

DIETARY EXPOSURE BRANCH, HED
DATA REVIEW QUICK FORM

FEB 10 1989

Date: _____

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
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division, TS-769C

RM

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

and

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

1. Petition No(s): 8E3696
2. DEB No(s): 4503 HED#: 9-0164A
3. MRID No(s): 408352-00, -01
4. Pesticide(s): Glyphosate
5. Tolerance Proposal (RACs & Levels): See #47, Background Info.
turnip roots @ 0.2 ppm
turnip greens @ 0.2 ppm
6. Petitioner: IR-4 and the Ag. Exp. Stations of
CA, FL, MI, and NY

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

8. Established Pesticide Tolerances: 40 CFR 180.364

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)
200	Alfalfa	0.2	Fescue
0.2	Alfalfa, Fresh	0.2	Figs
0.2	Alfalfa, Hay	0.1(N)	Grain Crops
1	Almond Hulls	0.2	Grapes
0.2	Asparagus	0.2	Grasses, Forage
0.2	Avocados	0.2	Guavas
200	Bahiagrass	0.2	Kiwi Fruit
0.2	Bananas (Plantains)	0.2(N)	Leafy Vegetables
200	Bermudagrass	0.4	Legumes, Forage (Except Soybeans & Peanuts)
200	Bluegrass	0.2	Mangoes
200	Bromegrass	0.2	Nuts
0.2	Citrus Fruits	0.2	Olive
200	Clover	0.2	Olives
0.1	Coconut	200	Orchardgrass
1	Coffee Beans	0.2	Papayas
15	Cotton, Forage & Hay	0.5	Peanut Forage & Hay
15	Cottonseed	0.5	Peanut Hulls
0.2	Cranberries	0.1	Peanuts
(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
0.25	Fish	0.5	Horses, Liver & Kidney
0.5	Goats, Liver & Kidney	0.5	Poultry, Liver & Kidney
(C) IRRIGATION WATER:			
0.1	Avocados	0.1	Grasses, Forage
0.1	Citrus	0.1	Hops
0.1	Cottonseed	0.5	Irrigation Water
0.1	Cucurbits	0.1	Leafy Vegetables
0.1	Fruiting Vegetables	0.1	Legumes, Forage
0.1	Grain Crops	0.1	Nuts
		0.5	Pome Fruits
		0.1	Root Crop Vegetables
		0.1	Seed & Pod Vegetables
		0.1	Stone Fruit
		0.5	Water Potable
		15	Soybean Forage & Hay
		6	Soybeans
		0.2	Stone Fruit
		0.2(T)	Sugar Beets, Tops
			Exp. 9/5/80
		200	Timothy
		200	Wheat Grass

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):

8/30/88 - 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 H₂O-soluble liquid containing 3 lbs glyphosate acid equivalent/gal.

14. Inerts Status: Under RD purview

15. Manufacturing Process: Submitted w/ PP#6E3380/EAP#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 nitroamines in Roundup® are not of concern (see memos of W. Dykstra, 2/11/88 and W. Chin, 2/25/88, PP#6E3424).

16. Proposed Use(s): for weed control prior to crop planting/emergence.
Use per directions specified in the "Cropping Systems" and "Weeds Controlled"
Sections of the Roundup label (EPA Reg. No. 524-308-AA). Rate is up to
5 gts (5 lbs a.i. - glyphosate isopropylamine salt, which is equivalent to 3.75 lbs
acid equivalent) of formulation per acre per application depending 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 gts (6 lbs ae) /A/year.
Do not harvest or feed treated crops for 8 weeks after application. 0.5-1.0 %
non-ionic 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 its N-aminomethyl
phosphonic acid (AMPA) metabolite from soil is limited (0.1-0.2%).
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: rats, rabbits, and cows (see PP#3F2809, 4/1/83 review, R. Perfetti); lactating goats and laying hens (see PP#6F3380, 1/30/89, W. Chin).
22. Animal Residues Comprised of: glyphosate and its metabolite, N-aminomethylphosphonic acid (AMPA)
[Applies to eggs, milk, and animal tissues]
23. Animal Metabolism Data Applicable Here: All (see #21)
24. Nature of Animal Metabolism Data (is) is not adequately defined.
The Residue of Concern is: per #22.
(For discussion, refer to 1/30/89 review, W. Chin, PP#6F3380.)
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 (found in 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 ^{Petition Method Validation?} ~~Method Trial~~? (Yes, No) At least three.
 If yes, provide details: Both a GLC and HPLC procedure have previously undergone successful petition method validation (PMV); see Residue Chemistry science support chapter (5/31/85).
 If no, is a ^{PMV} ~~Method~~ Trial needed? One has been requested for this HPLC procedure (7/7/87 memo, J. Stokes, PR# 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):
- | | | | |
|--------------|------------|----------|-----------|
| turnip roots | glyphosate | 0.08 ppm | 88%, 100% |
| | AMPA | " | 78%, 113% |
| turnip tops | glyphosate | 0.08 ppm | 75%, 113% |
| | AMPA | " | 78%, 88% |
| turnip roots | glyphosate | 0.2 ppm | 117%, 86% |
| | AMPA | " | 80%, 91% |
| turnip tops | glyphosate | 0.2 ppm | 92%, 86% |
| | AMPA | " | 80%, 94% |
29. Method Validation (limit of detection and/or sensitivity in ppm):
 Parent: 0.05 ppm
 Metabolite(s) (specify): AMPA, 0.05 ppm
30. Method Validation (state crops and control values reported):
turnip roots: <0.05 ppm glyphosate; <0.05 ppm AMPA
turnip tops: <0.05 " " <0.05 " "
31. Adequate Analytical Method(s) (are) are not Available for Enforcement Purposes.
 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: No data available, but this requirement is waived for this petition since only a minor crop (turnips) is involved.

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.

34. Residue Data (RAC(s) and Processed Commodities)

- 3 1987 studies (IL, SC, VT) conducted as requested by the Reg. Std. (see Table A, footnotes 9 and 12); namely, two preplant applications with 0.96% RTU equivalents foliarly applied to weeds. Turnips were seeded 3-8 days following the last application, grown to maturity, and root and top samples collected at harvest and frozen 'til analysis (3-7 months later) by HPLC (see #25).

NDR of glyphosate or its AMPA metabolite were reported in any turnip root or top sample. Method sensitivity = 0.05 ppm for each component of the residue in these matrices.

- 1 1987 field trial (CA) conducted per the proposed label directions for use; viz, 2 sequential preplant applications at the rates of 2.25 and 3.75 lbs ae (# 3.0 and 5.0 lbs ai) per acre using a high volume (48 gpa) or low volume (5 gpa) delivery rate. Turnips were seeded 4 days following the last application, and tops and roots collected for analysis at normal harvest. (Frozen storage interval = 6 months.) HPLC procedure (see #25) was used.

NDR of glyphosate or AMPA metabolite were reported in any turnip top or root sample, at a method sensitivity of 0.05 ppm each.

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.

turnip roots	glyphosate AMPA	0.08 ppm	100% 88%	2 months
" tops	"	"	113% 88%	"
" roots	"	0.2 ppm	91, 83 75, -	5-6 months 6 months
" tops	"	"	75, 58 60, -	5-6 months 6 months

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: _____

38. Residues will not exceed proposed tolerance(s) on (commodities)

turnip roots (0.2 ppm) or turnip greens (0.2 ppm)

but may exceed proposed tolerance(s) on (commodities) _____

N/A

39. Livestock Feeding Studies on (species): cattle, poultry, and swine (PP# 5F1536)(PP# 6F3380, 1/30/89 review)

40. Animal Feeding Levels: cattle, poultry, and swine using a 3:1 ratio of glyphosate:AMPA at dietary levels of 0, 10, 30, and 100 ppm (pp# 5F1536) and a 9:1 ratio of glyphosate:AMPA at dietary levels of 0, 40, 120, and 400 ppm (discussed in 1/30/89 review, W. Chin, pp# 6F3380).
41. Animal Residue Ingestion Levels from Proposed RAC Tolerance(s)
Levels (proposed tolerance level ^{0.2 ppm} x percent in diet ^{10-20%}): 0.04 ppm in beef cattle; 0.02 ppm in dairy cattle/goats; N/A ppm in hogs; N/A ppm in horses; N/A ppm in sheep; N/A ppm in poultry.
42. Livestock Tolerances are Adequate in (species) all regulated species, as established in 40 CFR 180.364 (b), but not adequate in N/A
43. Livestock Tolerances Need to be Established: Yes (No). If yes, species/levels: Already established: 40 CFR 180.364 (b)
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 IR4 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 turnips (see #28-30) and representative chromatograms were submitted as part of this petition.
46. Additional Information Needed: _____

None

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47. Background Information: Tolerances of 0.2 ppm are presently established (40 CFR 180.364(a)) for the combined residues of glyphosate and its AMPA metabolite in or on turnips (roots) as a member of the root crop vegetable group and turnips (greens) as a member of the leafy vegetable crop group. Those two crop groups are now obsolete, and no data (until now) were available to support the established tolerances on turnips when considered separately (i.e., apart from these now defunct crop groups). For this reason, the Reg. Std. (Table A, footnotes 9, 11, 12) and its Residue Chemistry Section Support Chapter (5/31/85 pp. 85-86 and 91-92) requested submission of field trial data for turnip roots and tops to support the establishment of tolerances for turnip roots and tops as individual tolerances dissociated from these obsolete crop groups. These data were needed to update the 40 CFR 180.364(a) listing and to permit the continued registration of the uses on turnips.
48. RECOMMENDATIONS: TOX considerations permitting, DEB recommends in favor of the requested tolerances, as proposed. (Also note # 49.)
49. Other Comments Under Recommendations: PM, turnips (greens) and turnips (roots) tolerances are to be individually listed in 40 CFR 180.364(a), and simultaneously deleted from inclusion in the leafy vegetable and root crop vegetable group listings of §180.364(a).
50. Compatibility with Codex Tolerances? (Explain) No; see attached. TOX considerations dictate inclusion of AMPA in USA tolerance expressions, and 0.2 ppm is needed for compatibility with USA tolerances on related crops within §180.364(a).

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

(2)

cc: RF, Circ, Reviewer, PP# 8E3696, DEB Chief, FDA, PMSD/ISB, TAS/SAOS/SACB.
Approved: RSQuick R. Quick 2/10/89; RALoranger R. Loranger 2/10/89.

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Glyphosate

CODEX NO. 159

CODEX STATUS:

☒ No Codex Proposal
Step 6 or above (for turnips)

Residue(if Step 8): _____

Glyphosate

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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PROPOSED U.S. TOLERANCES:

Petition No. 8E3696

RCB Reviewer Nelson

Residue: parent + AMPA

met. per 180.364(a)

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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turnip roots	0.2
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" greens	0.2
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CANADIAN LIMITS:

☐ No Canadian limit

Residue: _____

glyphosate

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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all food crops	0.1*
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MEXICAN LIMITS:

☒ No Mexican limit

Residue: _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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NOTES:

* Negligible residue limit