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

JAN 5 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4F2985 (RCB No. 1510) - Permethrin on Tomatoes -
No Accession Number - Amendment of September 18, 1986

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Background

A Section 408 tolerance for permethrin on tomatoes was issued by EPA on October 15, 1984. The use on tomatoes was restricted to tomatoes grown for 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 canning of whole tomatoes. Information was later received from one of the Florida canneries stating that they produced tomato paste, tomato puree, and tomato juice, and that processing was to begin again during mid-December 1984 (see D.D. Campt, Director of RD, memorandum of December 4, 1984 re: PP#4F2985).

Prior to the D.D. Campt memorandum of December 4, 1984, RCB comments/conclusions on available tomato processing data were as follows:

"According to an internal FMC memorandum from I.A. Rammer to W.E. Hymans entitled "Utilization of Tomato Pomace for Livestock Feed" dated June 14, 1984, the following discussion has been paraphrased (see California Bulletin 1888, "Economic Performance of the Processing Tomato Industry," April 1978, authored by J.A. Brandt, B.C. French, and E.V. Jesse):

' Raw tomatoes are allocated to six major uses: (1) canned round or pear-shaped . . . (2) juice, (3) catsup and chili sauce, (4) puree, (5) sauce, and (6) paste.'

Also according to the above internal FMC memorandum, the general range of percentage soluble solid in puree, catsup, and paste range from 8-24%, 14-16%, and 24-32%, respectively. Because of its lower water content, tomato paste could contain much higher residue levels than tomato puree.

Thus, without residue data for permethrin (parent plus metabolites) in tomato catsup and tomato paste, RCB is unable to draw any meaningful scientific conclusions concerning the need for food additive tolerances on processed tomato fractions.

In addition, RCB has previously noted that the above FMC study should be repeated using field treated tomatoes containing permethrin residues at or near the established tolerance level (i.e., 2 ppm) and reflecting analyses for parent and metabolites (DCVA and 3-PBA) in accordance with the Pesticide Assessment Guidelines - Residue Chemistry - Subdivision O §171(4)(c)(2)(iv).

RCB suggests that a new tomato processing study be performed as described above and according to the processing methods used by the Florida canneries for producing tomato puree, juice, catsup, and paste."

Consequently, one of the recommendations that the RD Director (Campt memorandum of December 4, 1984) forwarded to the OPP Director, was that ICI Americas, Inc. submit a new fractionation study following the guidelines recommended by RCB so that the Agency can make a determination as to the need for food additive tolerances for processed tomato products.

Present Consideration

In the present submission, the petitioner has submitted recovery and residue data on whole tomatoes, puree, and pizza sauce. The whole tomatoes were processed by the University of Florida, Food Science and Human Nutrition Department.

Analytical Methodology

The samples were analyzed for permethrin by using ICI Americas, Inc. Method Gram 1/2 and for the metabolites 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylic acid (DCVA) and (3-phenoxyphenyl) methanol (3-PBA) by using ICI Americas, Inc. Method Gram 5/4. Both methods are GLC analytical procedures. The recoveries for permethrin and its metabolites are summarized below:

	<u>cis/trans permethrin</u>	
	Amt. added, ppm	% Recovery
Whole tomatoes	0.32-1.2	95-106
Puree sauce	0.12	97-104
Pizza sauce	0.12	99-102

	<u>cis/trans DCVA</u>	
	Amt. added, ppm	% Recovery
Whole tomatoes	0.03-1.0	106-127
Puree sauce	0.03-1.0	87-118
Pizza sauce	1.0-3.3	87-106

	<u>3-PBA</u>	
	Amt. added, ppm	% Recovery
Whole tomatoes	0.02-0.5	89
Puree sauce	0.02-0.5	79-89
Pizza sauce	0.5-1.8	69

RCB concludes that the recovery data are appropriate.

Residue Data

For this fractionation study the petitioner claims that the tomatoes were treated with eight applications at the maximum label application rate of 0.2 lb ai/A followed by two applications at an exaggerated rate of 0.4 lb ai/A. He claims also that the tomatoes were harvested 3 days after the last application and, the following day, the tomatoes were processed into puree and pizza sauce.

According to a June 14, 1985 memorandum from Bob Bates (University of Florida) to Henry Yonce the tomatoes were processed as follows:

"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 from 1 1/2 minutes on a blancher belt.

Fruit were coarse chopped by passing through the rotary knife-fitted hopper of a Langsenkamp model 185 SC pulper-finisher, transferred directly to a steam kettle and heated to 185 °F within 5 minutes of chopping (not quite a hot break, but adequate to inactivate enzymes).

For puree manufacture the hot chopped tomatoes were passed through the pulper fitted with a 0.05" screen and concentrated from about 3.5° to 11° Brix within about 30 minutes in an open steam kettle. The puree at about 190 °F was hot filled into 303 cans, sealed, inverted, and air cooled overnight. Frozen 6/20/85.

Pizza sauce was made by passing the hot chopped tomatoes through the pulper fitted with a 5/16 inch screen, concentrating to 17° Brix within about 45 minutes and hot filled as indicated."

The residue data resulting from the above study are reported as below:

<u>Sample Description</u>	<u>Permethrin Treated</u>			<u>DCVA Treated</u>			<u>3-PBA Treated</u>
	<u>cis</u>	<u>trans</u>	<u>total</u>	<u>cis</u>	<u>trans</u>	<u>total</u>	
Whole Tomatoes	0.19	0.17	0.36 ^{e/}	0.01	0.07	0.08	0.03
Proc. Puree Sauce	0.02	0.02	0.04 ^{c/}	0.01	0.10	0.11	0.10
Proc. Pizza Sauce	0.04	0.04	0.08 ^{d/}	0.02	0.14	0.16	0.11

c/ Mean of two independent analyses.

d/ Mean of four independent analyses.

e/ Mean of six independent analyses.

The values of all controls were reported as < 0.01 ppm for cis/trans permethrin, cis/trans DCVA, or 3-PBA.

RCB's Comments/Conclusions on the Residue Data

First, the petitioner will need to provide individual analyses of the whole tomatoes, puree sauce, and pizza sauce samples instead of mean values as given above.

Secondly, there seems to be some inconsistency in the description of the samples and timing of sample analyses, etc. For example, in the "Description of Trial" portion of this submission the following is said:

Approximately 130 to 140 lbs of whole tomatoes were randomly sampled 3 days after the last application, placed on dry ice and frozen 5 hours later. The following day, the tomatoes were processed into puree and pizza sauce. The processed samples were later frozen and shipped to the ICI Americas, Inc., Biological Research Center, Goldsboro, NC where they were stored in a freezer at -20 °C prior to residue analysis. . . .

In the June 14, 1985 University of Florida memorandum of Bob Bates to Henry Yonce (Subject: Processing of Experimental Tomatoes into Puree and Pizza Sauce), the following is said:

. . . 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

One of the above descriptions of the samples talks about fresh tomatoes that were processed 1 day after harvest. The other description (Bob Bate's memorandum from the University of Florida where the processing was done) discusses tomatoes that were in poor condition.

In view of the above, RCB cannot approve of the submitted 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.

21 CFR 150.191 (Tomato concentrates) defines "tomato puree" as a food containing not less than 8.0 percent but less than 24.0 percent tomato soluble solids. The Florida fractionation study reflected a puree of 11.0° Brix. Therefore, the petitioner should assure us 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).

21 CFR 150.191 (Tomato concentrates) does not specify or give a definition for pizza sauce. Thus, the tomato soluble solids in pizza sauce may vary without limits.

Recommendations

RCB recommends that the petitioner read RCB Comments and Conclusions above and then repeat his fractionation study using wholesome (nondeteriorated) whole tomatoes in order for us to determine as to the need for food additive tolerances on puree sauce, pizza sauce, and tomato paste.

RCB continues to suggest, based on the above information, that FDA may wish to analyze for permethrin in concentrated tomato products intended for human consumption and in any cannery waste used for animal feed; and if possible, to analyze some of the preceding samples for both permethrin and its metabolites, DCVA and 3-PBA1c.

cc: R.F., S.F., Circ., Reviewer-Only, TOX, EEB, EAB,
PP#4F2985, FDA, PMSD/ISB

RDI: J.H.Onley:12/18/86:R.D.Schmitt:12/18/86
TS-769:RCB:CM#2:Rm810:X7324:Typis Kendrick:
edited by fm:1/2/86