MEMORANDUM


FROM: Nancy Dodd, Chemist Hazard Evaluation Division (TS-769C)

TO: Jay Ellenberger, Product Manager #12 Insecticide-Rodenticide Branch Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief Hazard Evaluation Division (TS-769C)

The petitioner Nor-Am Chemical Company has submitted an amendment dated July 18, 1985 which consists of a resubmission of a cover letter dated October 3, 1984 and revised labeling. The amendment was submitted in response to deficiencies contained in Jay Ellenberger's letter dated September 10, 1984, which was based on RCB's review of PP#4F2968 for amitraz on cattle dated July 19, 1984 (Al Smith).

The deficiencies listed in the July 19, 1984 review are outlined below followed by the petitioner's responses and RCB's conclusions.

Deficiency #1:

"The chemical components of the [redacted] have not been identified. These data are needed in order to determine if such components are cleared for use under §180.1001."
Petitioner's Response to Deficiency #1:

The petitioner states that he has submitted a letter and a Product Bulletin from □□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□]]
in the present amendment of July 8, 1985, the petitioner has submitted a revised label that reinstates the phrase, "Repeat applications as necessary" under the spray dipping instructions. RCB cannot accept the reinstatement of the phrase "Repeat applications as necessary" on the proposed label. The petitioner will need to submit a revised Section B/label where the sentence "For control of lice, a second treatment 10 to 14 days later is recommended" has been placed again in the spray dipping instructions.

2. An International Residue Limit Status sheet is attached to this review. No Mexican or Canadian tolerances are established for amitraz on cattle. Codex proposals are for the sum of amitraz, calculated as N-(2,4-dimethylphenyl)-N'-methylformamidine, and N-(2,4-dimethylphenyl)-N'-methylformamidine. U.S.A. tolerances are for amitraz and its metabolites containing the 2,4-dimethylaniline moiety. Codex proposals are 0.05 mg/kg for carcass meat of cattle, 0.2 mg/kg for cattle meat by-products, and 0.01 mg/kg for milk. Numerically, only the Codex proposal for carcass meat of cattle (0.05 mg/kg) corresponds to the U.S.A. tolerance proposal of 0.05 ppm for cattle meat. The residue data submitted will not permit compatibility of the U.S. and Codex meat by-product and milk tolerances.

**Recommendation**

RCB recommends **against** the proposed use of amitraz on cattle because of reasons discussed in item 1 under Other Considerations above.

**Attachment 1: International Residue Limit Status sheet**

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL: amitraz

CCPR NO.: 122

Codex Status: No Codex Proposal Step 6 or above

Proposed U.S. Tolerances

Residue (if Step 9): Sum of amitraz, calculated as \( N/(2,4\text{-dimethylphenyl})-N'\text{-methylformamidine, and containing the \(2,4\text{-dimethylamino} moiety.} \\

Crop(s) Limit (mg/kg)
- Carcass meat of cattle: 0.05
- Carcass meat byproducts: 0.2
- Milk: 0.01

CANADIAN LIMIT

Residue: ____________

MEXICAN TOLERANCIA

Residue: ____________

Crop Limit (ppm)
- None

Crop Tolerancia (ppm)
- None

\( N/(2,4\text{-dimethylphenyl})-N'\text{-methylformamidine.} \\

Notes: * at or about limit of determination.