267022
RECORD NO.

SHAUGHNESSEY NO.

103
REVIEW NO.

EEB REVIEW

DATE: IN 07/11/90 OUT 9/4/90

FILE OR REG. NO 56228-22

PETITION OR EXP. NO

DATE OF SUBMISSION: 6/26/90

DATE RECEIVED BY EFED: 7/11/90

RD REQUESTED COMPLETION DATE: 10/11/90

EEB ESTIMATED COMPLETION DATE: 10/11/90

RD ACTION CODE/ TYPE OF REVIEW: 325

TYPE PRODUCT(S): Predacide

ACCESSION NUMBER(S): 415371-01

PRODUCT MANAGER: Miller (16)

PRODUCT NAME(S): Compound 1080 LPC

COMPANY NAME: USDA/APHIS

PURPOSE OF SUBMISSION: Review Revised Skunk and Eagle Data

SHAUGHNESSEY NO.	CHEMICAL AND FORMULATION	%A.I.

PIRIB # 415371-01

ECOLOGICAL EFFECTS BRANCH

100.0 Purpose of Submission

The Registrant (United States Department of Agriculture-Animal, Plant and Health Inspection Service/ USDA-APHIS) has submitted a corrected version of a 1984 study entitled, "PRIMARY HAZARD OF THE 1080 TOXIC COLLAR TO SKUNKS AND GOLDEN EAGLES" conducted by Burns et al. 1984.

The EEB had initially accepted the study to support registration. However, after a laboratory audit was conducted, in which several errors in tabulating the data were uncovered as well as the fact that Good Laboratory Practice was not followed during the conduct of the study, the study was found to be unacceptable to support registration. As a result od EEB's review and subsequent meetings with the registrant, it was decided that if the tabular corrections were made and the changes did not significantly alter the results of the study, the study could be used to support registration.

101.0 Background

See previous review by R. Felthousen, dated March 3, 1990 in EEB files.

102.0 Discussion

Eagle Portion of the study

The USDA/APHIS has submitted a corrected copy for Table 12 (Consumption of beef hamburger and lamb/ewe muscle tissue by golden eagles during the first 13 days of the 2-phase pretreatment conditioning period of the simulated hazard study). However, they did not submit a corrected copy of Table 14. As mentioned in the Lab audit, .."The beginning and end treatment weights of the eagle's listed in Table 14 were supported by the raw data except that the data for eagles #9F and 10M were reversible. According to the raw data, the information given for eagle 9F was for bird 10M and visa versa.". These tabular corrections do not appear in the new submission.

Another problem is that the USDA/APHIS still has not documented what portions of food were prepared for the study. It is not known whether 75 gram or 50 gram portions of lamb were weighed. This could significantly change the dosage level administered to the birds and obviously alter the results (See conclusions from audit).

In addition to the data corrections and missing data,

the EEB has previously mentioned that another major problem with the study was sample size and data interpretation. It must be remembered that only 2 of the 5 eagles, tested, actually fed on the contaminated portion of the carcass (neck area of the animal). Its' important to note that both of these animals exhibited signs on intoxication (tremors, lethargy, erected feathers). Although these were only "mild" symptoms they still are effects. A third eagle (#8) also exhibited signs of intoxication even though it never actually fed on the contaminated area.

Finally, the EEB has recently received and reviewed another study, submitted by the Registrant, entitled, "Sodium fluoroacetate (Compound 1080) contamination on the necks of lambs with Livestock Protection Collars (LPCs) that are killed by coyotes." This study concluded that the "worse case" situation for the amount of 1080 contamination on the necks of sheep (both pouches punctured) was 4 times greater than what was applied to the simulated coyote-killed sheep used to feed to skunks and golden eagles in primary hazard study conducted by Burns et al. As such, it appears that, even if the data tables are corrected, the primary hazard study conducted by Burns et al in 1984 is not representative of expected residues likely to occur under actual use conditions and therefore, it is not indicative of the hazard to non-targets.

103.0 Conclusions

The EEB has reviewed the submitted data corrections and found that there are still data omissions and errors with the study. Whether the study can be used to support registration may be a moot point, however, in that a subsequent follow-up study shows that the amount of 1080 contamination used to conduct the skunk and golden eagle study (Burns et al, 1984) was 4 times less than the "worse case" contamination that occurred when coyotes actually attacked and killed sheep wearing the LPC (Savorie et al, 1990). Therefore, the EEB does not believe that the primary hazard study, even if corrected, provides "Core" information for use in conducting a hazard assessment. At best, the subject study can be considered only supplemental even if the omissions/errors are provided/corrected. Therefore, the data requirement has not been satisfied.

8/27/90

Richard W. Felthousen, Wildlife Biologist
EFED/EEB

8.28.90

Norm Cook, Head- Section 2
EFED/EEB

9/4/90

Jim Akerman, Chief
EFED/EEB