



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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8F3673. Glyphosate for Use In or On Field Corn.
DEB # 5941. HED Project # 0-0070. No MRID #.

FROM: Michael T. Flood, Ph.D., Chemist
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and

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THROUGH: Richard D. Schmitt, Ph.D., Chief
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Edward J. Schmitt for

This memo is intended to update our previous memo (2/1/89) based on DEB's conclusions from PP#6F3380/6H5502 (W.T. Chin, memo of 1/30/89).

Summary of Deficiencies Remaining to Be Resolved

- Deficiency #1 (Conclusion #1 of our 2/1/89 memo). Petitioner should confirm that proposed tolerances refer to combined residues of glyphosate and AMPA.
- Deficiency #3a. Section B should be revised to condense wording.
- Deficiency #3b. Either Section B should be revised to stipulate that ammonium sulfate should not be used or additional residue data should be submitted.
- Deficiency # 5b. Glyphosate and AMPA should be tested under multiresidue protocols.
- Deficiency #6b. Petitioner should explain why residues in corn grain and fodder were higher after 14-day PHI

than at 7-day PHI.

- Deficiency #6c. Petitioner should explain why corn forage was not analyzed.
- Deficiency #7. Section F should be revised to list tolerances for glyphosate residues at 2.0 ppm for corn grain and 35 ppm for forage and fodder.
- Deficiency #8b. Petitioner should conduct additional dry-milling study in which grain is processed into grits and flour.
- Deficiency #9. Revised Section F should be submitted which proposes tolerances of 1.0 ppm for glyphosate residues in liver and kidney of cattle, goats, swine, horses, poultry and sheep.

Conclusions (pertaining only to this submission)

1. The nature of the residue in animals is adequately understood. The residue to be regulated is glyphosate, per se, and its metabolite AMPA.
2. New animal feeding studies were submitted in PP#6F3380/6H5502. Glyphosate residue levels in kidney of cattle were significantly lower than levels found in an earlier study. Residues levels calculated using the earlier study on cattle can exceed the existing tolerance of 0.5 ppm in kidney, depending on the particular diet considered. The petitioner should therefore submit a revised Section F in which tolerances of 1.0 ppm are proposed for the liver and kidney of cattle, goats, swine, horses, poultry and sheep.

Recommendation

DEB continues to recommend against the proposed tolerances for reasons given in our 2/1/89 memo - Conclusions #1, #3a, #3b, #5b, #6b, #6c, #7 and #8b - and Conclusion #2 of this memo. (Conclusion #2 is a revision of Conclusion #9 of our previous memo.)

Detailed Considerations

Two of the conclusions from our 2/1/89 memo are affected by the review of PP#6F3380/6H5502:

- 4b. The nature of the residue in animals is not adequately understood. The Registration Standard has required additional studies in ruminants and poultry.

9. Based on the 30-day feeding studies in cattle, it appears that existing tolerances for glyphosate residues in animal products may be exceeded due to the proposed use of glyphosate. We defer final comment until the nature of the residue in animals is adequately understood.

Metabolism studies on lactating goats and laying hens were submitted in PP#6F3380/6H5502 and reviewed in W.T. Chin's 1/30/89 memo. According to that review, "[r]esults of the above metabolism studies in lactating goats and laying hens are consistent with the metabolism studies in rats, rabbits and cows...The majority residues are the parent compound and AMPA in eggs, milk and animal tissues. DEB concludes that the above metabolism studies are adequate and, therefore, deficiency "3b" is resolved."

Based on that review, we are revising Conclusion #4b. The nature of the residue in animals is now adequately understood. The residue to be regulated is glyphosate, per se, and its metabolite AMPA.

Although not required by the Registration Standard (6/86), Monsanto submitted feeding studies of glyphosate/AMPA in cattle, swine and poultry because of increases in tolerances for residues in/on crops such as corn and soybeans. The new feeding studies were reviewed in W.T. Chin's 1/30/89 memo. All animals were dosed at 0, 40, 120 and 400 ppm with a mixture of glyphosate and AMPA (9:1) for 28 days followed by a depuration period of an additional 28 days. At the 40 ppm (1x) feeding doses, highest residue levels were observed in kidneys of all species. These are shown in Table 1.

Table 1

Glyphosate/AMPA Average Residue Levels in Kidney
for Cattle, Swine and Poultry
40 PPM Feeding Level

	Glyphosate	AMPA
Cattle	0.26 ppm	---
Swine	0.37 ppm	0.07 ppm
Poultry	0.38 ppm	---

Residue levels varied linearly with dose. No residues were observed in fat or muscle of any of the animals at the 1x and 3x feeding levels. Residues were not found in eggs at these levels, and were not found in milk at any level. Complete results are given in W.T. Chin's aforesaid memo.

Based on an earlier cattle feeding study, reviewed in

PP#5F1536, we estimated in our 2/1/89 memo "that a dietary level of about 20 ppm glyphosate residues could yield residues in kidney in excess of the 0.5 ppm tolerance". In the first feeding study, an average level of glyphosate residue in kidney of cattle was reported in Monsanto's summary to be 0.7 ppm from a 30 ppm dose level of glyphosate and AMPA (3:1). A review of the raw data in that feeding study (PP#5F1536, Accession # 118951) indicates that the average residue level for combined levels of glyphosate and AMPA in kidney was 0.52 ppm, 0.64 ppm when corrected for recovery. Nevertheless, residues from the new study are significantly lower.

In W.T. Chin's 10/24/86 memo, estimated maximum beef cattle exposure to glyphosate residues was estimated to be 40 ppm. One-half of this concentration was due to soybean straw, of which the proposed tolerance is 200 ppm. Possible residues in beef from corn commodities are not much lower. For example, Morrison's Feeds and Feeding (1956) indicates that one possible diet for wintering beef calves could consist of as much as 86% corn fodder. If the fodder contained 35 ppm glyphosate residues -- the tolerance that we recommended Monsanto propose for corn fodder -- the concentration in the diet of glyphosate would be 30 ppm. When derived from the earlier feeding study, residues in kidney of cattle would be predicted to exceed the tolerance of 0.5 ppm but would be within tolerance if calculated from the more recent study. Because of the ambiguity in this case, Monsanto should submit a revised Section F in which the tolerance for kidney and liver of cattle, goats, hogs, horses, poultry and sheep is raised to 1.0 ppm.

cc: RF, Circu., PP#8F3673, ISB/PMSD(Eldredge),
Reviewer(MikeFlood)

H7509C:DEB:Reviewer(MTF):CM#2:Rm810:557-4362:typist(mtf):
11/15/89.

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