7-17-81

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: JUL 17 1981

SUBJECT: PP#0E2393: Bayleton in Melons and Tomatoes.
Amendment of May 6, 1981.

FROM: Alfred Smith, Chemist
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TO:
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and
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THRU: Charles L. Trichilo, Chief
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The amendment is in response to our memo of 12/2/80 (A. Smith) in which several questions were raised. Those questions are noted below.

"2. The analytical method is not adequate for the determination of total residues (free and conjugated) of Bayleton and its metabolite KWG0519. Conjugated residues are not determined. The method should be modified to determine the conjugated components."

"3a. The residue data do not reflect total residues (free and conjugated) of Bayleton and its metabolite KWG0519. Therefore, valid conclusions on residue levels in cucumbers and tomatoes cannot be made. Residue data must be submitted for total residues in cucumbers and tomatoes."

"3b. Fresh market restrictions are not generally practical for a permanent tolerance since tomatoes could be diverted to processing channels. Residue data should be submitted for the tomato by-products (paste; wet and dry pulp). If necessary, food additive tolerances should be proposed. Alternatively, the petitioner may be able to ascertain that imported tomatoes are not processed."

"4. If the fresh market restrictions are shown to be impractical and residues result in the feed item (tomato pulp), then livestock feeding studies will be necessary to show if residues occur in eggs, milk, and meat. If residues occur in eggs, milk and meat, then tolerance proposals will be necessary. A validated analytical method will also be needed to determine residues."

In response to items 2 and 3(a), the petitioner maintains that previously submitted studies (EPA Accession No. 099414, Report nos. 68593 and 68594) "--show that the 'conjugate residue' did not occur in tomato or cucumber fruit." As a result, the petitioner concludes that it is unnecessary for the analytical method to determine conjugated residue components.

Our review of the study (Mobay Report No. 68593) indicates that conjugated residues do occur in the fruit. For example, in Table VIII the tomato fruit had total radioactivity equivalent to 0.58 ppm at 14 days after the last of three applications.

1/2

The activity is further characterized as 83% organosoluble and 15% water-soluble. (The water-soluble activity comprises the conjugated residues.) The water-soluble activity had increased from 6% at 7 days. While the polar metabolite (conjugate of KWG0519) was not noted in fruit, the presence of other conjugated components (KWG1323, KWG1342) was indicated due to the water-soluble residues. Assuming the water-soluble residue to be primarily conjugated components, then about 0.09 ppm conjugated residues could be present in the tomato fruit at 14 days (using the total activity level of 0.58 ppm and a 15% water-soluble activity level).

The above data were derived from metabolism studies where fruit samples had received only 3 applications. The proposed use permits a maximum of 8 applications at 2.5 oz. act/A for tomatoes and a maximum of 3 applications at 1.8 oz act/A for cucumbers. The uses for cucumbers may be adequately reflected by the metabolism studies; however, the metabolism studies do not reflect residues likely to result from the proposed uses for tomatoes. For tomatoes we would expect the level of total residues as well as the quantity of conjugated residues to be higher from the maximum proposed use.

In view of the foregoing discussion, we conclude that items 2 and 3a have not been resolved.

In response to item 3b, the petitioner has submitted a certification from the National Union of Produce Growers in Mexico which states that the tomatoes imported into the United States are to be used as fresh produce.

RCB has received information from various sources which supports the petitioners contention that fresh tomatoes imported from Mexico will be used on the fresh market. However, with regard to processed tomatoes, the Agricultural Statistics for 1977, for example showed over 57 million pounds of tomato paste were imported. If Bayleton is approved for use in Mexico or any other country from which we import processed tomatoes, it is possible for such processed imports to contain Bayleton residues. Therefore a tomato processing study is needed. The study should reflect residue data on the fresh tomatoes (before processing) and on tomato juice, puree, catsup and dehydrated pulp.

While item 4 is resolved, item 3(b) is not.

In summary, we conclude that items 2, 3a and 3b above have not been resolved. The petitioner should be so informed.

Recommendation

We recommend against the proposed tolerance. A favorable recommendation is contingent upon resolution of questions raised in items 2, 3a and 3b above.

TS-769:RCB:A. Smith:gs:X77377:CM#2:RM810:7/16/81
cc: RF, Circ.(3), Smith, Watts, TOX, EEB, EFB, FDA,PP#0E2393
RDI: Quick, 7/14/81: Schmitt, 7/14/81