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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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1:11-661A

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: FAP#1H5310. Glyphosate on Tea.
Evaluation of analytical method and residue data.

FROM: K. H. Arne, Ph.D., Chemist *K.H. Arne*
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THRU: Charles L. Trichilo, Chief
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TO: Robert Taylor, Product Manager No. 25
Herbicide-Fungicide Branch
Registration Division (TS-767)
and
Toxicology Branch
Hazard Evaluation Division (TS-769)

Monsanto Agricultural Products Co. proposes tolerances for combined residues of the herbicide glyphosate (N-phosphonomethylglycine) and its metabolite aminomethylphosphonic acid (AMP) on tea at 1.0 ppm and on instant tea at 4.0 ppm.

Tolerances for the residues of glyphosate are established for several RACs ranging from 0.1 ppm for the liver and kidneys of cattle, goats, hogs, sheep, horses and poultry to 15 ppm for soybean forage and hay (Section 180.364). Tolerances for several commodities are pending.

Conclusions

1. The nature of the residue is adequately understood. In both plants and animals the residue of concern consists of the parent and a metabolite, aminomethylphosphonic acid.
2. Adequate analytical techniques are available for enforcement purposes.
- 3a. The residue data submitted for black tea and instant tea support the proposed tolerances. However, no residue data for green tea are available. This will be needed before we can make a final conclusion as to the adequacy of the proposed tolerances.
- 3b. In Section F, the petitioner proposes a tolerance of 1.0 ppm for tea and a 4 ppm food additive tolerance for instant tea. He apparently believes that tea is a raw agricultural commodity. Both tea and instant tea are processed foods and require food additive tolerances which is what we will consider both tolerances proposed in Section F to be. The petition has been correctly filed as a food additive petition.

4. The residue data in this petition are from Sri Lanka, India and Taiwan. Presumably these are the countries in which Monsanto intends to register use of glyphosate on tea. However, the petitioner should inform us as to which countries the use on tea is intended and assure us that the use in Section B is the use they intend to be registered in those countries. Additionally, the petitioner should provide us with pesticide registration procedures in the countries where use is intended. (Note: we already have information on the registration act in India).
5. Since tea is not normally used as animal feed there will be no problem of secondary residues in meat, milk, poultry and eggs.
6. An International Residue Limit Status sheet is attached. There are no Codex MRLs for glyphosate on tea nor are there such tolerances in Mexico or Canada.

Recommendation

We recommend against the proposed tolerance. For a favorable recommendation we require the following:

1. Residue data for green tea.
2. The petitioner should inform us as to which countries the use on tea is intended and assure us that the use in Section B is the one they intend to propose for registration in those countries. Presumably, use is intended in those countries where residue data were generated. Additionally, the petitioner should provide use with information on the pesticide registration procedures in the countries where use is intended (Note: We already have information on the registration act in India).

DETAILED CONSIDERATIONS

Manufacture and Formulation

The manufacturing process for technical glyphosate has been previously submitted and reviewed (e.g., PP#6G1826, memo of 11/30/76, D. Duffy).

Roundup, the formulation proposed for use, is an aqueous concentrate containing 41% (4 lbs/gallon) isopropylamine salt of glyphosate. This is equivalent to 3 lbs glyphosate per gallon.

The inert ingredients in this formulation consist of the surfactant

[redacted] (cleared under 40 CFR 180.1001 (d)), [redacted]

which are

not expected to present a residue problem.

INERT INGREDIENT INFORMATION REQUIRED

An additional impurity in the formulation product (an impurity in the technical material as well) is N-nitrosoglyphosate (NKG) which has been reported to be in Roundup at levels of 0.2-0.4 ppm. NKG has been subjected to a hazard assessment review (see 8/24/78 memo of R. Taylor, FUS to CPP, EPA) with the result that OPP does not bar the establishment of glyphosate tolerances because of this impurity.

Proposed Use

For control of weeds in established plantations or for site preparation prior to transplanting Roundup is to be applied at the rate of 6-8 liters/hectare (ca. 2.5-3.4 qts/A or 1.9-2.6 lb a.i./A) to actively growing weeds in young and mature plucking tea. No more than 18 liters/hectare per year are allowed. The PHI is 14 days.

Nature of the Residue

Radiotracer plant metabolism studies (corn, soybeans, wheat, cotton, rice, barley, oats, sorghum, sugarbeets sugarcane, potatoes, vegetable crops, grapes, coffee and citrus orchard fruits) have been submitted in conjunction with several petitions and were discussed in our reviews.

In all cases the major degradative pathway of glyphosate had been shown to entail C-N bond cleavage to form glyoxylate and the major metabolite, aminomethylphosphonic acid (AMP). Further metabolism involves significant incorporation of fragments of these compounds into natural plant products.

Tracer studies (submitted with previous petitions) in rats, rabbits and cows indicate that most of the radioactive dose is excreted (90% within 5-7 days) primarily in the feces. The major component of the residue is the parent with only trace amounts of AMP being found.

We conclude that the metabolism of glyphosate in plants and animals is adequately understood.

Analytical Method

Submitted with this petition is a general method for determining glyphosate residues in tea as well as modifications to that method made necessary by differences in the composition of teas from different locations.

Briefly, the sample is extracted with deionized water. It is cleaned up on an anion exchange column, then on a cation exchange column. The second column chromatography separates glyphosate from AMP. HPLC is used for the definitive step; a post column ninhydrin based reactor system is used for detection.

The tea matrix is comprised of a complicated series of compounds many of which can interfere with glyphosate residue determination. Relatively minor modifications in the analytical method were required for teas from Sri Lanka and Taiwan.

The following recovery values are submitted:

Substrate	recovery of glyphosate			recovery of AMP		
	fort. (ppm)	range (%)	avg (%)	fort. (ppm)	range (%)	avg (%)
brewed tea	0.1-1.6	56.3-88.8	74.8	0.1-1.6	46.8-88.9	71
tea	0.08-1.6	53.6-95.6	76.9	0.08-1.6	51.5-74.3	62.3
instant tea	0.33-3.33	78.8-89.6	84.2	0.33-3.33	52.4-69.8	61.1

The claimed method sensitivity for both compounds is <0.08 ppm. Check values ranged from <0.08 to 0.11 ppm for glyphosate and were consistently <0.08 for AMP.

A similar method has been successfully tried out on peanuts (PP#CF2329, memo of 1/19/81, R.W. Storrherr).

We are raising no questions concerning the extraction efficiency of glyphosate from aged tea leaves because glyphosate is water soluble and the extraction is with water.

Adequate analytical techniques are available for enforcement purposes.

Residue Data

Processed tea (i.e. black tea), instant tea and brewed tea, all from tea grown in either Sri Lanka, India or Taiwan, were examined for residues of glyphosate.

The treated tea was harvested and processed in the normal way to produce black tea which was examined for residues. The black tea was used to make instant tea by first brewing it in hot deionized water then filtering the leaves away and finally removing the water by evaporation. The remaining powder was termed instant tea; its weight was about 25% that of the tea used to make it.

For tea, i.e., processed black tea, residues as a result of 3 applications of 6 liter/hectare at a PHI of 14-15 days ranged from <0.08 to 0.64 ppm for glyphosate and were consistently <0.08 for AMP. Residues one day after the last application were as high as 11.7 ppm but quickly declined. Slightly higher residues were found when three applications of 18 liters/hectare were made, but at 14 days the highest combined residue was 0.62 ppm.

Residues in instant tea were about 4X that found in the precursor black tea leaves. For example, tea leaves that held 0.36, 0.29, 6.66 and 0.46 ppm glyphosate were processed into instant tea containing 1.54, 1.63, 19.25 and 1.93 ppm glyphosate, respectively.

Residue data is also available for brewed tea. Residues in brewed tea approximated the level in tea leaves in most cases. For example, tea leaves containing 0.13, 0.15, 3.04, 19.83, 6.66 and 8.11 ppm was made into tea containing 0.16, 0.29, 3.41, 18.55, 4.90 and 7.88 ppm glyphosate residues. Apparently the levels in brewed tea are reported on a dry weight basis; otherwise the residue level would be expected to drop by a factor of ca. 80. A reading of the residue method supports this contention.

No residue data are available for green tea. Since green tea is processed differently than black tea and tends to carry higher residues (for other pesticides) we will make no conclusions regarding an appropriate tolerance. The petitioner should submit residue data for green tea.

Meat, Milk, Poultry and Eggs

Because no livestock feed items are involved here, there will be no problem of secondary residues in meat, milk, poultry and eggs.

Other Considerations

Since the petitioner apparently intends use of glyphosate on tea in the countries of Sri Lanka, India and Taiwan we need information on the registration of pesticides in those countries. This information for India is already available to us so it is needed for just Sri Lanka and Taiwan.

Also, we need a letter from the petitioner in which he states that the use intended in these countries is the same as that outlined in Section B.

Attachment

TS-769:RCB:K. Arne:gs:X77324:Q#2:FM810:12/1/81
cc: RF, Circ., Arne, Watts, FDA, TOX, EEB, EFB, FAP#1H5310
RDI: Quick, 11/20/81:Schmitt, 11/20/81

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INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Glyphosate

PETITION NO. FAP#1H5310

CCPR NO. none

Codex Status

Proposed U.S. Tolerances

No Codex Proposal Step
6 or above

Residue (if Step 9): _____

Residue: 1) N-(Phosphonemethyl)glycine
2) aminomethylphosphonic acid

Crop(s) Limit (mg/kg)

Crop(s) Tol. (ppm)

None

tea 1.0 ppm
instant tea 4.0 ppm

CANADIAN LIMIT

MEXICAN TOLERANCIA

Residue: _____

Residue: _____

Crop Limit (ppm)

Crop Tolerancia (ppm)

None (on these commodities)

none

Notes:

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