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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

FEB 17 1982

MEMORANDUM

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

Subject: PP# 2F2634. Glyphosate in or on pineapple. Evaluation  
of analytical methodology and residue data.

From: M. Nelson, Chemist  
Residue Chemistry Branch  
Hazard Evaluation Division (TS-769)

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

To: Robert Taylor, P.M. Team 25  
Herbicide-Fungicide Branch  
Registration Division (TS-767)

and

Toxicology Branch  
Hazard Evaluation Division (TS-769)

The Pineapple Growers Association of Hawaii requests that Mr. Edwin L. Johnson, Deputy Assistant Administrator for Pesticide Programs, Environmental Protection Agency, have established on the Agency's initiative a negligible tolerance level for the residue of Roundup® (active ingredient: glyphosate) in or on pineapple.

The proposed negligible level tolerance is requested by the pineapple growers as a precautionary measure. A special local need registration [i.e., 24 (c)] for the proposed use [i.e., non-crop use of the herbicide Roundup® during intercycle in pineapple fields] has already been issued to the Pineapple Growers Association of Hawaii by the State of Hawaii (9/30/81; SLN No. Hi-810011), and has been deemed a non-food use by this Agency (see letter of E. L. Johnson, ca 1/19/82).

Tolerances for residues of glyphosate are presently established (40 CFR 180.364) on a variety of crops at levels ranging between 0.1-15 ppm, with food/feed additive tolerances (21 CFR 193.235 and 561.253) up to 30 ppm. A number of glyphosate petitions are also co-pending; proposed tolerances are within the 0.1-30 ppm range.

A letter of authorization permitting access to its confidential data files on Roundup® in support of this tolerance request is anticipated to be forthcoming from Monsanto. This review is being undertaken with the understanding that such authorization will be obtained in writing prior to the establishment (if/when) of the proposed tolerance. (Telecon between M. Nelson and R. Taylor, 2/10/82).

### Conclusions

1. The nature of the residue is considered to be adequately understood based on translation of data from other crops. The residue of concern is parent glyphosate and its aminomethylphosphonic acid metabolite.
2. Adequate analytical methodology is available for enforcement purposes. However, since the proposed use has been deemed non-food, the need for enforcement action is unlikely.
- 3a. Detectable residues (0.05 ppm each) of glyphosate or the aminomethylphosphonic acid metabolite are not expected to occur in pineapple or pineapple processing by-products as a result of the proposed non-food use.

A tolerance for pineapple, if and when established as a result of the proposed use, will be purely as a precaution that the petitioner desires. The appropriate level for such a tolerance would be 0.1(N) ppm, which represents the combined method sensitivity levels of glyphosate and aminomethylphosphonic acid.

- 3b. The petitioner indicates that pineapple plant material remaining after harvest will be incorporated into the soil by repetitive plowing and harrowing. To preclude any feed use possibility, however, we request a label prohibition against utilization in the diet of livestock of pineapple plant material (forage, fodder, ensilage) grown in treated fields.
4. There is no reasonable expectation of secondary residues in meat, milk, poultry, or eggs from the proposed non-food use.
5. There are no relevant IRL/Codex considerations.

### Recommendations

Contingent upon receipt of a letter of authorization from Monsanto permitting access to their confidential data files on Roundup to support this petition request, and provided the proposed labeling is suitably amended (see Conclusion 3b) and toxicological considerations permit, RCB would not object if the Agency considered it administratively desirable to establish a method sensitivities level (0.1 ppm) negligible residue tolerance for combined residues of glyphosate and its aminomethylphosphonic acid metabolite in or on pineapple from the proposed non-food use.

## Detailed Considerations

### Manufacture and Formulation

Roundup®, EPA Reg. No. 524-308-AA, is the formulated product (4 lbs. isopropylamine salt of glyphosate a.i./gal.; equivalent to 3 lbs. glyphosate acid a.i./gal.) involved in the proposed use. The inerts in the formulation are cleared under Sec. 180.1001.

The manufacturing process for technical glyphosate was submitted in re PP# 6E1809. Manufacturing impurities will not cause a residue problem.

N-nitrosoglyphosate, while present at low levels, is not considered to constitute a hazard (ref. hazard assessment review memos of 8/24/78 and 9/5/78, R. Taylor).

### Proposed Use

For control of weeds in pineapple fields temporarily fallowed prior to cultivation and planting (i.e., during intercycle), Roundup® is to be applied by ground application at a rate not to exceed 4 qts. (3 lbs. glyphosate acid as a.i.) per acre in at least 12 gpa of spray mix.

Restrictions: Use only in Hawaii. Do not plant within 2 weeks of application. All applicable label directions, restrictions, and cautions on the Roundup® label must be followed.

### Nature of the Residue

No information was provided. However, radiotracer metabolism studies with glyphosate in various plants and animals are available in our files from previous Monsanto petition submissions. By translation of that data, we can conclude that the nature of the residue in plants (including pineapple) and animals is adequately understood, with the residue of concern being parent glyphosate and its aminomethylphosphonic acid metabolite.

### Analytical Methodology

No analytical method or validation data for pineapples by such a method was provided.

This presents no difficulty since an enforcement method (HPLC) that has been validated on many diverse crops and the basics of which have undergone successful method trial is available in PAM II for glyphosate residues.

The limit of sensitivity by that enforcement method is 0.05 ppm each for glyphosate and the aminomethylphosphonic acid metabolite. These two entities constitute the regulable residue.

[Note: since the proposed use is non-food (per E. L. Johnson letter of ca 1/19/82), the need for an enforcement method is actually a moot point in this instance anyway.]

#### Residue Data

No residue data was provided; however, the timing of the proposed use (during intercycle) and the nature of glyphosate metabolism (relatively rapid breakdown and absence of translocation) have led the Agency to conclude that a non-food use is involved (see aforescited E. L. Johnson letter).

If the Agency considers it administratively desirable to establish a tolerance for this non-food use in the absence of known residues and no present glyphosate tolerance on pineapple, we would consider 0.1(N) ppm to be an appropriate level. This represents the combined method sensitivity levels of parent plus the aminomethylphosphonic acid metabolite, and is the lowest level at which glyphosate tolerances have heretofore been established. (A note from E. L. Johnson to D. Camp, 1/18/82, requests a glyphosate tolerance at a suitably low level be established in conjunction with the 24(c) registration on pineapples.)

Since no detectable residue is anticipated in harvested pineapples (built-in PHI of at least 21 months) from this non-food use, there is also no reasonable expectation of finding detectable residues in pineapple bran, a processing by-product and livestock feed item. We therefore conclude a feed additive tolerance is not required.

As for pineapple forage and fodder, the petitioner indicates that the pineapple plant material (referred to as trash) remaining after harvest is incorporated into the soil by repetitive plowing and harrowing. During the interim between harrowings, Roundup could be used for weed control.

We customarily consider pineapple forage and fodder (in the ensiled form) to be minor livestock feed items. Therefore, as a precautionary measure, we request that a restriction be added to the labeling to the effect: Do not utilize in the diet of livestock pineapple plant material (forage, fodder, ensilage) grown in treated fields.

#### Residues in Meat, Milk, Poultry, and Eggs

No detectable residues would be anticipated in pineapple bran from the proposed use. The feeding of pineapple plant material (i.e., forage, fodder, ensilage) will be prohibited by labeling.

There is thus no reasonable expectation of secondary residues in meat, milk, poultry, or eggs from the proposed non-food use.

Other Considerations

The IRL/Codex sheet is attached. There is no relevant foreign tolerance.

Attachment

TS-769:RCB:M.Nelson:MCH:X77377:OM#2:RM810:2/17/82  
cc: RF, Circ., M. Nelson, Thompson, TOX, EEB, EFB, FDA, PP# 2F2634  
RDI: Quick, 2/12/82; Schmitt, 2/12/82

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INTERNATIONAL RESIDUE LIMIT STATEMENT

CHEMICAL Glyphosate

PETITION NO 2F2634

CCPR NO. none

Codex Status

Proposed U. S. Tolerances

No Codex Proposal  
Step 6 or above

per 180.364

Residue (if Step 9): \_\_\_\_\_

Residue: glyphosate plus  
aminomethylphosphonic acid metabolite

Crop(s) Limit (mg/kg)

Crop(s) Tol. (ppm)

none

pineapple 0.1

CANADIAN LIMIT

MEXICAN TOLERANCIA

Residue: \_\_\_\_\_

Residue: \_\_\_\_\_

Crop Limit (ppm)

Crop Tolerancia (ppm)

none (on above commodity)

none

Notes:

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