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PRODUCT MANAGER: Miller (16)

PRODUCT NAME(S): 1080 Livestock Protection Collar

COMPANY NAME: USDA/APHIS/DWRC

PURPOSE OF SUBMISSION: Protocol reviews- primary hazard to
skunks and golden eagles from the LPC

<u>SHAUGHNESSEY NO.</u>	<u>CHEMICAL AND FORMULATION</u>	<u>%A.I.</u>
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ECOLOGICAL EFFECTS REVIEW

100.0 Submission Purpose

The United States Department of Agriculture, Animal Plant and Health Inspection Service (USDA/APHIS) has resubmitted two protocols for addressing the issue of primary hazards of Compound 1080 Livestock Protection Collars to striped skunks (Mephitis mephitis) and golden eagles (Aquila chryseatos).

101.0 Background

On November 24, 1986, the EEB completed a review of a laboratory audit, conducted at the Denver Wildlife Research Center (DWRC) on the ecological effects and secondary poisoning of Compound 1080 and Brodifacoum, respectively (See review completed by R. Felthousen in EEB files). The audit took place between July 14-16, 1986, and was conducted by an interagency inspection team at the request of the Office of Compliance and Monitoring (OCM), Office of Pesticides and Toxic Substances. The studies were audited through review of available raw data and reports, interviews with senior study personnel and visits to the laboratory areas where the studies were conducted.

The studies involving Compound 1080 were identified by the Ecological Effects Branch (EEB) as data requirements to support the Federal Registration of the 30 ml LPC. The studies in question were:

- 1) "Estimated Doses of Sodium Fluoroacetate Delivered to Coyotes by Toxic Collars" and,
- 2) "Primary Hazard of the 1080 Toxic Collars to Skunks and Golden Eagles".

As stated in Section 104.0- Conclusions- of EEB's 11/24/86 review, the EEB did not prepare a data evaluation report for any of the studies but instead relied heavily on those study deficiencies, conclusions and recommendations cited in the audit report in making its decision on the adequacy of the data to support a registration. The EEB concluded, based upon these findings, that the Compound 1080 studies were not adequate to support the registration.

On November 27, 1989 the USDA/APHIS requested that the EPA reconsider the need to repeat these studies in that the deficiencies cited would not significantly alter the results. In response to this request the EEB completed another review of the studies and determined that, in so

much as; missing data were still outstanding, data tables were incorrect, actual dosage levels could not be determined and the USDA/APHIS had not submitted any new analysis incorporating corrective data, the reported study results could not be scientifically validated, the studies could not be used to support a Section 3 Registration for the LPC (See review by R. Felthousen dated 3/6/90).

On February 14, 1990, the USDA/APHIS resubmitted the following two protocols for conducting the studies needed to support Section 3 Registration for the 30 ml LPC:

"Primary hazard of sodium fluoroacetate (Compound 1080) Livestock Protection Collars (LPCs) to striped skunks. (QA-66)

"Primary hazard of sodium fluoroacetate (Compound 1080) Livestock Protection Collars (LPCs) to golden eagles (QA-67).

101.0

Protocol Evaluation

The EEB has completed a review of the proposed protocols and believes the following comments are appropriate and need further consideration before actual testing commences.

It is imperative that only that portion of the lamb carcass that is contaminated (i.e. primarily the head and neck portion) is fed to the skunks and eagles. Although contamination to other areas of the carcass may occur, the EEB believes that a majority of the contamination will take place around the head and neck area of the collar lamb. In addition, this may also help reduce the food consumption problems associated with decomposition (i.e., It was mentioned in the previous study that whole carcasses tended to decompose rapidly which may have discouraged the skunks from actively feeding).

The EEB realizes there are difficulties with measuring food consumption with this type of study. However, reporting feeding activity as slight, light, moderate or heavy is too subjective and fails to provide any information on how much of the carcass was actually consumed by the test animal. Therefore, the protocol must be amended to make some attempt at determining how much of the carcass was actually consumed by the test animal/feeding period.

The EEB also believes that all test animals should be fasted for a minimum of 24-hours pre-treatment. This should encourage active feeding once the carcass is

presented.

Clinical observations on any behavioral or other toxicological symptom must be conducted and reported if they occur. In addition, upon termination of the treatment period, all animals exhibiting any toxicological symptom during treatment should be necropsied and pathological abnormalities reported. It is important to note that the purpose of conducting the study is to determine primary hazards. Although mortality is the most significant hazard, sub-lethal effects are also of great concern, and must be reported if they occur. The fact that mortality does not occur, does not necessarily mean there is no primary hazard to non-target species from use of the collar.

The EEB is greatly concerned about the precision and reliability of the methods and techniques for analytically measuring 1080 residues both in animal tissue (i.e., hip muscle) and from contaminated areas around the head and neck areas of the sheep. The EEB is still not satisfied that either the analytical method or extraction process is adequate enough to provide any meaningful data. The EEB is also concerned with certain statements made in the submitted protocol and previous correspondence (see attached letter) which make reference to the Compound 1080 residue data base. The EEB seriously questions the reliability of any previous residue analysis data and wonders how such data could be used in a hazard assessment.

102.0

Conclusions

The EEB has completed a review of two proposed protocols, submitted by the USDA/APHIS/DWRC, for determining the primary hazards to non-target raptors and carnivores from the use of the Compound 1080 Livestock Protection Collar. The EEB believes that those comments and issues discussed under Section 101.0 are appropriate and must be addressed before the EEB can concur with the protocols.

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