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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 23-APR-1999

SUBJECT: PP# 7F04854. **Sulfosate (Glyphosate-Trimesium) in or on Soybean and Animal RACs. Evaluation of Residue Data and Analytical Methods.** MRID#s 44313901 thru 44313903. Chemical ~~108201~~ 128501. Barcode D243318. Case 289000. Submission# S526352.

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The attached contractor's document has been reviewed and revised to reflect HED policy.

Executive Summary of Chemistry Deficiencies

- Revised Section F.

cc (with attachments): PP#7F4854, G. Kramer
RDI: Team (4/16/99), M. Morrow (4/22/99), S. Chun (4/16/99)
G.F. Kramer:806T:CM#2:(703)305-5079:7509C:RAB1

limited tolerances that had been established under 40 CFR §180.489(b) (62 FR 48597, 09/11/98); at the same time, tolerances that had been established under 40 CFR §185.5375 were moved to §180.489(a). The permanent tolerances were established for the following commodities: aspirated grain fractions; forage, stover, and grain of field corn; stover and grain of popcorn; prune; raisins; forage, hay, seed, and hulls of soybeans; fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep; milk; fat, meat, meat byproducts (except liver), and liver of poultry; and eggs.

The Agency has recommended for a petition (PP#7F04876) for sulfosate uses on fruiting vegetables pending revisions of the proposed labels (DP Barcode D243450, 9/28/98, J. Rowell and G. Kramer). In addition, RAB1 concluded in the same memorandum that sufficient data are available to support the proposed increase (to 8 lb ai/A/year) in the application rate of sulfosate on citrus, grapes, pome fruit group, tree nut group, soybeans, and stone fruit group. However, data available for corn are insufficient to raise the application rate of sulfosate from 4 to 8 lbs ai/A/year.

CONCLUSIONS

OPPTS 830 Series GLNs: Product Properties

1. Product chemistry data for sulfosate were previously submitted and reviewed by RD. No additional product chemistry data are required in support of this petition.

OPPTS GLN 860.1200: Proposed Uses

2. The specimen labels (Touchdown®, 6 lb/gal SC formulation, EPA Reg. No. 10182-324, and Touchdown® BTU, 5 lb/gal SC formulation, EPA Reg. No. 10182-429) adequately delineate the proposed use pattern for sulfosate on soybeans and glyphosate-tolerant soybeans.

OPPTS GLN 860.1300: Nature of the Residue - Plants

3a. Sulfosate metabolism studies in plants have been submitted in conjunction with previous petitions. The nature of the residue is considered to be understood in corn, grapes, and soybeans. The Agency concluded that the parent ions are the residues of regulatory concern for sulfosate in these crops.

3b. The submitted metabolism studies are adequate to delineate the metabolism of PMG and TMS in the seed of glyphosate-tolerant soybeans. The total radioactive residue (TRR) in soybean seed treated with three applications of [^{14}C]PMG-TMS at 1x the maximum proposed application rate was 10.0 ppm. PMG was identified at 26% TRR (2.6 ppm) and the metabolite AMPA (aminomethylphosphonic acid) was identified at 38% TRR (3.8 ppm). An additional 7% TRR was found to be associated with triglycerides and monosaccharides (radioactivity was observed in monosaccharides following hydrolysis of nonextractable

residues). These results are similar to the previously submitted soybean metabolism study with [^{14}C]PMG-TMS in which PMG and AMPA were the only metabolites identified. In the previous study, PMG and AMPA were identified at much lower levels, which is consistent with the difference in use patterns in the two studies.

3c. The TRR in soybean seed treated with three applications of PMG-[^{14}C]TMS at 1x the maximum proposed application rate was 23.0 ppm. TMS was identified at 90% TRR (20.7 ppm). A small amount of radioactivity (1% TRR) was found to be associated with triglycerides. These results are similar to the previously submitted soybean metabolism study with PMG-[^{14}C]TMS in which TMS was found to be the major residue. **HED thus concludes that the parent ions are also the residues of regulatory concern for sulfosate in glyphosate-tolerant soybeans.**

OPPTS GLN 860.1300: Nature of the Residue - Animals

4. Sulfosate metabolism studies in animals have been submitted in conjunction with a previous corn tolerance petition. The nature of the residue is considered to be understood in ruminants and poultry. The Agency concluded that the parent ions are the residues of regulatory concern for sulfosate in meat, milk, and eggs.

OPPTS GLN 860.1340: Residue Analytical Methods-Plant Commodities

5a. Method validation and successful petition method validation (PMV) by ACL of Method RR 92-042B (originally submitted with PP#3F04238 and PP#4F04343), for the determination of PMG, and Method RR 93-105B (originally submitted with PP#1F03950), for the determination of TMS, have been completed. The methods were revised to incorporate revisions required by the Agency, and the revised methods (RR92-042B RES and RR 93-105B RES) were approved by the Agency for the enforcement of tolerances for residues of the PMG and TMS ions of sulfosate in/on crops. The methods have been submitted to the FDA for inclusion in PAM II.

5b. The petitioner used the previously submitted enforcement methods (Methods RR 92-042B and RR 93-105B RES) for data collection in the submitted field trial studies on soybeans. Concurrent method recoveries demonstrated that methods RR 92-042B RES and RR 93-105B RES are adequate for data collection in/on soybean seed.

OPPTS GLN 860.1340: Residue Analytical Methods-Animal Commodities

6. Method validation and successful PMV by ACL of Methods RR 93-104B for the determination of PMG and RR 93-100B for the determination of TMS (originally submitted with PP#9F03796) have been completed. The methods were revised to incorporate revisions required by the Agency, and revised methods (RR 93-104B RES and RR 93-100B RES) were approved by the Agency for the enforcement of tolerances for residues of the PMG and TMS

ions of sulfosate in meat, milk, poultry and eggs. The methods have been submitted to the FDA for inclusion in PAM II.

OPPTS GLN 860.1360: Multiresidue Method

7. A report on the behavior of PMG and TMS (MRID 41209915) in FDA Multiresidue protocols I, II, III, and IV, has been forwarded to the FDA for review.

OPPTS GLN 860.1380: Storage Stability Data

8. Previously, the petitioner demonstrated that residues of PMG and TMS are stable in soybean seed and straw for up to 2 years. The soybean seed samples from the submitted field trials were analyzed within 6 months of collection; therefore, no additional storage stability data are required to support the submitted field trials on soybean seed.

OPPTS GLN 860.1500: Crop Field Trials

9a. The submitted residue data for soybean seed are adequate. The submitted data indicate that combined residues of PMG and TMS will not exceed the proposed tolerance of 21 ppm (of which no more than 13 ppm is trimethylsulfonium) in/on soybean seed harvested following the maximum proposed application rate. The combined residues of PMG and TMS were 1.78-20.27 ppm (1.16-12.47 ppm of which was TMS) in/on soybean seed harvested 6-7 days following the last of three broadcast applications of the 6 lb/gal SC formulation at a total rate of 8 lb ai/A (1x the maximum proposed seasonal application rate).

9b. Two residue decline studies were conducted for soybeans; both studies reflected posttreatment intervals less than and greater than the proposed PHI. The results of the decline studies indicated that combined residues of PMG and TMS neither increase or decrease with increasing posttreatment intervals.

9c. The requirements for soybean aspirated grain fractions residue data have been fulfilled by a previously submitted soybean processing study (DP Barcodes D208740, D208742, D213615, and D213612, 4/4/95, G. Kramer). Because the composition of the fractions of the grain dust in the study was not comparable to commercial aspirated grain fractions and because the petitioner reported residue results for each fraction separately, the Agency calculated expected concentration factors in aspirated grain fractions of 73.8x for PMG and 57.5x for TMS. Based on the highest average field trial (HAFT) residues from the soybean field trials and the calculated concentration factors, the expected residues in aspirated grain fractions are 1216 ppm [7.26 ppm PMG x 73.8 = 535.8 + 11.82 ppm TMS x 57.5 = 679.7]. Therefore, the proposed tolerance of 1300 ppm (of which no more than 720 ppm is trimethylsulfonium) for soybean aspirated grain fractions is appropriate. HED notes that the tolerance should be

established for "Aspirated grain fractions." **A revised Section F is required.**

OPPTS GLN 860.1520: Processed Food/Feed

10. The previous tolerance petition review (PP#0F03860) concluded that the soybean processing study for residues of glyphosate-trimesium was inadequate because the RAC samples did not contain quantifiable residues. In response, Zeneca submitted a new soybean processing study (MRID 43397004) which was previously reviewed. The processing data indicate that residues of PMG and TMS concentrated 2.5x and 2.0x, respectively, in soybean hulls. The HAFT (total residues) from soybean field trials reflecting the maximum proposed use pattern is 19.08 ppm. Based on this HAFT and the observed average concentration factor (2.3x), the maximum expected total residues are 42.93 ppm for soybean hulls (of which no more than 23.64 ppm is trimethylsulfonium). Therefore, the proposed tolerance of 45 ppm (of which no more than 25 ppm is trimethylsulfonium) for soybean hulls will not be exceeded.

OPPTS GLN 860.1480: Meat, Milk, Poultry, Eggs

11a. No additional feeding studies were submitted with this petition. Based on the proposed tolerances (and proposed tolerances for wheat commodities), the maximum theoretical dietary burdens of sulfosate to beef and dairy cattle are 379 and 396 ppm, respectively. A ruminant feeding study has been submitted previously and reviewed by the Agency (CBTS Nos. 6814, 6815, and 6816, 4/29/91, S. Koepke); the feeding study reflected dosing levels of 50, 300, and 1000 ppm. Based on the results of this study, the proposed tolerances for meat and milk commodities are not appropriate. **A revised Section F, proposing the following meat and milk tolerances, is required:**

Cattle, goat, hog, sheep, and horse kidney	6.0 ppm
Cattle, goat, hog, sheep, and horse meat byproducts (exc. kidney)	1.5 ppm
Cattle, goat, hog, sheep, and horse meat	1.0 ppm
Cattle, goat, hog, sheep, and horse fat	0.5 ppm
Milk	1.5 ppm

11b. No additional poultry tolerances were proposed and no additional poultry feeding studies were submitted with this petition. The maximum theoretical dietary burden of sulfosate to poultry is 9.6 ppm. The petitioner has previously submitted a poultry feeding study (CBTS Nos. 6814, 6815, and 6816, 4/29/91, S. Koepke) reflecting dosing levels of 0.5, 5, and 50 ppm. Based on the results of this study, the existing tolerance for eggs is not adequate. **A revised Section F, proposing the following tolerance is required:**

Eggs	0.05 ppm

OPPTS GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

12. The Agency has previously reviewed two confined rotational crop studies for sulfosate and concluded that rotational crop restrictions were not required for uses on crops in which the total seasonal application rate does not exceed 8 lb ai/A. No additional rotational crop data are required to support this petition.

RECOMMENDATIONS

Provided Section F is revised as specified in Conclusions 9c, 11a and 11b, HED concludes that there are no residue chemistry data requirements that would preclude amending the established tolerances for sulfosate in/on soybean and animal RACs. A human-health risk assessment will be prepared as a separate document.

DETAILED CONSIDERATIONS

OPPTS 830 Series GLNs: Product Properties

No new studies were submitted with this petition. Product chemistry data were reviewed by RD and found to be adequate (Memo dated 3/17/87, K. Liefer) when sulfosate was initially submitted for a nonfood use. There are no product chemistry data gaps (Letter dated 2/15/89, R. Taylor).

OPPTS GLN 860.1200: Proposed Uses

Amended labels have been proposed for use of sulfosate formulated as Touchdown®, 6 lb/gal SC formulation, EPA Reg. No. 10182-324, and Touchdown® BTU, 5 lb/gal SC formulation, EPA Reg. No. 10182-429 to add a preharvest use and to add uses on glyphosate-tolerant soybeans. Sulfosate is proposed multiple broadcast applications before, during, or after planting prior to crop emergence on minimum or no-till planted soybeans at 0.4-4 lb ai/A/application. Sulfosate formulations can also be applied as a spot spray (to weeds) and by wiper or wick. A preharvest application may be made at 1 lb ai/A as a harvest aid. The maximum yearly application, no matter which treatments are made, is 8 lb ai/A. A 7-day PHI is proposed following preharvest applications and wiper or wick applications. An 8-week PHI is proposed following spot applications. The grazing or harvesting for hay following harvest aid application is prohibited.

Sulfosate may also be applied preemergence, postemergence, and preharvest as multiple broadcast applications to soybean varieties that have been genetically modified to be tolerant to glyphosate herbicides. Preemergence applications may be made at 0.4-4 lb ai/A/application, postemergence applications may be made at 2 lb

ai/A/application, and preharvest applications may be made at 1 lb ai/A/application. The maximum yearly application, no matter which treatments are made, is 8 lb ai/A. A 7-day PHI is proposed following preharvest applications. Post-emergence applications may be made up to and including the full bloom stage of soybeans. The grazing or harvesting glyphosate-tolerant soybeans for feed is prohibited.

Broadcast applications may be made in 10-30 gal/A with conventional ground equipment or in 3-10 gal/A with low-volume ground equipment; applications may be made using aerial equipment in a minimum of 3 gal/A. The use of a surfactant or wetting agent is required. Sulfosate formulations may be tank mixed with other herbicides registered for these uses.

A restricted entry interval (REI) of 4 hours is established. Rotational crops may be planted back into treated areas 35 days after application. Grazing or harvest of treated cover crops for feed is prohibited.

Comments: The specimen labels (Touchdown®, 6 lb/gal SC formulation, EPA Reg. No. 10182-324, and Touchdown® BTU, 5 lb/gal SC formulation, EPA Reg. No. 10182-429) adequately delineate the proposed use pattern for sulfosate on soybeans and glyphosate-tolerant soybeans.

OPPTS GLN 860.1300: Nature of the Residue - Plants

Sulfosate metabolism studies in plants have been submitted in conjunction with previous petitions. The nature of the residue is considered to be understood in grapes (DP Barcode D182279, 12/7/93, G. Otakie), corn (DP Barcode D171509, 9/30/92, F. Griffith) and soybeans (DP Barcodes D208740, D208742, D213615, and D213612, 4/4/95, G. Kramer). The Agency concluded that the parent ions are the residues of regulatory concern for sulfosate in these crops.

The Agency has previously determined that the tolerance expression for sulfosate must include both of the parent ions (DP Barcode D211742, 2/9/95, G. Kramer, et al.). Tolerances for sulfosate should be expressed as "residues of sulfosate (sulfonium, trimethyl-salt with N-(phosphonomethyl)glycine (1:1)) in or on...." In situations where the levels of both ions are expected to be below the levels of quantitation (0.05 ppm), tolerances should be established as:

RAC = 0.05 ppm

In cases where quantifiable residues are expected, tolerances should be established as:

RAC (of which no more than x ppm is trimethylsulfonium) = y ppm,

where x is the maximum expected residue of TMS and
y is the maximum expected total of TMS and PMG.

Zeneca has submitted two volumes of interim data from two studies (citations listed below) investigating the metabolism of [^{14}C]trimethylsulfonium (TMS) glyphosate-trimesium and [^{14}C]phosphonomethylene (PMG) glyphosate-trimesium in glyphosate-

tolerant soybeans. The in-life and analytical phases of the study were conducted by the Western Research Center of Zeneca Ag Products (WRC; Richmond, CA). The submitted studies contain data depicting metabolism in soybean seed; the petitioner stated that metabolism data for forage and hay would be submitted in subsequent studies.

> 44313901 Ericson, J. (1997) ((Carbon 14)-phosphonomethylene)Glyphosate Trimesium: Nature of the Residue in Glyphosate-Tolerant Soybeans: (Interim Report): Lab Project Number: PMS 428: RR97-028B INT: RR 97-028B. Unpublished study prepared by Zeneca Ag Products. 50 p.
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> 44313902 Ericson, J. (1997) ((Carbon 14)-Trimethylsulfonium)Glyphosate Trimesium: Nature of the Residue in Glyphosate-Tolerant Soybeans: (Interim Report): Lab Project Number: PMS 431: RR97-029B INT. Unpublished study prepared by Zeneca Ag Products.45 p.

In the first study (1997; MRID 44313901), the test substance, radiolabeled [phosphonomethyl-^{14}C]glyphosate-trimesium ([^{14}C]PMG-TMS; specific activity 51 Ci/mmol, average radiochemical purity 91.0%), was mixed with water and applied to glyphosate-tolerant soybean plants grown in three plastic pots in a greenhouse. Three applications were made. The first application was made preemergence to the soil surface on the same day the seeds were planted at a rate equivalent to 5 lb ai/A of [^{14}C]PMG-TMS. The second and third applications were made postemergence 58 and 127 days after planting to the soil and surfaces of plants at rates equivalent to 2 and 1 lb ai/A of [^{14}C]PMG-TMS, respectively. The application solutions for postemergence applications also contained surfactant. The total application rate was equivalent to 8 lb ai/A (~1x the maximum proposed seasonal rate). One additional pot served as a control.

Soybean plants were harvested 7 days after the third postemergence application by cutting plants a few centimeters above ground level. Soybean seed samples were separated from the pods by hand.

Total radioactive residue (TRR)

At WRC, samples of soybean seed were homogenized to soybean seed flour then subjected to LSC following combustion. The TRR in soybean seed was 10 ppm as determined by summing the radioactivity in extracts and in nonextractable residues.

Extraction and hydrolysis of residues

Subsamples of soybean seed flour (homogenized seed) were subjected to extraction and hydrolysis procedures for residue characterization and identification. During the fractionation and characterization procedures, aliquots of extracts and nonextractable residues were analyzed for radioactivity by LSC or combustion/LSC. The general extraction procedures are summarized below.

Soybean seed flour was sequentially extracted with hexane (2x) and 0.1 N HCl (2x). The initial aqueous extracts were combined and

partitioned with dichloromethane (DCM) to yield DCM and Aqueous 1 fractions. The hexane and DCM fractions were combined to form a composite organic extract. A subsample of the combined organic extract was partially saponified with 1 N sodium hydroxide (at 60 C for 4 hours). The nonextractable residues were subjected to acid hydrolysis with 0.1 N HCl, and the additional aqueous extract (Aqueous 2) was combined with the Aqueous 1 fraction to form a composite aqueous extract. A subsample of the Aqueous 1 fraction was filtered through CHELEX iron-form resin. A subsample of the nonextractable residues was subjected to acid hydrolysis with 6 N HCl (at 100 C for 6 hours).

The distribution of ^{14}C-activity in the extracts and hydrolysates of soybean seed flour is presented in Table 1.

Characterization/identification of residues

Extracts were analyzed by TLC (Methods 1, 2, and 3) and HPLC (Method 1). TLC analyses were conducted on silica gel (60 F_{254}) plates using the following solvent systems: methanol:water:ammonium hydroxide:trichloroacetic acid (55:14:31:0.45, v:v:v:v) to resolve PMG from the metabolite aminomethylphosphonic acid (AMPA; Method 1), n-propanol:methanol:water (70:15:15, v:v:v) for sugars (Method 2), chloroform:methanol:acetic acid (98:2:1, v:v:v) and hexane:diethyl ether:acetic acid (94:5:0.2, v:v:v) for triglycerides (two-dimensional, Method 3). Radioactivity was detected and quantified using a bio-imaging analyzer system; nonlabeled standards were visualized using ninhydrin and carbon disulfide with UV light for Method 1; ethanol, concentrated sulfuric acid, and p-anisaldehyde for Method 2; and iodine vapor for Method 3. HPLC analyses were conducted using a BIO-RAD glyphosate analysis column and a BIO-RAD SCX precolumn with a mobile phase of methanol:aqueous phosphate buffer (4:96; v:v), and diode-array UV and refractive index (RI) detection; radioactivity was detected using a radioactivity flow-through monitor and quantitated by fraction collection and LSC. Metabolites were identified by cochromatography with reference standards and/or by MS analysis. The following reference standards were used for cochromatography: *N*-(phosphonomethyl)glycine; AMPA; sarcosine; *N*-methylphosphonomethylglycine, fructose, galactose, glucose, oleic acid, and linoleic acid.

Table 1. Distribution and characterization of radioactive residues in soybean seed flour following three applications of [^{14}C]PMG-TMS.

Fraction	% TRR	ppm	Characterization/Identification
Soybean seed flour (TRR=10.0 ppm)			
Hexane	N/R [a]	N/R	Reserved and combined with DCM fraction.
Nonextractable	N/R	N/R	Hydrolyzed with 0.1 N HCl.
0.1 N HCl	N/R	N/R	Partitioned with DCM.
DCM	N/R	N/R	Combined with hexane fraction.
Composite of organic fractions	5.4	0.5	Subsample of composited organic fraction subjected to partial saponification with 1 N aqueous sodium hydroxide. TLC Method 3 analysis characterized radioactivity consistent with oleic and linoleic acids (5% TRR; 0.5 ppm), indicating the incorporation of radioactivity into triglycerides.
Aqueous 1	72.4	7.2	Subsample of Aqueous 1 filtered through CHELEX iron-form resin.
Filtrate	10.1	1.0	Chromatograms provided for TLC Method 2; majority of radioactivity remained at the origin, consistent with proteins.
Nonextractable	N/R	N/R	Hydrolyzed with 0.1 N HCl.
Aqueous 2	10.8	1.1	Combined with a subsample of Aqueous 1.
Composite of aqueous extracts	83.2	8.3	HPLC Method 1 and TLC Method 1 resolved: PMG 26% TRR 2.6 ppm AMPA 38% TRR 3.8 ppm Plus poorly retained components present at 10.4% TRR, 1.0 ppm.
Nonextractable	11.4	1.1	Subsample hydrolyzed with 6 N HCl.
Acid hydrolysate	7	0.7	TLC Method 1 analysis characterized radioactivity associated with monosaccharides (2% TRR) and AMPA (1% TRR).
Nonextractable	3	0.3	Not further analyzed (N/A).

[a] N/R = not reported.

Storage stability

Samples of soybean seed flour and extracts were frozen (temperature unspecified) prior to analysis. Based on the dates provided by the petitioner, initial extraction and TLC and HPLC analyses were completed within <1-3 months of sample collection, therefore, supporting storage stability data are not required.

In the second study (1997; MRID 44313902), the test substance, radiolabeled [^{14}C-trimethyl sulfonium]glyphosate-trimesium (PMG-[^{14}C]TMS; specific activity 54.1 Ci/mmol, average radiochemical purity 95.8%), was mixed with water and applied to glyphosate-tolerant soybean plants grown in three plastic pots in a greenhouse. Three applications were made. The first application was made preemergence to the soil surface on the same day the seeds were planted at a rate equivalent to 5 lb ai/A of PMG-[^{14}C]TMS. The second and third applications were made postemergence 59 and 109 days after planting to the soil and surfaces of plants at rates equivalent to 2 and 1 lb ai/A of PMG-[^{14}C]TMS, respectively. The

application solutions for postemergence applications also contained surfactant. The total application rate was equivalent to 8 lb ai/A (~1x the maximum proposed seasonal rate). One additional pot served as a control.

Soybean plants were harvested 7 days after the third postemergence application by cutting plants a few centimeters above ground level. Soybean seed samples were separated from the pods by hand.

Total radioactive residue (TRR)

At WRC, samples of soybean seed were homogenized then subjected to LSC following combustion. The TRR in soybean seed was 23 ppm as determined by summing the radioactivity in extracts and in nonextractable residues.

Extraction and hydrolysis of residues

Subsamples of soybean seed flour were subjected to extraction and hydrolysis procedures for residue characterization and identification. During the fractionation and characterization procedures, aliquots of extracts and nonextractable residues were analyzed for radioactivity by LSC or combustion/LSC. The general extraction procedures are summarized below.

Soybean seed flour was sequentially extracted with hexane (3x), DCM:0.1 N HCl (1:1, v:v), 0.1 N HCl (2x), and hexane. The hexane and DCM fractions were combined and back-extracted with 0.1 N HCl to yield a composite organic fraction and an aqueous back extract. The aqueous back extract used to extract the nonextractable residues and then was combined with initial aqueous extracts to yield a composite aqueous fraction (Aqueous 1). The nonextractable residues were subjected to acid hydrolysis with 0.1 N HCl and then extracted with diethyl ether and ethanol.

The distribution of ^{14}C-activity in the extracts and hydrolysates of soybean seed flour is presented in Table 2.

Characterization/identification of residues

Extracts were analyzed by TLC (Methods 1, 2, and 3) and HPLC (Method 1). TLC analyses were conducted on silica gel (60 F_{254}) plates using a solvent system of 10% aqueous ammonium formate:methanol (50:50, v:v) to resolve TMS and trimethyl sufloxonium for Method 1; TLC Methods 2 and 3 were identical to Methods 2 and 3 described previously for the [^{14}C]PMG-TMS study. Radioactivity was detected and quantified using a bio-imaging analyzer system; nonlabeled standards were visualized using Dragendorff reagent for Method 1. HPLC analyses were conducted using a BECLMAN ULTRASIL CX column and precolumn with a mobile phase of methanol:0.5 M aqueous phosphate buffer (1:9; v:v), and diode-array UV and RI detection; radioactivity was detected using a radioactivity flow-through monitor and quantitated by fraction collection and LSC. Metabolites were identified by cochromatography with reference standards. The following reference standards were used for cochromatography: trimethylsulfonium

iodide, trimethylsulfoxonium chloride, dimethyl sulfone, fructose, galactose, glucose, oleic acid, and linoleic acid.

TMS was identified from the Aqueous 1 fraction by cochromatography in two different systems, HPLC and TLC.

Table 2. Distribution and characterization of radioactive residues in soybean seed flour following three applications of PMG-[^{14}C]TMS.

Fraction	% TRR	ppm	Characterization/Identification
Soybean seed flour (TRR=23.0 ppm)			
Composite of organic fractions	1	0.2	TLC Method 3 analysis characterized radioactivity associated with triglycerides (1% TRR).
Aqueous 1	87	20.1	HPLC Method 1 and TLC Method 1, 2, and 3 resolved TMS (82% TRR, 18.7 ppm).
Nonextractable	N/R [a]	N/R	Hydrolyzed with 0.1 N HCl and extracted with drying solvents diethyl ether and ethanol.
Aqueous 2	9	2.1	TLC Method 1 resolved TMS (8% TRR, 1.8 ppm).
Drying Solvents	1	0.1	Not further analyzed (N/A).
Nonextractable	2	0.5	N/A.

[a] N/R = not reported.

Storage stability

Samples of soybean seed flour and extracts were refrigerated prior to analysis. Based on the dates provided by the petitioner, initial extraction and TLC and HPLC analyses were completed within <1-3 months of sample collection, therefore, supporting storage stability data are not required.

Study summary:

The submitted metabolism studies are adequate to delineate the metabolism of PMG and TMS in the seed of glyphosate-tolerant soybeans. The TRR in soybean seed treated with three applications of [^{14}C]PMG-TMS at 1x the maximum proposed application rate was 10.0 ppm. PMG was identified at 26% TRR (2.6 ppm) and AMPA was identified at 38% TRR (3.8 ppm). An additional 7% TRR was found to be associated with triglycerides and monosaccharides (radioactivity was observed in monosaccharides following hydrolysis of nonextractable residues). These results are similar to the previously submitted soybean metabolism study with [^{14}C]PMG-TMS in which PMG and AMPA were the only metabolites identified. In the previous study, PMG and AMPA were identified at much lower levels, which is consistent with the difference in use patterns in the two studies.

The TRR in soybean seed treated with three applications of PMG-[^{14}C]TMS at 1x the maximum proposed application rate was 23.0 ppm. TMS was identified at 90% TRR (20.7 ppm). A small amount of

radioactivity (1% TRR) was found to be associated with triglycerides. These results are similar to the previously submitted soybean metabolism study with PMG-[^{14}C]TMS in which TMS was found to be the major residue.

OPPTS GLN 860.1300: Nature of the Residue - Livestock

Sulfosate metabolism studies in animals have been submitted in conjunction with a previous corn tolerance petition. The nature of the residue is considered to be understood in ruminants and poultry (DP Barcodes D205472, D209331, D209332, and D209333, 4/4/95, G. Kramer). The Agency concluded that the parent ions are the residues of regulatory concern for sulfosate in meat, milk, and eggs.

OPPTS GLN 860.1340: Residue Analytical Method - Plant Commodities

Enforcement analytical methods have previously been submitted for proposed tolerances; the petitioner used the previously submitted enforcement methods (Methods RR 92-042B and RR 93-105B RES) for data collection in the submitted field trial studies on soybean seed.

Method validation and successful PMV by ACL of Method RR 92-042B (originally submitted with PP#3F04238 and PP#4F04343), for the determination of PMG, and Method RR 93-105B (originally submitted with PP#1F03950), for the determination of TMS, have been completed. The methods were revised to incorporate revisions required by the Agency, and the revised methods (RR92-042B RES and RR 93-105B RES) were approved by the Agency for the enforcement of tolerances for residues of the PMG and TMS ions of sulfosate in/on crops (DP Barcodes D215869, 7/6/95, G. Kramer; D219447, D219460, and D221687, 1/23/96, G. Kramer). The methods have been submitted to the FDA for inclusion in PAM II (DP Barcodes D248046 and D248047, 8/17/98, G. Kramer).

Concurrent method recoveries were generated in conjunction with the submitted field trials. Untreated samples of soybean seed were fortified with PMG at 0.25-50 ppm and analyzed concurrently with the treated samples using method RR 92-042B; recoveries were 79.8-119.5% (average = 98.2%, 12 samples). Recoveries of TMS from samples fortified at 0.25-15 ppm and analyzed using method RR 93-105B RES were 75.4-102.7% (average = 93.8%, 17 samples).

OPPTS GLN 860.1340: Residue Analytical Methods - Animal Commodities

Enforcement analytical methods have previously been submitted for proposed tolerances. Method validation and successful PMV by ACL of Methods RR 93-104B for the determination of PMG and RR 93-100B for the determination of TMS (originally submitted with PP#9F03796) have been completed (DP Barcodes D219447, D219460, and D221687, 1/23/96, G. Kramer). The methods were revised to incorporate revisions required by the Agency and revised methods (RR 93-104B

RES and RR 93-100B RES) were approved by The Agency for the enforcement of tolerances for residues of the PMG and TMS ions of sulfosate in meat, milk, poultry and eggs (DP Barcode D242217, 4/4/98, G. Kramer). The methods have been submitted to the FDA for inclusion in PAM II (DP Barcodes D248043 and D248045, 8/17/98, G. Kramer).

OPPTS GLN 860.1360: Multiresidue Method

The report on the behavior of PMG and TMS in FDA protocols I, II, III and IV, has been forwarded to the FDA for review (Memo dated 10/25/90, S. Koepke).

OPPTS GLN 860.1380: Storage Stability Data

No storage stability data were submitted with this petition. The soybean seed samples from the submitted field trials were frozen within 5 hours of harvest. Samples were transported frozen either by ACDS freezer truck or by overnight express to Zeneca Ag Products, Western Research Center (Richmond, CA) where they were stored frozen (-18±5 C) until analysis. The total storage interval from harvest to analysis for soybean seed was 25-186 days (~1-6 months). The petitioner stated that five samples were inadvertently removed from the freezer and stored at ambient temperature for 5 days prior to analysis for TMS. To demonstrate that TMS residues were stable over this period, the petitioner reanalyzed two samples from one field trial after storage at room temperature for 5-6 days. Initial TMS residues were 3.34 ppm and 3.84 ppm and residues after storage were 4.2 ppm and 4.4 ppm, respectively, indicating that TMS residues are stable at room temperature for up to 6 days.

Previously, the petitioner demonstrated that residues of PMG and TMS are stable in soybean seed and straw for up to 2 years (CB Nos. 6814, 6815, and 6816, 4/29/91, S. Koepke). No additional storage stability data are required to support the submitted field trials on soybean seed.

OPPTS GLN 860.1500: Crop Field Trials

Soybean

Established tolerances: Tolerances have been established for the residues of sulfosate in/on soybean seed at 3 ppm (of which no more than 1 ppm is trimethylsulfonium), soybean aspirated grain fractions at 210 ppm (of which no more than 60 ppm is trimethylsulfonium), soybean forage at 2 ppm (of which no more than 1 ppm is trimethylsulfonium), and soybean hay at 5 ppm (of which no more than 2 ppm is trimethylsulfonium) [40 CFR §180.489(a)].

Proposed tolerances: The petitioner is proposing the following amended tolerances for sulfosate: soybean seed at 21 ppm (of which no more than 13 ppm is trimethylsulfonium) and soybean aspirated grain fractions at 1300 ppm (of which no more than 720 ppm is

trimethylsulfonium). No amended tolerances have been proposed for soybean forage and hay. We note that there is a feeding restriction on the label for the proposed amended uses on soybeans; however, the petitioner indicated that soybean hay data would be included in the final report.

The petitioner had previously submitted a tolerance petition (PP#0F03860; 4/29/91, S. Koepke; DP Barcodes D208740, D208742, D213615, and D213612, 4/4/95, G. Kramer; and DP Barcodes D219447, D219460, and D221687, 1/23/96, G. Kramer) for tolerances for soybean and animal commodities. This petition was based on use of sulfosate on soybeans prior to crop emergence at a maximum of 4 lb ai/A/year; spot applications (to weeds) were allowed with an 8-week PHI. Upon resolution of all residue chemistry deficiencies associated with this petition (DP Barcode D242224, 4/4/98, G. Kramer), permanent tolerances were established.

The proposed use pattern for this tolerance petition (PP#7F04854) to amend the tolerance for soybean seed includes application to soybeans genetically modified to be tolerant to glyphosate herbicides, and application as a harvest aid to all soybeans 7 days prior to harvest. The proposed seasonal application rate is not to exceed 8 lb ai/A for all application methods on all soybean types.

Zeneca submitted a single volume of interim soybean field trial data; the interim report provides data for soybean seed only. The petitioner elected to cancel the collection of soybean aspirated grain fractions because it was concluded that the requirement for residue data for aspirated grain fractions had been fulfilled by a previous study (DP Barcodes D208740, D208742, D213615, and D213612, 4/4/95, G. Kramer). The petitioner indicated that data for soybean hay samples will be included in the final report. The citation is listed below.

> 44313903 Iwata, Y. (1997) Glyphosate Trimesium: Magnitude of the Residue Study on Soybeans from Trials Conducted in the United States: (Interim Report): Lab Project Number: GLYP-96-MR-08: RR97-010B INT: 47-NC-96-841. Unpublished study prepared by Zeneca Ag Products. 96 p.

A total of 20 soybean field trials were conducted in 1996 in Regions 2 (NC and TN), 4 (AR, LA, and MS), and 5 [IA(3), IL(3), IN(1), KS(1), MN(2), MO(1), NE(1), OH(1), SD(1), and WI(1)]. Mature soybean seed was harvested 6-7 days following the last of three broadcast applications of the 6 lb/gal SC formulation (EPA Reg. No. 10182-324). The first application was made preemergence at 5 lb ai/A/application, followed by a second application made at the R2 growth stage at 2 lb ai/A/application, and the final application was made 6-7 days prior to seed harvest at 1 lb ai/A/application. The total application rate was 8 lb ai/A (1x the maximum proposed seasonal rate). Applications were made in 3-22 gal/A water with 1% volume of nonionic surfactant; the equipment used for application was not specified. Samples were collected either mechanically or by hand, bagged, and frozen within 5 hours of harvest. Samples were transported frozen either by ACDS freezer truck or by overnight express to Zeneca Ag Products, Western Research Center (Richmond, CA) where they were stored frozen (-18±5 C) until analysis.

Samples of soybean seed were analyzed for residues of PMG and TMS using Methods RR 92-042B and RR 93-105B RES, respectively. The method limit of quantitation (LOQ) was 0.25 ppm for both PMG and TMS. The petitioner stated that the levels of PMG and TMS in soybean seed (>0.25 ppm in all samples except one) precluded the need for lower LOQs. Apparent residues of PMG and TMS were each less than the LOQ (<0.25 ppm) in/on 20 untreated samples of soybean seed. A summary of the residues of PMG and TMS in the treated samples is presented in Table 3.

Table 3. Residues of PMG and TMS in soybean seed harvested 6-7 days following the last of three broadcast applications of the 6 lb/gal SC formulation at total rate of 8 lb ai/A (1x the maximum seasonal application rate).

EPA Region	Trial Location	PTI (days)	Residues (ppm) [a]		
			PMG	TMS	Total
2	Goldsboro, NC	7	0.94, 2.61	5.94, 11.20	6.88, 13.81
2	Murfreeboro, TN	7	4.19, 3.66	4.13, 5.88	8.32, 9.54
4	Georgetown, AR	7	<0.25, 0.26	3.34, 3.84	3.34, 4.10
4	Winsboro, LA	7	0.67, 0.95	3.86, 4.50	4.53, 5.45
4	Leland, MS	4	0.89	4.91	5.80
		7	0.58, 0.49	2.89, 3.12	3.47, 3.61
		9	0.63	5.00	5.63
		14	0.57	5.25	5.82
5	Albia, IA	7	0.56, 1.01[b]	3.19, 2.96	3.75, 3.97
5	Sheffield, IA	7	0.62, 1.18[b]	1.16, 1.32	1.78, 2.50
5	Boone, IA	7	1.33, 1.27[b]	1.42, 1.72	2.75, 2.99
5	Brimfield, IL	7	2.60[b], 2.63	3.17, 3.27	5.77, 5.90
5	Collison, IL	7	0.83[b], 1.25	2.35, 2.51	3.18, 3.76
5	Champaign, IL	2	2.24	2.01	4.25
		6	1.80, 1.55	4.45, 4.97	6.25, 6.52
		11	2.30	5.11	7.41
		14	2.33	5.25	7.58
5	New Richmond, IN	7	6.72, 7.88[b] HAFT=7.26 ppm	11.17, 12.47[b] HAFT=11.82 ppm	17.89, 20.27 HAFT=19.08 ppm
5	Desoto, KS	7	0.63, 0.84	1.83, 1.94	2.46, 2.78
5	Sanborn, MN	7	2.85, 2.77	4.72, 5.03[b]	7.57, 7.80
5	Brownton, MN	7	1.70, 1.80[b]	2.93, 3.00	4.63, 4.80
5	Gower, MO	7	0.68, 0.59	3.17, 3.52	3.85, 4.11
5	Crete, NE	7	1.02[b], 1.04[b]	4.55, 4.61	5.57, 5.65
5	Urbana, OH	7	2.47[b], 2.78	10.55, 10.73	13.02, 13.51
5	Emery, SD	7	3.21, 3.28	6.15, 6.11	9.36, 9.39
5	Lake Mill, WI	7	3.53, 3.71	4.88, 4.99	8.41, 8.70
Average					**6.72**

[a] Total residues of PMG and TMS were determined according to the HED tolerance expression; if both ions were less than the LOQ then the total was reported as <0.05 ppm (LOQ), and only quantifiable residues were totaled.

[b] Highest residue value from duplicate analyses.

Geographic representation of residue data is adequate. The current guidance (OPPTS 860.1500, Table 5) specifies that a minimum of 20 field trials should be conducted for soybean (dried). These trials should be conducted in Regions 2 (2 trials), 4 (3 trials), and 5 (15 trials). The current soybean field trials reflecting the registered use pattern were conducted in Regions 2 (2 trials; NC and TN), 4 (3 trials; AR, LA, and MS) and 5 (15 trials; IA, IL, IN, KS, MN, MO, NE, OH, SD, and WI).

Study summary: The submitted residue data for soybean seed are adequate. The submitted data indicate that combined residues of PMG and TMS will not exceed the proposed tolerance of 21 ppm (of which no more than 13 ppm is trimethylsulfonium) in/on soybean seed harvested following the maximum proposed application rate. The combined residues of PMG and TMS were 1.78-20.27 ppm (1.16-12.47 ppm of which was TMS) in/on soybean seed harvested 6-7 days following the last of three broadcast applications of the 6 lb/gal SC formulation at a total rate of 8 lb ai/A (1x the maximum proposed seasonal application rate).

Two residue decline studies were conducted for soybeans; both studies reflected posttreatment intervals less than and greater than the proposed PHI. The results of the decline studies indicated that combined residues of PMG and TMS neither increase or decrease with increasing posttreatment intervals. The highest 2 values from each site were thus used to calculate the average.

The requirements for soybean aspirated grain fractions residue data have been fulfilled by a previously submitted soybean processing study (DP Barcodes D208740, D208742, D213615, and D213612, 4/4/95, G. Kramer). Because the composition of the fractions of the grain dust in the study was not comparable to commercial aspirated grain fractions and because the petitioner reported residue results for each fraction separately, the Agency calculated expected concentration factors in aspirated grain fractions of 73.8x for PMG and 57.5x for TMS. Based on the HAFT residues from the soybean field trials and the calculated concentration factors, the expected residues in aspirated grain fractions are 1216 ppm [7.26 ppm PMG x 73.8 = 535.8 + 11.82 ppm TMS x 57.5 = 679.7]. Therefore, the proposed tolerance of 1300 ppm (of which no more than 720 ppm is trimethylsulfonium) for soybean aspirated grain fractions is appropriate. HED notes that the tolerance should be established for "Aspirated grain fractions." **A revised Section F is required.**

OPPTS GLN 860.1520: Processed Food/Feed

Established tolerances: A tolerance of 7.0 ppm (of which no more than 2.0 ppm is TMS) has been established for the residues of sulfosate in soybean hulls [40 CFR §180.489(a)].

Proposed tolerances: The petitioner is proposing to establish a tolerance for sulfosate in soybean hulls at 45 ppm (of which no more than 25 ppm is trimethylsulfonium).

An adequate soybean processing study has been submitted previously and reviewed by the Agency (MRID 43397004; DP Barcodes D208740,

D208742, D213615, and D213612, 4/4/95, G. Kramer). The processing data indicated that residues of PMG and TMS concentrated 2.5x and 2.0x, respectively, in soybean hulls and did not concentrate in soybean meal and refined oil (<0.28X). The HAFT residues from soybean field trials reflecting the maximum proposed use pattern are 7.26 ppm for PMG and 11.82 ppm for TMS. Based on these HAFT residues and the observed concentration factors, the maximum expected total residues are 42.93 ppm for soybean hulls (7.26 ppm PMG x 2.5 = 18.15 ppm plus 11.82 ppm x 2.0 = 23.64 ppm). Therefore, the proposed tolerance of 45 ppm (of which no more than 25 ppm is trimethylsulfonium) for soybean hulls is appropriate. For anticipated residues in soybean meal and refined oil, a value of 1.9 ppm (0.28 X ave. seed residue, 6.7 ppm) should be used.

OPPTS GLN 860.1480: Meat, Milk, Poultry, Eggs

Ruminants

Established tolerances: Tolerances have been established for the residues of sulfosate in milk at 0.20 ppm, and in the fat, meat byproducts, and meat of cattle, goats, hogs, horses, and sheep at 0.10, 1.00, and 0.20 ppm, respectively [40 CFR §180.489(a)].

Proposed tolerances: The petitioner is proposing to establish tolerances for residues of sulfosate in liver and kidney of cattle, goat, hog, sheep, and horse at 0.75 ppm and 3.5 ppm, respectively, and to amend the following tolerances:

Cattle, goat, hog, sheep, and horse meat byproducts (except liver and kidney)	1.0 ppm
Cattle, goat, hog, sheep, and horse meat	0.6 ppm
Cattle, goat, hog, sheep, and horse fat	0.2 ppm
Milk	1.1 ppm

No additional feeding studies were submitted with this petition. The petitioner based the proposed tolerances on the use of the maximum theoretical dietary burden in dairy cows for sulfosate resulting from a diet comprised of wheat RACs and soybean seed/meal (PP#5F04554; DP Barcodes D217458, D217440, and D217452, 11/28/95, G. Kramer). The petitioner provided a recalculation of the theoretical dietary burden for dairy cows at 394 ppm; see Table 4.

Table 4. The petitioner's recalculation of the maximum theoretical dietary burden of sulfosate to dairy cattle.

Feed Commodity	Proposed Tolerance (ppm)	% Dry Matter	Dairy Cattle	
			% of Diet	Burden (ppm)
Aspirated grain fractions	1300	85	20	306
Wheat, forage	35	25	60	84
Soybean, seed/meal	21	89	20	3.5
		TOTAL	100	394

A ruminant feeding study has been submitted previously and reviewed by the Agency (CBTS Nos. 6814, 6815, and 6816, 4/29/91, S. Koepke). The feeding study reflected dosing levels of 50, 300, and 1000 ppm. The petitioner recalculated the predicted residue levels of sulfosate by comparing.the dietary burden of 394 ppm to the **average** results found at the 300-ppm feeding level using the following formula:

$$\frac{394 \text{ ppm}}{300 \text{ ppm}} = \frac{x}{\text{Amount of TMS or PMG found in the } \textbf{average} \text{ of three cows in tissues, fat, or milk in the study}}$$

Comments: The petitioner's calculation of the maximum theoretical dietary burden of sulfosate to dairy cattle is appropriate. The Agency has calculated the maximum theoretical dietary burden to beef cattle to be 379 ppm; see Table 5. Based on these recalculated dietary burdens, the dosing levels of 300 and 1000 ppm (CBTS Nos. 6814, 6815, and 6816, 4/29/91, S. Koepke) represent 0.8x and 2.6x the maximum theoretical dietary burden to beef cattle and 0.7x and 2.4x the maximum theoretical dietary burden to dairy cattle.

Table 5. The Agency's calculation of the maximum theoretical dietary burden of sulfosate to beef cattle.

Feed Commodity	Proposed Tolerance, ppm	% Dry Matter	Beef Cattle	
			% of Diet	Burden, ppm
Aspirated grain fractions	1300	85	20	306
Wheat, forage	35	25	25	35
Wheat, hay	100	88	25	28
Wheat, straw	75	88	10	8.5
Soybean, hulls	45	89	20	4.7
		TOTAL	100	379

To determine expected levels of sulfosate in animal tissues for the theoretical dietary burden of 394 ppm, the Agency believes that a formula similar to that used by the petitioner is appropriate with the exception that the **maximum** residue result observed at the 300-ppm dosing level in each commodity should be used. The appropriate formulae are thus:

$$\frac{394 \text{ ppm}}{300 \text{ ppm}} = \frac{x}{\textbf{Maximum} \text{ residues of TMS and PMG found in milk at 300-ppm dosing level}}$$

$$\frac{379 \text{ ppm}}{300 \text{ ppm}} = \frac{x}{\text{Maximum residues of TMS and PMG found in tissues and fat at 300-ppm dosing level}}$$

The Agency-predicted residues in tissues, fat, and milk from the feeding dairy cattle at the Agency-recalculated maximum theoretical dietary burden of sulfosate are presented in Table 6.

Table 6. Agency-calculated residues of PMG and TMS in the tissues, fat, and milk of dairy cattle.

Commodity	PMG residues [a] (ppm)	TMS residues (ppm)	Combined residues (ppm)	Agency Recommended Tolerance
Milk	0.03	1.23	1.26	1.5
Kidney	3.3	2.4	5.7	6.0
Liver	0.20 [b]	0.87	1.07	1.5
Fat	0.08	0.13	0.21	0.5
Muscle	0.03 [b]	0.80	0.83	1.0

[a] In a previous review (CBTS Nos. 6814, 6815, and 6816, 4/29/91, S. Koepke) the anion is referred to as carboxymethylamino phosphonate (CMP) and in subsequent reviews the anion is referred to as N-(phosphonomethyl)glycine anion (PMG).

[b] Because residues of PMG were less than the LOQ at the 300-ppm dosing level, the results from the 1000-ppm dosing level were used, with the appropriate calculation.

A revised Section F, proposing the following meat and milk tolerances, is required:

Cattle, goat, hog, sheep, and horse kidney . . . . . 6.0 ppm
Cattle, goat, hog, sheep, and horse meat byproducts (exc. kidney) . . . . . 1.5 ppm
Cattle, goat, hog, sheep, and horse meat . . . . . 1.0 ppm
Cattle, goat, hog, sheep, and horse fat . . . . . 0.5 ppm
Milk . . . . . 1.5 ppm

Poultry

Established tolerances: Tolerances have been established for the residues of sulfosate in eggs at 0.02 ppm, poultry fat at 0.05 ppm, poultry liver at 0.05 ppm, poultry meat byproducts (exc. liver) at 0.10 ppm, and poultry meat at 0.05 ppm [40 CFR §180.489(a)].

No additional poultry tolerances were proposed and no additional feeding studies were submitted with this petition. The petitioner stated that the proposed use on soybeans will have no impact on the poultry tolerances based on the Agency's conclusion that the maximum theoretical dietary burden in poultry for sulfosate

resulted from a diet comprised of wheat grain and wheat milled byproducts (DP Barcode D243313, 5/5/98, G. Kramer),

The petitioner should note that the Agency's conclusion regarding the maximum theoretical dietary burden to poultry was made when the expected tolerances for wheat commodities were much greater than the established soybean tolerances. At that time, the Agency calculated a maximum theoretical dietary burden for poultry of 1.3 ppm. With the amended use on soybeans resulting in higher tolerances for soybean commodities, the poultry dietary burden must be recalculated. Based on a diet consisting of 80% wheat grain (proposed tolerance of 0.75 ppm) and 20% soybean hulls (proposed tolerance of 45 ppm), the maximum theoretical dietary burden of sulfosate to poultry is 9.60 ppm. The petitioner has previously submitted a poultry feeding study (CBTS Nos. 6814, 6815, and 6816, 4/29/91, S. Koepke) reflecting dosing levels of 0.5, 5, and 50 ppm. Based on the results of this study, the appropriate tolerances for poultry commodities are:

Poultry meat byproducts	0.10 ppm
Poultry meat	0.05 ppm
Poultry fat	0.05 ppm
Eggs	0.05 ppm

Only the tolerance for eggs differs from those already established. **A revised Section F must be submitted.**

OPPTS GLN 860.1850/1900: Confined/Field Accumulation in Rotational Crops

The Agency has previously reviewed two confined rotational crop studies for sulfosate and concluded that rotational crop restrictions were not required for uses on crops in which the total seasonal application rate does not exceed 8 lb ai/A (DP Barcode D209543, 4/21/95, G. Kramer). No additional rotational crop data are required to support this petition.

EPA MEMORANDA CITED IN THIS REVIEW

DP Barcode:	None
Subject:	Multiresidue Test Information for Updating PAM I.
From:	S. Koepke
To:	L. Sawyer, FDA
Dated:	10/25/90
MRID(s):	None

CB No.: 6814, 6815, 6816
DP Barcode: None
Subject: PP#0F3860 Sulfosate (Touchdown) in or on soybean seed, forage, and hay. Evaluation of analytical methods and residue data.
From: S. Koepke
To: R. Taylor/C. Giles and Toxicology Branch II
Dated: 4/29/91
MRID(s): 41462102-41462106 and 41209919

CB No.: 15072
DP Barcode: D211742
Subject: February 7, 1995 Meeting with Tox concerning residues of regulatory concern for glyphosate-trimesium (formerly known as sulfosate).
From: G. Kramer, R. Loranger, P. Errico, R. Hurley, W. Dykstra, and R. Gardner
To: Chemistry Branch Files
Dated: 2/8/95
MRID(s): None

CB No.: 15282
DP Barcode: D213279
Subject: PP#s 9F03796, 0F03860, 3F04238, and 4F04343. Glyphosate-trimesium (formerly known as Sulfosate) in or on corn, soybeans, citrus fruit, stone fruit, and the nut crop group (except almonds). Results of Petition Method Validation (PMV)
From: G. Kramer
To: R. Taylor
Dated: 3/21/95
MRID(s): 42848702 and 43165802

CB No.: 13993, 14726, 14727, and 15174
DP Barcode: D205472, D209331, D209332, and D209333
Subject: PP# 9F03796. Glyphosate-trimesium (formerly known as Sulfosate) in or on Corn and Animal RACs. Amendments of 6/16/94 and 11/7/94.
From: G. Kramer
To: R. Taylor and J. Smith
Dated: 4/4/95
MRID(s): 43298101, 43298102, 43273601-43273611

CB No.: 14617, 14618, 15346, and 15347
DP Barcode: D208740, D208742, D213615, and D213612
Subject: PP# 0F03860. Glyphosate-trimesium (formerly known as Sulfosate) in or on Soybean RACs. Amendments of 10/3/94 and 3/20/95.
From: G. Kramer
To: R. Taylor and J. Smith
Dated: 4/4/95
MRID(s): 43397001-43397003, 43589500, and 43419801

CB No.: 14729
DP Barcode: D209543
Subject: ID# 010182-00324. Label Amendment for Glyphosate-trimesium (Touchdown Herbicide).
From: G. Kramer
To: R. Taylor and J. Smith
Dated: 4/21/95
MRID(s): 43450901 and 43450902

CB No.: 15649
DP Barcode: D215869
Subject: PP#s 9F03796, 0F03860, 3F04238, and 4F04343. Glyphosate-trimesium (formerly known as Sulfosate) in or on corn, soybeans, stone fruit, and the nut crop group (except almonds). Amendment of 5/1/95.
From: G. Kramer
To: R. Taylor
Dated: 7/6/95
MRID(s): 43631301

CB No.: 16276
DP Barcode: D219866
Subject: PP#s 9F03796, 0F03860, 3F04238, 0F3890, 1H03950, and 4F04343. Glyphosate-trimesium (formerly known as Sulfosate) in or on corn, soybeans, citrus fruit, grapes, stone fruit, and the nut crop group (except almonds). Results of Petition Method Validation (PMV).
From: G. Kramer
To: R. Taylor
Dated: 10/17/95
MRID(s): 43273604

CB No.: 15931, 15932, and 15933
DP Barcode: D217458, D217440, and D217452
Subject: PP#s 5F04554 and 5H05727. Glyphosate-trimesium in/on Pome Fruit and Wheat. Evaluation of Residue Data and Analytical Methods.
From: G. Kramer
To: R. Taylor and K. Whitby
Dated: 11/28/95
MRID(s): 43712801-43712805

CB No.: 16576
DP Barcode: D221382
Subject: PP#s 9F03796, 0F03860, 0F03890, and 4F04343. Glyphosate-trimesium (formerly known as Sulfonate) in or on corn, soybeans, citrus fruit, and the nut crop group. Results of Petition Method Validation (PMV) - TMS in/on Animal RACs.
From: G. Kramer
To: R. Taylor
Dated: 1/22/96
MRID(s): 43273608

CB No.: 16253, 16252, and 16707
DP Barcode: D219447, D219460, and D221687
Subject: PP#s 0F03860. Glyphosate-Trimesium in or on Soybeans and Animal RACs. Amendments of 7/24/95 & 11/29/95.
From: G. Kramer
To: R. Taylor and K. Whitby
Dated: 1/23/96
MRID(s): 43743801 and 43864801

DP Barcode: D242217
Subject: PP#0F03860. Sulfosate (Glyphosate-Trimesium) in or on Soybean and Animal RACs. Amendment of ?. Revised Analytical Methods for Animal Tissues.
From: G. Kramer
To: J. Tompkins/T. Colvin-Snyder
Dated: 4/4/98
MRID(s): 44246701 and 44246702

DP Barcode: D248046
Subject: Analytical method (determination of the PMG ion in/on crops) for inclusion in PAM Vol II.
From: G. Kramer
To: M. Clower
Dated: 8/17/98
MRID(s): 43631301

DP Barcode: D248047
Subject: Analytical method (determination of the TMS ion in/on crops) for inclusion in PAM Vol II.
From: G. Kramer
To: M. Clower
Dated: 8/17/98
MRID(s): 43864801

DP Barcode: D248043
Subject: Analytical method (determination of the PMG ion in meat, milk, poultry and eggs) for inclusion in PAM Vol II.
From: G. Kramer
To: M. Clower
Dated: 8/17/98
MRID(s): 44246701

DP Barcode: D248045
Subject: Analytical method (determination of the TMS ion in meat, milk, poultry and eggs) for inclusion in PAM Vol II.
From: G. Kramer
To: M. Clower
Dated: 8/17/98
MRID(s): 44246702

DP Barcode: D243450
Subject: PP# 7F04876. Sulfosate (i.e. Touchdown) in/on Fruiting Vegetables (Except Cucurbits). Evaluation of Residue Data and Analytical Methods.
From: J. Rowell and G. Kramer
To: J. Tompkins/T. Colvin-Snyder
Dated: 9/21/98
MRID(s): 44326501-44326503