MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Glyphosate-trimesium in/on Pome Fruit and Wheat PP# 5FO4554 and PP# 5H05727.

FROM: Brian Steinwand
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Science Analysis Branch/HED (7509C)

Through: Elizabeth Doyle, Section Head
Dietary Risk Evaluation Section
SAB/Health Effects Division

TO: R. Taylor/T. Stowe, PM Team 25
Registration Division (7505C)

Action Requested

Provide a dietary exposure analysis for the use of glyphosate-trimesium in/on pome fruit and wheat. The petition requests but CBTS recommends against a tolerance of 0.05 ppm be established on pome fruit and 10 ppm on wheat.

Discussion

The proposed tolerance on pome fruit and wheat would require the establishment of animal commodity tolerances (See memo, G. Kramer, 11/28/95). However, with the exception of meat and poultry by-products, proposed animal commodity tolerances currently exist (PP# OFO3860) at equal or higher levels than those proposed for this petition. Thus, the higher existing levels were used for the purposes of this analysis. Tolerance levels for meat and poultry by-products were raised accordingly.
Toxicological Endpoint:

The Reference Dose (RfD) used in the analysis is 0.1 mg/kg bwt/day, based on a NOEL of 10.0 mg/kg bwt/day) from a one year dog feeding study with an uncertainty factor of 100 that demonstrated emesis and salivation (See memo, G. Ghali, 6/26/94). The RfD has been approved by the HED RfD committee (3/10/94), but has not been reviewed by the joint Committee meeting of the WHO/FAO. Glyphosate-trimesium is classified as a Group E carcinogen.

Residue Information

As a new chemical, tolerances for glyphosate-trimesium have yet to be published in the CFR. Tolerance level residues and 100 percent crop treated assumptions were made for the proposed commodities. Anticipated residues and percent crop treated information were not available for this analysis.

Prior new tolerances for grapes and bananas were upgraded to pending status for this analysis.

Results

A summary of the residue information considered in this analysis is attached as Table 1. A DRES chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. Summaries of the TMRCs and their representations as percentages of the Reference Dose (RfD) are included as Table 2 and 3.

Chronic Exposure Analysis

Exposure from Pending Tolerances for glyphosate-trimesium:

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Exposure (mg/kg/day)</th>
<th>%RfD</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Population</td>
<td>0.005542</td>
<td>5.5</td>
</tr>
<tr>
<td>Children (1-6 years)</td>
<td>0.012601</td>
<td>12.6</td>
</tr>
</tbody>
</table>

Proposed new Tolerances on pome fruit and wheat:

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Exposure (mg/kg/day)</th>
<th>%RfD</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Population</td>
<td>0.014219</td>
<td>14.2</td>
</tr>
<tr>
<td>Children (1-6 years)</td>
<td>0.031860</td>
<td>31.9</td>
</tr>
</tbody>
</table>

If the new tolerances on pome fruit and wheat are approved:

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Exposure (mg/kg/day)</th>
<th>%RfD</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Population</td>
<td>0.019760</td>
<td>19.8</td>
</tr>
<tr>
<td>Children (1-6 years)</td>
<td>0.044461</td>
<td>44.5</td>
</tr>
</tbody>
</table>
Conclusions

The chronic analysis for glyphosate-trimesium is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with glyphosate-trimesium. Even without refinements, the chronic dietary risk exposure to glyphosate-trimesium appears to be minimal for this petition on pome fruit at 0.05 ppm and wheat at 10 ppm and does not exceed the RfD for any of the DRES subgroups.

Attachments
cc: DRES; Caswell 893C; RCAB; CBTS (G. Kramer); Tox I
TOLERANCE ASSESSMENT SUMMARY FOR Glyphosate trimesium
CASWELL #893C

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING TOLERANCES (PUBLISHED ONLY)
RESULT IN A TMRC OF: 0.000000 MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO: 0.00 % OF THE ADI.

PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)
RESULT IN A TMRC OF: 0.014219 MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY: 14.218 % OF THE ADI.

IF THE NEW TOLERANCES (CURRENT PETITION ONLY)
ARE APPROVED THE RESULTANT TMRC WILL BE:
THE NEW TMRC WILL OCCUPY 0.014219 MG/KG/DAY
14.218 % OF THE ADI.

OTHER PENDING TOLERANCES EXCLUDING THE
CURRENT NEW PETITION HAVE A TMRC OF:
THIS TMRC WILL OCCUPY 0.005542 MG/KG/DAY
5.542 % OF THE ADI.

IF ALL PENDING TOLERANCES (INCLUDING THE
CURRENT NEW PETITION) ARE GRANTED
THE RESULTANT TMRC WILL BE:
THE TOTAL TMRC WILL OCCUPY 0.019760 MG/KG/DAY
19.760 % OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: CHILDREN (1-6 YEARS OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)
RESULT IN A TMRC OF: 0.000000 MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO: 0.00 % OF THE ADI.

PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)
RESULT IN A TMRC OF: 0.031860 MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY: 31.860 % OF THE ADI.

IF THE NEW TOLERANCES (CURRENT PETITION ONLY)
ARE APPROVED THE RESULTANT TMRC WILL BE:
THE NEW TMRC WILL OCCUPY 0.031860 MG/KG/DAY
31.860 % OF THE ADI.

OTHER PENDING TOLERANCES EXCLUDING THE
CURRENT NEW PETITION HAVE A TMRC OF:
THIS TMRC WILL OCCUPY 0.012601 MG/KG/DAY
12.601 % OF THE ADI.

IF ALL PENDING TOLERANCES (INCLUDING THE
CURRENT NEW PETITION) ARE GRANTED
THE RESULTANT TMRC WILL BE:
THE TOTAL TMRC WILL OCCUPY 0.044461 MG/KG/DAY
44.461 % OF THE ADI.