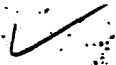


US EPA ARCHIVE DOCUMENT

MAY 7 1981



MEMORANDUM

SUBJECT: EPA 2490. Glyphosate in or on mangoes. Evaluation of analytical methodology and residue data.

FROM: S. Nelson, Ph.D., Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Minor Uses Officer
Process Coordination Branch
Registration Division (TS-767)
and
Toxicology Branch
Hazard Evaluation Division (TS-769)

INFO: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

IR-4, on behalf of the IR-4 Technical Committee and the Agricultural Experiment Stations of Florida and Puerto Rico, proposes the establishment of a tolerance for combined residues of glyphosate (Roundup; N-phosphonomethyl glycine) and its metabolite aminomethylphosphonic acid resulting from herbicide application of the isopropylamine salt of glyphosate in or on the raw agricultural commodity mangoes at 0.2 ppm.

A considerable number of pesticide (40 CFR 180.364) and food (21 CFR 193.235) and feed (21 CFR 541.253) additive tolerances are already established--or co-pending--for aforesaid combined residues on a wide variety of commodities at levels of 0.1-30 ppm, including various tree fruit (avocados, bananas, citrus, guavas, papayas, pear fruit, stone fruit) and nut crops at 0.2 ppm.

This petition contains a letter of authorization from Monsanto permitting EPA to use data in Monsanto's files to support this tolerance proposal by IR-4.

Conclusions

1. The nature of the residue in plants and animals is adequately defined. The residue of concern is glyphosate and its aminomethylphosphonic acid metabolite.
- 2a. Aminomethylphosphonic acid is an impurity of the technical and formulated products. However, as a result of a hazard assessment review, this will not be a bar to the proposed tolerance.

NEED INGREDIENT INFORMATION Deleted

- 2b. [] is an impurity of the surfactant presently used in the formulation. [] has expressed concern over this and requested additional information. Little, if any, residue of [] would be expected in ranges from the proposed use (directed spray to the orchard floor). [] is cleared under 40 CFR 180.1001(d) for use as a (co)solvent.
- 3. Adequate analytical methodology is available to enforce the proposed tolerance.
- 4. Based on translation of residue data from various other tree crops (e.g., guavas, panayas, avocados) treated by this same proposed use pattern, we would expect residues (if any are detectable) to be well within the proposed tolerance level.
- 5a. A label restriction prohibits feeding or foraging for 8 weeks after application. Any residues remaining in cover crops after that period should not result in overtolerance residues in meat or milk. (There are cover crop and meat and milk tolerances already established.)
- 5b. There are no feed items associated with mangoes. There will thus not be any transfer of residues to meat, milk, poultry, or eggs from that commodity.
- 6. An International Residue Limit (IRL) Status sheet is attached. According to it, no IRL's for glyphosate residues in mangoes have been established in Canada, Mexico, or by Codex. There is a Canadian IRL for glyphosate (parent only) residues in stone fruits at 0.1 ppm.

Recommendation

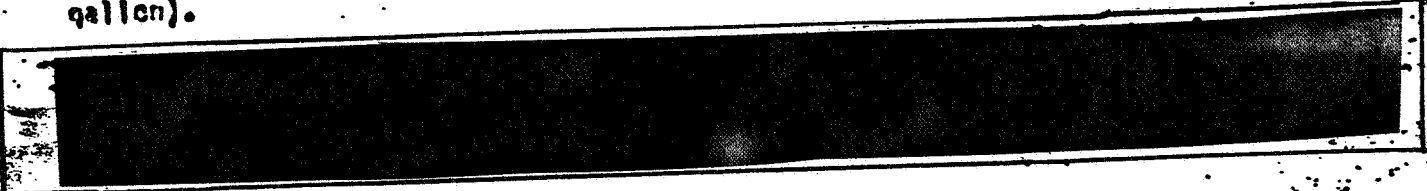
Toxicological considerations permitting (see Conclusion 2b), we recommend for the establishment of the proposed tolerance. (The TOX review has not yet been received in RCB.)

DETAILED CONSIDERATIONS

Manufacture and Formulation

The manufacturing process for technical glyphosate has previously been submitted (PP#6L1309).

The technical product is formulated as an aqueous concentrate containing 41% of the isopropylamine salt of glyphosate as active ingredient. This formulation, trade name Roundup (EPA Reg. No. 524-252-AA), contains 4 lbs of the active ingredient per gallon (which is equivalent to 3 lbs of glyphosate (acid) per gallon).



INERT INGREDIENT INFORMATION
Deleted

OK
2/1/78
PS

An additional impurity of the technical product also present in the formulation is N-nitrosoglyphosate (NNG), which has previously been reported at levels up to 0.4 ppm. NNG has been subjected to a hazard assessment review (see 8/24/78 memo of R. Taylor, RD) with the consequence that OPP does not bar the establishment of glyphosate tolerances because of its presence (per 9/5/78 memo of R. Taylor, RD).

Recently, Monsanto (11/17/80 letter) has advised EPA that the present surfactant (presumably [redacted] used in Roundup herbicide contains a trace impurity of [redacted] is cleared for solvent use under 40 CFR 180.1001(d) and little, if any, [redacted] residue would be expected in or on manages because of the nature of the proposed use (orchard floor treatment). However, we note that questions re [redacted] have been raised by TOX (12/4/80 memo of S. Burin, PPFs 9E2421/1E2443/1E2448) in other recent glyphosate petitions, and that TOX is apparently withholding their support of pending glyphosate petitions pending resolution of this issue.

Proposed Use

The proposed use for Roundup in mango orchards is the same as that presently registered for other tree crops.

For the control of a variety of annual or perennial weeds, Roundup is to be applied postemergence to weeds with ground rig equipment as a directed spray to the orchard floor at rates up to 5 quarts of formulation (2.5 lbs ai)/20-100 gallons of H₂O/A. Repeat treatment(s) are permitted, so long as the combined total of all treatments does not exceed 10.6 qts per acre per year.

Restrictions: Allow a minimum of 14 days between last application and harvest. Do not feed or forage treated areas for 8 weeks after application. Avoid contact of spray, drift, or mist with green foliage, green bark, or bark of trees established less than 2 years, suckers, or fruit of desirable trees, crops, plants, or other desirable vegetation.

Nature of the Residue

Radiotracer metabolism studies with glyphosate in various plants (corn, soybeans, wheat, cotton, rice, barley, oats, sorghum, sugarbeets, sugarcane, potatoes, vegetables, grapes, coffee, citrus) and animals (rats, rabbits, cows) have previously been submitted and reviewed. No additional metabolism studies have been submitted with this present petition.

Briefly, in plants, the major metabolic pathway entails C-H bond cleavage to form aminomethylphosphonic acid (CP 50435) and glyoxalate. Further metabolism involves incorporation of fragments of these compounds into natural plant products.

For this proposed use (directed spray to the orchard floor), any residues in or on the tree fruit would be as a result of spray drift contamination.

In animals, glyphosate is rapidly excreted (90% within 5-7 days), mostly in the feces. The major component of the residue is glyphosate per se, with only trace amounts of aminomethylphosphonic acid being found.

We consider the nature of the residue in plants and animals to be adequately defined. The parent and its aminomethylphosphonic acid metabolic constitute the residue of concern.

Analytical Methodology

No analytical methodology was submitted with this petition since we are being asked to translate residue data from previous glyphosate petitions on related tree fruit crops to support the proposed tolerance on mangoes.

This presents no difficulty, however, since the basic methodology for glyphosate (plus metabolite) residues has previously undergone successful HPLC (soybeans, beef liver) by our chemists and has been adjudged adequate (1/5/77 memo of J. Cummings) for enforcement purposes.

That basic methodology has been validated for use on many diverse crops, including avocados, guavas, and papayas, and we consider it would be equally applicable to mangoes.

We conclude that adequate analytical methodology (GLC-FPD) is available in PAM II to enforce the proposed tolerance.

[Confirmatory methodology (HPLC) is also available, if needed.]

Residue Data

No residue data was submitted with this petition. In lieu of it, the petitioner requests we translate data from other tree crops (e.g., avocados, guavas, papayas, et al.) having established glyphosate tolerances (0.2 ppm) based on use patterns identical to those proposed for mangoes.

PCB does not object to translating residue data to support the presently proposed mango tolerance. On that basis, we would not expect any detectable residue (0.05 ppm each) of either glyphosate or its aminomethylphosphonic acid metabolite to be found in mangoes.

We can thus conclude that combined residues of glyphosate and aminomethylphosphonic acid will not exceed the proposed tolerance of 0.2 ppm from the proposed usage.

Residues in Meat, Milk, Poultry, and Eggs

A label restriction prohibits feeding or foraging areas for 8 weeks after application. Any residues remaining in cover crops after that period should not result in over-tolerance residues in meat or milk. (In addition to meat and milk, there are also established tolerances on forage: grasses, legumes, and alfalfa.)

There are no feed items associated with mangoes. There will thus not be any transfer of residues to meat, milk, poultry, or eggs from that commodity.

Other Considerations

An International Residue Limit (IRL) Status sheet is attached. According to it, no IRL's for glyphosate residues in mangoes have been established in Canada, Mexico, or by Codex. There is a Canadian IRL for glyphosate (parent only) residues in stone fruits at 0.1 ppm.

TS-769:RCH:H. Nelson:gs:X77377:CI#2:RMB10:5/4/81
cc: RF, Circ., Nelson, Watts, FDA, TOX, EEB, EFB, PP#1E2490
RDI: Quick, 4/16/81:Schmitt, 4/17/81

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Glyphosate*

PETITION NO. IE2420

CCPR NO. --

Codex Status

Proposed U.S. Tolerances

No Codex Proposal Step 6 or above

Residue (if Step 9): _____

Residue: glyphosate plus

NONE

aminomethylphosphonic acid metabolite

Crop(s) Limit (µg/kg)

Crop(s) Tol. (ppm)

NONE

Mangoes 0.2

CANADIAN LIMIT

MEXICAN TOLERANCIA

Residue: Parent

Residue: NONE

Crop Limit (ppm)

Crop Tolerancia (ppm)

Stone fruit 0.1

NONE

Notes: *H-phosphonomethylglycine