PP# 8E3676

DIETARY EXPOSURE BRANCH, HED

DATA REVIEW QUICK FORM

Date: OCT 20 1988

MEMORANDUM

SUBJECT: Petition Review for Establishment of Tolerance(s). Evaluation of Analytical Method(s) and Residue Data.

FROM: Maxie Jo Nelson, Chemist
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division, TS-769C

mjn

THRU: Robert S. Quick, Section Head
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RSQ

TO: Hoyt Jamerson PM 43
Registration Division, TS-767C

and

Toxicology Branch - HFA Support
Health Effects Division, TS-769C

1. Petition No(s): 8E3676
2. DEB No(s): 4284 HED#: 8-1093A
3. MRID No(s): 407831-00, -01
4. Pesticide(s): Glyphosate
5. Tolerance Proposal (RACs & Levels): onions @ 0.2 ppm
(See #47 for Background Information)
6. Petitioner: IR-4 and the Ag. Exp. Stations of CA, NY, Fla, and MI

(1) 1/13

7. Tolerance Expression: glyphosate and its metabolite N-aminomethylphosphonic acid (AMPA).

8. Established Pesticide Tolerances: 40 CFR 180.364

9.

N-PHOSPHONOMETHYL GLYCINE AND METABOLITE: AMINOMETHYL PHOSPHONIC ACID
40 CFR 180.364; 185.3500; 186.3500

(A) HERBICIDE and AMINOMETHYL PHOSPHONIC ACID:

0.2	Acerola	0.5	Cucurbits (Vegetable Group)	0.1	Pineapples
200	Alfalfa	200	Fescue	0.2	Pistachio Nuts
0.2	Alfalfa, Fresh	0.2	Figs	0.2	Pome Fruits
0.2	Alfalfa, Hay	0.1(N)	Grain Crops	0.2(N)	Root Crop Vegetables
1	Almond Hulls	0.2	Grapes	200	Ryegrass
0.2	Asparagus	0.2	Grasses, Forage	0.2(N)	Seed & Pod Vegetables
0.2	Avocados	0.2	Guavas	0.2(N)	Seed & Pod Vegetables, Forage & Hay
200	Bahiagrass	0.2	Kiwi Fruit	0.2	Small Fruits & Berries Group
0.2	Bananas (Plantains)	0.2(N)	Leafy Vegetables	15	Soybean Forage & Hay
200	Bermudagrass	0.4	Legumes, Forage (Except Soybeans & Peanuts)	6	Soybeans
200	Bluegrass	0.2	Mangoes	0.2	Stone Fruit
200	Bromegrass	0.2	Nuts	0.2(T)	Sugar Beets, Tops Exp. 9/5/80
0.2	Citrus Fruits	0.2	Olives	200	Timothy
200	Clover	200	Orchardgrass	200	Wheat Grass
0.1	Coconut	0.2	Papayas		
1	Coffee Beans	0.5	Peanut Forage & Hay		
15	Cotton, Forage & Hay	0.5	Peanut Hulls		
15	Cottonseed	0.1	Peanuts		
0.2	Cranberries				

10.

(B) GLYPHOSATE ISOPROPYLAMINE SALT for herbicidal and plant growth regulator purposes and/or the SODIUM SESQUI SALT for growth regulator purposes:

0.5	Cattle, Liver & Kidney	0.5	Hogs, Liver & Kidney	0.5	Sheep, Liver & Kidney
0.25	Fish	0.5	Horses, Liver & Kidney	2	Sugarcane
0.5	Goats, Liver & Kidney	0.5	Poultry, Liver & Kidney		

(C) IRRIGATION WATER:

0.1	Avocadoes	0.1	Grasses, Forage	0.1	Nuts
0.1	Citrus	0.1	Hops	0.1	Pome Fruits
0.1	Cottonseed	0.5	Irrigation Water	0.1	Root Crop Vegetables
0.1	Cucurbits	0.1	Leafy Vegetables	0.1	Seed & Pod Vegetables
0.1	Fruiting Vegetables	0.1	Legumes, Forage	0.1	Stone Fruit
0.1	Grain Crops			0.5	Water Potable

11. Is Pesticide a Registration Standard Chemical? (Yes/No) Yes

If yes, date Guidance Document issued: June 1986

12. Letter(s) of Authorization (if applicable):

7/20/88 - Monsanto access authorized to files on Roundup® (see #13)

13. Formulation(s): 3 lb ae/gal SC/L:

Roundup® Herbicide, EPA Reg. No. 524-308-AA, a H_2O-soluble liquid containing 3 lbs glyphosate acid equivalent/gal.

14. Inerts Status: Under RD purview

15. Manufacturing Process: Submitted w/ PP#6F3380/FAP#6H5502, MRID# 401558-01, -02; see memos of J. Stokes, 9/1/87 and W. Chin, 8/13/87. Levels of N-nitrosoglyphosate in the technical product and nitrosoamines in Roundup® are not of concern (see memos of W. Dykstra, 2/11/88 and W. Chin, 2/25/88, PP#6E3424).

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16. Proposed Use(s): For control of various annual and perennial weeds, apply uniformly with conventional ground equipment (boom or hand-held) as a broadcast spray to weeds prior to crop emergence. Rate (1-5 qts; 0.75-3.75 lb ae/A/application) depends on weed height and species. Any repeat treatment(s) must also be made prior to crop emergence. The combined total of all treatments must not exceed 8 qts (6 lbs ae)/A/year. Do not harvest or feed treated crops for 8 weeks after application. 0.5-1% nonionic surfactant concentration may be present in the spray mix. 2% dry ammonium sulfate may also be added; see #44.

17. Plant Metabolism Data on: No new studies were submitted. Metabolism studies on a variety of crops (citrus, coffee, pome fruits, alfalfa, grapes, sugarcane, soybeans, nuts, cotton, wheat, corn, string beans, peas, carrots, cabbage) have been submitted in previous petitions and are discussed in the Residue Chemistry science support chapter (dated 5/31/85) to the Glyphosate Registration Standard.

18. Plant Residues Comprised of: See Residue Chemistry science support chapter (5/31/85) for extensive discussion. Also note #20. The studies show that uptake of glyphosate or AMPA from soil is limited (0.1-2%).

19. Plant Metabolism Data Translatable Here: All.

20. Nature of Plant Metabolism on the Subject RAC(s) of This Petition

(is)/is not adequately defined.

The Residue of Concern is: parent glyphosate and its N-aminomethylphosphonic acid (AMPA) metabolite.

21. Animal Metabolism Data on: N/A. There are no animal feed items associated with this petition.

22. Animal Residues Comprised of: N/A; see #21.

23. Animal Metabolism Data Applicable Here: None. See #21.

24. Nature of Animal Metabolism Data is/is not adequately defined.
The Residue of Concern is: N/A; see #21.

25. Analytical Method(s) (Give Reference and/or Brief Description)
"HPLC-Fluorometric method for the analysis of glyphosate and aminomethylphosphonic acid in raw agricultural commodities and water", MRID# 405780-03 (refers to PP# 8E3631).

The analytical method has been considered in PP6F3380 (J. Stokes, July 7, 1987) and PP8F3631 (C. Deyrup, July 5, 1988). A petition method trial has been requested of Beltsville for this method but the method trial has not been conducted at this time. In the absence of the results of the method trial mentioned above, we can draw no conclusion re the adequacy of the HPLC method for enforcement purposes.

The method has been validated by the registrant and we can conclude that it is adequate for obtaining residue data.

Also see #45.

26. Has there been a Method Trial? (Yes) No) At least three.

If yes, provide details: Both a GLC and HPLC procedure have previously undergone successful PMVs; see Residue Chemistry science support chapter (5/31/85).

If no, is a Method Trial needed? One has been requested for this HPLC procedure (7/7/87 memo, J. Stokes, PP# 6F3380).

27. Residues Determined by Method(s): glyphosate and its metabolite AMPA, separately.

28. Method Validation (RACs/"spike chemical"/fortification level(s)/ recovery range/average recovery):

Dry bulb onions	glyphosate	0.08 ppm	94%	0.4 ppm	91%
	AMPA	"	70%	"	103%
Green onions	glyphosate	0.08 ppm	88%	0.4 ppm	95%
	AMPA	"	75%	"	103%
Leeks	glyphosate	0.08 ppm	94%	0.2 ppm	85%
	AMPA	"	94%	"	90%

MRID# 407831-01

29. Method Validation (limit of detection and/or sensitivity in ppm):

Parent: <0.05 ppm

Metabolite(s) (specify): AMPA <0.05 ppm

MRID# 407831-01

30. Method Validation (state crops and control values reported): *contaminated

Dry bulb onions	<0.05 ppm glyphosate;	<0.05 ppm AMPA
Green onions	<0.05-0.21* ppm " ;	<0.05-0.09* ppm "
Leeks	<0.05-0.06 " " ;	<0.05-0.06 " "

MRID 407831-01

31. Adequate Analytical Method(s) (are)/are not Available for Enforcement Purposes. (The GLC procedure is too long to really be practical.)

These Method(s) are located: PAM II (Method 3 is similar to the HPLC procedure used in this petition.)

32. PAM I Multiresidue Methods Data are available for parent pesticide tested via Protocols I II III IV (circle, as applicable). Additional multiresidue test information for parent compound that is needed: PAM I Appendix has no listing to indicate glyphosate has ever been tested through the multiresidue method (MRM) protocols. The Residue Chemistry support chapter (5/31/85) has no mention of this either. Glyphosate needs to be tested using the Decision Tree for MRM testing as guidance; not all protocols may be applicable. Since this requirement will be raised in co-pending PP#8F3573, we waive it for this IR-4 petition!

33. PAM I Multiresidue Methods Data are available for metabolite(s) tested via Protocols I II III IV (circle, as applicable). Additional multiresidue test information for metabolite(s) that is needed: See #32; MRM testing is needed for AMPA, also. Since the requirement will be raised in co-pending PP#8F3573 (glyphosate/field corn), we waive it for this IR-4 petition.

34. Residue Data (RAC(s) and Processed Commodities) MRID# 407831-01

5 1987 studies: dry bulb (CA, NY); green (CA, TX); leeks (NJ)
2 applications: first @ 2.25 lb ae (3 qts)/A
second @ 3.75 " " (5 ")/A } total = 6 lbs ae/A
both applications were preplant, preemergence, or (leeks) pretransplant. Timing and rates were as specified by the Residue Chemistry science support chapter (5/31/85, p. 94) and the Req. Std (p. 67).
PHI's were 45 days (for transplanted leeks); 103-144 days (bulb onions grown from seed); 70-77 days (green onions grown from seed).
5 varieties of onions; 4 soil types.
Samples were frozen stored (-10°F) 1-8 1/2 months prior to residue analysis.
1-4 replicates and 1-4 control samples per field trial.

Summary of Residues Reported:

Dry bulb onions - CA	<0.05 ppm Gly.	<0.05 ppm AMPA
" " " - NY	"	"	"
Green onions - CA	"	0.06-0.11 ppm	"
" " - TX	"	<0.05	"
Leeks - NJ	<0.05-0.06 "	<0.05-0.06	"

MAXIMUM TOTAL RESIDUE = <0.16 ppm

35. Frozen Storage Stability Data (are)/are not Available.

If yes, give RACs/fortification levels/length of storage/recovery range/conditions of storage (°C): -10% F, chopped sample

Dry bulb onions	glyphosate	0.2 ppm	70%	
	AMPA	"	55%	4½ months
" " "	glyphosate	0.2 "	112 %	
	AMPA	"	111 %	3 weeks
Green onions	glyphosate	0.2 "	70 %	
	AMPA	"	63 %	7 months
Leeks	glyphosate	0.08 "	88 %	
	AMPA	"	100 %	2½ months

MRID# 407831-01

36. Regional Registration is/(is not) involved.

If yes, list States in which use is sought: N/A

If yes, indicate/explain (see 51 FR 11341, 4/2/86 - Policy on Minor Uses) if a bona fide "Minor Use" is involved: N/A

37. Geographic Representation (is)/is not adequate. If no, list RAC(s) and States from which additional data are needed: Studies on dry bulb (CA, NY) and green (CA, TX) onions were conducted in the states specified by the Residue Chemistry science support chapter (5/31/85, p. 94) and the Reg. Std. (p. 67).

38. Residues will not exceed proposed tolerance(s) on (commodities) onions @ 0.2 ppm or on the bulb vegetable crop group @ 0.2 ppm

but may exceed proposed tolerance(s) on (commodities) N/A

39. Livestock Feeding Studies on (species): N/A; See #21

40. Animal Feeding Levels: N/A; see #21.

41. Animal Residue Ingestion Levels from Proposed RAC Tolerance(s) Levels (proposed tolerance level x percent in diet): _____ ppm in beef cattle; _____ ppm in dairy cattle/goats; _____ ppm in hogs; _____ ppm in horses; _____ ppm in sheep; _____ ppm in poultry.

N/A

42. Livestock Tolerances are Adequate in (species) _____ N/A; see #21, but not adequate in _____.

43. Livestock Tolerances Need to be Established: Yes/No. If yes, species/levels: N/A; see #21

44. Other Comments: The use of ammonium sulfate as an adjuvant with glyphosate (Roundup) has recently been commented on (see 6/8/88 memo, C. Deyrup, Gly. Reg. Std. file). Since this IR-4 petition is limited to preemergence use, there is no problem here.

45. Other Considerations: The results of an interlaboratory study on the HPLC-fluorometric method have been published (J. Ag. Food Chem. 34:955, 1986). Validation data on onions (see #28-30) and representative chromatograms were submitted as part of this petition.

46. Additional Information Needed: None

47. Background Information: A 0.2 ppm tolerance for combined residues of glyphosate and AMPA is currently established under 40 CFR 180.364(a) for the now obsolete crop group "root crop vegetables", of which onions was a member. Thus, there are registered uses for onions. In order to support the continued registration of the uses on onions, the Reg. Std. indicated that either a separate tolerance on "onions" would be needed, for which there was no supporting residue data available, or a tolerance would need to be established in terms of the appropriate new crop group of which onions is now a member, "bulb vegetables", for which no data were available either. The minimum data requirement to support an "onions" tolerance was specified to be field studies on dry bulb onions (CA, NY) and green (spring) onions (CA, TX). The minimum data requirement to support a "bulb vegetables" crop group tolerance would be residue data on green and bulb onions plus either garlic, leeks, or shallots (See 40 CFR 180.34 (f)(9)(iii)).

It was in response to this data gap identified by the Reg. Std. that IR-4 has submitted this present petition. It specifically addresses the data requirement for an "onions" tolerance as stated in the Std (p 67) and its Residue Chemistry Science support chapter (pp 93-94). Leeks residue data are also submitted, so the minimum data requirement for a "bulb vegetables" crop group tolerance has also now been met.

48. RECOMMENDATIONS:

Toxicological considerations permitting, DEB recommends for the establishment of a 0.2 ppm tolerance for combined residues of glyphosate and N-aminomethylphosphonic acid

49. in or on the crop grouping "bulb vegetables", of which onions is a member. (The data requirements for this crop group tolerance have been met, so this tolerance is more appropriate than one on onions per se.)

50. Compatibility with Codex Tolerances? (Explain) See Attachment. There is no Codex Proposal @ step 6 or above for glyphosate and no Mexican limits either. The Canadian IRL is 0.1 ppm for residues of glyphosate per se on all food crops. In the USA, toxicological considerations have dictated inclusion of AMPA in the regulation as well, thus no compatibility in tolerance level or expression with Canada is possible. [Note: Even when only parent regulated on onions a 0.2 ppm tolerance level would be needed.]

ATTACHMENT(S): (1) International Residue Limits Status Sheet (IRL)

(2)

(7) (MN)

cc: RF, Circ, Reviewer, PP# 8E3676, PMSD/ISB, FDA.

Approved: RSQuick RMI 10/20/88; RDSchmitt for 10/20/88.

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m/n 11/8/88

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Glyphosate

CODEX NO. 153

CODEX STATUS:

☑ No Codex Proposal Step 6 or above (for onions)

Residue(if Step 8): _____

glyphosate

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 8E3676

RCB Reviewer Nelson

Residue: glyphosate + metabolite aminomethylphosphonic acid

Crop(s)	Limit (mg/kg)
Onions	0.2

CANADIAN LIMITS:

☐ No Canadian limit

Residue: _____

glyphosate

Crop(s)	Limit (mg/kg)
all food crops	0.1 *

MEXICAN LIMITS:

☑ No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES:

* negligible residue type limit

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information — Does Not Contain National Security Information (E.O. 12065)

48223 HQ

1. CHEMICAL NAME			
Glyphosate	8/25/88 mm	8/23/88	
2. IDENTIFYING NUMBER	**3. ACTION CODE**	**4. ACCESSION NUMBER**	**TO BE COMPLETED BY PM**
8E 3676	200	407331-00	5. RECORD NUMBER 22 1919
		407831-01	6. REFERENCE NUMBER -1-
			7. DATE RECEIVED (EPA) 08-23-88
	4284		8. STATUTORY DUE DATE 12/13
			9. PRODUCT MANAGER (PM) JAmcAv.
			10. PM TEAM NUMBER 43

14. CHECK IF APPLICABLE

- ☐ Public Health/Quarantine
- ☑ Minor Use
- ☐ Substitute Chemical
- ☐ Part of IPM
- ☐ Seasonal Concern
- ☐ Review Requires Less Than 4 Hours

AH

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS 9-22-88

12. PRIORITY NUMBER 29

13. PROJECTED RETURN DATE 10-25-88

15. INSTRUCTIONS TO REVIEWER

A. HED
- ☐ Total Assessment - 3(c)(5)
- ☑ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

B. SPRD (Send Copy of Form to SPRD PM)
- ☐ Chemical Undergoing Active RPAR Review
- ☐ Chemical Undergoing Active Registration Standards Review

C. ☐ BFSD
D. ☐ TSS/RD
E. ☐ Other

F. INSTRUCTIONS

RCB; IR-4 proposes a tolerance for combined residues of glyphosate and its metabolite in/on onions at 0.2 ppm.

16. RELATED ACTIONS

17. 3(c)(1)(D)

- ☑ Use Any or All Available Information
- ☐ Use Only Attached Data
- ☐ Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

- ☑ TB
- ☐ EEB
- ☐ EF
- ☐ PL
- ☑ RCB
- ☐ EFB
- ☐ CH
- ☐ BFSD

19.	To	TYPE OF REVIEW	NUMBER OF ACTIONS: Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED		TOXICOLOGY								
HED		ECOLOGICAL EFFECTS								
HED	✓	RESIDUE CHEMISTRY		1						
HED		ENVIRONMENTAL DATE								
RD/TSS		CHEMISTRY								
RD/TSS		EFFICACY								
RD/TSS		PRECAUTIONARY LABELING								
BFSD		ECONOMIC ANALYSIS								

20.	21.	22.	23.	24.
☐ Label Submitted with Application Attached	☐ Confidential Statement of Formula	☐ Representative Labels Showing Accepted Uses Attached	Date Returned to RD (to be completed by HED)	Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

EPA Form 8570-13 (Rev. 11-81) PREVIOUS EDITIONS ARE OBSOLETE.

11

Bulb Vegetables Group

Conclusions for the Bulb Vegetables Group:

A crop group tolerance is not appropriate at the present time for the following reason:

- o No residue data have been presented for any member of this group. In order to satisfy minimum data requirements, data should be submitted for onions (green and bulb) and either garlic, leeks or shallots.

Onions

Tolerances:

A tolerance of 0.2 ppm (negligible residues) has been established for the combined residues of glyphosate and its metabolite aminomethylphosphonic acid (AMPA) in or on onions as a member of the root crop vegetable group as defined at the time of registration [40 CFR 180.364(a)].

Use directions and limitations:

The 3 lb ae/gal SC/L formulation is registered for use on onions at 0.75-3.75 lb ae/A/application. Broadcast applications may be repeated prior to crop emergence (not to exceed 6 lb ae/A/year) using conventional ground equipment. Applications with hand-held or high volume ground equipment may be made at 3-15 lb ae/100 gal of spray solution except in CA where the rate is limited to 6 lb ae/100 gal. Treated areas may not be grazed by livestock within 8 weeks after application.

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Conclusions:

No data are available to support the established 0.2 ppm tolerance for residues in or on onions. The following data are required:

- Combined residues of glyphosate and AMPA in or on onions (bulb and green) following preemergence applications with the 3 lb ae/gal SC/L formulation totaling 6 lb ae/A (the final application must be at 3.75 lb ae/A). Spring onions must be tested in CA (40%) and TX (50%) and dry bulb onions must be tested in CA (25%) and NY (13%); state production percentages as reported in Agricultural Statistics, 1982, p. 164 appear in parentheses.

Upon submission of these data, we recommend that a separate tolerance be established for residues in or on onions since the root crop vegetable group in which this commodity was included is now obsolete (40 CFR 180.34). Alternatively the registrant could satisfy the data requirements for the appropriate current crop group (see Conclusions for the Bulb Vegetables Group for details of the data requirements). No Codex MRL, Canadian, or Mexican tolerance exists for glyphosate residues in or on onions.

Reference (used):

N/A.

Discussion of the data:

N/A.

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