



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

Rereg. Stand. File
10-8-92

OCT 8 1992

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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Response to the Glyphosate Reregistration Standard:
Residue Chemistry (MRID # 42398401, CBRS # 10256,
Barcode: D180793).

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

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

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

and

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

Attached is a review of residue chemistry data submitted in response to the glyphosate Reregistration Standard. This review was completed by Dynamac Corporation under supervision of CBRS, HED. It has undergone secondary review in the branch and has been revised to reflect Agency policies.

A revised Tentative Residue Chemistry Summary sheet is included.

If you need additional input please advise.

Attachment 1: Glyphosate Residue Chemistry Data Review.

cc (With Attachment 1): RBP, Glyphosate Reregistration
Standard File, Glyphosate Subject File, RF, Circ. and Dynamac.

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Final Report

GLYPHOSATE
Shaughnessy No. 103601
(CBRS No. 10256; DP Barcode D180793;
Case 0178)

TASK 4
Registrant's Response to Product
Chemistry Data Requirements

September 14, 1992

Contract No. 68-D2-0053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

GLYPHOSATE

Shaughnessy No. 103601

(CBRS No. 10256; DP Barcode D180793; Case 0178)

Task 4

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

BACKGROUND

The Glyphosate Residue Chemistry Science Assessments for issuance of Reregistration Eligibility Document were drafted by Dynamac Corporation on 8/7/92 and are currently undergoing secondary review at CBRS, HED. The Assessments identify the following residue chemistry data deficiencies: storage stability; magnitude of residues in olives; and processing studies in peanuts and olives.

In response to a letter from L. Rossi of SRRD dated 3/25/92 and the requirements of the Guidance Document dated 6/86, Monsanto Agricultural Company submitted current product labels from Greece, Italy, and Spain where use of isopropylamine salt of glyphosate on olive groves is permitted. The registrant also submitted field residue data (MRID 42398401 under CBRS No. 10256) from tests conducted in Spain pertaining to residues of glyphosate and its metabolite AMPA in or on olives and olive oil. These labels and residue data are evaluated in this document for their adequacy in fulfilling outstanding residue chemistry data requirements.

The tolerances listed in 40 CFR §180.364(a) are for the combined residues of glyphosate and its metabolite AMPA, resulting from application of isopropylamine salt of glyphosate and/or the monoammonium salt of glyphosate. A tolerance of 0.2 ppm has been established for the combined residues of glyphosate and its metabolite AMPA in or on domestically grown olives [40 CFR §180.364(a)]. A food additive tolerance of 0.1 ppm has been established for the combined residues of glyphosate and its metabolite AMPA in imported olives [40 CFR §185.3500(a)(2)].

The Conclusions and Recommendations stated in this document apply only to the magnitude of the residue in or on olives and olive oil. All other data requirements identified in the Glyphosate Residue Chemistry Science Assessments for RED remain outstanding.

CONCLUSIONS AND RECOMMENDATIONS

1. The registrant has submitted current product labels from Greece, Italy, and Spain. The maximum use patterns described in these labels reflect the residue data previously evaluated in PP#9F2223/FAP#OH5255. The registrant stated that a description of the olive-curing process was included in Monsanto's letter of 9/3/87. No additional data and/or documentation are required.
2. The registrant has responded to Agency's concern over the fact that olives which have fallen to the grove floor may be directly contacted by glyphosate by submitting additional field residue and processing data, and offering explanations of the typical use of ground-fallen olives in Spain.

The additional field residue data indicate that the combined residues of glyphosate and its metabolite AMPA will range up to 2.0 ppm in or on fresh olives harvested from the orchard ground collected 0-41 days following treatment with a single broadcast application of the SC/L formulation at 1x the maximum registered application rate for this use pattern in Spain. The registrant has explained that the use of glyphosate on ground-fallen olives is an approved use in Spain to control emergent weeds in order to facilitate harvest of fallen olives. The registrant further stated that the only commercial use of olives that have fallen to the grove floor is for processing into olive oil because the poor quality of ground-fallen olives prevents their use as table olives. Only olives that have been hand-picked from the trees are used as table olives; table olives are never directly contacted by the glyphosate spray.

Since the fallen olives will only be used for processing and since the submitted processing data indicate that the combined residues of glyphosate and AMPA were nondetectable (<0.10 ppm) in samples of olive oil processed from ground-fallen olives collected from treated groves and bearing significant residues, CBRS concludes that the established tolerance in imported olives is acceptable and a food additive tolerance is not needed for olive oil.

DETAILED CONSIDERATIONS

Monsanto Agricultural Company (1992; MRID 42398401 under CBRS 10256) submitted current product labels from Greece, Italy, and Spain where use of glyphosate on olive groves is permitted; olives from these glyphosate-treated groves are exported by these countries into the U.S. The registered uses of glyphosate in these countries are described below.

Greece: The 36% (3 lb/gal, Roundup® AS Herbicide) SC/L formulation is registered in Greece for postemergence ground application to established olive groves at 0.48-0.63 lb ae/A for the control of annual weeds and at 1.58-3.14 lb ae/A for the control of perennial weeds. Application should not touch the foliage or soft shoots. Application in conjunction with cultivation and before harvest is prohibited.

Italy: The 360 g/L (Roundup® Herbicide) SC/L formulation is registered in Italy for postemergence ground application to established olive groves at 0.63-1.27 lb ae/A for the control of annual weeds and at 0.95-3.8 lb ae/A for the control of perennial weeds. Application is made by spouted low pressure ground spray equipment and/or by contact (rope or sponge).

Spain: The 120 g/L (Sting® SE Herbicide) SC/L formulation is registered in Spain for postemergence application to established olive groves at a maximum of: (i) 1.29 lb ae/A for the control of annual weeds; (ii) 2.14 lb ae/A for the control of perennial weeds; and (iii) 0.31 lb ae/A in olive groves where olives have fallen. Application is made by ground equipment in a volume of 100-400 L/ha.

The use directions from the submitted product labels indicate that the maximum seasonal application rates are 3.77 lb ae/A in Greece, 5.07 lb ae/A in Italy, and 3.43 lb ae/A in Spain. Based on this information, it appears that the maximum use pattern of glyphosate registered in Italy is not supported by data evaluated in PP#9F2223/FAP#OH5255 and does not support the established food additive tolerance. However, the registrant provided explanations regarding this matter. According to the registrant, although it appears that the maximum seasonal application rate would be exceeded in Italy if a grower were to treat both annual and perennial weeds in the same season, it is unlikely that this would occur. The treatment for annual weeds occurs in the spring and is generally applied as a broadcast treatment; the treatment for perennial weeds, however, is made as a spot treatment where only 10% of the grove is treated. This is in accordance with economics and good agricultural practices. Therefore, the registrant pointed out that even if both annual and perennial weeds were treated in the same season, the maximum seasonal rate would not likely exceed 3.8 lb ae/A in Italy.

CBRS concurs with the registrant's justifications; no additional foreign use pattern information of glyphosate on olives is required.

In a letter from L. Rossi of SRRD dated 3/25/92, the Agency expressed concern over the fact that olives which have fallen to the grove floor may be directly contacted by glyphosate. In response to this concern, Monsanto Agricultural Company (1992; MRID 42398401 under CBRS 10256) submitted data from six tests conducted in Spain depicting residues of glyphosate and its metabolite AMPA in or on ground-fallen olives collected from the soil 0, 1, 7, 24, 30, 32, and 41 days following a single broadcast application of the 120 g/L (12%) SC/L formulation at 0.36 kg acid equivalent/ha (0.32 lb ae/A); the applied rate is 1x the maximum registered application rate for this use pattern in Spain. Applications were made using a low pressure ground equipment in 200 L/ha of water.

Ground-fallen olives from the treated orchards were also collected for processing into olive oil. The processing was conducted at the Monsanto Technical Center (Louvain-La-Neuve, Belgium; 1990) and C+E Analítica, SA (La Rinconada, Spain; 1991-1992) using an adequately described semi-industrial methodology that included blending and stirring the olives with water, centrifugation to separate the oil and water from solid residues, and decantation of the supernatant to separate oil from water. The combined residues of glyphosate and its metabolite AMPA are presented in Table 1.

Glyphosate and its metabolite AMPA were analyzed by Monsanto Technical Center (Louvain-La-Neuve, Belgium) using a modified HPLC method with a fluorometric detector specific for compounds which produce a fluorophore upon reaction with o-phthalaldehyde (OPA) in the presence of 2-mercaptoethanol; the detection limit for each compound was 0.05 ppm. This method was previously described in the Glyphosate Update, dated 4/26/90 and deemed adequate for data collection (R.W. Cook, CBRS No. 4287, dated 11/22/88). The modification included a second extraction with water followed by Ultraturrax extraction, and centrifugation. The method recoveries from olive samples fortified with glyphosate and its metabolite AMPA at 0.05-5 ppm of each compound and from olive oil samples fortified with each compound at 0.05-0.1 ppm are presented in Table 2.

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Results are eight

Table 1. Combined residues of glyphosate and its metabolite AMPA in or on ground-fallen olives (and in olive oil processed from ground-fallen olives) collected from the soil following a single broadcast application of the 120 g/L (12%) SC/L formulation at 0.36 kg acid equivalent/ha (0.32 lb ae/A).

Commodity		Residues (ppm) ^a		
PTI	No. of Samples	Glyphosate	AMPA	Combined residues
Olives				
0	4(3) ^b	0.08-1.8	-- ^c	--
1	2(2)	0.9, 1.1	--	--
7	2(2)	1.1, 1.2	--	--
24	1(1)	0.4	<0.05	<0.45
30	1(1)	2.0	<0.05	<2.05
32	1(1)	0.8	<0.05	<0.85
41	1(1)	0.4	<0.05	<0.45
Control	12	<0.05	<0.05 ^d	<0.10
Olive oil				
0	4	<0.05	<0.05	<0.10
1	2	<0.05	<0.05	<0.10
7	2	<0.05	<0.05	<0.10
24	1	<0.05	<0.05	<0.10
30	1	<0.05	<0.05	<0.10
32	1	<0.05	<0.05	<0.10
41	1	<0.05	<0.05	<0.10
Control	12	<0.05	<0.05	<0.10

^a Residues from composited samples, corrected for average recovery.

^b Number of samples with tolerance-exceeding residues are in parentheses.

^c Not reported.

^d Results from eight control samples.

Table 2. Method recoveries from olive samples fortified with glyphosate and its metabolite AMPA at 0.05-5 ppm of each compound and from olive oil samples fortified with each compound at 0.05-0.1 ppm.

Fortification level (ppm)	Percent Recoveries	
	Glyphosate	AMPA
Olives		
0.05	63-87(5) ^a	53-70(3)
0.1	62-104(6)	57-76(3)
0.2	71(1)	55-61(4)
0.5	62-70(4)	68(10)
1	61-98(4)	53(1)
5	70(1)	--
Olive oil		
0.05	66-96(7)	57-95(7)
0.1	66-97(7)	55-75(7)

^a Number of samples are in parentheses.

Samples were frozen shortly after collecting, sent to the analytical laboratory, and stored frozen (unspecified temperature) for 14-169 days prior to analysis by Monsanto Technical Center (Louvain-La-Neuve, Belgium). No storage stability data were submitted to validate olive residue samples stored under similar conditions and intervals.

Geographic representation is adequate since Spain represents 88% of the 1988 U.S. import of processed olives (Foreign Agricultural Trade of the United States, Fiscal Year 1988 Supplement, CED, ERS, USDA, p. 358). The additional field residue data indicate that the combined residues of glyphosate and its metabolite AMPA will range up to 2.0 ppm in or on fresh olives harvested from the orchard ground collected 0-41 days following treatment with a single broadcast application of the SC/L formulation at 1x the maximum registered application rate for this use pattern in Spain.

The registrant has explained that the use of glyphosate on ground-fallen olives is an approved use in Spain to control emergent weeds in order to facilitate harvest of fallen olives; a product label from Spain with English translation was provided. The registrant further stated that the only commercial use of

olives that have fallen to the grove floor is for processing into olive oil because the poor quality of ground-fallen olives prevents their use as table olives. Only olives that have been hand-picked from the trees are used as table olives; table olives are never directly contacted by the glyphosate spray.

We note that adequate residue data (MRID 00108175) reflecting a maximum seasonal rate of 3.8 lb ae/A (1x) in processed table olives were reviewed in the Residue Chemistry Science Chapter of the Glyphosate Registration Standard dated 7/15/85.

Since the fallen olives will only be used for processing and since the submitted processing data indicate that the combined residues of glyphosate and AMPA were nondetectable (<0.10 ppm) in samples of olive oil processed from ground-fallen olives collected from treated groves and bearing significant residues. CBRS concludes that the established tolerance in imported olives is acceptable and a food additive tolerance is not needed for olive oil.

MASTER RECORD IDENTIFICATION NUMBERS

References (used):

42398401 Hontis, A.M. (1992) Residues of Glyphosate/AMPA in Olives and Olive Oil Following Use of Sting SE - Spanish trials 1990-1992. Study No. MLL-30297, (Unpublished study prepared by Monsanto Company).

GLYPHOSATE (Case No. 0178/Code 099101)
TENTATIVE RESIDUE CHEMISTRY DATA SUMMARY THROUGH 9/28/92¹

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	

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GLYPHOSATE (Case No. 0178/Code 099101)
TENTATIVE RESIDUE CHEMISTRY DATA SUMMARY THROUGH 9/28/92¹

Guideline Number and Topic ²	Are Phase V data requirements satisfied?	MRID(s) ³
171-4(k) Cucurbit Vegetables Group	Y	
171-4(k) Citrus Fruits Group [see 171-4(l)]	Y	
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)]	Y ¹⁰	42398401
Papayas	Y	
Peanuts [see 171-4(l)]	Y	
Pineapple [see 171-4(l)]	Y	
Pistachio	Y	
Sugarcane [see 171-4(l)]	Y ¹¹	
Tea [see 171-4(l)]	Y	
171-4(l) Processed Food/Feed		

GLYPHOSATE (Case No. 0178/Code 099101)
TENTATIVE RESIDUE CHEMISTRY DATA SUMMARY THROUGH 9/28/92¹

Guideline Number and Topic ²	Are Phase V data requirements satisfied?	MRID(s) ³
Corn	Y ¹²	
Olives	Y	
Peanuts	Y ¹³	00144334
Sorghum	Y ¹⁴	
Soybeans	Y ¹⁵	00156793
Wheat	Y ^{16,17}	
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.

¹⁰ CBRS No. 10,256, RBP, 9/28/92. No additional data/information are needed for olives. The residue data and processing study indicate that the tolerance for imported olives is adequate and that no food additive tolerance is needed for olive oil.

¹¹CBRS 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.

¹²CBRS 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.

¹³ 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.

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.

¹⁵CBRS 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.

¹⁶CBRS 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.

¹⁷CBTS 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.

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