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OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: PP#OE2393: Bayleton on Cucumbers and Tomatoes.  
Amendment of 7/26/82.

From: Alfred Smith, Chemist  
Residue Chemistry Branch  
Hazard Evaluation Division (TS-769)

Thru: Charles L. Trichilo, Chief  
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To: H. M. Jacoby (PM-21),  
Registration Division (TS-767)

and

Toxicology Branch  
Hazard Evaluation Division (TS-769)

The amendment contains additional residue data for tomatoes and a tomato processing study. These data were requested in our letter of 8/6/81 (H.M. Jacoby) to the petitioner.

Conclusions

1. The nature of the residue in plants is adequately understood. the significant components of plant residues are the parent residues are the parent Bayleton and its metabolite KWG0519 (free and conjugated).
2. Adequate analytical methods are available for residue determinations. The results of pending method trials (PP#1F2474) should determine the method's adequacy for enforcement.

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3a Residue data for tomatoes reflecting 8 applications at the proposed rate and at a 0 day PHI show levels ranging up to 0.15 ppm. Tomatoes receiving 10 applications at a 0 day PHI show residues of 1.65 ppm. The petitioner should either satisfactorily explain this wide variation in levels or submit additional residue data for tomatoes. As a result, we are withholding our conclusions on the adequacy of the proposed 0.2 ppm tolerance on tomatoes. b) Likewise, we are withholding our conclusion on the adequacy of the proposed 0.1 ppm tolerance on cucumbers until the tomato question is resolved. The use on cucumbers proposes fewer applications than the use for tomatoes but the PHI for cucumbers is also 0 days as is the PHI for tomatoes.

4. The absence of valid residue levels in the feed item, tomato pomace, precludes valid conclusions on residues in eggs, milk, and meat of livestock as warranted under §180.6.

#### Recommendations

We recommend against the proposed tolerances for residues of Bayleton, 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone, and its metabolite beta-(4-chlorophenoxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol in or on cucumbers at 0.1 ppm and tomatoes at 0.2 ppm.

Favorable recommendations are contingent upon resolution of the questions raised in Conclusion 2, 3(b) and 4.

#### Analytical Method

In our reject letter of 8/6/81, the petitioner was informed that the analytical method did not determine conjugated residues and was therefore not adequate for the determination of total residues of Bayleton.

The petitioner has modified the analytical method to include steps which permit the determination of both free and conjugated residues. The method can determine the parent compound Bayleton and its metabolites KWG0519, KWG1323, and KWG1342.

A ground sample is initially homogenized with a methanol/water solution and refluxed. The cooled solution is filtered, and the filtrate is evaporated to the aqueous phase.

The aqueous phase is diluted with a sodium acetate buffer solution and incubated with the enzyme cellulase (this frees conjugated components). The components are extracted from the cooled solution with dichloromethane which is evaporated.

The residue is taken up with chloroform and cleaned up using gel permeation chromatography. The eluate is evaporated to dryness.

The residue is taken up with a petroleum ether/ethyl ether solution and further cleaned up on a florisil column. The residue are eluted with a mixture of hexane/ethyl acetate. (This eluate contains Bayleton, KWG0519, and traces of KWG1323.) The remaining KWG1323 and KWG1342 are eluted with an ethyl acetate/methanol solvent mixture.

All eluates are evaporated, and the hexane/ethyl acetate residue is taken up in acetone and analyzed by gas chromatography.

The residue from the ethyl acetate/methanol fraction is taken up with methanol. The residue is treated with trifluoroacetic anhydride to form the trifluoro acetate derivatives of KWG1323 and KWG1342. The derivatives are determined by gas chromatography.

The foregoing procedure is the same as that submitted in PP#2F2665 (Bayleton in barley and wheat) and judged adequate for residue determinations. Method trials are currently underway to determine the method's adequacy for enforcement purposes (PP#1F2474).

Untreated (control) samples of tomatoes and its processing fractions (puree, juice, paste, ketchup) had <0.01-0.03 ppm Bayleton equivalent residues. Samples of control tomatoes and its processing fractions were fortified with Bayleton and its metabolites KWG0519, KWG1323, and KWG1342 at levels of 0.05-0.5 ppm. Recoveries were 72-108%.

The method is adequate for the determination of residues of Bayleton and its metabolites in tomatoes and cucumbers. The method's adequacy for enforcement is contingent upon the results of method trials now underway (PP#1F2474).

#### Residue Data

Samples of tomatoes were obtained from plots in Mexico. The crops had received 8 applications at the rate of 2.5 oz act/A (maximum proposed treatment). Samples were collected at intervals of 0-15 days after the last treatment. Combined residues of Bayleton and its metabolites (KWG0519, KWG1342) were <0.01-0.05 ppm for all samples. (Previous residue data for Bayleton and KWG0519 showed levels of 0.02-0.15--see memo of 12/2/80. Variations in sampling and inherent errors in analysis could account for the different levels noted.)

### Tomato Byproducts

A tomato sample was collected from a crop which had been treated 10 times at the proposed rate of 2.5 oz act/A and collected on the day of the last treatment (0-day). Residues on the whole tomato were 1.65 ppm. The tomatoes were processed, and the fractions were analyzed for residues. The residue levels were: puree (0.77 ppm); juice (0.35 ppm); paste (1.22); ketchup (0.83 ppm). No concentration of residues beyond the fresh fruit level was noted in the byproducts.

### Discussion of whole tomato residue data

The residue data which reflects the proposed use (8 applications at 2.5 oz act/A) had maximum residues of 0.15 ppm at 0-day (i.e., day of last application). However, when treated 10 times at 2.5 oz act/A, residues on the whole tomato were 1.65 ppm. This level is 11X the level from the proposed use. This variation in residues is not expected as a result of the two additional applications.

The petitioner should submit a reasonable explanation for the wide variation in the two sets of residue data. Alternatively, additional residue data could be submitted which might resolve the question.

We are withholding conclusions on residue levels in tomatoes and its byproducts pending resolution of the questions raised.

Likewise, we are withholding our conclusions on cucumbers until the tomato question is resolved. Although the tomato use does permit more applications than the cucumber use, both crop uses bear a 0 day PHI and the petitioner's response to our tomato question could have a bearing on the cucumber data.

### Meat and Milk

Tomato pomace or pulp may be fed to livestock. We have indicated that the level of residues in the pomace is questionable. Therefore, we are unable to arrive at valid conclusions on residues in eggs, milk, and meat until questions on the tomato pomace residue levels are resolved.

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cc: RF, Circ., Smith, Thompson, FDA, TOX, EFB, EEB, PP#OE2393  
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