PP# 9E3715

DIETARY EXPOSURE BRANCH, HED

DATA REVIEW QUICK FORM

Date: APR 5 1989

MEMORANDUM

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

FROM: Maxie Jo Nelson, Chemist mjn
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division, H7509C

THRU: Robert S. Quick, Section Head RSQ
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division, H7509C

TO: Hoyt Jamerson PM 43
Registration Division, H7505C

and

Toxicology Branch—HFA Support
Health Effects Division, H7509C

1. Petition No(s): 9E3715
2. DEB No(s): 4907 HED No.: 9-0746A
3. MRID No(s): NONE
4. Pesticide(s): Glyphosate
5. Tolerance Proposal (RACs & Levels): Longan, Mamey Sapote, Lychee, Sapodilla, and Passion Fruit @ 0.2 ppm
6. Petitioner: IR-4 and Ag Exp Station of Fla

(1) 1/10

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

8. Established Pesticide Tolerances: 40 CFR 180.

N-PHOSPHONOMETHYL GLYCINE AND METABOLITE: AMINOMETHYLPHOSPHONICACID
40 CFR 180.364; 185.3500; 186.3500

(A) HERBICIDE and AMINOMETHYLPHOSPHONICACID:

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

9.

(B) GLYPHOSATE ISOPROPYLAMINE SALT and its metabolite AMINOMETHYLPHOSPHONICACID 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	3.0	Shellfish
0.5	Goats, Liver & Kidney	0.5	Poultry, Liver & Kidney	2	Sugarcane

10.

(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):

11/17/88 - 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).

16. Proposed Use(s): For control of various emerged annual and perennial weeds. Add longan, mamey sapote, lychee, and sapodilla to the Roundup label under Tree Crops - Tropical Fruit and passion fruit under Vine Crops. Apply as a directed spray onto emerged weeds at rate(s) dependent upon weed height and species. Repeat treatment(s) are allowed. Do not apply more than 10.6 qts of product/A/year. Allow a minimum of 14 days between last application and harvest. Avoid contact of spray with desirable vegetation. 0.5-1.0 % nonionic surfactant concentration may be present in the spray mix. 2% dry ammonium sulfate may also be added (See #45).

USAGE ON TREE AND VINE CROPS:

→ The registered label allows tank mixtures of Roundup® with various other pesticidal products, none of which have tolerated residues on the subject RACs of this petition. Revised directions for use are needed for these subject RACs which specify that application of tank mixtures is not permitted.

17. Plant Metabolism Data on: No new studies were submitted. Metabolism studies on a variety of crops (citrus, coffee, pome fruits, nuts, alfalfa, grapes, sugarcane, soybeans, 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)
N/A. No residue field trials or analytical methodology were submitted for the RACs of this petition.

Enforcement methodology is available; see PAM II.

(Petition Method Validation)

26. Has there been a Method Trial? (Yes, No) Yes, 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? _____

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):

See petitions on other tree and vine crops with tolerated residues of glyphosate and AMPA (see #8). Those data are being translated to support the tolerance requests of this petition.

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

Parent: See comments, #25 and #28.

Metabolite(s) (specify): Ibid.

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

See comments, #25 and #28.

31. Adequate Analytical Method(s) (are)/are not Available for Enforcement Purposes.

These Method(s) are located: PAM II.

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: Per MRM Decision Tree; however, these data are waived for this minor crops 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.

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

None; see #25 and #28.
See #8 for a listing of tree and vine crops with tolerated residues of glyphosate and AMPA.
See Roundup® label (pp 19-20, this petition) for similarities in treatment regimen.
As indicated in #18, only a limited uptake of residue would be expected.

Based on the existing data base (plant metabolism and residue field trial) on fruit tree and vine RACs treated with glyphosate, and the established tolerances @ 0.2 ppm on such RACs, the requested tolerances of this petition are supported (by translation of existing data and tolerances on related tree and vine RACs).

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

If yes, give RACs/fortification levels/length of storage/recovery range/conditions of storage (°C): Same comment as in #28.

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

If yes, list States in which use is sought: _____

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

37. Geographic Representation is/is not adequate. If no, list RAC(s) and States from which additional data are needed: _____

N/A; see #34. By translation of data from other related crops, geographic representation is adequate.

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

#5

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: _____

45. Other Considerations: The use of ammonium sulfate as an adjuvant with Glyphosate (Roundup) has recently been commented on (see 6/8/88 memo, C. Deyrup, Cty. Reg. Std. file). Since this IR-4 petition does not propose foliar applications to RACs, the concern raised by DEB in the aforecited memo does not apply to this petition.

46. Additional Information Needed: None.

47. Additional Data Needed: None.

There were no deficiencies raised by the Glyphosate Registration Standard which would preclude the translation of the existing data from the fruit tree and vine RACs with tolerated levels of glyphosate and AMPA to support the requested tolerances on the RACs of this petition.

48. RECOMMENDATIONS: TDX considerations permitting, PEB recommends in favor of the establishment of the proposed tolerances (per #5, for 40 CFR 180.364(a)), PROVIDED the petitioner submits the requested revised Section B (see #16).

49. Other Comments Under Recommendations:

50. Compatibility with Codex Tolerances? (Explain) See Attachment. There is no Codex proposal @ step 6 or above for glyphosate and no Mexican IRL 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 regulations too. Thus, no compatibility in tolerance level or expression with Canada is possible.

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

(2)

cc: RF, Circ, (7) Reviewer, PP# 9E3715, R. Schmitt, [redacted] (Eldredge), PMSD/ISB, [redacted]

Approved: RSQuick RMS 4/4/89; RALoranger LED 4/4/89.

INTERNATIONAL RESIDUE LIMIT STATUS

T. Nelson 11/3/89

CHEMICAL Glyphosate

CODEX NO. 158

CODEX STATUS:

☑ No Codex Proposal (on crops listed)
Step 6 or above

Residue (if Step 8): _____

glyphosate parse (on other crops)

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. 9E3715

RCB Reviewer Nelson

Residue: glyphosate and N-aminomethylphosphonic acid

Crop(s)	Limit (mg/kg)
Longan, Mamey Sapote, Lychee, Sapodilla, Passion Fruit	0.2

CANADIAN LIMITS:

☑ No Canadian limit

Residue: _____

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

MEXICAN LIMITS:

☑ No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES:
* Negligible residue limit

Form revised 1986