Memorandum:


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TO: George LaRocca/Adam Heyward, PM-13
Insecticide/Rodenticide Branch
Registration Division (H7503C)

Merck & Co., Inc. has proposed a 0.035 ppm tolerance for the combined residues of avermectin B₁ and its delta 8,9-isomer in/on pears. CBTS requested a validation of the analytical methodology, "HPLC-Fluorescence Determination of Avermectin B₁ and its Delta 8,9-isomer in Pears", Method No. 8000.

The following is a summary of the report from the Analytical Chemistry Section, Analytical Chemistry Branch (See Attachment #1 for details of the validation trial).

1. Since the term "delta 8,9 isomer" can be a source of confusion in the discussion of avermectin residues, the petitioner is required to define these residues as 8,9-α-avermectin B₁a and 8,9-β-avermectin B₁b throughout the method.

2. The petitioner must provide the EPA repository with adequate analytical standards according to the Agency requirements.

3. The use of the B₁a calibration curve to quantitate both
B\textsubscript{1}\textsubscript{a} and B\textsubscript{1}\textsubscript{b} is not analytically correct, and will not be acceptable unless the two analytes are demonstrated to produce equivalent HPLC responses in the method.


5. The limit of detection for this method was not determined by ACS, but it appears to be less than 1 ppb. Percent recoveries for samples of pears fortified with 32.6 ppb of avermectin B\textsubscript{1}\textsubscript{a} were 94 and 102, with 65.2 ppb of avermectin B\textsubscript{1}\textsubscript{a} were 101 and 104, with 2.4 ppb of avermectin B\textsubscript{1}\textsubscript{b} were 74 and 99, with 4.8 ppb of avermectin B\textsubscript{1}\textsubscript{b} were 96 and 88. Percent recoveries for samples of pears fortified with 35 ppb of 8,9-Z-avermectin B\textsubscript{1}\textsubscript{a} were 92 and 94, and with 70 ppb of 8,9-Z-avermectin B\textsubscript{1}\textsubscript{a} were 94 and 94.

6. Method required a minimum of two full days to prepare and complete analyses of fortified samples. Unknown samples may require a repeat run for quantitation if these are not in the narrow calibration curve.

7. The method marginally meets the requirements for an enforcement method. However, if the above comments are addressed adequately, the method could meet the Agency requirements for the proposed use on pears.

**Recommendation:**

CBTS does not consider the Method No. 8000 for the analysis of avermectin B\textsubscript{1} and 8,9-Z-avermectin B\textsubscript{1} residues in/on pears acceptable for enforcement purposes. The corrections/comments of the Agency lab, Analytical Chemistry Section must be addressed by the petitioner before CBTS can make a decision as to the adequacy of the method.


cc with Attachment 1: J. Stokes (CBTS); PP#9F3787; avermectin S. F.

cc without Attachment 1: R.F.; Circu(7)
RDL: PERrico: 4/6/92; RLOranger: 4/7/92