(661A)

RESIDUE CHEMISTRY BRANCH, HED
PETITION REVIEW QUICK FORM

JUL 14 1982

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FROM: M. Nelson, Chemist
Residue Chemistry Branch
HED (TS-769)

THRU: C. Trichilo, Chief
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R P Schmitt for

TO: R. Taylor, PM 25
Registration Division (TS-767)

and

Toxicology Branch
HED (TS-769)

1. Petitioner: Monsanto
2. Petition No(s).: 2F2680/2H5339
3. Chemical(s): Glyphosate
4. Tolerance Proposal (RAC's & Levels): copra – 0.1 ppm (rac) coconut oil, copra meal, desiccated coconut – 0.1 ppm (FAT's
5. Tolerance Expression: glyphosate and its metabolite aminomethylphosphonic acid
6. Established Tolerances: 40 CFR 180.364; 21 CFR 561.253 and 193.235. 0.1-30 ppm. Includes 0.1 ppm – palm oil
7. Letter(s) of Authorization (if applicable): N/A
8. Formulation(s): Roundup (EPA Reg. No. 524-308) Contains 3 lbs glyphosate (acid form)/gal.
9. Inerts Status: all cleared

10. Manufacturing Process: Submitted with PP# 6E1809; detailed in D. Duffy review of 11/30/76, PP# 6G1826/FAP# 6H5140.

N-nitrosoglyphosate is present as an impurity and has previously undergone hazard assessment review (see 5/25/78 memo, R. Taylor, FAP# 6H5149 correspondence).

11. Proposed Use(s): As a directed foliar postemergent spray to undesired vegetative growth in coconut plantations. Do not apply more than 5.3 qts (4 lbs ai)/A/application. Do not exceed 16 qts (i.e., 3 applications)/A/year. Minimum 7-day PHI. Avoid contact with coconut fruit, foliage, branches, and suckers because damage or destruction may occur.

12. Plant Metabolism Data on: Orchard and tree nut crops, vegetables, root crops, small grains, cotton, et al.

13. Plant Residues Comprised of: parent undergoes C-N bond cleavage to form glyoxylate (natural plant constituent) and major metabolite aminomethylphosphonic acid.

14. Plant Metabolism Data Translatable Here: #12, especially tree nut crops.

15. Nature of Plant Metabolism Data (is)/is not adequately defined. The Residue of Concern is: parent and aminomethylphosphonic acid metabolite

16. Animal Metabolism Data on: rats, rabbits, and cows

17. Animal Residues Comprised of: parent mainly with some aminomethylphosphonic acid metabolite

18. Animal Metabolism Data Applicable Here: #16, especially cow.

19. Nature of Animal Metabolism Data (is)/is not adequately defined The Residue of Concern is: parent and aminomethyl-phosphonic acid metabolite

20. Analytical Methods (reference or brief description): None submitted. Residue data will be translated from oil palms (FAP# 6H5144) and that data was obtained via the PAM II method. Glyphosate and metabolite are extracted, cleaned up, derivatized, and analyzed (as 2 peaks) by FPID-GLC. Sensitivity: 0.05 ppm per component. MTD in PP# 5F15

21. Method Validation (crop recoveries): palm oil fortified with 0.05-0.4 ppm parent or metabolite. Recoveries: 53-97%. (Translate to coconut). Tree nut data also available.

22. Method Validation (control values): palm oil < 0.05 ppm each component (translate to coconut). Other, incl. tree n

23. Residues Determined by Method: See #20

24. Enforcement Methodology (is)/is not available.

25. Residue Data (crop and maximum residue from Proposed Use):

Crop (ppm range): translating from palm oil (FAP* 6HS in which NDR were reported. No f trial data submitted for coconuts.

NDR (<0.05 ppm each component)

1-2X rates (4-8 lbs ai/A/applm)

1-14 day PHI's

4 locations in Malaysia

Other Comments: Glyphosate exhibits only limited uptake from soil a proposed use is for a directed spray to weeds (not to contact coconut plant pa There NDR would be expected (conservative only) in "coconuts". We are translating residue data from palm oil in absence of coconut data; use is identical and cultural practice and botany closely related.

26. Residues will not exceed proposed tolerance on (commodities) "coconut" (the rac) or its processed byproducts, inclu copra oil (aka coconut oil); NDR (<0.05 ppm, each residue component) are expected in any of these commoditi

27. Livestock Feeding Studies on (species): cattle, poultry, swine

28. Animal Feeding Levels: 10, 30, 100 ppm

29. Animal Residue Ingestion Levels from Proposed Crop Tolerance Levels (proposed tol. level x % in diet): COPRA MEAL-0.1 ppm 0.015 ppm in beef cattle; 0.015 ppm in dairy cattle/goats; N/A ppm in hogs; 0.015 ppm in horses; 0.01 pp in sheep; 0.015 ppm in poultry.

30. Livestock Tolerances are Adequate in (species) cattle, goats, horses, poultry, and sheep, but not adequate in _____, _____, _____, _____

(species/levels): Necessary livestock tolerances already exist.

32. Other Comments: Import tolerance(s) are involved in this petition. Clarification is requested as to the specific countries of intended use and information on the registration policies in those countries should be submitted.

33. Other Considerations: What to regulate? We consider the rac to be "coconut". This would include the fresh "meat" and the "milk" but, i enduzing the "shell" would be excluded as with other nuts. The terminol "coconut" is also consistent with the Codex commodity definitions. Coconut byproducts are copra ("dried meat"), copra oil (aka coconut oil), copra meal a desiccated coconut. In this petition, food additive tolerances are not needed for these since no concentration in byproducts would be expected. Revised Sec F ~~34. Additional Data Needed.~~ Are there feed item(s)? If copra is processed into oil within the USA, which is a possibility, then the residue: copra meal — would be a livestock feed item. If processing of the oil is performed outside the USA, which is most likely the case to a lar extent, we consider it unlikely that it would be economically advanta to import copra meal for feed usage. In any event, the "coconut" tolerance would cover residues therein and adequate meat tolerances exist.

35. Recommendations: Negative. We need: (1) revised Section F proposing a pesticide tolerance for "coconut" at 0.1 ppm. All other proposed tolerance are unnecessary and should be deleted. No food additive tolerances needed. "Coconut" is considered the rac. Ref. #33; (2) clarification as to the specifi countries of intended use and information on the regulatory policies in those countries. Ref. #32.

36. Other Comments under Recommendations:

37. Compatability with Codex Tolerances: N/A for coconut or its by-products. See attachment.

cc: RF, Circ, Reviewer, Thompson, Tox, EEB, EFB, FDA, PP#

Approved: Quick 7 | 14 | 82 DNI Schmitt 7/14/82 RA

CHEMICAL Glyphosate

CCPR NO. None

PETITION NO 2F2680/2H5339

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Codex Status

☑ No Codex Proposal Step 6 or above

Proposed U. S. Tolerances

for 180.364 and 193.235

Residue (if Step 9): _____

Residue: glyphosate and aminomethylphosphonic acid

Crop(s)	Limit (mg/kg)
None	

Crop(s)	Tol. (ppm)
Copra	0.1
coconut oil	0.1
copra meal	0.1
desiccated coconut	0.1

FAT's

CANADIAN LIMIT

Residue: _____

Crop	Limit (ppm)
none (on above commodities)	

MEXICAN TOLERANCIA

Residue: _____

Crop	Tolerancia (ppm)
none	

Notes: