



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

File 8.26.92

AUG 26 1992

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Response to the Glyphosate Reregistration Standard:
Product and Residue Chemistry (MRID #'s 41573601,
41940701 and 00144301, CBRS # 10124, Barcode:
D179482).

FROM: R. B. Perfetti Ph.D., Chemist
Reregistration Section 1
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C) *R B Perfetti*

THRU: P. Deschamp, Acting Section Head
Reregistration Section 1
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C) *P Deschamp*

TO: Lois Rossi, Chief
Reregistration Branch
Special Review & Reregistration Division (H7508W)

and

E. Saito, Acting Chief
Chemical Coordination Branch
Health Effects Division (H7509C)

Monsanto has responded to a product and residue chemistry review dated 2/3/92 (R.B. Perfetti). The following are our comments on their responses;

1) A storage stability study (Guideline 63-17) was required. The Registrant has referenced a previously submitted experiment which indicated that the 62% IPA salt FI (EPA Reg. No. 524-333) is stable in polypropylene vials for 19 months. This satisfies the requirements for 63-17. No additional data are needed.

① 1/6



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2) A storage stability study (Guideline 171-4(e)) was required. The Registrant has referenced MRID 41940701 in response to this requirement. This study was reviewed in our memo of 4/2/92 (R. B. Perfetti). Additional data are required. Please see that memo for our conclusions regarding the storage stability study.

3) Processing studies were required for potatoes and sorghum. The available data were generated by Craven and therefore the Registrant has committed to repeat the studies. CBRS has no further comment.

4) A FAT (409) tolerance of 12 ppm for residues of glyphosate in wheat milling fractions was required. The Registrant has submitted a tolerance petition proposing appropriate tolerances. CBTS has recommended in favor of establishment of the proposed tolerance (Nos. 9686 through 9650, 5/29/92). Instead of "wheat milling fractions the FAT's should be set at 12 ppm on each of wheat bran, shorts and middlings. CBRS has no further comments on this subject.

4) Adequate label directions were required for olives. The Registrant has committed to respond to this requirement within 90 days. CBRS has no further comments on this subject.

5) A peanut processing study was required. The Registrant has responded by referencing PP# 5F3157 (MRID # 00144341) wherein a processing study was submitted. This study was reviewed in our review of 5/1/85 (M. Bradley) and it was concluded that residues of glyphosate concentrated 1.5X in peanut meal. No other concentration was observed. Since the present tolerance for peanuts is 0.1 it is our judgement that no tolerance for peanut meal is needed for this marginal concentration factor. No additional data are needed for peanuts as long as the spot treatment for peanuts is not on the glyphosate labels.

The HED Metabolism Committee has determined that aminomethylphosphonic acid (AMPA) the metabolite of glyphosate no longer needs to be regulated and therefore this compound will be dropped from the tolerance regulation. This step will also harmonize the U.S. tolerance expression with Codex. Recommendations for harmonization of tolerance levels with the MRL's will be made in the Residue Chemistry RED chapter. Attached please find copies of the initial proposal to the Committee as well as the signed document describing the conclusions reached by said Committee.

If you need additional input please advise.

cc: RBP, Glyphosate Reregistration Standard File, Glyphosate Subject File, Circ. and RF.

2

GLYPHOSATE (Case No. 0178/Code 099101)
TENTATIVE RESIDUE CHEMISTRY DATA SUMMARY THROUGH 8/14/92¹

Guideline Number and Topic ²	Are Phase V data requirements satisfied?	MRID(s) ³
171-3 Directions for use	N	N/A
171-4(a) Plant Metabolism	Y	
171-4(b) Animal Metabolism	Y	
171-4(c) Residue Analytical Methods - Plants	Y	
171-4(d) Residue Analytical Methods - Animals	Y	
171-4(e) Storage Stability	N ⁴	41940701
171-4(k) Root and Tuber Vegetables Group		
Carrots	Y	
Beets, garden	Y	
Parsnips	Y	
Potatoes [see 171-4(l)]	Y	
Radish	Y	
Rutabagas	Y	
Sugar beets [see 171-4(l)]	Y	
Sweet potato	Y	
Turnips	Y	
171-4(k) Leaves of Root and Tuber Vegetables		
Beets, greens	Y	
Chicory leaves	Y	
Sugar beet tops	Y	
Turnip tops	Y	
171-4(k) Bulb Vegetables Group		
Onions (green and dry bulb)	Y	
171-4(k) Leafy Vegetables (except Brassica)		
Celery	Y	
Lettuce (leaf)	Y	
Lettuce (head)	Y	
Spinach	Y	
171-4(k) Brassica Leafy Vegetables Group		
Broccoli	Y	
Cabbage	Y	
Cauliflower	Y	
Kale	Y	
Mustard greens	Y	
171-4(k) Legume Vegetables (succulent/dried)		
Beans (succulent and dried)	Y	
Peas (succulent and dried)	Y	
Soybeans [see 171-4(l)]	Y	
171-4(k) Foliage of Legume Vegetables		
Bean vines and hay	Y	
Soybean forage and hay	Y	
171-4(k) Fruiting Vegetables Group	Y	
171-4(k) Cucurbit Vegetables Group	Y	
171-4(k) Citrus Fruits Group [see 171-4(l)]	Y	

3

GLYPHOSATE (Case No. 0178/Code 099101)
TENTATIVE RESIDUE CHEMISTRY DATA SUMMARY THROUGH 8/14/92¹

Guideline Number and Topic ²	Are Phase V data requirements satisfied?	MRID(s) ³
171-4(k) Pome Fruits Group	Y	
171-4(k) Stone Fruits Group	Y	
Plums (fresh prunes) [see 171-4(l)]	Y	
171-4(k) Small Fruits and Berries Group		
Grapes [see 171-4(l)]	Y	
171-4(k) Tree Nuts Group		
Almonds	Y	
171-4(k) Cereal Grains Group		
Corn (field) [see 171-4(l)]	Y ⁶	
Corn (fresh) [see 171-4(l)]	Y	
Corn (pop)	Y	
Sorghum [see 171-4(l)]	Y ⁶	
Wheat [see 171-4(l)]	Y ^{7,8}	
171-4(k) Forage, Fodder, and Straw of Cereal Grains		
Corn (field and pop) forage and fodder	Y	
Corn (fresh) forage	Y	
Sorghum forage and fodder	Y	
Wheat forage and straw	Y ⁹	
171-4(k) Grass Forage, Fodder, and Hay Group	Y	
171-4(k) Non-grass Animal Feeds		
Alfalfa [see 171-4(l)]	Y	
171-4(k) Miscellaneous Commodities		
Acerola	Y	
Asparagus	Y	
Avocados	Y	
Bananas	Y	
Coffee [see 171-4(l)]	Y	
Cotton [see 171-4(l)]	Y	
Figs [see 171-4(l)]	Y	
Kiwi	Y	
Mangoes	Y	
Olives [see 171-4(l)]	N	
Papayas	Y	
Peanuts [see 171-4(l)]	Y	
Pineapple [see 171-4(l)]	Y	
Pistachio	Y	
Sugarcane [see 171-4(l)]	Y ¹⁰	
Tea [see 171-4(l)]	Y	
171-4(l) Processed Food/Feed		

GLYPHOSATE (Case No. 0178/Code 099101)
TENTATIVE RESIDUE CHEMISTRY DATA SUMMARY THROUGH 8/14/92¹

Guideline Number and Topic ²	Are Phase V data requirements satisfied?	MRID(s) ³
Corn	Y ¹¹	
Olives	N	
Peanuts	Y ¹²	00144334
Sorghum	N	
Soybeans	Y ¹³	00156793
Wheat	Y ^{14,15}	
Alfalfa	Y	
Apples	Y	
Coffee	Y	
Cotton	Y	
Figs	Y	
Grapes	Y	
Pineapples	Y	
Potatoes	N	
Sugarbeets	Y	
Sugarcane	Y	
171-4(j) Meat/Milk/Poultry/Eggs	Y	
171-4(f) Potable Water	Y	
171-4(g) Fish	Y	
171-4(h) Irrigated Crops	Y	
171-4(i) Food Handling Establishments	N/R	
171-5 Reduction of Residues	N/R	

¹Registration Standard issued 6/86. Reregistration Standard Update issued 4/26/90.

²N/A = Guideline requirement not applicable.

³MRIDs that were reviewed in the current submission are designated in shaded type.

⁴CBRS No. 8337 (R. Perfetti, 4/2/92). The data support the storage stability of glyphosate residues in plant commodities for a period of 1 year. Additional data will be needed for a leafy vegetable, a root crop, an oilseed or tree nut and an orchard crop if any of the samples used to support these tolerances were stored for more than 1 year. Sample histories for all residue data used to support tolerances should be submitted in a comprehensive report. For additional specifics please see the referenced review.

⁵CBRS No. 8196 and 8220 dated 1/31/92 by R. Perfetti. The registrant has responded to the deficiencies noted in the Update for this crop. No additional data are required.

⁶CBRS No. 8196 and 8220 dated 1/31/92 by R. Perfetti. The registrant has responded to the deficiencies noted in the Update for this crop. No additional data are required.

⁷CBRS No. 8196 and 8220 dated 1/31/92 by R. Perfetti. The registrant has responded to the deficiencies noted in the Update for this crop. No additional data are required.

⁸CBTS Nos. 9686 through 9690 dated 5/29/92 by R. Cook. PPOF3865/FAP2H5635. CBTS recommends for establishment of a 4 ppm tolerance for combined residues of glyphosate and its aminomethylphosphonic acid metabolite in or on wheat grain.

⁹CBTS Nos. 9686 through 9690 dated 5/29/92 by R. Cook. PPOF3865/FAP2H5635. CBTS recommends for establishment of a 85 ppm tolerance for combined residues of glyphosate and its aminomethylphosphonic acid metabolite in or on wheat straw.

¹⁰CBRS No. 8196 and 8220 dated 1/31/92 by R. Perfetti. The registrant has responded to the deficiencies noted in the Update for this crop. No additional data are required.

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¹² CBRS# 10124, RBP, 8/14/92. A peanut processing study was required. The Registrant has responded by referencing PP# 5F3157 (MRID # 00144341) wherein a processing study was submitted. This study was reviewed in our review of 5/1/85 (M. Bradley) and it was concluded that residues of glyphosate concentrated 1.5X in peanut meal. No other concentration was observed. Since the present tolerance for peanuts is 0.1 it is our judgement that no tolerance for peanut meal is needed for this marginal concentration factor. No additional data is needed for peanuts as long as the spot treatment for peanuts is not on the glyphosate labels.

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¹⁴CBRS No. 8196 and 8220 dated 1/31/92 by R. Perfetti. The registrant has responded to the deficiencies noted in the Update for this crop. No additional data are required.

¹⁵CBTS Nos. 9686 through 9690 dated 5/29/92 by R. Cook. PPOF3865/FAP2H5635. CBTS recommends for establishment of Monsanto's proposed a 12 ppm FAT for combined residues of glyphosate and its aminomethylphosphonic acid metabolite in wheat milling fractions (except flour).

cc: RBP; Reregistration Standard File for Glyphosate; L. Rossi, SRRD.