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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Review of Protocol for Captan Dairy Cow Feeding Study,
No. 10182-293, Record No. 255730, DEB No. 6051

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TO: J. Miller PM-23
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The Captan Task Force has submitted for review a protocol (CAPT-89-AT-01) of a dairy cow feeding study. This study is being done in anticipation of future needs, and not in response to a Registration Standard Data Call-in.

Experimental Design

The anticipated dietary burden was previously estimated by RCB to be 11 ppm for beef cattle and 7 ppm for dairy cattle (N. Gray 12/14/87). Accordingly the Captan Task Force has proposed a 1X feeding level of 10 ppm.

The dosing levels for the four treatment groups (each consisting of four animals) will be 0, 10, 30, or 100 ppm captan. Feed consumption will be monitored during the acclimation period to determine the individual animal test material dose. The dose will be administered once daily after the morning feeding for 28 days, in a gelatin capsule by balling gun. The cattle will be fed and milked twice a day. Milk samples will be collected one day prior to the initial dosing and on days 1, 4, 7, 10, 14, 21, 28, 30, 32, and 34. Milk from the a.m. and p.m. milkings will be composited in equal amounts.

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Within 24 hours of the final dose three of the four animals in each experimental group will be sacrificed. The fourth animal in each group will be sacrificed at the end of a 7 day withdrawal period.

Duplicate 500 g tissue samples will be collected from each animal including the liver, kidney, adipose tissue (equal amounts of omental and renal fat), and muscle (triceps, gracilis, and longissimus dorsi). Samples from each animal will not be combined within a treatment group. All samples will be stored and shipped frozen.

Each sample will be analyzed for the metabolites only, including tetrahydrophthalimide (THPI), 3-hydroxy-THPI, and 5-hydroxy-THPI. The proposed detection limit is 0.05 ppm. The protocol states that storage stability data are available to support the residue data. The Captan Task Force should ensure that storage conditions from previous studies adequately reflect the conditions and length of time proposed for this study.

Conclusions

The protocol seems to be complete. The proposed dosing level still appears to be appropriate, in light of changes in captan registrations described in the PD4 (54FR8116, 2/24/89) completing the Special Review. The husbandry and dosing scheme are adequate. Sample collection, storage, and analysis should be sufficient, assuming residues in milk have plateaued by the completion of the study. Additional samples will have to be taken if a plateau has not been observed. Overall the protocol should fulfill the requirements for magnitude of residue in cattle meat and milk if executed as proposed.

cc: CLOlinger (DEB), Circulate (7), RF, SF, E. Eldredge
(PMSD/ISB), RDSchmitt
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RDI: WJHazel: 12/28/89 EZager: 12/29/89