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EXPEDITE

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

NOV 26 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4F3081. Amitraz in Meat, Fat, and Meat Byproducts of Hogs. Evaluation of the October 13, 1986 Amendment. (Revised Section F). (No Accession Number) [RCB #1590]

FROM: Francis D. Griffith, Jr., Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Dennis Edwards (Acting PM-12)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

The reveiw of this amendment is being expedited at the request of Edwin F. Tinsworth, Director of the Registration Division in his memorandum dated November 25, 1986, to John W. Melone, Director of the Hazard Evaluation Division. Nor-Am Chemical Company has submitted this amendment consisting of cover letters and a revised Section F (a new tolerance proposal). The amendment has been submitted in response to several deficiencies outlined in our review of amitraz (trade named Baam® and TAKTIC®) in meat, fat, and meat byproducts of hogs by E. T. Haeberer on July 11, 1984, and F. Griffith, Jr., on September 6 and December 19, 1985; and June 23 and October 15, 1986. The deficiencies are listed below in the order they appeared in the June 23 and October 15, 1986 amendments reviews, followed by the petitioner's response, then RCB comments and conclusions.

Deficiency 5d (Sept. 6, 1985, review and reiterated in June 23, 1986, review)

RCB defers judgment on any amitraz in hog meat byproducts proposed tolerance until we have reviewed the amitraz results in cooked hog skin.

(October 15, 1986, review)

For hog meat byproducts which include hog skin and puffed rind, RCB observes valid residue data exceeding the proposed hog meat byproducts amitraz tolerance of 0.2 ppm. RCB reiterates the petitioner should resubmit a Section F that proposes amitraz hog meat byproducts at a 0.3 ppm tolerance level.

Petitioners Response

In the revised Section F the petitioner proposes the following tolerances:

It is proposed that 40 CFR 180.287 be amended as follows:

That a permanent tolerance be established for the combined residues of amitraz (N'-(2,4-dimethyl phenyl)-N-(2,4-dimethyl phenyl)imino]methyl]-N-methyl methanimidamide and its metabolites N-(2,4-dimethyl phenyl)-N-methyl formamide and N-(2,4-dimethyl phenyl)-N-methylmethanimidamide (both calculated as the parent) in or on the following raw agricultural commodities at the following levels:

hog meat	-	0.05 ppm
hog fat	-	0.1 ppm
hog liver	-	0.2 ppm
hog kidney	-	0.2 ppm
hog meat by-products	-	0.3 ppm

RCB Comments and Conclusion

Deficiency 5d is resolved

Other Considerations

An updated International Residue Limit Status Sheet is attached. The Codex and proposed U.S. tolerance expression for amitraz and its metabolites are nearly identical. Codex has published an amitraz tolerance in hog carcass meat at 0.05 ppm. This level is identical to the proposed U.S. tolerance. Thus, the U.S. tolerance and Codex are compatible. However, Codex has not established any amitraz tolerance for amitraz in hog

fat. From the time of the first review of the petition until now Codex has established a 0.2 ppm amitraz tolerance for "pig meat byproduct." The Codex definition for pig meat by-products, unlike the U.S. definition, includes liver and kidney. The proposed U.S. tolerance for amitraz in kidney and liver at 0.2 ppm is compatible with the Codex tolerance. The U.S. residue data and the proposed dermal use patterns for amitraz on swine show the need for a higher U.S. tolerance in hog meat byproducts. Thus, this part of the U.S. amitraz tolerance is not compatible with Codex. The U.S. definition of hog meat by products includes skin and other parts of the hog not considered as meat. Since there are no Canadian or Mexican amitraz swine tolerances compatibility is not a problem at this time.

The second cover letter involves the Confidential Statement of Formula. Nor-AM proposed change in inert ingredients, one of which is not currently cleared under 40 CFR 180.1001(c) or (d), is the subject of a separate expedited RCB review. RCB will not comment further on the inerts question in this review.

RCB Recommendation

RCB concludes amitraz and its metabolites residues from the proposed dermal applications on hogs will not exceed the proposed 0.05 ppm tolerance in hog meat, the 0.1 ppm tolerance in hog fat, the proposed 0.2 ppm tolerance in hog kidney and liver, and the 0.3 ppm tolerance in hog meat by products. RCB recommends for these tolerance being established as requested, TOX consideration permitting and contingent upon the successful resolution of the inerts problems in the TAKTIC® formulation.

cc:R.F.,Circu,EAB, EEB, TOX, FDA, Reviewer:FDG, PMSD/ISB,PP#4F3081
RDI:MJNelson:11/14/86:RDSchmitt-11/14/86
TS-769C:RCB:FDGriffith:CM#2:Rm814b:557-0826
typed by wh:11/17/86

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Amitraz (Baam® or Taktic®)

CODEX NO. 122

J. Voss 11/13/86

CODEX STATUS:

☐ No Codex Proposal Step 6 or above

Residue(if Step 8): sum of amitraz (calculated as N-(2,4-dimethylphenyl)-N'-methylformamidine) and N-(2,4-dimethylphenyl)-N'-methyl-formamidine

Crop(s)	Limit (mg/kg)
Carcase meat of pigs	0.05
Pig meat byproducts	0.2

PROPOSED U.S. TOLERANCES:

Petition No. 4F3081

RCB Reviewer F.D. Griffith Jr 11/13/86

Residue: combined residues of amitraz* and its metabolites

Crop(s)	Limit (mg/kg)
Hog Meat	0.05
Hog Fat	0.1
Hog Liver & Kidney	0.2
Hog Meat Byproducts	0.3

CANADIAN LIMITS:

☑ No Canadian limit

Residue: _____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

☑ No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES: N'-(2,4-dimethylphenyl)-N-(2,4-dimethylphenyl)imino]methyl]-N-methyl-methanimidamide