MEMORANDUM


FROM: Jesse E. Mayes, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Thru: John Onley, Ph.D., Section Head
Tolerance Petition Section 2
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Hoyt Jamerson, PM 43
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

The petitioner, IR-4, submitted this amendment in response to EPA's letter of September 13, 1984 which reflected the deficiencies in the RCB memo of 7/30/84 (M. Kovacs). The memo contained the following information regarding deficiencies:

1. A favorable tolerance consideration is contingent upon TOX Branch expressing no concern regarding maximum calculated residues of the impurities HCB at <0.002 ppm and PCBN at <0.05 ppm on cranberries following the proposed use of BRAVO 500 formulation. However, if TOX Branch is concerned, then the petitioner must provide RCB with either (1) assay data on the BRAVO 500 formulations used in the residue trials submitted, all reflecting impurity levels of HCB and PCBN at less than [redacted] respectively or as an alternative (2) reanalyses of
selected cranberry samples for residues of both HCB and PCBN all treated at the maximum proposed use rate. If reanalyses of these samples reveals finite residues of HCB and PCBN at levels of concern to TOX Branch then these residues may need to be included in a revised tolerance expression for cranberries. (see conclusion 1a of our M.F. Kovacs 1/13/84 review of PP3F2939).

2. For further tolerance consideration, the petitioner should revise Section B to reflect ground application only or as an alternative, additional residue studies must be submitted from WA, WI, MA and NJ reflecting both aerial and ground applications to cranberries. The petitioner should conduct additional residue studies in WA at the maximum proposed use rates and minimum PHI's permitted on the label, and in the absence of a revised Section B, as recommended above, the submitted data should reflect both ground and aerial applications. The petitioner should also submit the results of sample analyses to include check samples and representative chromatograms.

The Petitioner's Response and RCB Comments Follow.

Petitioner's Response #1.

There was no response to deficiency #1.

RCB Comment #1.

Deficiency #1 is a matter which required an opinion from TOX Branch before RCB could arrive at a final conclusion relative to its resolution. TOX Branch has indicated in a memo of 5/17/85 (D. Ritter) that they consider the low levels that would result from this proposed use to be of no toxicological significance. Hence, this deficiency is considered resolved.

Petitioner's Response #2.

The petitioner submitted additional residue data from Oregon, Washington and New Jersey. The NJ residue studies reflect both ground and air applications. He also submitted a letter from Carl H. Shanks, Superintendent and Entomologist of the Southwestern Washington Research Unit at Washington State University stating that, "There is no use of air
craft for applying pesticides to cranberries in Washington."

The petitioner has also submitted a revised Section F raising the tolerance for residues of chlorothalonil and its metabolite 4-OH chlorothalonil on cranberries from 2ppm to 5ppm based on the data submitted.

RCB Comment #2.

Two of the submitted residue studies from NJ and WA are comparable to the maximum recommended application rate. The NJ study involved either three ground applications or three applications by air each reflecting 5.21 lb ai/A (1x) with a 49 day PHI (50 day PHI recommended). The Grayland, WA study involved four ground applications at 5.21 lb ai/A with a 54 day PHI. The Long Beach, Washington residue studies reflected two ground applications with rates varying from 2.09 to 4.17 lb ai/A and PHI's varying from 56 to 70 days. The Bandon, Oregon residue study reflected three ground applications via a sprinkler system with application rates of 4.17 lb ai/A and PHI's of 92 to 94 days.

The (1x) studies are presented below:

<table>
<thead>
<tr>
<th>Location</th>
<th>Appl. Method</th>
<th>PHI Days</th>
<th>Chlorothalonil ppm</th>
<th>4-Hydr. met. ppm</th>
<th>HCB ppm</th>
<th>PCBN ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grayland Washington</td>
<td>Ground</td>
<td>54</td>
<td>4.28</td>
<td>ND</td>
<td>0.003</td>
<td>0.049</td>
</tr>
<tr>
<td>Chatsworth New Jersey</td>
<td>Ground</td>
<td>49</td>
<td>1.37</td>
<td>ND</td>
<td>ND</td>
<td>0.008</td>
</tr>
<tr>
<td></td>
<td>Air</td>
<td>49</td>
<td>0.75</td>
<td>ND</td>
<td>ND</td>
<td>0.006</td>
</tr>
</tbody>
</table>

The high chlorothalonil residue reported in the Grayland, WA study (4.28 ppm) reflected (4 vs. 3) applications. But in the absence of adequate data at the requisite number of applications (3) we will have to use this level as the maximum expected residue. Therefore, RCB concludes that the 5 ppm tolerance, as requested by the petitioner, is appropriate.

The application by aircraft in the NJ study resulted in about half the residue obtained following ground applica-
tion. The proposed 5 ppm tolerance level would therefore adequately cover residues expected following aerial applications. Although no additional residue data were submitted reflecting aerial applications in WA, WI and MA as originally requested in deficiency #2, the additional aerial residue data submitted from NJ representing the eastern part of the United States did indicate a reduction of approximately 50% in total chlorothalonil residues vs. comparable ground applications.

These data coupled with the 11/20/84 letter submitted by Carl H. Shanks Jr., Washington State University, Vancouver, WA to Dr. M. Burt IR-4 stating that "There is no use of air craft for applying pesticides to cranberries in Washington" including information previously cited in RCB's Culture Practices File (cranberries) (see M. Kovacs 1/13/84 memo re: PP# 3E2939) now permits RCB to conclude that a revised Section B to reflect ground application only to cranberries is no longer needed. Accordingly, deficiency #2 is considered resolved.

Recommendations:

TOX and EAB considerations permitting RCB recommends that a tolerance of 5 ppm for combined residues of chlorothalonil and its 4-OH metabolite be established for cranberries.

Other Considerations:

An "International Residue Limits Status Sheet" is attached. The Codex limit above step 9 is 5 ppm for chlorothalonil. This does not include the metabolite 4-hydroxy-2,5,6-tri-chloroisophthalonitrile as is included in the U.S. tolerance expression, but the tolerance levels are the same. In view of this, there is compatibility between the U.S. and Codex tolerances.

There are no Canadian or Mexican tolerances for chlorothalonil on cranberries.

cc: R.F., Circu, J. Mayes, TOX, EEB, EAB, PMSD/ISB, PP#3E2939, FDA, Robert Thompson (RTP)
RDI: J. Onley, 5/29/85; R. Schmitt, 5/30/85
INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL: Chlorothalonil

CCPR NO.: 51

Codex Status

[ ] No Codex Proposal
Step 6 or above

Residue (if Step 9):

Chlorothalonil

Crop(s) Limit (mg/kg)

Cranberries 5.0

CANADIAN LIMIT

Residue:

Crop Limit (ppm)

None (on cranberries)

MEXICAN TOLERANCIA

Residue:

Crop Tolerancia (ppm)

None (on cranberries)

NOTES:

Temporary pending establishment of full MI.

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PETITION NO. 352939

Reviewer:

(AMENDMENT)

Jesse E. Mayer

Proposed U.S. Tolerances

40 CFR 180.275

Residue: Chlorothalonil & Art.

4-hydroxy-2,5,6-trichloro-

isophthalonitrile

Crop(s) Tol. (ppm)

Cranberries 5.0 ppm