417300

R. Taylor PM 25
8-20-96

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

AUG 20 1996

MEMORANDUM

SUBJECT: PP#8F03673, Amendment Dated 6/20/96. Response to Review, Revised Section F. Glyphosate on Corn. Chemical# 417300, DP Barcodes: D228424, Case: 280709, CBTS#: 17442, MRID#: None.

FROM: William D. Cutchin, Chemist
Tolerance Petition Team I
Chemistry Branch I: Tolerance Support
Health Effects Division (7509C)

THROUGH: Elizabeth Haeberer, Acting Chief
Chemistry Branch I: Tolerance Support
Health Effects Division (7509C)

TO: Debbie McCall, Acting Section Head
Risk Assessment and Analysis Branch
Health Effects Division (7509C)

Executive Summary of Residue Chemistry Deficiencies

Additional Corn Residue Trials.
Additional Aspirated Grain Fractions Studies.

CBTS is recommending for a time limited tolerances while additional residue data are generated.

Background

Monsanto Agricultural Co. requests increases in the tolerances of the herbicide glyphosate (N-phosphonomethyl glycine) on corn grain to 1 ppm, corn fodder (stover) to 100 ppm, and aspirated grain fractions at 200 ppm. The registrant also requests the amendment of the Roundup® Herbicide (EPA Reg. No. 524-445) label for a new preharvest use (i.e., prior to the harvest of the mature corn grain). An increase in the corn forage tolerance is not requested since corn forage would be harvested before the preharvest application takes place.

Tolerances for the combined residues of glyphosate and its metabolite aminomethylphosphonic acid (AMPA) exist on corn grain and fodder as part of the dated grain and forage grasses crop groups at 0.1 ppm and 0.2 ppm respectively (40 CFR § 180.364). These dated crop group tolerances should eventually be eliminated by tolerances reassessment in conjunction with reregistration. Food additive and feed additive tolerances are established under 40 CFR §185.3500 and §186.3500, respectively, for the combined residues of glyphosate and AMPA.

The Product and Residue Chemistry Chapters for the Glyphosate Reregistration Eligibility Decision Document (DP Barcode: D183202, CBRS#: 10665) were completed, 10/27/92. The HED Metabolism Committee has determined that AMPA does not need to be regulated and should be dropped from the tolerance expression in the future (Memo, R. Perfetti, 8/19/92).

Conclusions

1a. Residue data submitted in support of PP#8F3673 are inadequate. Considering the variability observed in residues in the submitted field trials, these studies reflect an insufficient number of geographically represented sites.

1b. The previous Section F indicated the tolerances are to be established on corn. The correct terminology is corn, field, grain and corn, field, fodder. The registrant has submitted a revised Section F satisfying this deficiency.

2. Data on aspirated grain fractions submitted in support of PP#8F3673 are inadequate. While glyphosate residues appear to concentrate on corn aspirated grain fractions (AGF), the rate varies considerably within the processing studies. The registrant has provided a rationalization for the disparity between the two concentration factors. The explanation indicates that the studies were not conducted in a manner to simulate common practice. Portions of cob, leaf, and stalk would not be present in commercial aspirated grain fractions. Two additional processing studies will be necessary to provide a more accurate concentration factor. CBTS will continue to use the higher concentration factor to calculate the tolerance on aspirated grain fractions and from that the dietary burden. With the HAFT of 0.54 ppm and 395x concentration, the 200 ppm tolerance is appropriate. The tolerance level may change depending on the results of the requested residue trials and additional AGF studies.

3. Corn grain, forage, fodder, aspirated grain fractions, and milled byproducts are animal feed items. The dietary burden to livestock from this proposed use, and the transfer of glyphosate residues from livestock feed items to meat, milk, poultry, and eggs are covered by established tolerances with the exception of kidney. The transfer of glyphosate residues from this proposed use is

covered by the 4 ppm tolerance on kidney recommended by CBTS in PP#4F4312 and established on April 5, 1996 (61 FR 15192).

Recommendations

For the reasons cited in conclusion 1a and 2, CBTS recommends against the permanent increase of glyphosate tolerances in or on field corn grain to 1 ppm, field corn fodder to 100 ppm, and aspirated grain fractions at 200 ppm. However, based on the submitted field trials, CBTS can recommend for time limited tolerances at these levels while additional residue data are generated. Based on the latest Table 1 (7/31/96) listing RACs and processed commodities, the "field corn fodder" tolerances should be expressed as "field corn stover."

A DRES run using the above tolerances was initiated with our previous review. Another run is not indicated at this time.

Detailed Considerations

Magnitude of Residue

Considering the variability observed in residues in the field trials (see Table I in our 3/21/96 review), the residue data submitted with this petition are insufficient to establish the requested tolerances. The results of twelve corn residue studies were submitted. Eleven studies were conducted in Region V and one study in Region VI. As specified in the Agency's June 1994 guidance on number and location of field trials, a total of twenty successful residue studies with the correct geographic diversity are necessary to establish tolerances in/on field corn. CBTS reiterates that eight more studies with the correct geographic diversity are necessary to establish the requested tolerances. CBTS has no objection to these additional trials being conducted in conjunction with a conditional registration and time limited tolerance.

The registrant has submitted a revised Section F. The terminology of the RAC and processed commodities for which increases in tolerances are requested are now correct.

Commodity	ppm
corn grain, field	1
corn fodder, field	100
aspirated grain fractions	200

We note, however, that "fodder" should be changed to "stover" when tolerances are published (see Table 1 for RAC terminology).

Processing Studies

Glyphosate residues appear to concentrate on some corn processed commodities. Samples of field corn from two field trials were milled to produce corn processed commodities. The corn grain was milled in a manner to simulate common practice. A batch process was used instead of a continuous mode due to the small sample size.

The results of the analysis of the individual processed commodities are listed in Table II in our 3/21/96 review. The concentration factors are calculated by dividing the glyphosate level found in the processed commodity by the glyphosate level found on the corresponding RAC. The highest concentration factor was 672 on grain screenings from Illinois.

The requested tolerance for aspirated grain fractions is based on the highest average field trial (HAFT) grain residue found, 0.54 ppm, multiplied by the highest concentration factor found on grain dust, 395. A tolerance on milled byproducts would be calculated from the highest average grain residue, 0.54 ppm, multiplied by the average concentration factor found on dry milled commodities, 1.12 ((1.71 + 0.52)/2), found on flour. The result of this calculation, 0.6 ppm (0.54 ppm * 1.12), is lower than the requested tolerance on the corn grain, therefore no feed additive tolerance is required for milled byproducts.

Current CBTS policy indicates that the average concentration factors found in processing studies are to be used to calculate tolerances on processed commodities. While the difference in the concentration factors used to calculate the tolerance for dry milled commodities is not significant, 1.71 vs 0.52, the difference between the concentration factors for AGF is significant, 395 vs 14.4 (27x). Using the average AGF concentration factor from two studies would cut the tolerance on aspirated grain fractions in half.

The registrant has provided a rationalization for the disparity between the two concentration factors.

> "The processed grain dust and screening samples contain not only grain dust, but also portions of cob, leaf and stalk. The leaf and stalk particles would be expected to have high residues, as indicated by the fodder residue levels and the method of application. A variation in the ratio of actual grain particles to leaf and stalk particles in the grain fractions would therefore be expected to cause the variability in residue levels in these fractions, rather than variability in how the residues are actually concentrating in the grain."

The registrant's explanation indicates that the variability in concentration factors is a result of processing which does not simulate common practice. Portions of cob, leaf, and stalk would

not be present in commercial aspirated grain fractions. The registrant should conduct two more studies that more closely simulate common commercial practice. In the interim, CBTS will use the higher concentration factor from the previously submitted studies to calculate the tolerance on aspirated grain fractions and from that the dietary burden. With the HAFT of 0.54 ppm and 395x concentration, the 200 ppm tolerance is appropriate. When the requested additional residue trials and processing are received, the HAFT and concentration factors will be recalculated, and an adjustment to the tolerance on aspirated grain fractions may be necessary.

Geographic Representation

CBTS reiterates that the geographic diversity of the studies are inadequate to represent the U.S. field corn growing regions. Twenty successful field corn studies with the correct geographic diversity are required to support a permanent tolerance. The twelve residue studies submitted here were located in Region 5 (11) and in Region 6 (1). This represents 86% of the domestic field corn growing regions. However due to the large acreage of domestic field corn production and the variability observed in the residues, eight more successful studies are necessary to establish a permanent tolerance: six more in Region 5 (midwest), one in Region 1 (northeast), and one in Region 2 (southeast).

Meat, Milk, Poultry, and Eggs

Glyphosate tolerances for the kidney of cattle, goats, hogs, horses, poultry, and sheep have been raised to 4 ppm on April 5, 1996 (61 FR 15192). The tolerances are for a preharvest use of glyphosate on alfalfa. Based on the available feeding study the addition of the dietary burden of at most 78 ppm glyphosate residues on corn commodities (Table III in our 3/21/96 review, beef cattle, if an all corn commodities diet were fed) will be covered by the new tolerances. The secondary residues on cattle meat and milk are not expected to be a problem even if alfalfa hay is added to the diet (see Table V in our 3/21/96 review) with the establishment of the 4 ppm kidney tolerance.

cc: RF, PP#8F03673, circ., Cutchin, R. Taylor - PM Team 25 (7505W)

7509C: CBTS, Reviewer (WDC), CM#2, Rm 804P, 305-7990, WDC: 8/19/96
R/I: Br. Sr. Sci.: R. Loranger, 8/9/96;
Act. Br. Chief: E. Haeberer, 8/13/96