Memorandum

Subject: 89-WA-11, 89-WY-02. Section 18 Specific Exemption for the Use of Chlorpyrifos (Lorsban® 4E, EPA Reg. No. 464-448) on Spring and Winter Wheat and Barley. No Accession Number / No MRID Number DEB # 5283, 5284

From: Jane S. Smith, Chemist Special Registration Section I Dietary Exposure Branch Health Effects Division (H-7509C)

Thru: Andrew Rathman, Section Head Dietary Exposure Branch Health Effects Division (H-7509C)

To: R. Forrest PM Team 41 Registration Support and Emergency Response Branch Registration Division (H-7505C)

The Wyoming Department of Agriculture and Washington State Department of Agriculture are requesting emergency exemptions for the use of chlorpyrifos (Lorsban® 4E, 4 lbs a.i./gallon, EPA Reg. No. 464-448) on spring and winter wheat to control Russian wheat aphids. The Washington State Department agriculture is also requesting the same exemption for the treatment of barley.

Tolerances have been established (40 CFR 180.342) for residues of chlorpyrifos (0,0-diethyl 0-3,5,6-trichloro-2-pyridyl) phosphorothioate and its metabolite 3,5,6-trichloro-2-pyridinol (TCP) in/on a variety of raw agricultural commodities ranging from 0.05 ppm for beans to 15 ppm for alfalfa hay.

A tolerance of 0.6 ppm (of which no more than 0.3 ppm is chlorpyrifos) is proposed to cover residues of chlorpyrifos and its TCP metabolite in/on wheat grain is currently pending. Also, a food additive tolerance of 2 ppm (of which no more than 1 ppm is chlorpyrifos) for the same residues in/on wheat milling fractions (except flour) is currently pending.

The Second Round Review (SRR) of the Product/Residue Chemistry Chapter of the Registration Standard was issued 10/14/88.
Proposed Use
Washington State proposes ground or aerial applications at the same rate, 1 pint (0.5 lb a.i.)/acre, as Wyoming, but in a minimum of 15 gallons of water (ground spray) or in a minimum of 5 gallons of water (aerial spray). Approximately 250,000 acres would be treated between May 1st and December 31st. Restrictions include a 14 day period before grazing, only 2 applications for the season, and a 28 day pre-harvest interval.

Wyoming proposes ground spray applications at a rate of 1 pint (0.5 lb a.i.) / acre in 10-20 gallons of water and aerial applications at the same rate, but diluted in a minimum of 2 gallons of water. Approximately 325,000 acres would be treated between mid April and the end of October. The restrictions are the same as Washington State except the PHI is 21 days.

Nature of the Residue
According to the SRR the qualitative nature of the residues of chlorpyrifos in plants and animals is adequately understood and the residues of concern are chlorpyrifos and its metabolite 3,5,6-trichloro-2-pyridinol. However, in a recent addendum to the residue chemistry chapter of the SRR (memo, 1/13/89 from D. Edwards [DEB] to C. Kent [RD]), it was determined that TCP should be dropped from the tolerance expression. Since the tolerance expression has yet to be changed, the residues of concern remain unchanged for the purposes of this Section 18.

Analytical Methods
Adequate methods are available for data collection and enforcement of tolerances for residues in plant and animal commodities, according to the SRR. The methods used to determine chlorpyrifos in plants are published in PAM Vol. II as methods I, II, and VI. The method to determine residues in animal tissues and milk is published in PAM Vol.II as method IV. The methods for determining residues of TCP in tissues and plants are published in PAM Vol. II and methods V and VII, respectively.

Residue Data
Residue data were submitted in connection with PP#F2947 (memo of V.F. Boyd, 1/20/84) represent 13 studies form 9 wheat-growing states in which Lorsban® 4E was applied to wheat at 0.5-1.0 lb a.i./A. The following is a summary of the maximum residues of chlorpyrifos and TCP found in/on grain and grain-based products:

<table>
<thead>
<tr>
<th>Substrate</th>
<th>lb a.i. per Acre (days)</th>
<th>Chlorpyrifos (ppm)</th>
<th>TCP (ppm)</th>
<th>Combined (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grain</td>
<td>1.0+0.5 28</td>
<td>0.23</td>
<td>0.38</td>
<td>0.61</td>
</tr>
<tr>
<td>Straw</td>
<td>1.0+0.5 28</td>
<td>4.2</td>
<td>1.6</td>
<td>5.8</td>
</tr>
<tr>
<td>Forage</td>
<td>1 X 1 14</td>
<td>2.3</td>
<td>0.23</td>
<td>2.5</td>
</tr>
</tbody>
</table>

continued
Milling and Baking Fractions

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Grain</td>
<td>0.5</td>
<td>14</td>
<td>0.55</td>
</tr>
<tr>
<td>Grain</td>
<td></td>
<td></td>
<td>0.25</td>
</tr>
<tr>
<td>Flour</td>
<td></td>
<td></td>
<td>0.8</td>
</tr>
<tr>
<td>Break Shorts</td>
<td>1.0</td>
<td>14</td>
<td>0.42</td>
</tr>
<tr>
<td>Red Shorts</td>
<td>1.4</td>
<td></td>
<td>1.4</td>
</tr>
<tr>
<td>Red Dog</td>
<td></td>
<td></td>
<td>0.62</td>
</tr>
<tr>
<td>Bread</td>
<td>0.06</td>
<td></td>
<td>0.06</td>
</tr>
</tbody>
</table>

*Method sensitivity for chlorpyrifos is 0.05 ppm except for grain and straw which is 0.01 ppm.
**Method sensitivity is 0.05 ppm for TCP.

On the basis of the residue data previously submitted, we conclude that residues of chlorpyrifos and TCP are not likely to exceed 0.6 ppm in wheat grain, 5 ppm in the straw, and 3 ppm in the forage, and 2 ppm in the milling fractions (other than flour) of wheat as a result of the proposed use based on a 28 day PHI. Wheat flour would contain <0.5 ppm.

For the purposes of this Section 18 only, we can translate the residue data above to barley and conclude that residues of chlorpyrifos and TCP are not likely to exceed 0.6 ppm in barley grain, 5 ppm in the straw, 3 ppm in the forage, and 2 ppm in the milling fractions (other than flour) of barley as a result of the proposed use. Barley flour would contain <0.5 ppm.

Meat, Milk, Poultry, and Eggs

Existing tolerances are 0.1 ppm for eggs, 0.5 ppm for the meat, fat, and meat by-products of hogs and poultry (including turkeys), 1.0 ppm for the meat, fat, and meat by-products of cattle and 0.5 ppm in milk fat (representing 0.02 ppm in whole milk).

Feeding Studies

In PP#F1306, it was reported that no chlorpyrifos residues were found in whole milk after dairy cattle had been fed chlorpyrifos at levels of 1, 3, and 10 ppm in the diet for 14 days. Chlorpyrifos residues of 0.02 ppm were found in whole milk after a 30 ppm feeding level. At the 1 and 3 ppm feeding levels, the maximum residue levels were 0.04 and 0.15 ppm, respectively. After withdrawal periods of 1-5 days, neither the milk nor the cream contained any detectable residues.

Beef cattle were fed chlorpyrifos in the daily diets at levels of 3, 10, 30, and 100 ppm for 30 days. The feeding level of 3 ppm gave maximum residues of 0.16-0.23 ppm residues in liver, and the 10 ppm level gave a maximum residue of 0.5 ppm in the kidney. The 30 ppm level gave a maximum residue of 1.7 ppm in the liver. At the 100 ppm level, a maximum of 5 ppm was found in the beef.
fat; this decreased to 0.04 ppm 35 days after cessation of feeding. It appears that no analyses were made for residues of TCP.
Pigs were fed chlorpyrifos in the daily diets at 0.3, 1, 3, and 10 ppm for 30 days. Residues (parent plus TCP) were not detected in any tissues at the 1 ppm feeding level. The 3 and 10 ppm levels gave maximum residue values of 0.08 and 0.3 ppm in liver. No residues were found in any tissues 21 days after cessation of feeding.

Dietary Burden of Cattle, Swine, and Poultry
Wheat forage may constitute up to 70% of the dairy cattle diet which would be equivalent to 2.1 ppm of chlorpyrifos plus TCP.
Wheat grain may constitute up to 50% of beef and dairy cattle's diet equivalent to 0.25 ppm of chlorpyrifos plus TCP, and up to 90% of finishing swine's diet (0.45 ppm chlorpyrifos plus TCP).
Straw in general is not fed at more than 10% of livestock's diet, equivalent to 0.05 ppm. Wheat bran may be fed to cattle at 25% of the diet, equivalent to 0.375 ppm of chlorpyrifos and TCP in the diet.

Barley forage may constitute up to 40% of the dairy cattle diet which would be equivalent to 1.2 ppm of chlorpyrifos plus TCP.
Barley grain may constitute up to 80% of beef cattle's diet, 50% of dairy cattle's diet, and 80% of boar's/sow's diet which is equivalent to 0.4 ppm, 0.25 ppm, and 0.40 ppm of chlorpyrifos and TCP, respectively. Straw generally constitutes no more than 10% of the diet in beef and dairy cattle equivalent to 0.05 ppm.
Milled products from barley are generally not animal feed items.

Considering the feeding studies, the dietary burden, and translating the residue data on wheat/feeding studies to barley, we find that residues of chlorpyrifos plus TCP which might occur in milk and the fat, meat, and meat by-products of cattle and swine will be covered by the established tolerances as a result of the emergency exemption.

Wheat grain may constitute up to 70% of the poultry diet (.35 ppm chlorpyrifos plus TCP) and wheat bran up to 10% of the diet (0.15 ppm chlorpyrifos and TCP). Barley grain may constitute up to only 50% of the poultry diet (0.25 ppm chlorpyrifos plus TCP) and milled products of barley are not animal feed items.
According to the Residue Chemistry Chapter of the Registration Standard (dated 2/29/84) and the SRR, existing tolerances will be adequate to cover all secondary residues of chlorpyrifos and TCP which might occur in eggs and the fat, meat and meat by-products as a result of poultry ingesting a diet containing 5.5 ppm chlorpyrifos.

DEB concludes that the existing tolerance for eggs and the fat, meat, and meat by-products of poultry will be adequate to cover
any secondary residues of chlorpyrifos and TCP which might occur as a result of this emergency exemption.

Conclusions

1) The metabolism of chlorpyrifos in plants and animals is understood. The residues of concern are the parent compound and its metabolite, 3,5,6-trichloro-2-pyridinol for the purposes of this Section 18.

2) Adequate analytical methods are available for enforcement purposes. The methods used to determine chlorpyrifos in plants are published in PAM Vol. II as methods I, II, and VI. The method to determine residues in animal tissues and milk is published in PAM Vol. II as method IV. The methods for determining residues of TCP in tissues and plants are published in PAM Vol. II methods V and VII, respectively.

3) Residues of chlorpyrifos and its TCP metabolite will not exceed 0.6 ppm in the barley and wheat grain, 0.5 ppm in the straw, 3 ppm in the forage and 2 ppm in the milling fractions of barley and wheat other than flour which would contain <0.5 ppm as a result of the proposed use based on a 28 day PHI.

4) Secondary residues of chlorpyrifos and its metabolite 3,5,6-trichloro-2-pyridinol will not exceed currently established tolerances of 2.0 ppm for the meat, fat and meat by-products of cattle; 1.0 ppm for the meat, fat, and meat by-products of goats, horses, and sheep; 0.5 ppm for the meat, fat, and meat by-products of hogs and poultry (including turkey); 0.1 ppm for eggs; and 0.5 ppm for milk fat, representing 0.02 ppm in whole milk.

5) Analytical reference standards are available from the Pesticide and Industrial Chemicals Repository.

Recommendations

Tox considerations permitting, DEB has no objections to this Section 18 contingent upon revision of the proposed use (for Wyoming) to include a 28 day PHI (versus 21 days). An agreement should be made with the FDA regarding the legal status of the treated commodities in commerce.

cc:RF, Circ, Section 18 F, PMSD/ISB, Tomerlin (SACB), JSmith, RDSchmitt
RDI:ARathman:05/08/89:EZager:05/08/89
H-7509C:DEB:jss:JSmith:Rm812d:CM2:05/08/89