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

MAY 11 1982

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Jay Ellenberger (12)
Registration Division (TS-769)

THRU: Orville E. Paynter, Chief
Toxicology Branch
Hazard Evaluation Division (TS-769) 5/11/82

SUBJECT: PP#1F2527, 1H5308 and 2139-~~EUP~~ KEE; Addendum to Review of April 30, 1982 (Request for tolerances of Thidiazuron on Cotton; Milk; Eggs; Meat; Fat and Byproducts of Cattle, Goats, Hogs, Horses, Poultry and Sheep; and Cottonseed Hulls). CASWELL #659A

Registrant: Nor-Am Agricultural Products
350 West Shuman Blvd.
Naperville, Illinois 60540

On pages 9-10 of my memo of April 30, 1982, I reviewed a rat teratology study conducted by Reprotox Gmbh of Munster, West Germany. My review noted increased post implantation fetolethality at each dose level (percentages of post implantation losses were 82.9, 39.5 and 53.5 for the 100, 300 and 900 mg/kg groups, respectively, compared to 9.5 in the controls). Though not apparently dose related, the incidence of fetolethality is much greater in treated animals and the extent of the incidence of lethality among treated groups makes it unlikely that this finding is due to chance. The increased fetolethality must therefore be considered to be compound related. However, the repeat of this study did not reveal increased fetolethality among treated groups at dose levels of 25, 50, 100 and 300 mg/kg. Further complicating an interpretation of the effect of test material on fetolethality is the apparent increase in fetolethality observed in the first rabbit teratology study conducted by Hazelton Laboratories of Europe (reviewed in my memo of April 30, 1982). An increase in fetolethality was observed in all treated groups (25, 75 and 250 mg/kg/day) compared to the control group. However, the repeat of rabbit teratology study (at dose levels of 2.5, 7.5, 25, 75 and 250 mg/kg) found no effect on fetolethality which could be associated with compound exposure. The findings of the four studies are therefore contradictory with respect to fetolethality.

It is noted that an explantation of this finding was requested from Mrs. Margareta Lambert of Nor-Am. As of May 3, 1982, an explanation has not yet been received. Therefore, this issue as well as the data gaps listed in our 4/30/82 memo must be resolved before a favorable toxicology recommendation on the proposed tolerances.

Gary J. Burin 5/6/82

Gary J. Burin, Toxicologist
Toxicology Branch
Hazard Evaluation Division (TS-769)

TS-769:th:TOX/HED:GJBurin:5-6-82:card 3

2