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

SEP 30 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCE

MEMORANDUM

SUBJECT: PP#6E3424 (RCB#1528) - Glyphosate on Atemoya, Carambola and Sugar Apple - Evaluation of Analytical Methodology and Residue Data (Accession No. 263498)

FROM: Michael P. Firestone, Ph.D., Chemist
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

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

TO: Hoyt L. Jamerson, Minor Uses Officer
Registration Support and Emergency Response Branch
Registration Division (TS-767)

Interregional Research Project Number 4 (IR-4), on behalf of the IR-4 National Director, Dr. R. H. Kupelian, and the Agricultural Experiment Station of Florida, requests the establishment of a tolerance for the combined residues of the herbicide glyphosate [N-(phosphonomethyl) glycine] and its metabolite aminomethylphosphonic acid (AMPA) in or on the raw agricultural commodities atemoya, carambola and sugar apple at 0.2 ppm under 40 CFR 180.364.

The formulation proposed for use on the above three tropical fruits is Roundup herbicide, produced by Monsanto Company (EPA Reg. No. 524-308) which contains the isopropylamine salt of glyphosate as the active ingredient (3 lb acid equivalent/acre). Thus, IR-4 is actually requesting establishment of a glyphosate tolerance under subsection (a) of 40 CFR 180.364.

Glyphosate tolerances have been established under 40 CFR 180.364 for numerous crops at residue levels ranging from 0.1 to 200 ppm including several tree crop tolerances at 0.2 ppm (acerola, avocados, citrus fruits, figs, guava, mangoes, nuts, olives, papayas, pistachio nuts, pome fruits and stone fruit).

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IR-4 has included in its petition a letter from Monsanto Company dated June 6, 1986 (F. Serdy of Monsanto to J. Baron of IR-4) which authorizes EPA to refer to data in the Agency's files on glyphosate (EPA Reg. No. 524-308) in support of the registration of Roundup herbicide for use on atemoya, carambola, and sugar apple.

The glyphosate product and residue chemistry Registration Standard chapters were completed July 15, 1985.

Conclusions

1. RCB can reach no final conclusion regarding the likelihood that contaminants in the technical product will or will not result in a residue problem until issues involving identification/quantitation of nitrosamines presented in the Glyphosate Registration Standard (RS) have been resolved. However, since atemoya, carambola and sugar apples are minor crops, RCB defers to TOX as to whether it would be toxicologically feasible to forgo the preceding issues.

2. The nature of the residue in plants is considered adequately understood to support the proposed use; the parent compound and its metabolite N-aminomethylphosphonic acid (AMPA) are considered to be the residues of concern in plants.

3. Analytical methodology is available in the Pesticide Analytical Manual, Volume II (PAM-II) for enforcement purposes.

However, the published method is time-consuming, RCB has received reports from FDA and state agencies of difficulty in running the PAM-II method, and the method is not suitable for peanut vines and hay (PP#0F2329). RCB feels that the Registrant's HPLC ninhydrin post-column reactor method should be made available in PAM-II for enforcement purposes (see May 1, 1985 review of PP#5F3157/FAP#5H5446). Although the preceding concept is under consideration, it will not be considered as a deficiency in this review; the petitioner should be informed.

4. No residue data have been submitted to support the proposed glyhosate tolerances for atemoya, carambola and sugar apple.

However, since glyphosate tolerances of 0.2 ppm are established for a variety of different tree crop commodities for which the use pattern is very similar, RCB concludes that the proposed 0.2 ppm tolerances for the minor crops atemoya, carambola and sugar apple are adequately supported.

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It should be noted that additional residue data for some tree crop commodities (stone fruit, citrus fruit and mangos) have been requested in conjunction with the Glyphosate Registration Standard. Should these residue data demonstrate the inadequacy of established 0.2 ppm tolerances for any of these tree crop commodities, then tolerances of 0.2 ppm for atemoya, carambola and sugar apple may need future revision.

5. Since neither atemoya, carambola, or sugar apple are animal feed items, RCB concludes that there is no reasonable expectation of finite secondary residues in meat, fat, milk, poultry or eggs in accordance with 40 CFR 180.6 (a)(3).

6. An International Residue Limit Status sheet is included with this review as Attachment 1.

There are no compatibility problems with Codex and Mexico since no limits/tolerances are established for glyphosate residues in/on atemoya, carambola, and sugar apple.

The proposed 0.2 ppm tolerances are not compatible with Canada's 0.1 ppm "negligible residue type" limit established for all food crops.

Recommendation

RCB could recommend for the proposed glyphosate tolerances covering residues in/on atemoya, carambola and sugar apple at 0.2 ppm if the deference to TOX regarding the Registration Standard data gap on the identification/quantitation of possible nitrosamines present in glyphosate can be relinquished for these minor crop (see Conclusion No. 1 above).

Detailed Considerations

Manufacture and Formulation

The manufacture of glyphosate is discussed in the Registration Standard of July 15, 1985; data gaps involving description of beginning materials and manufacturing process (guideline reference No. 61-2), discussion of the formation of impurities (guideline reference No. 61-3), and analysis and certification of product ingredients (guideline reference Nos. 62-1, 62-2 and 62-3) are outstanding. RCB can reach no conclusion regarding the likelihood that contaminants in the technical product will or will not result in a residue problem until issues involving identification/ quantitation of nitrosamines presented in the Glyphosate Registration Standard have been resolved.

However, since atemoya, carambola and sugar apples are minor crops, RCB defers to TOX as to whether it would be toxicologically feasible to forgo the preceding issue.

The formulation proposed for use on atemoya, carambola and sugar apple is Roundup Herbicide (EPA Reg. No. 524-308), a water soluble liquid, which contains 41.0% isopropylamine salt of glyphosate (4 lb ai/gal or 3 lb acid equivalent/gal).

Proposed Use on Atemoya, Carambola, and Sugar Apple

Glyphosate is recommended for weed control in established groves or orchards. Applications made be made with boom equipment, shielded sprayers, hand-held and high-volume wands, lances, or orchard guns, or with wiper applicator equipment.

The label limits the amount of glyphosate applied per year to 10.6 quarts (7.95 lb acid equivalent) per acre.

Also, the label includes a minimum PHI (preharvest interval) of 14 days.

The use pattern is the same as that established for mangos and avocados.

Nature of the Residue in Plants

The metabolism of glyphosate in plants has been discussed in the July 15, 1986 Registration Standard (RS). Foliarly applied glyphosate is readily absorbed and translocated from treated areas to untreated shoot regions and fruits of tree crops such as apples, pears and citrus. The metabolism of glyphosate occurs via N-methylation and ultimately yields N-methylated glycine and phosphonic acids. According to the RS, the metabolism of glyphosate in plants has been adequately described; the parent compound and its metabolite N-aminomethylphosphonic acid (AMPA) are considered to be the residues of concern in plants.

Analytical Methodology

The analysis for glyphosate and AMPA (described in Pesticide Analytical Manual, Vol. II) involves aqueous extraction, clean-up with ion exchange chromatography and activated charcoal, derivatization with trifluoromethylacetic anhydride and diazomethane or methyl pseudourea and GLC quantitation; a 10% DC-200 or 3.8% OV-17 column and a FPD detector are used. The method has been used for enforcement purposes.

However, the published method is time-consuming, RCB has received reports from FDA and state agencies of difficulty in running the PAM method, and the method is not suitable for peanut vines and hay (PP#0F2329). Thus, RCB feels that the Registrant's HPLC ninhydrin post-column reactor method should be made available in PAM-II for enforcement purposes (see May 1, 1985 review of PP#5F3157/ FAP#5H5446). Although the preceding concept is under consideration, it will not be used as a deficiency in this review, the petitioner should be informed.

Residue Data

No residue data have been submitted with the subject petition.

According to IR-4:

"Tolerances for combined residues of glyphosate and its metabolite have been established for several tree crop groups and other individual tree commodities (40 CFR 180.364). The tree crop tolerances have been established at the 0.2 ppm level and are as follows: Acerola; Avocados; Citrus fruits; Figs; Guava; Mangoes; Nuts; Olives; Papayas; Pistachio nuts; Pome fruits; and Stone fruit. These tolerances were established in support of postemergence applications to orchard floors. Based upon the established tolerances for residues of glyphosate in the above subject tree crops and associated directions for use (label, Section A), it is reasonable and logical to extend these established tolerances to include the tolerances proposed for Atemoya, Carambola and Sugar Apple (Section F). The fate and behavior of glyphosate in plants is well known and understood and, based upon this knowledge, it is unlikely that the proposed tolerance for residues of glyphosate in or on Atemoya, Carambola, and Sugar Apple (Section F) will be exceeded when the herbicide is used as directed (Section B)".

RCB's Comments/Conclusions re: Residue Data

Since glyphosate tolerances of 0.2 ppm are established for a variety of different tree crop commodities for which the use pattern is very similar, RCB concludes that the proposed 0.2 ppm tolerances for the minor crops atemoya, carambola and sugar apple are adequately supported.

It should be noted that additional residue data for some tree crop commodities (stone fruit, citrus fruit and mangos) have been requested in conjunction with the Glyphosate Registration Standard. Should these data demonstrate the inadequacy of established 0.2 ppm tree commodity tolerances, tolerances of 0.2 ppm for atemoya, carambola and sugar apple may need future revision.

Residues in Meat, Milk, Poultry and Eggs

Since neither atemoya, carambola, or sugar apple are animal feed items, RCB concludes that there is no reasonable expectation of finite secondary residues in meat, milk, poultry or eggs in accordance with 40 CFR 180.6 (a)(3).

Other Considerations

In International Residue Limit Status sheet is included with this review as Attachment 1.

There are no compatibility problems with Codex and Mexico since no limits/tolerances are established for glyphosate residues in/or atemoya, carambola, and sugar apple.

The proposed 0.2 ppm tolerances are not compatible with Canada's 0.1 ppm "negligible residue type" limit established for all food crops.

TS-769:RCB:M.Firestone:vg:CM#2:Rm804:X77484:9/25/86
cc: Reading File, PP#6E3424, M. Firestone, FDA, EAB, EEB, Circu, PMSD/ISB Boyd
RDI: J. Onley, 9/12/86; R. Schmitt, 9/12/86

Attachment 1:

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL: glyphosate

PETITION NO.: 6E3424

CCPR NO.:

REVIEWER: Michael P. Firestone

F. Firestone 9/5/86

Codex Status

☑ No Codex Proposal Step 6 or above

Residue (if Step 9):

Proposed U.S. Tolerances

Residue: glyphosate and its metabolite aminomethylphosphonic acid

Crop(s)	Limit (mg/kg)
none	

Crop(s)	Tol. (ppm)
atemoya	0.2
carambola	0.2
sugar apple	0.2

CANADIAN LIMIT

Residue:

Crop(s)	Limit (ppm)
all food crops	0.1 1/

MEXICAN TOLERANCIA

Residue:

Crop(s)	Tolerancia (ppm)
None	

Notes: 1/ Negligible residue type tolerance

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