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

DEC 16 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4F3081 Amitraz on Hog Meat, Fat, and Meat Byproducts.
Evaluation of Method Tryout Report.

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

THRU: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

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

Residue Chemistry Branch (RCB) has been informed by Analytical Chemistry Laboratory (ACL), Chemical Operations Branch (COB), Benefits and Use Division (BUD) of the completion of the initial review of the amitraz method. This initial review of the amitraz in tissues method was reported by Warren R. Bontoyan in his memo dated November 19, 1986.

The method trial was requested for amitraz, trade named Baam® and Tactic® (N'-(2,4-dimethylphenyl-N-([2,4-dimethylphenyl imino]methyl)-N-methyl methanimidamide), and its formamide and methylmethanimidamide metabolites in hog skin (see memorandum by F.D. Griffith Jr., dated November 2, 1986, to COB/BUD). The method trial was requested for the Nor-Am Chemical Company Procedure coded 12002, authored by L. Castro, C. Pawley, and M. Ramos, and dated July 2, 1986. The title of the method is "Analytical Method for the Determination of Total Residues of Amitraz and its Major Metabolites BTS 27271 and BTS 27919 in Selected Hog Tissue". RCB requested the method be validated for amitraz and its metabolites residues in hog skin at 0.3 ppm (the proposed tolerance) and at 0.15 ppm (1/2 x).

No method tryout has been completed as requested. Instead during ACL's initial review of the method various points stand out which ACL feels should be addressed before ACL proceeds further. RCB will not comment on these points until the petitioner has reviewed and commented on them. RCB suggests the PM refer the ACL review (op. cit.) directly to the registrant for action and comments. RCB further suggests the petitioner consider a conference to review method concerns before extensive revision is completed. RCB feels it is in the petitioner's best interest to expeditiously resolve these method concerns as we see the concerns reflecting Nor-Am's ability to resolve the existing Registration Standard deficiency on analytical methods.

While all eight points are of interest to RCB point one will definitely be reviewed carefully by RCB when the registrant responds to the Registrant Standard method deficiency. The registrant could resolve points five and six by agreeing to provide EPA's Repository a known quantity (and purity) of the derivatized standards.

RCB Conclusion

A successful method tryout for amitraz and its metabolites residues using an improved method to update PAM-II has not been completed. The petitioner needs to resolve the ACL concerns as RCB concludes they are germane to the petitioner's resolving the amitraz Registration Standard analytical method deficiency.

RCB Recommendation

The PM should forward ACL's initial review of the amitraz method to the petitioner for action and comment. At this time no copies of the method will be forwarded to FDA's Technical Editing Group to be published in PAM-II or to ISB/PMSD to be made available to all interested parties.

Attachment: ACL's Initial Review of Amitraz (send to PM 12 only)

TS-769C:RCB:Reviewer(FDG):CM#2:Rm814B:557-0826:vg:12/11/86:
edited:fdg:12/15/86
cc: PP#4F3081, PM 12, TOX, Special Review Branch, Amitraz R.S. File,
RF, Circ., Reviewer,D.Marlow(COB/BUD), ISB/PMSD
RDI:Section Head:R.S.Quick:12/8/86:R.D.Schmitt:12/9/86

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

Analytical Chemistry Section
Building 306, ARC-East
Beltsville, Maryland 20705

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

November 19, 1986

MEMORANDUM

SUBJECT: Initial Review of Amitraz
Petition Method Validation (PP#4F3081) Method

FROM: Warren R. Bontoyan, Head *WRB*
Analytical Chemistry Section

TO: Francis Griffith
Residue Chemistry Branch

We have reviewed the method and data for Amitraz and metabolites in Hog Tissues, Lab Study Number 12002 submitted by Nor-Am Chemical Company and have returned the file to you for further consideration for the following reasons:

1. The apparatus used in the method is not commercially available. A telephone conversation with Christopher Davis, Nor-Am Chemical Company, confirmed this. Mr. Davis mentioned that other equipment might be substituted, but he was not sure if it would work.
2. Uncorrected recoveries range from 43.5% to 83.9%.
3. Recoveries are corrected by using a similar compound spiked at the beginning and carried through the procedure. The assumption is that the recovery of this added compound will be identical to the amitraz and metabolites.
4. The response of the derivatized standard is not linear in spite of the fact that an electron capture detector was used. A computer curve-fit was used to correct for the non-linearity.
5. A procedure is given for making derivatized standards but no purity is given for the standard.

6. The time needed for preparing the derivatized standards and assaying purity is too time consuming for regulatory purposes.

7. Spiking volumes (example section 3.2) were considerably less than 1 ml. We have found that normally this is a source of error.

8. A problem exists in not analyzing the parent compound. The procedure breaks the pesticide and metabolites down to an aniline - there are more problems with interfering compounds both naturally and through other potential pesticide usage with this procedure.

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