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EEB REVIEW

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DATA ACCESSION NO(S).

PRODUCT MANAGER NO. W. Miller(16)

PRODUCT NAME(S) Compound 1080 Toxic Collar

COMPANY NAME USDA

SUBMISSION PURPOSE Submission of toxicity data on 60 ml livestock protection collar.

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.

EEB REVIEW

Chemical Name: Compound 1080 (Sodium Flouroacetate)

100.0 Submission Purpose

The United States Department of Agriculture's (USDA), Animal and Plant Health Inspection Service (APHIS), in response to an EPA letter, dated July 12, 1985 (see attached) has submitted a report entitled," Residues of sodium fluoroacetate (1080) in coyotes and on the necks of sheep due to the use of large (60 ml) compound 1080 livestock protection collars. These data were submitted to support modification of EPA Registration No. 6704-85 (small collar, 30 ml, 300 mg 1080) to include the large (60 ml, 600 mg 1080) collar.

101.0 Study Description and Methods

See attached copy of final report for specifics on study description and methods.

102.0 Discussion

The EEB has reviewed the report entitled, " Residues of sodium flouroacetate (1080) in coyotes and on the necks of sheep due to the use of the large (60 ml) compound 1080 livestock protection collar", and believes the following points, regarding the adequacy of the study, must be addressed before the data presented can be used to support registration of the 60 ml collar.

Although the report presents data which shows exposure to coyotes that puncture the large collar is considerablly greater than the small collar (5,8 and 11 times higher, respectively for hip muscle, stomach contents and vomitus), because of the small sample size (i.e., 3,4 and 5 samples, respectively, were collected to determine average residues in stomach contents, vomitus and hip muscle) and amount of variation between samples, the EEB questions the reliability of these data to predict either the average or maximum exposure levels that are likely to occur.

For example, stomach samples ranged from 0.74 to 8.2 ppm (1 order of magnitude difference), and averaged 4.0 ppm with a standard deviation of 3.8 ppm. Using the upper 95% C.I. for these data, the average residue in stomach contents could be as high as 11.8 ppm (i.e., 3.8 X 2 + 4.0) or nearly 3X greater than the reported average.

The variation in the amount of residue in vomitus was even greater. Vomitus samples ranged from 0.11 to 14 ppm (2 orders of magnitude difference), and averaged 3.7 ppm with a standard deviation of 6.9 ppm. Using the upper 95% C.I for these data, the average residue in vomitus could be as high as 17.5 ppm (i.e., 6.9 X 2 + 3.7) or nearly 5X greater than the reported average.

Although not as pronounced, variation in hip muscle residue data was also quite large. Hip muscle samples ranged from 0.26 to 1.6 ppm (approx. 1 order of magnitude difference), and averaged 0.82 ppm with a standard deviation of 0.51 ppm. Using the upper 95% C.I. for these data, the average residue in vomitus could be as high as 1.82 ppm (i.e., 0.51 X 2 + 0.82 = 1.82) or 2X greater than the reported average.

Small sample size was also a problem with the sheep exposure aspect of the study. For example, based upon five samples, the average amount of residue per sheep, on wool and skin around the head and neck, was 36 mg. However, samples ranged from 8.5 to 74.7 with a standard deviation of 25.8 mg. Using the upper 95% C.I. for these data, the average residue in these samples could have been as high as 87.64 mg (i.e., 25.8 X 2 + 36 = 87.64).

Another concern was the extraction technique used to prepare the samples. For example, a greater amount of 1080 was recovered from the third and last extraction than from the second extraction. The report points out that this finding was "unexpected". The EEB is concerned about these results in that it implies that the procedure used to extract and analyse for 1080 may not be appropriate for the amount of sample collected. The EEB notes that the report specifically states that "... the procedure for 1080 analysis was designed for 1 g tissue samples with 5-10 ml solvent... and that ..." in contrast, 3-4 liters of solvent were used to extract each wool and skin sample and each weighed several hundred grams. However, there is no further discussion as to how this procedure may have accounted for the "unexpected" results and/or whether such a procedure is appropriate for analytical purposes. In addition, the EEB is concerned about; what additional residues would have been found if a fourth extraction was conducted; and why the researchers stopped after conducting only three extractions when such high residues (relative to the sensitivity if the method i.e., 0.04 ppm) were still being found on the samples?

This leads the EEB to question whether a similar problem occurred in those tests conducted to evaluate exposure on goats fitted with the 30 ml collar (Burns et al., 1984). For example, in that study, only two replicate samples were analyzed to determine residue levels. Residues ranged from 33 to 39 mg with an average of 37 mg. The obvious question is; would residues have been higher if a third or fourth replicate had been taken? Is the procedure reliable for both goats and sheep or is a separate extraction method needed for each species? Because such data are critical to determining exposure, the EEB believes that it is imperative for these tests to be redone using sufficient samples and appropriate analytical procedures. If results from these tests indicate that exposure is significantly greater than previously reported, the EEB believes it appropriate to reassess its prior hazard assessment for the 30 ml collar in light of the new data.

The average time to death for coyotes exposed to 1080 from puncturing the large collar was two hours and thirty four minutes as compared to four hours and thirty nine minutes for the small collar. Again, these data indicate that coyotes which puncture the large 60 ml collar will be exposed to higher 1080 residues than coyotes that puncture the smaller 30 ml collar.

103.0 Summary

The data presented indicate that coyotes which puncture the large compound 1080 livestock protection collar will be exposed to more toxicant than those coyotes puncturing the small (30 ml) collar. Residue levels in hip muscle, stomach contents and vomitus were 5,8 and 11 times greater, respectively, in coyotes that punctured the large (60 ml) collar as compared to coyotes that punctured the small (30 ml) collar. Additional support for this finding is that the time to death for coyotes killed by the large collar was nearly 2 hours shorter than coyotes killed by the small collar. However, because of the small sample size, upper confident limits for the data could result in values that are 2,3 and 5 times greater than those cited in the report.

Small sample size was also a deficiency with the collared animal aspect of the study. Although the average amount of 1080 on the head and neck area was reported to be 36 mg, upper 95% confidence limits for these same data show that the average value could have been as high as 87.6 mg.

Based on the results of this study, the report claims that the average amount of toxicant likely to occur on collared animals is similiar for both the 30 and 60 ml collars. However, because of the small sample size and analytical problems with the extraction procedure, the EEB seriously doubts the reliability of the data for both collars and is requesting further explanation of the extrapolation procedure. As such, the EEB questions whether the reported results are representative of either the average or maximum levels of exposure likely to occur both to the target coyote as well as to the collared animal. Data on such exposure levels are needed in order to develop a "worse case" hazard assessment scenario for non-target species, especially threatened and endangered species. The EEB cautions that, if these issues are not adequately addressed, additional testing will be required for both the 30 and 60 ml collars.

The EEB also concludes that, because of the potential for increased exposure, both to the attacking coyote as well as the collared animal, formal Section 7 Consultation with the USFWS may be required prior to any registration of the 60 ml collar. However, the EEB will not initiate this consultation until such time as the issues identified in this review are addressed and a comprehensive hazard assessment, to determine if a "may effect" situation exists, has been completed.

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