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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 9 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8E3682. Glyphosate (Roundup) in or on Brassica (Cole) Leafy Vegetables Crop Group. EPA Reg. No. 524-308. IR-4 Response to the Registration Standard Data Call-In, June, 1986. (MIRD No. 408028-00, -01, -02. DEB No. 4361).

FROM: Freshteh Toghrol Ph.D., Chemist *F. Toghrol*
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THRU: Philip V. Errico, Section Head *Philip V. Errico*
Tolerance Petition Section III
Dietary Exposure Branch
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TO: Hoyt L. Jamerson, PM - 43
Emergency Response and Minor Use Section
Registration Division (TS-767C)

BACKGROUND

The IR-4 National Director, Dr. R. H. Kupelian, on behalf of the IR-4 project and the Agricultural Experiment Stations of California, Florida, Michigan and New York request the establishment of a tolerance for the combined residues of glyphosate [N-(phosphonomethyl) glycine] and its metabolite amino- methylphosphonic acid (AMPA) in or on the raw agricultural commodity group Brassica leafy vegetables at 0.2 ppm. This tolerance is to cover residues resulting from preplant/preemergence uses.

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The Guidance for Reregistration of Pesticide Products Containing Glyphosate as the Active Ingredient was issued in June 1986.

Monsanto Agricultural Products Co. informed IR-4 in September 1986, that, in order to protect the registration of glyphosate on minor crops IR-4's research work on Brassica leafy vegetables would be needed. IR-4 has submitted this petition (PP#8E3682) to address the data gap in the Registration Standard.

Tolerances are established for combined residues of glyphosate and its metabolite AMPA, in or on number of raw agricultural commodities ranging from 0.1 ppm to 200 ppm (40 CFR, 180.364).

A tolerance of 0.2 ppm for the combined residues of glyphosate and its metabolite AMPA, in or on leafy vegetables group is established (PP#7F2016, 12/6/77, 42 FR 61626). However the crop grouping "leafy vegetables", is obsolete, having been replaced partially by "Brassica (Cole) leafy vegetables".

The Registration Standard required residue data for broccoli and mustard greens, to establish a tolerance for Brassica (cole) leafy vegetables crop group. A tolerance of 0.2 ppm has been established for the combined residues of glyphosate and its metabolite AMPA, in or on cabbage, a representative commodity of the Brassica (cole) leafy vegetables group.

Reference Footnote 19, and 20 Table A, in the Glyphosate Registration Standard raises the following data gaps for establishing a group tolerance for the Brassica leafy vegetable group:

19/ A crop group tolerance is not appropriate because no residue data have been presented for broccoli and mustard greens, which are representative commodities of this group. The following data are needed if a crop group tolerance is desired:

- ° Combined residues of glyphosate and AMPA in or on mustard greens following preemergence applications with the 3 lb acid equivalent (ae)/gal SC/L formulation totaling 6 lb ae/A (with the final application must be at 3.75 lb ae/A). Separate tests must be conducted utilizing both high and low volume ground equipment.

- ° A use on broccoli must be proposed and residue data reflecting the proposed use must be submitted.

20/ A separate tolerance of 0.2 ppm should be established (on cabbage) since the tolerance was established as a member of the leafy vegetable group now obsolete. Alternatively, the

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appropriate crop group tolerance could be sought upon completion of the requirements."

Conclusion

1. With a revised section B as discussed in conclusion 2, the data submitted by the petitioner supports the proposed tolerance for glyphosate in or on Brassica leafy vegetables at 0.2 ppm.
2. The registered label allows "Tank Mixtures" of Roundup plus Banvel or Roundup plus 2,4-D amine. Since no tolerances have been established for either 2,4-D amine or Banvel in or on cabbage, cauliflower, kale, broccoli and mustard green, the petitioner should remove these pesticides from the tank mixture recommendations on the label.
3. Analytical Chemistry Branch (ACB) is validating the HPLC-fluorometric methodology. The adequacy of the HPLC method for enforcement purposes will be handled in PP#6F3380. There is a GLC enforcement method available in PAM II to support this tolerance request.
4. The data only support a proposed tolerance for the Brassica leafy vegetables group. The established tolerance for "leafy vegetables" should not be deleted until the remaining crops in the leafy vegetables group which are not included in the Brassica leafy vegetables group, have been included in their respective new crop groupings under 180.34(f)9.

RECOMMENDATION

DEB does not recommend for the proposed tolerances of glyphosate and its metabolites amino-methylphosphonic acid (AMPA) in or on the Brassica leafy vegetables at 0.2 ppm, until the petitioner submits a revised section B (see conclusion 2).

Note to PM

The glyphosate label is a good candidate in the Agency's label revision program. The registered use direction under "cropping systems" refers the user back to the "General Information" and "Mixing, Additives and Application Instructions" sections. The actual rates of applications for the formulation are in the "Weeds Controlled" section, which also contains a subsection for tank mixtures with other pesticides which may or may not have registered uses and/or tolerances for the crops listed under the "Cropping Systems" section. The registered label is confusing and has been previously discussed by C. Deyrup in the review of 7/5/88 (PP#8E3631).

Petitioner's Response:

In this submission are three volumes:

- 1.) " Petition Proposing a Tolerance for Glyphosate use in Brassica Leafy Vegetables Crop Group", 2.) " Glyphosate - Magnitude of Residue on Broccoli", and 3.) " Glyphosate - Magnitude of Residue on Mustard Greens".

Monsanto has authorized EPA personnel to use files regarding Roundup to support the proposed use on the brassica leafy vegetables group.

The registered use for broccoli and mustard greens indicates that the combined total of all treatments must not exceed 8 quarts per acre /year, equal to 6 lb acid equivalent (ae)/ Acre used in this study. This use is the same as that registered in cabbage.

The field trials for broccoli were located in California and Maryland. The mustard greens field trials were located in California, Maryland, South Carolina and Georgia.

The application rate was 2.25 lb ae / acre, for the first application (except for mustard greens in GA) followed by 3.75 lb ae/acre (boom or hand-held spray equipment). These rates are the same as a total of 6 lb of ae / acre /year suggested by the Registration Standard. In all trials, two pre-plant applications (sequential) were made one day apart. The crops were planted three to four days after the last spray into treated and untreated soil. The crops were harvested (see table for PHI) frozen at -20 °C and shipped while frozen to the IR-4 Laboratory in Geneva, N.Y.

The analytical method used was HPLC-fluorimetry, a method under going method validation (see J. Stokes's memo of 7/7/87, PP#6F3380). Recovery from fortified samples is 85% - 100%. This HPLC method uses shorter time and gives higher recover than the GLC enforcement method in PAM II.

SUMMARY OF THE RESIDUE DATA:

Commodity Residues	Appl. Rate (ae, lb/Acre)	Volume gal/Acre	PHI (days)	Combined	
				Gly. (ppm)	AMPA
Broccoli					
CA	2.25 + 3.75	5.0	86	<0.05	<0.05
	2.25 + 3.75	48.0	86	<0.05	<0.05
MD	2.25 + 3.75	4.9	68	<0.05	<0.05
	2.25 + 3.75	40.0	68	<0.05	<0.05
Mustard Greens					
CA	2.25 + 3.75	5.0	57	<0.05	<0.05
	2.25 + 3.75	48.0	57	<0.05	<0.05
MD	2.25 + 3.75	4.9	33	<0.05	<0.05
	2.25 + 3.75	40.0	33	<0.05	<0.05
SC	2.25 + 3.75	5.1	89	<0.05	<0.05
	2.25 + 3.75	40.8	89	<0.05	<0.05
GA	1.68 + 2.81	5.0	60	<0.05	<0.05
	1.68 + 2.81	40.0	60	<0.05	<0.05

Discussion

A tolerance for glyphosate and its metabolite AMPA at 0.2 ppm in or on cabbage, as a member of the "leafy vegetables group" has been established (PP#7F2016, MIRD 00108159). Cabbage, broccoli and mustard greens are now representative commodities of the Brassica leafy vegetables group [180.34(9)(v)(B)].

The nature of the residue in plants is adequately understood. The nature of the residue in animals (ruminant) is not adequately understood.

The Registration Standard concluded that the GLC method (Method I) published in PAM II is not satisfactory for enforcement purposes, because the method is long and complicated. The analytical method used for this study is HPLC-fluorimetry (see J. Stokes memo of 7/7/87, PP#6F3380), a method under method validation. DEB will reserve its conclusion on the adequacy of the method for enforcement purposes, until we have received and evaluated the results of the method validation. This evaluation will be handled in PP#6F3380.

Although broccoli, cabbage and mustard greens are feed items for livestock, the residues are not detectable (<0.05 ppm), therefore the established tolerances in meat and milk are

adequate to cover any secondary residues from these uses.

Results of the analysis indicates that there are no residues of glyphosate or its metabolite AMPA greater than the level of sensitivity (0.05) in any treated or untreated samples. The residue data support the proposed tolerance for glyphosate in or on brassica (cole) leafy vegetables at 0.2 ppm .

The registered label allows "Tank Mixtures" of Roundup plus Banvel or Roundup plus 2,4-D amine . Since no tolerances have been established for either 2,4-D amine or Banvel in or on cabbage, cauliflower, kale, broccoli and mustard green, the petitioner should remove these pesticides from the tank mixture recommendations on the label.

cc: PP#8E3682, Glyphosate Reg. Std. File, RF., SF., Circ.,
Reviewer (F. Toghrol), PMSD/IBS (Eldrige).
RDI:Section Head P.V. Errico:12/6/88, Deputy Chief:R.D.
Schmitt:12/6/88
TS-769C: DEB: Reviewer F.T: CM#2, RM:803, 557-7887, F.T.
(12/7/88).