

IRS EFFICACY REVIEW

IN 2/6/85 OUT 2/22/85

FILE OR REG. NO. 6704-IL

PETITION OR REG. PERMIT NO. _____

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PRODUCT VER. NO. 16

PRODUCT NAME(S) SODIUM FLUOROACETATE (COMPOUND 1080) LIVESTOCK
PROTECTION COLLARS

COMPANY NAME U. S. Department of the Interior

SUBMISSION PURPOSE Registration

GENERAL COMMENTS: 1.08% Sodium Monofluoroacetate

Efficacy Review: SODIUM FLUOROACETATE (COMPOUND 1080) LIVESTOCK PROTECTION
COLLARS, 6704-IL
U. S. Department of the Interior
U. S. Fish & Wildlife Service
Washington, D.C. 20240

200.0 INTRODUCTION

200.1 Use

A 1.08% Sodium Monofluoroacetate (Compound 1080) solution enclosed in a two-pouched rubber vessel which is attached to Velcro or elastic bands which hold the two pouches in place in the throat regions of sheep or goats subject to predatory attacks by coyotes.

200.2 Background Information

See: efficacy reviews of 3/30/79, 9/26/79, 12/15/80, 8/19/82, and 9/29/83 for 6704-EUP-14; efficacy reviews of 3/15/82, 2/2/83, 12/23/83, and 6/29/84 for 6704-IL; and efficacy reviews of 5/3/80, 6/27/80, 12/10/81, 10/4/82, 11/12/82, 3/23/83, and 1/24/84 for 35899-EUP-5 (an EUP granted to the Texas Agricultural Experiment Station, Texas A & M University, for researching the livestock protection collar in cooperation with USDI). USDI believes that its current submissions for this product collectively satisfy all requirements for Section 3 registration. The most recent submission (of 2/12/85) included a first draft of the Technical Bulletin (see efficacy reviews of 2/2/83 and 6/29/84, along with OPP letter of 4/24/84) and a revision of the Use Restrictions. Drafting of the Technical Bulletin was delayed because USDI has assumed that the training manual being developed through a contract through the Compliance Monitoring staff and USDA would take the place of the technical bulletin. The problem with that approach is that the training manual cannot be completed until USDI indicates how the collar is to be used (i.e., until USDI provides a technical bulletin).

The package under review also includes some efficacy and safety data developed in laboratory and pen trials from April of 1980 through July of 1984. A proposed label was also submitted.

201.0 DATA SUMMARY

201.1 Research Findings

The data report contains results from a variety of studies and published papers all relevant in some way to the development of the 1080 livestock protection collar but not necessarily directly related to one another. In this section, results are summarized and briefly discussed.

Toxicity

USDI reports an LD₅₀ of 1.23 mg/kg body weight (range 1.16-1.31 mg/kg) for the European (fitch) ferret. This animal is used in toxicity tests as a surrogate species for the endangered black-footed ferret which typically occurs in association with prairie dog towns. This result suggests 1080 is about one-tenth as toxic to ferrets as to coyotes. Ferrets would be at risk from 1080 since they are smaller than coyotes and 1080 is still very toxic to them. It is not clear that use of 1080 in Livestock Protection Collars would pose a hazard to the black-footed ferret.

USDI ran several toxicity studies with black-billed magpies, a species known to consume carrion from sheep killed by coyotes. Attempting to isolate factors affecting toxicity, USDI ran studies under various conditions and obtained the following results:

<u>Season</u>	<u>Test Condition</u>	<u>LD₅₀</u>
Summer	Indoors, caged separately	1.78 mg/kg
Summer	Outdoors, group caged	1.91 mg/kg
Winter	Outdoors, group caged	2.30 mg/kg

These results suggested some lability in the toxicity of 1080 to this species, but all results round to 2 mg/kg. These data were consistently higher than the 0.6-1.3 mg/kg LD₅₀ value reported for 1080 by Atzert (1971), but all data on hand indicate that 1080 is very toxic to magpies.

USDI reviews research results which it claims have "definitely proved" that fluorocitrate, not fluoroacetate, is the toxic principle in 1080 poisoning. 1080 is reportedly inefficiently metabolized to fluorocitrate. LD₅₀s of fluorocitrate to animals are higher than those for 1080. The apparent paradoxes in the preceding statements are explained by Savarie (1984, in submission) by the findings that fluorocitrate is less efficiently absorbed by tissues than is fluoroacetate (which is smaller molecule) but that fluorocitrate is perhaps 100 times more toxic in the central nervous system than 1080. It appears, then, that animals are dosed more efficiently with 1080 than with fluorocitrate but that once the material enters the tissues, fluorocitrate reaching the central nervous system is the principal toxic agent.

Hazards From Livestock Protection Collars

Three of five lambs equipped with collars which had been deliberately slit on the underside were killed. The apparent route of administration was via solution leaking toward the mouth and being consumed by the lambs. Neither this study or previous studies have suggested significant absorption of collar solution through intact skin.

The heads and necks of these lambs (with collars in place) were fed to five dogs. Two dogs died. Since the contents of large-size collars were experimentally emptied on the necks of these lambs, there was more 1080 available than has been indentified on the heads and necks of livestock killed by coyotes. For example, necks of "small-collared" goats killed by coyotes had residues of less than 50 mg of 1080, much less than the 275-550 mg 1080 potentially on the lambs whose heads and necks were fed to the dogs.

After the dogs were finished with the remains of these lambs, the heads and necks were fed to groups of black-billed magpies. No deaths were recorded even though the magpies fed on the remaining flesh and eyes of the lambs.

Alfalfa hay which had received measured amounts of 1080 solution (similar to solution used in collars) was fed to sheep to assess the hazard associated with contaminated forage. Results were as follows:

<u>Amount of Solution</u>	<u># Sheep Exposed</u>	<u># Sheep Dying</u>	<u>1080 in Muscle</u>
0.94 ml	2	0	—
1.88 ml	3	2	ND - 0.06 ppm
3.75 ml	2	2	0.07 - 0.19 ppm
15.0 ml	2	2	0.39 - 0.47 ppm

The apparent hazards from alfalfa hay treated with 3.75 ml of 1080 solution were reduced by simulated rainfalls of 1" or more but not by sunlight.

Sheep feeding in pens which included a 12 ft² area of forage contaminated by collar solution were observed for signs of 1080 poisoning. One of two sheep feeding in pens contaminated by 20 ml of 1080 solution died (0.21 ppm 1080 residue in muscle). Both sheep feeding in pens contaminated by 30 ml of 1080 solution also died (0.41 - 0.47 ppm 1080 residue in muscle).

These studies confirm the toxicity of 1080 to sheep. However, aside from some early incidents involving leaking collars, livestock were apparently not killed by 1080 in five years of experimental trials with livestock protection collars.

Residues

USDI reports that it has improved its procedures for residue analysis to the point where tissue levels as low as 0.1 ppm 1080 can be detected.

USDI has concluded that 1080 residues are highly correlated with the dose of 1080 received. The product-moment correlation coefficient (r) is +0.97 but confidence limits are wide. USDI fit data from coyotes that received known doses of 1080 into the linear equation

$$\text{FAC Dose} = 0.17 + 2.16 ([\text{FAC}] \text{ in Muscle})$$

where "FAC" stands for sodium monofluoroacetate (or 1080).

Using this formula, USDI calculated back from muscle residues of 12 coyotes that were definite or probable victims of toxic collar poisoning and concluded that the animals had received 1.7 - 33.7 mg 1080 (or 0.17 - 2.16 mg/kg). The median dose was 3 mg 1080. Doses were somewhat higher when coyotes had punctured both collar pouches.

The "Pink Teeth" Phenomenon

Early in 1080 toxic collar research, USDI personnel observed that coyotes killed by puncturing collars characteristically had pink (or purple) teeth. This finding was initially ascribed to the Rhodamine B dye used in the 1080 solution. Subsequent research has revealed, however, that the color comes to the teeth internally and not from surface deposits of dyed solution. Coyotes killed by undyed 1080 solution also had pink or purple teeth. A coyote killed by Methomyl did not. Sunlight is apparently necessary for teeth to change color, but prolonged exposure to sunlight will cause teeth to fade.

The bottom line to this discussion is that pink or purple teeth will not enable an investigator to determine whether a coyote so marked was killed by 1080 from a toxic collar or by 1080 obtained in another way.

Efficacy

The current submissions do not contain any reports of field trials of the collar. A few efficacy related tests are reported, however. In one study, USDI repeated one experimental group run in its 1977-1979 experiments to determine the appropriate concentration of 1080 in the collar solution. 10 mg/ml had been selected as the appropriate concentration because it was the lowest concentration tested which produced 100% mortality with relatively short times to death. While 100% mortality was also obtained with the five subjects tested at 5 mg/ml in the collar, some animals took more than 10 hours to die, suggesting that less than 100% kill might be obtained in operational use. It took 7 animals to get 5 collar punctures in the 1984 pen trials. All coyotes puncturing collars dosed at 10 mg/ml died. These include 5 from 1984 and 5 from the earlier years. Where observed, deaths occurred from about 1.5 to 7.25 hours after exposure.

In trials with confined animals, USDI found that the coyotes tested showed a marked preference for killing kid goats over killing lambs. This result was obtained even when there were many more lambs available than sheep and when relative body size should not have been a factor. This apparent preference has not been successfully exploited in targeting strategies for using collars in the field. USDI notes simply

"Pilot tests in Idaho with goats in one range flock and one farm flock of sheep yielded discouraging results."

201.7 Label and Labeling

Use Restrictions

In the "Initial Decision" in the 1080 Predicide Hearings, Administrative Law Judge Spencer T. Nissen identified 13 "Use Restrictions for Sodium Monofluoroacetate (Compound 1080) Livestock Protection Collars". In his "Final Decision", Lee M. Thomas (then Assistant Administrator for Solid Waste and Emergency Response, now Acting Administrator for the EPA) noted that additional use restrictions were needed to set "dose limitations" for the livestock protection collar and to provide for "proper labelling to prevent accidental mishandling of the collars."

USDI has submitted a list of 19 Use Restrictions. These include ALJ Nissen's original 13 (with minor modifications) plus six more. I have examined these restrictions and have entertained comments from certain persons involved in developing certification programs for livestock protection collars, along with EPA regional and Compliance Monitoring personnel. The bulk of the discussions on this matter took place in Dallas, TX, on February 13-15, but other inputs were received prior to the Dallas meetings.* The discussions which follow consider use restrictions proposed by USDI and present suggested modifications. These suggestions generally reflect the consensus of the group which met in Dallas.

Restriction #1

"Use of collars shall conform to all applicable Federal, State, and local regulations."

After a brief discussion of the implications of local regulations, it was decided that this restriction should remain as written.

Restriction #2

"Collars shall be sold or transferred only by registrants or their agents and only to certified applicators or persons under the direct supervision of certified applicators. Collars shall be used only by certified applicators or persons under their direct supervision."

* A list of attendees is appended.

This restriction was discussed extensively. The term "agents" was questioned at Dallas but was not modified. The Dallas group strongly recommended deleting the language which permitted collars to be sold or transferred to "persons under the direct supervision of certified applicators." The consensus was that this language could open the door to unauthorized purchases. The group felt that use of collars by "persons under the direct supervision of certified applicators" should be permitted. Compliance Monitoring felt very strongly, however, that this restriction should be expanded to indicate that applicators must be specifically certified for this use and to include language clarifying what is meant by "direct supervision" in this context. The group recommended modifying this restriction to read as follows:

- "2. 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. Direct supervision must, at a minimum, meet the requirements established under 40 CFR 171.6.

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 at the application site where collars are applied by a noncertified person. However, the noncertified person who has received appropriate verifiable instructions from the certified applicator may store collars, check collars in the field, remove collars, repair or dispose of damaged collars in accord with use restrictions, retrieve collars lying in the field, and properly dispose of contaminated material and animal carcasses."

Restriction #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 collars.
- (b) Training in disposal of punctured or leaking collars, contaminated animal remains, contaminated vegetation and soil, and contaminated clothing.
- (c) Instructions for practical treatment of 1080 poison in humans.
- (d) Instructions on record keeping."

The Dallas group did not suggest modifying this restriction. The only change that I believe necessary is to change "poison" to "poisoning" in "(c)".

Restriction #4

"Registrants or their agents shall keep records of all collars sold or transferred. Records shall include name and address of each recipient and dates and numbers of collars sold or transferred."

The term "agents" was again questioned. "Agents" did not appear in this restriction as it was adopted by ALJ Nissen. State personnel wanted to know whether "agents" was synonymous with "dealers" and whether "dealers" was a better term. State and Regional personnel wanted to know whether registrants would be required to name specifically authorized dealers. This point should be addressed by EPA and state regulatory agencies, but probably should not be mentioned in the Use Restrictions.

State personnel also indicated that it was important to note the state in which the collar purchaser was certified and the individual's certification number. Incorporating the suggested modifications, this restriction would read

- "4. Registrants or their agents ("dealers?") shall keep records of all collars sold or transferred. 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."

Restriction #5

"Each applicator shall keep records dealing with the use of toxic collars and the results of such use. Such records shall include, but need not be limited to:

- (a) The number of collars attached on livestock.
- (b) The location of collared livestock.
- (c) The dates of each attachment, inspection, and removal.
- (d) The number and location of livestock with ruptured or punctured collars and the apparent reason.
- (e) The number, date, and approximate location of collars lost.
- (f) Species, location, and date of animals killed by toxic collars.
- (g) All accidents or injuries to humans or domestic animals resulting from collar use.

Several issues were raised regarding this restriction. The question of how long records should be kept led to discussions of how best to keep track of collars and how time should be measured. The modification below reflects the group's consensus. Other modifications have been suggested to remove the unrealistic precision demanded for keeping records of the location of lost collars (one does not know exactly where lost collars are) and for concluding that animals or persons have definitely been killed by collars. The expression "accidents and injuries" has been replaced by "suspected poisonings" since these would be the incidents of greatest concern.

"5. Each applicator shall keep records dealing with the use of Livestock Protection 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 collars. Such records shall include, but need not be limited to:

- (a) The number of collars attached on livestock.
- (b) The pasture(s) where collared livestock were placed.
- (c) The dates of each attachment, inspection, and removal.
- (d) The number and locations of livestock found with ruptured or punctured collars and the apparent cause of the damage.
- (e) The number, dates, and approximate location of collars lost.
- (f) The species, locations, and dates of all animals suspected to have been killed by Livestock Protection Collars.
- (g) All suspected poisonings of humans or domestic animals resulting from collar use."

Restriction #6

"Any poisoning of threatened or endangered species will be reported immediately to the appropriate regulatory agency, as will each accident or injury to humans or domestic animals."

Modifications similar to those in Restriction #5 were suggested to indicate that suspected poisonings are the incidents of primary concern. To determine the actual cause of death in a suspected poisoning requires skill, equipment, and advanced training. This restriction should be modified to read

"6. Any suspected poisoning of threatened or endangered species will be reported to the appropriate regulatory agency, as will each suspected poisoning of humans or domestic animals."

Restriction #7

"Only registrants are authorized to load collars with 1080 solution. Certified applicators are authorized to receive and attach only loaded collars."

Participants at the Dallas meeting felt that the words "load" and "loaded" should be replaced with "fill" and "filled", respectively. They also questioned whether the term "registrant" was meant to include the collar manufacturer since the collars would probably not be manufactured by USDI under the proposed registration. In a technical sense, a Livestock Protection Collar is "manufactured" as a pesticide the moment that the 1080 solution is injected into it. If, as apparently was the case during the EUP, collars were to be both built and injected by Rancher's Supply, USDI, as registrant, would be in violation of this restriction. This matter must be clarified prior to registration.

Restriction #8

"Collars shall be used only to take coyotes that prey upon domestic sheep or goats within fenced pastures up to 50,000 acres in size. Collars shall not be used on unfenced, open range."

Discussion on this restriction dealt with the specifying of target species, the term "fenced pastures" and the size limitation imposed upon such pastures. While it is clear that the collar is designed to kill depredatory coyotes, the question arose as to whether the language of this restriction would make the taking of another predator a violation even though the victim was poisoned through puncturing a collar in the process of attacking a sheep or goat. By deleting the word "only", the label would allow for the taking of other predators in the manner in which the collar is supposed to kill coyotes. The words "that prey upon domestic sheep or goats" could be deleted since this thought is more appropriately covered under Restriction #9.

A definition for "fenced pasture" had been proposed by one member of the certification committee. The Dallas group recommended that a modified version of this definition be incorporated into Use Restriction #8. The 50,000 acre limit to fenced pasture was discussed, but no specific changes were recommended. A pasture of this size would contain nearly 80 square miles of land. Locating collared animals could be very difficult under such conditions as could locating carcasses if terrain and vegetation prevented unobstructed viewing of the area from a vehicle or on horseback.

As modified, this restriction would read

- "8. Collars shall be used to take coyotes within fenced pastures up to 50,000 acres in size. Fenced pastures include all pastures which are enclosed by livestock fencing. In addition to wire livestock fences, these may include natural or man-made barriers such as rock walls, escarpments, or dense shrubs as part of such fencing, or natural or man-made water barriers such as oceans, lakes, or rivers. Collars shall not be used on unfenced, open range."

Reducing the limit on pasture size to 5,000 would accommodate nearly all situations in which the collar might conceivably be used effectively.

Restriction #9

"Collars shall be used only where livestock losses due to predation by coyotes are occurring or, based on prior experience, where coyote predation can reasonably be expected to occur."

The question of replacing "coyote" with a broader term such as "wild canids" was discussed. "Coyote" was retained, however, because the collar would not be a control method of choice in situations where other animals were the main predators on livestock.

Because of the intended use of the collar, it is appropriate to replace "livestock losses" with "losses of sheep or goats". "Livestock" includes many types of animals for which use of Livestock Protection Collars would not be appropriate. As modified, Restriction #9 would read

- "9. Collars shall be used only where losses of sheep or goats due to predation by coyotes are occurring or, based upon prior experience, where coyote predation can reasonably be expected to occur."

Restriction #10

"Where collars are in use, each logical point of access shall be conspicuously posted with a bilingual (English/Spanish) warning sign not less than 8" X 10" in size. Such signs shall be inspected weekly to ensure their continued presence and legibility and will be removed when collars are removed."

The principal area of discussion on this restriction dealt with the appropriateness of specifying Spanish as the second language for warning signs. In some sheep areas, it was felt that another second language would be more appropriate. It was, therefore, suggested that the term "bilingual" not be qualified. It might be better to replace "(English/Spanish)" with "(English and Spanish or another second language appropriate for the region)".

Restriction #11

"Each collar in use shall be inspected at least once a week to ensure it is properly positioned and intact."

This restriction was found to be incomplete and grammatically awkward. A suggested modification is as follows:

- "11. Inspections shall be held at least once per week to ensure that collars in use are accounted for, properly positioned, and intact."

Restriction #12

"Damaged, punctured, or leaking collars shall be removed from the field and either returned to the manufacturer for replacement or disposed of properly."

This restriction provoked considerable discussion at Dallas. Most participants did not approve of the practice of shipping collars back to the manufacturer, particularly collars which had sustained some damage. Such shipments may not be legal in view of hazardous materials regulations and other use restrictions (e.g., #2). The Dallas group felt that certified applicators should be permitted to repair collars which had sustained only minor damage and were not empty or leaking, but that all other damaged collars should be properly disposed.

Many felt that directions for handling damaged collars were needed. Minimal directions are included in the proposed revision below.

- "12. Damaged, punctured, or leaking collars shall be removed from the field for repair or proper disposal. Damaged collars shall be placed individually in impermeable containers while awaiting repair or proper disposal. Leaking or punctured collars must be disposed.

Restriction #13

"Disposal of damaged, punctured, or leaking collars and contaminated leather clothing, animal remains, vegetation, and soil shall be accomplished by burial under 3 feet of soil in a sanitary landfill or safe field location at least 1/2 mile from human habitation and water supplies. If deep burial is impractical, burn the contaminated materials to ashes and cover the ashes with soil."

This restriction provoked many questions. One issue raised was whether sanitary land fills would accept damaged collars. Another was how long collars could be held until disposed. This issue is of great concern in areas where soil is difficult to penetrate due to frigid weather or other prevailing conditions. A third issue dealt with the locations where collars could be burned legally. These issues must be resolved prior to registration.

The proposed revision of this restriction is made assuming that it would be legal to burn or bury contaminated materials on the property where collars are used or in sanitary landfills. Certain editorial changes have been made to improve clarity.

- "13. Disposal of punctured, leaking, or otherwise unrepairable, damaged collars, contaminated leather gloves and boots, animal remains, vegetation, and soil shall be accomplished by burial under 3 feet of soil in a sanitary landfill or a safe field location at least 1/2 mile from human habitation and water supplies. If deep burial is impractical, burn the contaminated materials to ashes and cover the ashes with soil, preferably on property owned or managed by the applicator."

Restriction #14

"All persons authorized to possess and use toxic collars shall store such collars under lock and key in a dry place away from food, feed, domestic animals, and corrosive chemicals. Collars will not be stored in any structure occupied by humans."

Although no specific alternate language was proposed, Dallas participants noted that the most suitable structures for storing collars safely on some operations might also be occupied by humans.

Restriction #15

"Collars shall not be used where gray wolves (Canis lupus) or grizzly bears (Ursus horribilis) are known to occur."

This restriction was discussed but formal changes were not proposed because of the upcoming reviews by HED and the Office of Endangered Species. The questions raised include whether there could be seasonal allowances for winter inactivity of grizzly bears, and whether the occurrence of these species would be specified by state, by county, or by pasture. The historical ranges of these species cover much more territory than the animals now occupy. The limitations of use of collar should be based upon recent information.

Restriction #16

"The number of collars shall be the minimum necessary for effective livestock protection. The maximum number of collars shall not exceed 20 in any pasture under 100 acres in size nor more than 50 per section (640 acres). The maximum number of collars provided to any producer in one year shall be 20 plus one for each 10 head of sheep or goats owned by that producer."

This restriction was discussed at length. Although numbers of collars were debated, no adjustments to the numbers were offered. Several people suggested deletion of the last sentence since costs of collars might effectively limit the number obtained by any one producer. The group felt that the discussion of collar numbers should refer to the collars in use at any one time, not to the total on hand. The proposed revision incorporates these suggestions

"16. The number of collars used shall be the minimum necessary for effective livestock protection. The maximum number of collars in use shall not exceed 20 in any pasture under 100 acres in size nor shall it exceed 50 per section (640 acres) of fenced pasture used by the producer whose livestock are to be protected by collars."

Restriction #17

"Supervisors of collar applicators shall check their records and collars at least once per year to verify that all applicable laws, regulations, and restrictions are being strictly followed."

This restriction is unclear. It could be construed as being contradictory to Restriction #10 depending upon the meaning of the expression "supervisors of collar applicators". If this refers to the certified person for whom noncertified applicators work, the language would pertain to a yearly inspection of all collars on-hand, whether in use or not, and would be conducted in addition to the inspections conducted under Restriction #10.

If "supervisors of collar applicators" were changed to "Certified Livestock Protection Collar applicators", the goal of yearly inspection of all collars and yearly review of all practices would be directed.

Restriction #18

"Each applicator will have 1-ounce bottle of syrup of ipecac available when attaching, inspecting, removing, or disposing of collars."

This restriction was not discussed at length. It could be improved by adding "a" between "have" and "1-ounce".

Restriction #19

"No contaminated animal will be used for food or feed consumption."

This restriction was found to be unclear. Dallas participants were not sure of the meaning of "contaminated animal" or "feed consumption". For example, would any animal which had ever worn a collar or had ever been touched by 1080 solution be forever judged as contaminated, would there be a time-period after which surviving animals could be judged to be clean, or would this term apply only to animals which had had their collars punctured? Does "feed consumption" apply to all processing for animal or human consumption? If so, the restriction might be amended to state

"19. No animal which wore a leaking collar or which wore a collar punctured by a predator attack or any other cause shall be used in any way for human or animal food."

Whether additional restrictions are needed is a matter which must be resolved prior to registration. One Dallas participant suggested, for example that the restrictions should specify that collar users should carry sufficient water into the field to accomodate the washing of materials which might become contaminated.

Technical Bulletin

The draft bulletin covers most of the areas needed for such a document. These areas were outlined in the efficacy review of 2/2/83 and in OPP's letter of 4/24/84. The bulletin is generally well done, but there are a number of areas in which it could be improved. Users are recommended to do more experimentation in their use of the collar than seems advisable, even though attempting to control coyotes is a highly interactive process. Specific comments on the bulletin appear under "Conclusions".

Product Label

Certain changes are needed in the product label to make it consistent with material in the Use Restrictions and in the Technical Bulletin. To the extent that these documents are modified, additional label revisions would be needed.

202.0 CONCLUSIONS

The Use Restrictions proposed for the Livestock Protection Collar have been reviewed by Registration Division and Enforcement personnel as well as by members of the Toxic Collar Committee on training and certification. The attached Use Restrictions list contains the modifications suggested as a result of these reviews.

There are several unresolved questions pertaining to the Use Restrictions. These questions include

1. Would the list of restrictions adopted for the USDI registration be appropriate for all potential registrants of Livestock Protection Collars? Should restrictions be modified to suit conditions of use proposed by registrants or states to meet their own particular needs?
2. In Restrictions 2 and 4, does the term "agents" refer to specifically authorized parties named by the registrant and accepted by EPA and/or appropriate state agencies. Would these "agents" be "dealers"?
3. Who would fill collars registered by USDI? If the collars were to be filled by Rancher's Supply, there would be a violation of Restriction 7, as worded, since the registrant would not be filling collars. The party which fills the collars becomes the manufacturer of the product as a pesticide even though the empty collars may have been build by someone else. This problem could be resolved if USDI were to become the party which fills collars, or if the wording of Restriction 7 were changed to allow for the filling of collars by the "manufacturer", or if Rancher's Supply were to be designated as an official producing establishment for USDI.
4. Is the maximum size of fenced pasture proposed as the upper limit for applications too large to permit effective monitoring of the safety and efficacy of the Livestock Protection Collar?
5. Should Spanish be stipulated in Restriction 10 as a mandatory second language for bilingual labeling, or should the second language be left as an option so that the second language most appropriate to the area where collars are to be used might be selected?
6. Is it appropriate or even legal for certified Livestock Protection Collar applicators to ship damaged collars to the manufacturer for repair or replacement? The proposed revision does not allow for return of collars to the manufacturer. The "return" provision would allow for physical documentation of all recovered, damaged collars and thus act as a buffer against abuse of the registration.
7. Will sanitary landfills accept damaged collars, as implied in Restriction 13. How long may collars be held until disposal? Where could collars be burned legally? What should one do where weather or soil conditions make burial impossible and burning is illegal?

8. Is Restriction 14 intended to make the use of collars illegal by one whose dwelling is the only available structure where collars could be secured? Would storage of collars be permitted in functionally distinct buildings that are connected to the buildings inhabited by humans?
9. Should Restriction 15 be expanded to include other endangered species? Should prohibitions be limited to seasons when the animals in question are active in the areas where collars are to be used? Should prohibitions be specified in terms of historical ranges, current ranges, states, counties, townships, or smaller units.
10. What is meant by the term "supervisors of collar operators"? The proposed amendment assumes that this term means the person in charge of the use of the collar at a given site or operation.

Additional use restrictions might be needed to accomodate such potential problems as the washing of equipment that becomes contaminated in the field. It might be appropriate to require that sufficient amounts of water be transported to the pastures where collars are used to permit initial washing of contaminated materials on site.

The product label must be consistent with the Use Restrictions as they are finally established. To be consistent with the revisions proposed above, changes would be needed in the storage and disposal statements. The text under "RESTRICTED USE PESTICIDE" would also require revision. Changes in the precautionary labeling might also be needed.

The draft Technical Bulletin has been reviewed. While the document is well written, well organized, and generally complete, there are a few areas where revisions are needed. Specific comments on the Technical Bulletin follow:

Page 1

In footnote 1/, delete "as part of the training program".

In first sentence of second paragraph, replace "do everything right" with "attach collars properly".

In fourth sentence of second paragraph , delete "and it is a waste . . . those conditions".

Delete fifth sentence of second paragraph.

In seventh sentence of second paragraph, replace "that meet two criteria:" with "with".

Page 2

In fourth paragraph, revise third sentence to read "Humans can be poisoned only through ingestion of collar contents."

In sixth sentence of fourth paragraph, replace "prudence" with "caution".

In seventh sentence of fourth paragraph, insert "and Use Restrictions" between "label" and "carefully".

End fifth sentence of fifth paragraph with "guard dogs."

Page 3

Delete material in first paragraph, which is a continuation of fifth paragraph on Page 2.

Amend first sentence of third paragraph to read: "Many wildlife species may occur in sheep pastures and goat pastures."

In third sentence of third paragraph, add "of safety" after "guarantee".

At end of fourth paragraph, add the following sentence "Collars which have suffered minor damage to straps or fastenings may be repaired by applicators as long as the 1080 reservoirs have not been punctured and do not leak."

In first sentence of fifth paragraph, should "velcro" be capitalized and identified as a trade name?

In third sentence of fifth paragraph, replace "The" with "A".

In seventh paragraph (and its continuation on Page 4), if you feel strongly that only collars with velcro straps should be used at this time, the registration should be limited to those designs. If there are ways in which the elastic-strapped designs can be used effectively, these should be identified. Is it possible, for example, to solve the sliding collar problem with goat by tying the collar to the horns?

Page 4

In first paragraph (a continuation of seventh paragraph on Page 3), the second sentence should be amended to read

"These instructions are intended to cover any model of Livestock Protection Collars which are accepted for use under this registration by the U. S. Environmental Protection Agency."

Delete the third sentence of the first paragraph.

Page 4 (continued)

Modify point "1" to read: "Things to do before putting collars on livestock:".

Modify subpoint "e" to read:

"Inform neighbors of your intent to use Livestock Protection Collars and advise them of the potential hazards to free-roaming dogs."

Page 5

Under subpoint "i" (from Page 4), modify last sentence to read:

"Also have a few good quality plastic bags or other suitable containers on hand for packaging damaged collars."

In first sentence of first paragraph under point "2", replace "check for proper size" with "determine the size of collar needed for each animal."

Page 6

Last sentence of third paragraph ("Place warning signs.") should appear as its own paragraph.

Sentence comprising (old) fourth paragraph should be amended by replacing "toxic collars" with "Livestock Protection Collars".

In fifth sentence of (old) fifth paragraph, delete "as soon as possible".

Page 7

In fourth sentence of fourth paragraph, replace ", feed sack, or other convenient" with "or an impermeable". After this sentence, add the following sentence:

"Even with good quality plastic bags, it may be necessary to double the bags to prevent leakage."

Page 8

In sixth sentence of third paragraph, replace "poisoned coyotes" with "coyotes suspected to have been poisoned by Compound 1080". After this sentence, add "Coyotes poisoned by Compound 1080 may have pink or purple teeth."

In first sentence of fourth paragraph, replace "you should" with a comma.

In second sentence of fourth paragraph, add "suspected" between "any" and "poisoning".

Page 9

Third paragraph must be consistent with Use Restrictions, particularly with Restriction 19 which prohibits use of contaminated animals as food or feed.

Fifth and sixth paragraphs must be consistent with Use Restrictions, particularly with Restriction 13, regarding disposal of collars and other contaminated items or objects.

Page 10

In third sentence of first paragraph, change "Four" to "Three".

In fourth sentence of first paragraph, delete "or others".

In second sentence in example "a.(1)", delete "As you might think" and begin sentence with "When". Since example "a.(2)" seems to belong under "c." ("Target flocks are too small."), example "a.(1)" might be more appropriately placed in a paragraph lettered "a". "Some examples:" could then be replaced by "For example," as a lead-in to a sentence which would continue with "twenty lambs were . . ." This paragraph should conclude with a "moral" (e.g., "Collared animals must be easily found by coyotes."), is the case with the other lettered paragraphs.

Is infrequent predation, as discussed under "b." grounds for not attempting to use collars?

The example from "a.(2)" might be added here as a second example or deleted.

Page 11

In first sentence under "f.", delete comma between "animals" and "in". In second sentence under "f.", replace "This is false economy as coyotes are unlikely to" with "Coyotes often do not".

Under "g.", delete ", particularly in research . . . monitoring" from first sentence. In second sentence, replace "Often it seems that coyotes are" with "Coyotes are often", replace "will" with "may", and replace "on account of it" with "as a result".

Under "2. a.", change first sentence to "Collaring all sheep and goats on a ranch would solve the targeting problem."

Page 12

Under "a." (from Page 11), insert comma between "kids" and "it" in sentence "Likewise, in flocks of . . . individuals." Delete the last two sentences of this paragraph.

Page 12 (continued)

In the first paragraph under "b.", replace "is" with "would be" in the fourth sentence. In the fifth sentence, change "there" to "them".

In the first sentence of the second paragraph under "b.", delete "to date". In the third sentence, replace "used as a preventive measure by" with "employed in".

In the first sentence under "c.", delete "It is well known that" and insert "usually" between "Coyotes" and "prefer".

The second paragraph under "c." should read:

"This strategy has not been tested on sheep and is not recommended at this time.

Delete all remaining material in the second paragraph under "c." and all of the third paragraph under "c.". This includes material on Page 13.

Page 13

Delete all material under "d." This method appears to be too unreliable to be incorporated into the Technical Bulletin at this time. If research reveals an efficient way to use this method, it may be added in the future. In spite of the directions aimed at providing for the intended victim's comfort, tethering is a somewhat cruel procedure which offers little "redeeming value" as far as attracting killer coyotes is concerned.

William W. Jacobs
Biologist
IRB/TSS
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