

DIETARY EXPOSURE BRANCH, HED
DATA REVIEW QUICK FORM

JUL 20 1990

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, H7509C *mjn*

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

TO: H. Jamerson / A. Beard PM 43
Registration Division, H7505C

and

Toxicology Branch
Health Effects Division, H7509C

1. Petition No(s): OE3873
2. DEB No(s): 6828 HED No.: 0-1524
3. MRID No(s): None
4. Pesticide(s): Glyphosate
5. Tolerance Proposal (RACs & Levels):
genip @ 0.2 ppm
(genip = a tropical fruit tree)
6. Petitioner: IR-4 and Ag Exp. Stn. of PR

PPM CROP PPM CROP PPM CROP
 GLYPHOSATE (A - HERBICIDE, B - GROWTH REGULATOR,
 C - IRRIGATION WATER)
 N-PHOSPHONOMETHYL GLYCINE AND METABOLITE: AMINOMETHYLPHOSPHONICACID
 40 CFR 180.364; 185.3500; 186.3500

7.

(A) GLYPHOSATE and its metabolite AMINOMETHYLPHOSPHONIC ACID resulting from the application of the isopropylamine salt of glyphosate and/or the monoammonium salt of glyphosate			
0.2	Acerola	0.1	Fruiting Vegetable Group (Except Cucurbits)
200.0	Alfalfa	0.1(N)	Grain Crops
0.2	Alfalfa, Fresh	0.2	Grapes
0.2	Alfalfa, Hay	0.2	Grasses, Forage
1	Almond Hulls	0.2	Guavas
0.2	Artichokes, Jerusalem	0.2	Horse radish
0.5	Asparagus	0.2	Jaboticaba
0.2	Atemoya	0.2	Jackfruit
0.2	Avocados	0.2	Kiwi Fruit
200.0	Bahia grass	0.2(N)	Leafy Vegetables
0.2	Bananas (Plantains)	0.4	Legumes, Forage (Except Soybeans & Peanuts)
0.2	Beets	0.2	Longan
200.0	Bermudagrass	0.2	Lycée
200.0	Bluegrass	0.2	Mamey Sapote
0.2	Breadfruit	0.2	Mangoes
200.0	Bromegrass	0.2	Nuts
0.2	Bulb Vegetables	0.2	Olives
0.2	Canistel	0.1FA	Olives, Imported
0.2	Carrots	200.0	Orchardgrass
0.2	Carambola	0.1FA	Palm Oil
0.2	Chicory	0.2	Papayas
0.2	Citrus Fruits	0.2	Parasprings
0.4FA	Citrus Pulp, Dried	0.2	Passion Fruit
200.0	Clover	0.5	Peanuts Hulls
0.1	Coconut	0.1	Peanuts
1	Coffee Beans	0.5	Peanuts, Forage
15	Cotton, Forage	0.5	Peanuts, Hay
15	Cotton, Hay	0.2	Persimmons
15	Cottonseed	0.1	Pineapples
0.2	Cranberries	0.2	Pistachio Nuts
0.5	Cucurbits (Vegetable Group)	0.2	Pome Fruits
0.2	Dates	0.2	Potatoes
200.0	Fescue		
0.2	Figs		
		0.2	Radishes
		0.2	Rutabagas
		200.0	Ryegrass
		0.2	Salsify
		0.2	Sapodilla
		0.2	Sapote, Black
		0.2	Sapote, White
		0.2(N)	Seed & Pod Vegetables
		0.2(N)	Seed & Pod Vegetables, Forage
		0.2(N)	Seed & Pod Vegetables, Hay
		0.2	Small Fruits & Berries Group
		0.2	Soursop
		6	Soybeans
		15	Soybeans, Forage
		15	Soybeans, Hay
		20 FA	Soybeans, Hulls
		0.2	Stone Fruit
		0.2	Sugar Apple
		0.2	Sugar Beets
		30.0 FA	Sugarcane Molasses
		0.2	Sweet Potatoes
		0.2	Tamarind
		1.0 FA	Tea
		1.0 FA	Tea, Dried
		4.0 FA	Tea, Instant
		200.0	Timothy
		0.2	Turnips
		0.2	Vegetables, Leafy, Brassica (Cole)
		200.0	Wheat Grass
		0.2	Yams

(B) GLYPHOSATE and its metabolite AMINOMETHYLPHOSPHONIC ACID resulting from the application of the glyphosate isopropylamine salt and/or glyphosate monoammonium 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	Horses, Liver & Kidney	0.5	Poultry, Liver & Kidney
0.25	Fish	0.1	Peanuts	0.5	Sheep, Liver & Kidney
0.5	Goats, Liver & Kidney	0.5	Peanuts, Hay	3.0	Shellfish
0.5	Hogs, Liver & Kidney	0.5	Peanuts, Hulls	2	Sugarcane

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): _____

3/21/90 - Monsanto

access authorized to all pertinent data on glyphosate

13. Formulation(s): Roundup® Herbicide, EPA Reg. No. 524-308,
a water-soluble liquid formulation containing 4 lbs per US gallon
of the a.i. glyphosate, in isopropylamine salt form.

14. Inerts Status: Under RD purview

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

16. Proposed Use(s): As a directed spray to the orchard floor for control of various emerged annual and perennial weeds. Rate(s) are dependent upon weed height and species. Repeat applications are allowed. Do not apply more than 10.6 quarts (10.6 lbs ai) of product /A/year. 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 #15). A minimum PHI of 14 days is proposed.

→ Section B needs to be revised to specify usage is to follow that of "Tree and Vine Crops" on the registered Roundup label. Genip should be added to the label under the "Tree Crops - tropical fruit" subheading of the "Tree and Vine Crops" portion of the label.

→ Also, Section B needs to be revised to add a restriction against tank mixing in conjunction with the proposed use.

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.

[RAC = raw agricultural commodity]

(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):
Reference petitions on other tree crops with tolerated residues
of glyphosate and AMPA (see #7). 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 Enforce-
ment Purposes.
These Method(s) are located: PAM II.

32. PAM I Multiresidue Methods Data are available for parent pesticide tested via Protocols **A B C D E** (circle, as applicable).

Additional multiresidue test information for parent compound that is needed: Not applicable, owing to the chemical nature of the chemical. See discussion of F. Griffith, 7/13/90 review, PP# 8F3673.

33. PAM I Multiresidue Methods Data are available for metabolite(s) tested via Protocols **A B C D E** (circle, as applicable).

Additional multiresidue test information for metabolite(s) that is needed: Same as #32.

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

None for the subject RAC, genip. (See #25 and 28).
See #7 for a listing of numerous tree crops with tolerated residues of glyphosate and AMPA @ 0.2 ppm.
See Roundup® label (p. 21, this petition) under "Tree Crops" for similarities in treatment regimen.
As indicated in #18, only a limited uptake of residues would be expected.

Based on the existing data base (plant metabolism and residue field trial) on various fruit tree RACs treated with glyphosate, the similarities in directions for use, and the established tolerances @ 0.2 ppm on such RACs, the requested tolerance of this petition is supported (by translation of existing data and tolerances on related fruit tree 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
N/A in beef cattle; _____ ppm in dairy cattle/goats; _____ ppm in
hogs; _____ ppm in horses; _____ ppm in sheep; _____ ppm in
poultry.
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, Gly. Reg. Std. file). Since this IR-4 petition
does not propose foliar applications to RACs, the concern raised by DEC in
the cited memo does not apply to this petition.
46. Additional Information Needed: None.

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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 numerous fruit tree RACs with tolerated levels of glyphosate, and AMPA to support the requested tolerance on the RAC of this petition.

48. RECOMMENDATIONS: TOX considerations permitting, DEB recommends in favor of the establishment of the proposed tolerance (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)

cc: RF, Circ, Reviewer, PP# OE3873, R. Schmitt, ^{(C. Furlow) (J. Kariya)} PIB/FOD, DRES/SACB, FDA.
Approved: RSQuick DMP 7/20/90; RALoranger RAL 7/20/90.

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Glyphosate

CODEX NO. 158

CODEX STATUS:

☒ No Codex Proposal
Step 6 or above (on genip)

Residue(if Step 8): _____

glyphosate parent

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

Petition No. OE3873

RCB Reviewer Nelson

Residue: parent + AMPA

(40 CFR 180.364)

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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genip

0.2

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*

MEXICAN LIMITS:

☒ No Mexican limit

Residue: _____

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

* Negligible residue type tolerance

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