoned carcass can be several months, depending on the decomposition rate of the animal. A study of carcasses of common brushtail possums (*Trichosurus vulpecula*) poisoned by sodium fluoroacetate in New Zealand detected residues in carcasses 75 days after the possum control operation (Meenken and Booth 1997). However, the study occurred during winter, and the cold temperatures likely slowed the decomposition rate (see Section 2). The possum carcasses remained intact through day 39; however, decomposition advanced between days 40 and 75. Mean concentrations of sodium fluoroacetate in stomachs at days 25 and 75 were 30.6 mg/kg and 4.9 mg/kg, respectively (Meenken and Booth 1997). A 20 kg dog would be at risk of poisoning if it consumed a possum

carcass even 75 days after possum poisoning (Meenken and Booth 1997). A study conducted during the summer months on three Sika deer that died from ingesting sodium fluoroacetate following aerial bait application detected concentrations of the poison in the bone marrow, stomach, and muscles (Ross and McCoskery 2012). At day 30, 1.89 and 1.33 mg/kg was detected in muscle and 0.59 mg/kg in bone marrow. At day 40, 5.66 mg/kg was detected in the stomach. Sodium fluoroacetate (<1 mg/kg) still was detectable in bone marrow 213 days after poisoning. At this point in the decomposition, researchers estimated that a 20 kg dog could receive a lethal dose if it consumed 17 kg of deer marrow (Meenken and Booth 1997, Eason et al. 2012).

Scavengers have selective feeding from wounds on the carcass, which reduces their exposure to the contaminated skin surface of the head or neck of the livestock carcass. Sodium fluoroacetate is an emetic that induces vomiting, reducing the risk of scavengers ingesting a toxic chemical. The USEPA (2018b) reviewed several studies on the secondary exposure of sodium fluoroacetate. Five golden eagles exposed to collared lamb carcasses showed slight effects after 6 to 10 days of exposure, but no mortality occurred. Researchers observed that the eagles preferred to feed on tissues other than neck tissues. Magpies exposed to coyote carcasses that died from sodium fluoroacetate in LPCs showed no adverse effects up to 7 days after exposure. In field tests on the efficacy of LPCs in controlling predatory coyotes, no nontarget animals were found dead, and no adverse impacts on these species were noted during the study period of 5 to 156 consecutive nights (Connolly and Burns 1990).

The labels instruct the prompt disposal of carcasses of collared livestock and coyotes suspected of being poisoned by sodium fluoroacetate. The label requires applicators to search for collared livestock once a week. If the applicator does not locate an animal after 2 consecutive weeks or if more than three collared animals are unaccounted for, they must do an intensive search for the animal.

An LPC may get damaged while the animal is wearing it. Punctures can occur from prickly vegetation and barbed-wire fencing. Studies have shown that adult sheep can be poisoned fatally by eating forage contaminated with at least 1 mL of sodium fluoroacetate (USEPA 2022b). WS has not observed this in the field and considers this exposure pathway low-risk. The LPC labels require applicators to check LPCs for damage every 7 days at a minimum. WS removes LPCs that are damaged and remove any contaminated wool, disposing of both according to the label instructions.

Half of the LPCs that are missing from the carcasses of sheep or goats are not recovered (USEPA 2022b). Coyotes may hide or bury LPCs, contributing to a lack of recovery. The labels require the termination of LPC use in a pasture if more than nine LPCs or collared animals are unaccounted for during a 60-day period.

Exposure to aquatic species and terrestrial plants and insects is low given sodium fluoroacetate's environmental fate properties and WS use pattern. Sodium fluoroacetate has the potential to leach into groundwater; however, the WS use pattern suggests this risk is negligible because LPCs contain a small amount of sodium fluoroacetate (300 mg of sodium fluoroacetate), and it is unlikely that the entire amount would spill on to the ground. In addition, the number of LPCs is limited over a given area.

The LPC labels restrict the use of collars in habitats occupied by certain federally listed T&E species (those that may prey or scavenge on sheep or goats) or within the geographical range of these select T&E species. This further reduces the risk of exposure to protected wildlife that are at risk from sodium fluoroacetate use.

5 UNCERTAINTIES AND CUMULATIVE EFFECTS

WS may not always recover the carcass of the sheep, goat, or predator and in these instances, would be unable to determine if nontarget animals also fed on a carcass and potentially were exposed to sodium fluoroacetate. Between FY 2011 and FY 2020, WS reported an annual average of 16.8 missing LPCs that scavengers may have torn off or moved while moving the carcass. During the same reporting time, an average of 3.8 LPCs were punctured without known take, and 12.4 were damaged or torn. WS does not know the outcome for these LPCs, but no nontarget species were found. In one study, LPCs on 32 sheep were punctured during an attack, but only 3 dead coyotes were found, although it was presumed all coyotes that punctured LPCs died (Connolly and Burns 1990).

WS does not expect cumulative effects from its use of LPCs. WS may use LPCs in pastures where other non-chemical predator control methods are in use. However, WS would not use LPCs if other chemical methods to manage coyote predators are in use in the same pasture. LPCs are restricted use pesticides, and the labels impose limits on the number of LPCs allowed in a single pasture. The application area (pasture) in which WS uses LPCs would not overlap with other entities' use of LPCs in the same pasture.

6 SUMMARY

Sodium fluoroacetate is highly toxic to humans and many nontarget species, including mammal and bird species. However, exposure of the public to sodium fluoroacetate through WS use of LPCs is negligible. Applicators and individuals at the manufacturing facility that fills the LPCs are at some risk of exposure (most likely dermal exposure); however, this risk is reduced when they follow the labels and wear the appropriate PPE.

Risks to nontarget species, such as aquatic vertebrates and invertebrates, are negligible based on the use pattern for sodium fluoroacetate and its low toxicity to aquatic organisms. There is a low risk of exposure to most terrestrial nontarget species, except for scavengers. Several factors reduce the risk to scavengers, including the low frequency that WS uses LPCs, and the labels' requirements that reduce exposure to scavengers.

WS does not often use LPCs to address coyote depredations, with an annual average of 23 projects attaching almost 400 LPCs. Take has been about 12 coyotes per year, suggesting that projects are effective where they were used (a few projects result in two or three coyotes taken). Conditions such as having sheep or goats pastured within a fence limit the use of LPCs but ensure that the depredating individual is taken.

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Position: USDA-APHIS-WS, Operational Support Staff, Staff Wildlife Biologist, Madison, TN
Education: BS Wildlife Management and Ecology – Northwest Missouri State University
Experience: Special expertise in wildlife biology, ecology, and damage management. Seventeen years of service with APHIS Wildlife Services, including operations and research, conducting a wide variety of programs, including bird damage research and management, livestock protection, invasive species management, wildlife hazard management at airports, property, and natural resource protection. Expert in preparing environmental documents for WS programs to comply with the National Environmental Policy Act and the Endangered Species Act.

8.3 Internal Reviewers

USDA APHIS Wildlife Services

Reviewer: Scott C. Barras
Position: USDA APHIS WS, State Director, Virginia
Education: Ph.D. Fisheries and Wildlife, Utah State University, M.S. Wildlife Ecology, Mississippi State University, B.S. Forestry/Wildlife Option, Mississippi State University
Experience: Wildlife Biologist with APHIS-WS for 23 years total, State Director in a state that uses LPCs for 15 years.

Reviewer: Jon Grant
Position: USDA-APHIS-WS, State Director, New Mexico
Education: BS Wildlife - Univ. Wisconsin, Stevens Point
Experience: Expertise in wildlife biology and wildlife damage management operations and research. Twenty-six years of service in APHIS Wildlife Services operational programs in WI and NM. Experience in a wide variety of damage management to include livestock protection. Have experience applying and supervising the use of sodium fluoroacetate in livestock protection collars.

8.4 Peer Review

The Office of Management and Budget requires agencies to have peer review guidelines for scientific documents. The APHIS guidelines were followed to have "Use of Exclusion in Wildlife Damage Management" peer reviewed. WS worked with the Association of Fish and Wildlife Agencies to have experts review the documents.

8.4.1 Peer Reviewers Selected by the Association of Fish and Wildlife Agencies

South Dakota Game, Fish and Parks

Montana Fish, Wildlife & Parks

Utah Division of Wildlife Resources

8.4.2 Comments

1. Page 1. Sheep and goat predation losses. This was 8 years ago. Is there not a more recent report on livestock losses that could be used to be more contemporary?

Response: USDA recently updated the sheep predation loss report in 2020. In 2020, predation caused 32.6% (71,440 animals) of adult sheep death losses and 40.1% (155,470 lambs) of lamb death losses (USDA 2020). The estimated loss value from predation is $16 million and jus over $29 million for sheep and lambs, respectively. Coytoes accounted for 46.9% of these predation deaths. In 2020, the number of adult sheep and lambs injured by predators was 17,540 and 18,130, respectively (USDA 2020). The data reported is the most recent data specific to goat loss due to predators. The National Agricultural Statistics Service does provide reports on goat death loss on an annual basis, but this data includes all causes of goat deaths, not specific to predators. Previous USDA data on goat deaths due to predators have been updated on a 5 year basis.

2. How long does it take the coyote to succumb to the sodium fluoroacetate after biting the LPC?

Response: The time to death of coyotes occurs between 2 to 7 hours after puncturing an LPC with 300 mg of sodium fluoroacetate (USEPA 2017). This information is provided in Section 2.1. Early testing of LPC prototypes in a pen study observed an average time to death of 270 minutes for similar-style LPC with 300 mg of sodium fluoroacetate (Connolly and Burns 1990). This information is provided in Section 4.2.

3. Significant generally implies a statistical test was used; substantive or substantial conveys the intended meaning without implying statistical significance.

Response: The term "significant" can imply a statistical test was used, especially in scientific publications. We have edited the risk assessment to use the term substantial in place of significant in reference to damage in the introductory sections of the risk assessment. We have left the term "significant" in the Human Health and Ecological Exposure and Risk sections as significant has a specific meaning in that context.

4. If an incident involving common predators similar to the target species occurs these are not recorded on these forms. What are examples of the target species not recorded?

Response: An example of a target species or "other common predator" would be feral dogs. This is another predator that is also known to predate on sheep, lambs, and goats. So, although the LPC was not intended to target this species, it is an example of another target species that predates lambs, sheep, and goats. A nontarget take animal would be a pet dog, or a bobcat predating on sheep, lambs, or goats, or a mesocarnivore that is scavenging on a dead carcass but not targeting the sheep, lamb, or goat as prey.

5. Section 2.4.1 What does "dose not given" mean?

Response: We have edited this sentence to make it more clear. The report did not provide the dose given to mice in the study.

6. What does "plasma half-life of sodium fluoroacetate mean? I find it interesting that this document provides an example when suggesting an applicator count sheep (e.g., 50 adult and 50 lambs), but there is no definition of something far more well known like plasma-half-life. I would suggest that better explanation should be provided so that a reader might more easily understand.

Response: Plasma half-life is the time required for the plasma concentration of the drug to diminish by 50%. This section describes the time needed for an animal to metabolize sodium fluoroacetate. Studies were conducted in rats, mice, sheep, and goats (Easton et al. 1994, Tecle and Casida 1989).

7. Do the sheep exposed to sodium fluoroacetate that excrete sodium fluoroacetate in urine survive?

Response:The study referred to in this section (Easton et al. 1994) dosed sheep and goats with 0.1 mg/kg sodium fluoroacetate. This dose of sodium fluoroacetate is equivalent to one-quarter

the published LD50 of 0.4 mg/kg in sheep and less than one-quarter the value for goats of 0.6 mg/kg. All sheep and goats in this study dosed with sodium fluoroacetate survived the oral dose.

8. Any information on toxicity for coyotes? These are all species for which 1080 cannot be used any longer, what is the LD50 for coyotes?

Response: This section describes the acute toxicity of sodium fluoroacetate in lab animals that are required testing for registration of pesticides by USEPA. Toxicity information for wildlife, including coyotes and nontargets, is provided in Section 3.2.

9. Section 4.1. [APHIS recommends against deep burial]. Recommends or does not do it? A recommendation is of little utility here. Is this direction provided to WS applicators?

Response: APHIS, Environmental Risk Analysis Service, and the APHIS WS Pesticide Registration Unit recommend against deep burial. These programs have been working with the USEPA Office of Pesticide Programs to update labels and the APHIS registration. WS generally avoids the use of deep burial to dispose of LPCs or contaminated material. We have updated these sections for clarification.

10. Can you explain why? There was information on decay in water earlier. Is this the rationale or simply that the event is unlikely?

Response: WS does not consider this a likely route of exposure because the combination of an LPC rupturing in a water source or an animal killed with Sodium fluoroacetate dying near or in a water source is unlikely to occur.

11. Incident cases of what?

Response: The OPP Incident Data System and Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health Sentinel Event Notification System for Occupational Risk-Pesticides databases track reported incidents with pesticides. This section refers to the pesticide incident cases on the active ingredient fluoroacetate acid derivatives that were reported to these systems from 1998-2014. We have edited this section for clarification.

12. Section 4.2 Earlier noted that a large proportion of coyotes are not found after biting LPCs. Should acknowledge that here.

Response: Section 4.2 addresses all ecological exposure and risk. Earlier in this section, the Risk assessment discusses the risk of animals that died from sodium fluoroacetate being left on the landscape (paragraphs on scavengers). We do not feel it is necessary to include the information again.

Comments received not requiring a response.

1. After a thorough review of the document on the use of Sodium Fluoroacetate, I have no comments except to say that the document looks good. Thank you for the opportunity to review this document.

2. The assessment fully evaluates the consequences of use for sodium fluoroacetate focusing on targeted animal exposure, non-targeted animal exposure, and human exposure. Documentation of the adverse effects and non-targeted exposures was present in the assessment, with uncertainties stated in the document as well as environmental impacts to water and soil.

3. The list of standard operating procedures and minimizing the adverse impacts are complete and state several methods of safeguards for unwanted exposure to non-targeted animals and humans. The important procedures include posting signs that LPDs are in use in the pasture, placement of the devices on sheep/ goats for appropriate species, monitoring the collars once a week, tracking down the collars if they are missing, etc.

4. The assumptions and uncertainties have been clearly stated.

5. There was appropriate selection of literature in support for the MRA and the techniques used in the field.