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

21 APR 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4F2985 (RCB#3479). Permethrin on Tomatoes.
Amendment of 10/1/87. MRID# 403244-01.

FROM: Nancy Dodd, Chemist *Nancy Dodd*
Tolerance Petition Section II
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Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief
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and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

Introduction

With regard to permethrin, Food Additive Tolerances (Section 409) could not previously be established. However, the Agency established a 2.0 ppm tolerance (Section 408) for permethrin on Florida (FL) tomatoes intended for the fresh market only. Then a FL refinery indicated the intent to process tomatoes. Subsequently, ICI submitted a tomato fractionation study involving some tomato fractions, but it was rejected by RCB because of sample integrity. In response to RCB's rejection, the petitioner, ICI Americas Inc., now submits this amendment which consists of a letter dated 10/1/87 and an 8/19/87 addendum to the tomato fractionation study which was discussed and rejected previously by RCB.

Recommendation

409 Tolerances are needed to cover residues on processed tomatoes. Therefore, RCB recommends that RD consider revoking the current 2.0 ppm tolerance on tomatoes, or establishing 409 tolerances under the National Academy of Sciences/Delaney Follow-up Project after appropriate processing data are obtained. Depending on the results of these studies, RCB may recommend for an EPA Lab Audit with regard to this action at a later date.

Summary of Deficiencies Pertaining to this Amendment

1. Since 409 tolerances are needed to cover residues on processed tomatoes, RCB defers to RD as to whether or not the current 2.0 ppm tolerance on tomatoes should be revoked. This tolerance was established with the provision that the only processing of tomatoes in FL involved canning of whole tomatoes, and this provision is no longer correct. Alternatively, RD may wish to establish 409 tolerances under the National Academy of Sciences/Delaney Follow-up Project after processing data are obtained.
2. The petitioner should provide the requested processing study (see RCB's 1/5/87 review of Amendment 9/1/86) on tomatoes, if registration is to be continued.
3. The petitioner also needs to adequately explain how tomato samples harvested and frozen on 6/5/85 could contain so many split, moldy, and rotten tomatoes the next day (on 6/6/85) when they were processed. [Refer to 6/14/85 memo from Bob Bates (U. of Fl.) to Henry Yance.]

History

A.) Background information relating to the proposed use of permethrin on tomatoes can be found in RCB's reviews of PP#2F2243 (see J. Onley memo of 6/1/84) and PP#4F2985 (see M. Firestone memo of 8/30/84), in which RCB recommended against establishment of a 2.0 ppm tolerance on tomatoes grown in Florida for fresh market only because of the following reasons:

1. Tolerances on major crops are set on a national basis and are not restricted to one state.
2. Label restrictions against feeding cannery by-products are impractical, since canners do not know which pesticides have been used on the product to be processed.
3. Tomatoes grown in Florida could be processed into tomato paste outside of Florida.
4. RCB is unable to estimate the level of permethrin residues in Florida tomato cannery by-products (culls and skin) which could be fed to livestock and for which a Section 409 feed additive tolerance may be required.
5. Residues in meat and milk could exceed established tolerances, if tomato pomace or possibly other cannery wastes were fed.

6. If the Agency allows this permanent use of permethrin on tomatoes in Florida, it will be difficult to deny similar uses in other states.
7. The National Food Processors have already been in contact with EPA concerning confusing and impractical label restrictions in feeding cannery by-products. The Agency will just compound this problem by allowing regional use with impractical label restrictions on crops such as tomatoes.
8. Finally, it may be more advantageous for the state of Florida to submit a Section 18 for the proposed use of permethrin on tomatoes. In the meantime, the petitioners (FMC/ICI) may submit residue data reflecting a pre-blossom use.

B. In a 9/26/83 letter from the Florida Tomato Exchange (Wayne Hawkins) to EPA (Edwin Johnson), the following information on tomatoes was provided:

Less than three percent of the total marketable volume of tomatoes was processed in each of the years 1981, 1982, and 1983 (USDA Crop & Livestock Reporting Service in Orlando, Florida). The main product of the five processors in FL is canned whole tomatoes.

C. According to a 3/10/88 Benefits and Use Division memo on tomatoes, a small volume of end-of-season fresh market tomatoes in FL (estimated at <1%) are canned whole.

Subsequent to historical items A and B above, a 12/4/84 memo from the Director of Registration Division (D. Camp) to the Director of OPP (S. Schatzow) stated:

"A section 408 tolerance for permethrin on tomatoes was issued on October 15, 1984. The use on tomatoes was restricted to tomatoes grown for the fresh market in Florida. One of the conditions leading to the establishment of that tolerance was information furnished to the Agency by the Florida Tomato Exchange indicating that the only processing of tomatoes in Florida was the canning of whole tomatoes. Subsequent to the establishment of the tolerance for permethrin on tomatoes, information was received from one of the Florida canneries stating that they produce tomato puree which could require a Section 409 Food Additive Tolerance. The processing for this season will begin about mid-December 1984."

The memo recommended that:

(1) the Agency request the Food and Drug Administration to sample the processed tomato products produced by Golden

Harvest Foods and the other Florida canneries to determine that permethrin residues in the processed tomato products are at or below the established tolerance for the raw agricultural commodity;

(2) that EPA notify Golden Harvest Foods informing them that their processed tomato products may be subject to an enforcement action if they are sampled and found to contain residue of permethrin exceeding the established tolerance of 2 ppm;

(3) that EPA require the petitioner, ICI Americas Inc., to submit a new fractionation study following the guidelines recommended by RCB so that the Agency can make a determination as to the need for a Food Additive Tolerance for processed tomato products.

In response to the Agency's concern, the petitioner submitted an amendment of 9/18/86 (see RCB's review of 1/5/87) that contained some residue data on whole tomatoes, puree sauce, and pizza sauce. Because the integrity of the tomatoes was in question, RCB recommended in its 1/5/87 review that the petitioner should repeat his fractionation study.

Conclusions

1. Since approximately 1/3 of the tomatoes which were to be processed were discarded because of poor condition (split, moldy, and rotten), sample integrity became questionable. This was pointed out in RCB's 1/5/87 review of the 9/18/85 amendment to PP#4F2985. Therefore, another processing study should be conducted, if the tolerance is to be continued. The tomatoes should contain residues of approximately 2.0 ppm and should be carefully preserved between sampling and analysis. Residues in whole tomatoes, wet pomace, dry pomace, puree, juice, and paste should be determined.
2. Individual analyses of whole tomatoes, puree sauce, and pizza sauce from the 1985 processing study have been submitted.
3. The petitioner needs to adequately explain how tomato samples harvested and frozen on 6/5/85 could contain so many tomatoes in poor condition the next day (on 6/6/85). Under frozen conditions, it is difficult to believe that roughly one-third of the shipped tomato samples became split, moldy or rotten between 6/5/85 and 6/6/85; this reflects only one day. Such a loss could hardly be tolerated by commercial shippers.
4. If tomato pomace or cannery by-products (culls and skins) are available as animal feed items from tomatoes which are processed in Florida and tomatoes are converted into puree, paste, and juice, then further evaluation for food/feed additive

tolerances on tomato products (dry pomace, puree, paste, and juice) needs to be continued. Higher meat and milk tolerances would be needed. RCB defers to RD as to whether or not the 2.0 ppm tolerance for permethrin on tomatoes should be revoked at this time, since it was established with the understanding that the only processing of tomatoes in FL was canning of whole tomatoes, which is no longer correct. Alternatively, RD may wish to establish 409 tolerances under the National Academy of Sciences/Delaney Follow-up Project after processing data are obtained.

Detailed Considerations

The outstanding deficiencies which were listed in the 1/5/87 review and restated in EPA's 6/15/87 letter are outlined below, followed by the petitioner's responses and RCB's discussions/conclusions:

RCB's Deficiency #1(a)

"RCB cannot approve residue data on puree and pizza sauce samples generated from deteriorated tomatoes."

"In order to make a determination as to the need for food additive tolerances for processed tomato products (puree sauce, pizza sauce, and tomato paste), the petitioner will need to repeat the fractionation study on nondeteriorated tomatoes."

Petitioner's Response to Deficiency #1(a)

The petitioner has submitted a letter from Professor Bates, University of Florida, which indicates that all of the damaged, moldy or rotten fruit was removed before processing:

"We carefully sorted out all damaged, moldy, and rotten fruit and processed only sound tomatoes. The noted damage was caused by the rigors of packing and transportation -- a normal occurrence when delicate mature-ripe tomatoes are shipped long distances for evaluation. We deal routinely with such situations which in no way reflects on the harvest quality of the fruit nor the subsequent evaluation procedure."

"Consequently, the canned samples were comparable to commercial tomato puree and sauce manufacturing procedures regarding raw material quality. Although we didn't perform Howard mold counts on the processed products, I would estimate that levels would be well within regulatory standards and below average for such commercial products. If you have samples remaining, such a test would reflect starting fruit quality."

RCB's Discussion/Conclusion #1(a)

The petitioner has not adequately explained how tomatoes harvested and frozen on 6/5/85 could contain so many tomatoes that are split, moldy and rotten on the next day (6/6/85) as described in the 6/14/85 memo from Bob Bates (U. of Florida) to Henry Yance:

"Samples were received on June 6, 1985 and processed the same day. Tomatoes were in poor condition and inspected to remove the more obvious splits, molded or rotten fruit. Roughly one-third of both check and Ambush treated fruit were in this category. To approximate fluming and roller spray washing, inspected tomatoes were dipped for 1 minute in a water tank and then water sprayed for 1 1/2 minutes on a blancher belt."

Samples to be analyzed for residues should be properly preserved between sampling and analysis to minimize any loss of pesticidal residues. This also helps to prevent the fruit from becoming moldy and rotten; however, we are not interested in mold counts on the tomatoes.

Deficiency #1(a) is not resolved. If the tolerance is to be continued, the petitioner should conduct another processing study on tomatoes which have residues of approx. 2.0 ppm and which are properly preserved between sampling and analysis. Residues in whole tomatoes, wet pomace, dry pomace, puree, juice, and paste should be determined.

RCB's Deficiency #1(b)

"Individual analyses of the whole tomatoes, puree sauce and pizza sauce must be submitted instead of mean values as submitted previously."

Petitioner's Response to Deficiency #1(b)

The petitioner has submitted an addendum (MRID# 403244-01) dated 8/19/87 to the tomato fractionation study dated 9/18/86. The individual analyses of whole tomatoes, puree sauce, and pizza sauce are given as follows:

<u>FRACTION</u>	<u>CIS-PERMETHRIN, ppm</u>	<u>TRANS-PERMETHRIN, ppm</u>
Whole Tomatoes	0.22, 0.20, 0.16, 0.15, 0.20, 0.21	0.22, 0.15, 0.16, 0.18 0.20, 0.12
Puree Sauce	0.04, 0.04, 0.05, 0.05	0.04, 0.04, 0.04, 0.04
Pizza Sauce	0.02, 0.02	0.02, 0.03

RCB's Discussion/Conclusion #1(b)

Deficiency #1(b) is resolved by submission of the individual analyses for cis- and trans-permethrin on whole tomatoes, puree sauce, and pizza sauce.

RCB's Deficiency #2

"There seems to be some inconsistency in the timing of sample analyses."

Petitioner's Response to Deficiency #2

The petitioner repeats that "...the whole tomatoes were picked on 6/5/85, placed on dry ice and frozen 5 hours later. The pizza sauce and puree sauce were processed and canned on 6/6/85. In the report, under 'Description of Trial', it is correctly stated that 'the following day, the tomatoes were processed...' It is also correct that the tomatoes were 'received and processed the same day' at the University of Florida, on 6/6/85".

RCB's Discussion/Conclusion #2

Deficiency #2 is not resolved. The petitioner has not adequately explained how tomatoes sampled on 6/5/85 could contain so many moldy and rotten tomatoes on 6/6/85.

RCB's Deficiency #3

"The petitioner should assure RCB that the tomato puree produced in Florida will not exceed 11.0° Brix (11% tomato soluble solids) since there is some indication that permethrin residues may be proportional to the percentage of tomato soluble solids (Note: For tomato puree with 11.0° Brix, the total residue is 0.25 ppm; for tomato pizza sauce with 17.0° Brix, the total residue is 0.35 ppm)."

Petitioner's Response to Deficiency #3

"As pointed out in the 6/14/85 memo from Bob Bates, University of Florida, the processing study submitted to the EPA was based on discussions and information supplied by Steinfeldt-Thompson, a Florida tomato processor. Based on the flow chart and commercial processor recipe supplied by that company, it is apparent that tomato puree will not exceed 11.0° Brix. It is doubtful that the processor would make his tomato puree thicker than necessary. To do so would require more tomatoes, and tomatoes are money. At any rate, the analyses indicate that even if the puree were to become considerably thicker, the 2.0 ppm tolerance would not be exceeded."

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RCB's Discussion/Conclusion #3

Deficiency #3 is resolved by the petitioner's assurance that the tomato puree produced in Florida will not exceed 11.0° Brix.

Other Considerations

If tomato pomace or cannery by-products (culls and skins) are available as animal feed items from tomatoes which are processed in Florida, then further evaluation for food/feed additive tolerances on tomato products (dry pomace, puree, paste, and juice) is needed. Higher meat and milk tolerances would definitely be needed.

The 2.0 ppm tolerance on tomatoes was established with the understanding that the only processing of tomatoes in FL was canning of whole tomatoes. If this is no longer the case, RCB defers to RD as to whether or not the 2.0 ppm tolerance on tomatoes should be revoked.

cc: RF, SF, Circu, Reviewer-N.Dodd, TOX, PP#4F2985,
PMSD/ISB, Ann Lindsay, Herb Harrison, Karl Arne

RDI: J.H.Onley:4/7/88:R.D.Schmitt:4/7/88
TS-769:RCB:CM#2:RM810:1681:nd:fmm:557-7324:4/14/88