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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 09-NOV-2000

SUBJECT: ID# 000524-00475. **Glyphosate. Review of Corn Field Trial Data Submitted in Response to Condition of Registration.** Chemical 103601 & 417300. Barcode D265963. Case 034794. Submission S579656. MRID 450669-01.

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THROUGH: G. Jeffrey Herndon, Chemist, Acting Branch Senior Scientist G. Jeffrey Herndon
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TO: Vickie Walters/Jim Tompkins, PM Team 25
Registration Division (RD) (7505C)

As a condition of registration for preharvest field corn use of the active ingredient glyphosate, the petitioner was required to submit eight additional residue field trials regarding magnitude of the residue on field corn and two additional processing studies on aspirated grain fractions (AGF) (D228424, W.D. Cutchin, 19-AUG-1996). To comply with this condition, Monsanto Company submitted MRID# 450669-01.

Currently, as specified in 40 CFR 180.364, tolerances are established for residues of glyphosate (N-(phosphonomethyl)glycine) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, and/or the ammonium salt of glyphosate in or on the following corn-related raw agricultural commodities (RACs):

corn, field, stover	100 ppm
corn, field, forage	3.0 ppm
corn, field, grain	1.0 ppm
poultry, liver	0.5 ppm
poultry, kidney	0.5 ppm
liver*	0.5 ppm

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kidney* ..... 4.0 ppm
aspirated grain fractions ..... 200 ppm
soybeans, aspirated grain fractions ..... 50.0 ppm

* Of cattle, goats, hógs, horses, and sheep

CONCLUSION

Monsanto Company has provided adequate corn field trial data to depict the magnitude of glyphosate residues expected in corn RACs and adequate processing data to derive the concentration factor in aspirated grain fractions. These data demonstrate that the existing tolerance levels for glyphosate on corn grain and stover are adequate; however, the results of the corn processing studies indicate that the glyphosate tolerance for aspirated grain fractions should be reduced to 50 ppm, and that the existing tolerance level of 50.0 ppm for "soybeans, aspirated grain fractions" should be removed. Provided that Monsanto Company submits a revised Section F requesting a glyphosate tolerance level of 50 ppm for aspirated grain fractions, the condition of registration has been satisfied. Upon receipt of the revised Section F, the registration for preharvest corn use may be considered permanent.

DETAILED CONSIDERATIONS

OPPTS GLN 860.1500: Magnitude of the Residue - Plants

Monsanto Company submitted data (citation shown below) from nine corn field trials conducted during 1997 (7 trials in Region 5, 1 trial each in Regions 1 and 2). Field corn received one preharvest over-the-top broadcast spray application of Roundup Ultra herbicide at a rate of 3 quarts (2.25 lb acid equivalents (a.e.)) per acre (1X the maximum seasonal use rate). The application was made 7 ± 1 days before harvest of the crop. Samples of grain and stover were collected at all field sites at crop maturity. At two sites, additional grain samples were harvested for processing into AGF.

> 450669-01. McCann, Melinda C. (2000) Magnitude of Glyphosate Residues in Corn Raw Agricultural Commodities Following Preharvest Application of Roundup Ultra Herbicide Report Number: MSL-14917. Protocol Number 97-63-R-1. Unpublished study submitted by Monsanto Company. 376 p.

Table 1 presents the glyphosate residue levels in corn grain and stover following the preharvest application of Roundup Ultra® herbicide. Although data were also reported for AMPA, this information was not included in Table 1 because AMPA is not a residue of concern and was only found in small amounts.

Table 1. Residues of Glyphosate in Corn Grain and Stover Following Preharvest Application of Roundup Ultra® Herbicide.

Trial Location	Application Rate (lb a.e./A)	PHI (days)	Glyphosate Level in Corn Grain (ppm)	Glyphosate Level in Corn Stover (ppm)
Guthrie County, Iowa	2.25	7	0.051 0.058	6.75 6.57
Greene County, Iowa	2.25	7	<0.05 <0.05	4.89 4.65
Jefferson County, Iowa	2.28	7	<0.05 <0.05	3.06 3.72
Clinton County, Illinois	2.25	7	<0.05 <0.05	56.4 31.1
Jersey County, Illinois	2.25	7	**0.114** **0.064**	23.3 47.4
Burt County, Nebraska	2.25	7	<0.05 <0.05	2.59 2.64
York County, Nebraska	2.25	6	0.104 <0.05	2.15 1.98
Wayne County, New York	2.31	7	3.10[a] 2.90[a]	**60.8** **45.6**
Wilson County, North Carolina	2.37	7	0.063 <0.05	37.3 47.8

[a] Considered to be an outlier: preharvest application was made at an earlier growth stage than was specified in the study protocol. This earlier growth stage was described as "early maturity", with green leaves still present.

Summary

Excluding the outlier corn grain data from the Wayne County, NY field trial, the maximum residue observed in corn grain in the other eight trials was 0.11 ppm, while the maximum in corn stover was 61 ppm. These levels are less than the established tolerance levels of 1.0 and 100 ppm for corn grain and stover, respectively. The tolerance levels were based on maximum residues of 0.57 and 94 ppm in corn grain and stover, respectively (D216229, W.D. Cutchin, 21-MAR-1996). The highest average field trial (HAFT) values for corn grain and stover are 0.54 and 92 ppm, respectively (D216229, W.D. Cutchin, 21-MAR-1996). The additional field trials were conducted in the proper EPA regions requested (D228424, W.D. Cutchin, 19-AUG-1996),

and together with the previously reviewed data provide 20 acceptable field trials to support the corn use. Thus, the data requirements for preharvest glyphosate use on field corn have now been met.

AGF Processing Studies

Due to the variability of the results of the original corn processing studies (concentration factors of 14 and 395 (D216229, W.D. Cutchin, 21-MAR-1996)), the registrant was requested to provide two new AGF processing studies (D228424, W.D. Cutchin, 19-AUG-1996). As detailed previously (D228424, W.D. Cutchin, 19-AUG-1996), Monsanto attributed the wide variability in concentration factors to the presence of cob, leaf, and stalk particles in the AGF samples. Thus, the earlier studies were based on a processing method that did not adequately simulate commercial practice. While awaiting results from the new grain dust processing study, a tolerance was established based on the highest concentration factor from the available data. There was no need for the registrant to provide further processing studies concerning other processed commodities of corn since the original study was found adequate for all items except grain dust.

After determining the moisture content of the incoming RAC the sample were dried in a Proctor Schwartz oven at 110-150°F until the moisture content was 10-13%. Following drying, each sample, in turn, was placed in a dust generation room containing a grain-conveyor system consisting of holding bins, drag conveyors and a bucket conveyor intended to simulate industrial practices. As samples were moved in the system, aspiration was used to remove the grain dust, which was then classified according to particle size by sieving. Table 2 gives the results of this process for the two treated dust samples.

Table 2. Sample Weights of Various Particle Sizes of Corn Aspirated Grain Fraction Samples.

AGF Particle Size, microns	Sample ZA-62 (NE)		Sample ZA-58 (IA)	
	Sample Weight (g)	Fraction Weight %	Sample Weight (g)	Fraction Weight %
>2540	23.5	17.1	22.7	8.3
>2030	9.3	6.8	13.4	4.9
>1180	21.8	15.8	28.0	10.3
>850	6.2	4.5	6.6	2.4
>425	7.8	5.7	5.3	1.9
<425	69.1	50.2	196.9	72.2
Ash content of Combined AGF <2540	2.0 %		2.0 %	

Prior to residue analysis, AGF of particle size below 2540 microns were recombined and analyzed for ash content. Then, the samples were analyzed for glyphosate residues, allowing calculation of the concentration factors presented in Table 3.

Table 3. Residues of Glyphosate in Corn AGF Following Preharvest Application of Roundup Ultra Herbicide.

Commodity	Location	Glyphosate (ppm)	Concentration Factor
Corn Grain	Guthrie County, Iowa	0.032 0.027	NA
	York County, Nebraska	0.055 0.050	NA
AGF	Guthrie County, Iowa	1.53 1.60	53
	York County, Nebraska	0.749 0.664	13

Summary

Normally, at least 50% of commercial elevator AGF have a particle size < 400 microns. In addition, AGF are defined according to the American Feed Control Association to contain ash at less than 15% (memo, E. Saito and E. Zager, 07-JUN-1994). Thus, the 2% ash content and particle size distribution of the grain dust in this study is acceptable, indicating that the AGF samples in the present study adequately simulate commercial practice.

Typically, the appropriate glyphosate AGF tolerance from corn experiments would be based on the product of the corn grain HAFT value (0.54 ppm (D216229, W.D. Cutchin, 21-MAR-1996)) and the average concentration factor from the available processing studies. However, due to the remaining variability in the concentration factors (13 and 53 in separate determinations), it is more appropriate to make use of the highest concentration factor from the present studies in calculating a tolerance level: 53 X 0.54 ppm = 29 ppm.

The AGF tolerance applies to aspirated grain fractions derived from corn, wheat, sorghum, and/or soybeans. Although a separate tolerance of 50.0 ppm exists for "soybeans, aspirated grain fractions", it is superfluous since soybeans are included in the AGF tolerance. HED recommends that the soybean AGF tolerance be dropped and that a tolerance level of 50 ppm be set for "aspirated grain fractions". Monsanto Company should submit a revised Section F requesting this tolerance.

cc: W. Donovan
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