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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 20-MARCH-2001

SUBJECT: PP#s 7F4853, 7F4876, 5F4554, 9F6032. **SULFOSATE (GLYPHOSATE TRIMESIUM): COTTON, ROOT AND TUBER VEGETABLES, PISTACHIO, GRAIN SORGHUM, SWEET CORN, WHEAT, FRUITING VEGETABLES (EXCEPT CUCURBITS), EDIBLE-PODDED LEGUME VEGETABLES, SUCCULENT SHELLED PEA AND BEANS, AND DRIED SHELLED PEA AND BEANS (EXCEPT SOYBEANS). HED Risk Assessment.**
Barcodes D254801, D269399. PC Code 128501. Case 289001, 292164.
Submission S526513, S565507.

FROM: Dana Vogel, Chemist
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THROUGH: G. Jeffrey Herndon, Branch Senior Scientist
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TO: Susan Stanton, PM Team 25
Jim Tompkins, PM
Registration Division (7505C)

The Health Effects Division (HED) of the Office of Pesticide Programs (OPP) is charged with estimating the risk to human health from exposure to pesticides. The Registration Division (RD) of OPP has requested that HED evaluate hazard and exposure data and conduct dietary, occupational, residential and aggregate exposure assessments, as needed, to estimate the risk to human health that will result from all registered and proposed uses of sulfosate in/on cotton, root and tuber vegetables, pistachio, grain sorghum, sweet corn, wheat, fruiting vegetables (except cucurbits), edible-podded legume vegetables, succulent shelled pea and beans, and dried shelled pea and beans (except soybeans).

A summary of the findings and an assessment of human risk resulting from the proposed uses of sulfosate is provided in this document. The risk assessment was provided by Dana Vogel of

Registration Action Branch 1 (RAB1), the hazard characterization was provided by Jessica Kidwell of RAB1, the residue chemistry data review and dietary risk assessment by Jennifer Tyler of RAB1, the occupational/residential exposure and risk assessment by Mark Dow, Ph.D. of RAB1, and the drinking water assessment by Pat Jennings of the Environmental Fate and Effects Division (EFED).

Recommendation for Tolerances and Registration

Provided the petitioner submits **revised Section Fs and B as detailed below** (see Section 8.1), the submitted residue chemistry data support the establishment of permanent tolerances for residues of sulfosate (the trimethylsulfonium salt of glyphosate) per se in/on the following commodities:

Wheat, grain	10 ppm (of which no more than 2.5 ppm is TMS)
Wheat, straw	90 ppm (of which no more than 40 ppm is TMS)
Wheat, hay	1.0 ppm (of which no more than 0.50 ppm is TMS)
Vegetable, fruiting, group	0.05 ppm
Vegetable, legume, edible podded, subgroup	0.50 ppm (of which no more than 0.3 ppm is TMS)
Pea and bean, succulent shelled, subgroup	0.20 ppm (of which no more than 0.1 ppm is TMS)
Pea and bean, dried shelled, except soybean, subgroup	6.00 ppm (of which no more than 1.5 ppm is TMS)
Cotton, gin byproducts	120 ppm (of which no more than 35 ppm is TMS)
Cotton, undelinted seed	40 ppm (of which no more than 10 ppm is TMS)
Pistachio	0.05 ppm
Radish, roots	16 ppm (of which no more than 15 ppm is TMS)
Radish, tops	10 ppm (of which no more than 8.0 ppm is TMS)
Vegetable, root, except radish, subgroup	0.15 ppm (of which no more than 0.10 ppm is TMS)
Vegetable, tuberous and corm, subgroup	1.0 ppm (of which no more than 0.50 ppm is TMS)
Vegetable, leaves of root and tuber, except radish, group	0.30 ppm (of which no more than 0.20 ppm is TMS)
Sorghum, grain, grain	35 ppm (of which no more than 15 ppm is TMS)
Sorghum, grain, forage	0.20 ppm (of which no more than 0.10 ppm is TMS)
Sorghum, grain, stover	140 ppm (of which no more than 60 ppm is TMS)
Corn, sweet, forage	20 ppm (of which no more than 5.0 ppm is TMS)
Corn, sweet, kernels plus cob with husks removed	0.15 ppm (of which no more than 0.10 ppm is TMS)
Corn, sweet, stover	170 ppm (of which no more than 65 ppm is TMS)
Poultry, meat byproducts	0.5 ppm

The existing toxicological database for sulfosate supports the establishment of permanent tolerances for residues of sulfosate in/on the commodities listed above. **However, the registration should be conditional until the petitioner satisfactorily addresses the toxicology deficiencies listed below** (see Section 8.2).

Deficiencies/Data Needs

1) Chemistry

- Revised Section B to include:
  Legumes: a restriction against application of sulfosate to beans and peas grown for feed.

Cotton: a maximum of two preharvest broadcast applications at up to 1.0 lb ai/A/application with a minimum retreatment interval of 7 days between the two preharvest applications.

- Revised Section F's to include:
  The HED recommended tolerance levels.
  The following commodity definitions: "Vegetable, fruiting, group," "Vegetable, legume, edible podded, subgroup," "Pea and bean, succulent shelled, subgroup," "Pea and bean, dried shelled, except soybean, subgroup," "Vegetable, root, except radish, subgroup" and "Vegetable, leaves of root and tuber, except radish, group," "Vegetables, tuberous and corm, subgroup," "Sorghum, grain, grain," "Sorghum, grain, forage," and "Sorghum, grain, stover," "Corn, sweet, stover," "Corn, sweet, kernel plus cob with husks removed," and "Corn, sweet, forage."

2) Toxicology

- Developmental neurotoxicity study (DNT) in the rat (OPPTS Guideline No. 870. 6300)

- 28-day inhalation toxicity study. [The protocol for the existing 90-day inhalation toxicity study (OPPTS Guideline No. 870.3465) should be followed with the exposure (treatment) ending after 28 days, instead of 90 days.]

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1.0. EXECUTIVE SUMMARY

Syngenta, (formerly, Zeneca Ag Products, Zeneca Inc.), is proposing the registration of sulfosate for new uses on cotton, root and tuber vegetables, pistachio, grain sorghum, sweet corn, wheat, fruiting vegetables (except cucurbits), edible-podded legume vegetables, succulent shelled pea and beans, and dried shelled pea and beans (except soybeans). Sulfosate is a liquid, emulsifiable concentrate, nonselective foliar systemic herbicide which may be applied by air or ground depending upon crop and stage of crop growth.

Sulfosate is currently registered for control of annual and perennial weeds in bananas, citrus fruits, coffee, corn (field, pop, and seed), grapes, pome fruits, soybeans, stone fruits, tree nuts, and wheat using ground or aerial equipment. Sulfosate can be applied to these crops as preplant or preemergence broadcast applications, as a postemergence directed applications, directed spot applications, or a wiper/wick application. The use on soybeans also allows for a pre-harvest broadcast application as a harvest aid at up to 1 lb ai/A.

For broadcast and directed applications, the maximum single application rates specified for control of annual and perennial weeds are 2 and 4 lb ai/A, respectively. Spot applications may be made using 0.4-3% v/v solutions (0.02-0.16 lb ai/gal solution), and wiper/wick applications may be made using a 1.25 lb ai/gallon solution. Retreatment intervals of 14-21 days are specified for postemergence spot applications. The maximum seasonal application rate is 8 lb ai/A/year.

Broadcast ground and aerial applications should be made in 3-40 and 3-15 gallons of water per acre, respectively, and applications may include a nonionic surfactant or wetting agent at up to 0.25% v/v. Applications through any type of irrigation system are prohibited.

The general use directions specify a restricted entry interval (REI) of 12 hours and prohibit the grazing or harvest of cover crops for feed. The label also specifies a 35-day rotational crop restriction for any crops not listed on the label.

Hazard Assessment

The acute toxicity data for sulfosate technical show that this chemical is not acutely toxic by the oral, inhalation, and dermal routes of exposure [Toxicity Categories III and IV]. It is a mild skin and eye irritant and a slight dermal sensitizer. Sulfosate is a neurotoxic chemical. Evidence of neurotoxicity was seen in several studies in rats, dogs, and mice. Signs of neurotoxicity included Functional Observation Battery (FOB) effects in rat neurotoxicity studies and clinical findings of treatment-related salivation and emesis in the dog following subchronic and chronic exposures. Salivation was the most consistent sign. Dogs appear to be the most sensitive species for these effects, with high intra-individual variability in sensitivity. There were also concerns for hydrocephalus in all dog studies and possible treatment related histopathology in the mouse carcinogenicity and 21-day dermal rat studies. Developmental toxicity studies in rats and rabbits

and a two-generation reproduction study in rats provided no indication of increased susceptibility in rats or rabbits from *in utero* and/or post natal exposure to sulfosate. Based on the available mutagenicity studies, there are no concerns for mutagenicity at this time. Sulfosate is classified as a "Group E" chemical (no evidence for carcinogenicity in humans).

Dose Response Assessment

The Food Quality Protection Act (FQPA) Safety Factor Committee (SFC) determined that the data indicate that there is no increased susceptibility to young rats or rabbits following *in utero* exposure in prenatal studies or in the postnatal study in rats. However, the FQPA SFC recommended that the FQPA Safety Factor should not be removed, instead it should be reduced to 3X, because of the need for a developmental neurotoxicity study to characterize the concern for the overall neurotoxicity exhibited in long-term studies in adult animals (mice, rats, and dogs).

An acute reference dose (aRfD) of 1.0 mg/kg/day was established for the general population, including infants and children based on a developmental no-observed-adverse-effect level (NOAEL) of 100 mg/kg/day from an acute neurotoxicity study in the rat. An uncertainty factor (UF) of 100 (10-fold for interspecies extrapolation and 10-fold for intraspecies variability) was applied to the NOAEL to derive the RfD. The lowest-observed-adverse-effect level (LOAEL) of 300 mg/kg was based on mortality, decreased body weight and food consumption, and neurotoxicity. This endpoint is appropriate for risk assessment since it was observed after a single dose in the acute neurotoxicity study. **The FQPA safety factor of 3X is applicable for acute dietary risk assessment. Thus, the acute population adjusted dose (aPAD) is 0.33 mg/kg/day (aPAD = aRfD/SF).** The chronic reference dose (cRfD) of 0.25 mg/kg/day was determined on the basis of two subchronic (capsule and gavage) dog toxicity studies and a chronic (gavage) dog toxicity study. A UF of 100 (10-fold for interspecies extrapolation and 10-fold for intraspecies variability) was applied to the NOAEL of 25 mg/kg/day to derive the cRfD. The NOAEL of 25 mg/kg/day is based on salivation and emesis, clinical signs of neurotoxicity, and hydrocephalus seen at a LOAEL of 50 mg/kg/day. **The FQPA safety factor of 3X is applicable for chronic dietary risk assessment. Thus, the chronic population adjusted dose (cPAD) is 0.083 mg/kg/day (cPAD = cRfD/SF).**

The HED/RfD Committee (document dated 26-JUL-1994) has classified sulfosate as a "Group E" - no evidence of carcinogenicity in male and female rats as well as in male and female mice. A cancer risk assessment is not required.

The short- and intermediate-term dermal endpoints were chosen from a 21-day dermal toxicity study in the rat using the formulated product. The adjusted NOAEL/LOAEL is 167/667 mg/kg/day based on sciatic nerve fiber degeneration. [The NOAEL and LOAEL have been adjusted to the 60% technical since the study being used was conducted on a 40% formulation.] Although the study used for risk assessment is conducted with the formulation, it is considered appropriate since the neurotoxic potential of sulfosate in the rat has been demonstrated in other

studies.

The short-, and intermediate-term inhalation endpoints were the same as those used to determine the cRfD. Since an oral route was used, an inhalation absorption factor of 100% was used for route-to-route extrapolation for short- and intermediate-term inhalation assessments.

The uses under consideration in the current risk assessment do not include long-term dermal or inhalation exposures since long-term exposures are not expected for the proposed uses of sulfosate.

Margin of Exposure (MOE): The level of concern for MOEs for dermal and inhalation occupational exposure risk assessment is 100. There are no residential uses at this time.

Occupational Handler Exposures

Depending upon crop and crop growth stage, sulfosate may be applied by ground or aerially. Again, depending upon crop and growth stage, ground applications may be broadcast, shielded/hooded, wiper/wick or spot applications. It may be applied as a preharvest aid (i.e., desiccant) for cotton, wheat, sorghum, and a number of dried beans, peas, lentils and for catjang and guar.

The maximum application rate is 4.0 lb active ingredient per acre with two applications per season. It is expected that commercial applicators and grower applicators will have short-term exposures (1-7 days). Commercial applicators may have intermediate-term exposures (> 7 days).

MOEs for all handler activities assessed are greater than 104 and since the estimated exposures are based on conservative, screening level assumptions, do not exceed HED's level of concern.

Occupational Post-application Exposures

Post-application, re-entry exposures are not expected as a result of the proposed use patterns.

Dietary Risk Estimates

Acute and chronic dietary exposure analyses for sulfosate were performed using the Dietary Exposure Evaluation Model (DEEM™).

A conservative Tier 1 acute dietary analysis for sulfosate was performed using tolerance level residues, DEEM default processing factors, and assuming 100% crop treated (CT). For the acute dietary risk estimates, HED's level of concern is >100% aPAD. The acute exposure estimates at the 95th percentile were <100% of the aPAD for the general U.S. population and all subgroups, with children 1-6 years old, having the highest exposure estimate (55% of the aPAD). The

results of this analysis indicate that the acute dietary risk estimates for the general U.S. population and all population subgroups associated with the existing and proposed uses of sulfosate do not exceed HED's level of concern.

A partially refined Tier 2 chronic dietary analysis for sulfosate was performed using tolerance level residues, DEEM default processing factors, and %CT information for some commodities. For chronic partially refined dietary risk estimates, HED's level of concern is >100% cPAD. The chronic exposure estimates were <100% of the cPAD for the general U.S. population and all subgroups, with children 1-6 years old as the most highly exposed population subgroup (60% of the cPAD). The results of the chronic analysis indicate that the chronic dietary risk estimates associated with the existing and proposed uses of sulfosate do not exceed HED's level of concern.

Drinking Water

The maximum acute and chronic surface water estimated environmental concentrations (EEC) for the total sulfosate residue (glyphosate free acid and trimesium) were estimated by the surface water Tier 1 model GENEEC version 1.2. For surface water resources, the maximum acute EEC was 125.5 μg/L (ppb) and the chronic EEC was 27.8 μg/L.

The predicted ground water EEC of the total residue (glyphosate free acid and trimesium) using the ground water Tier 1 model SCI-GROW was 0.328 μg/L (ppb) which can be considered as an acute and chronic value.

Aggregate Exposure and Risk Assessment

Acute aggregate risk estimates are below HED's level of concern. The acute dietary (food only) exposure estimates at the 95th percentile were <100% of the aPAD for the general U.S. population and all subgroups, with children 1-6 years old as the highest exposure estimate with 55% of the aPAD. Thus, the acute dietary risk associated with the proposed uses of sulfosate does not exceed HED's level of concern (>100% aPAD). The surface and ground water EECs were used to compare against back-calculated drinking water levels of concern (DWLOCs) for aggregate risk assessments. For the acute scenario, the DWLOC is 1500 ppb for children 1-6 years old. For ground and surface water, the EECs for sulfosate are less than HED's DWLOCs for sulfosate in drinking water as a contribution to acute aggregate exposure. Therefore, HED concludes with reasonable certainty that residues of sulfosate in drinking water do not contribute significantly to the acute aggregate human health risk at the present time.

Chronic aggregate risk estimates are below HED's level of concern. The chronic dietary (food only) exposure estimates were <100% of the cPAD for the general U.S. population and all subgroups, with children 1-6 years old having the highest exposure with 60% of the cPAD. Thus, the chronic dietary risk associated with the proposed uses of sulfosate does not exceed HED's level of concern (>100% cPAD). The surface and ground water EECs were used to

compare against back-calculated DWLOCs for aggregate risk assessments. For the chronic scenario, the DWLOC is 330 ppb for children 1-6 years old. For ground and surface water, the EECs for sulfosate are less than HED's DWLOCs for sulfosate in drinking water as a contribution to chronic aggregate exposure. Therefore, HED concludes with reasonable certainty that residues of sulfosate in drinking water do not contribute significantly to the chronic aggregate human health risk at the present time.

Recommendation for Tolerances and Registration

Provided the petitioner submits a **revised Section F and B as detailed below** (see Section 8.1), the submitted residue chemistry data support the establishment of permanent tolerances for residues of sulfosate(glyphosate trimesium) in/on the following commodities:

Wheat, grain	10 ppm (of which no more than 2.5 ppm is TMS)
Wheat, straw	90 ppm (of which no more than 40 ppm is TMS)
Wheat, hay	1.0 ppm (of which no more than 0.50 ppm is TMS)
Vegetable, fruiting, group	0.05 ppm
Vegetable, legume, edible podded, subgroup	0.50 ppm (of which no more than 0.3 ppm is TMS)
Pea and bean, succulent shelled, subgroup	0.20 ppm (of which no more than 0.1 ppm is TMS)
Pea and bean, dried shelled, except soybean, subgroup	6.00 ppm (of which no more than 1.5 ppm is TMS)
Cotton, gin byproducts	120 ppm (of which no more than 35 ppm is TMS)
Cotton, undelinted seed	40 ppm (of which no more than 10 ppm is TMS)
Pistachio	0.05 ppm
Radish, roots	16 ppm (of which no more than 15 ppm is TMS)
Radish, tops	10 ppm (of which no more than 8.0 ppm is TMS)
Vegetable, root, except radish, subgroup	0.15 ppm (of which no more than 0.10 ppm is TMS)
Vegetable, tuberous and corm, subgroup	1.0 ppm (of which no more than 0.50 ppm is TMS)
Vegetable, leaves of root and tuber, except radish, group	0.30 ppm (of which no more than 0.20 ppm is TMS)
Sorghum, grain, grain	35 ppm (of which no more than 15 ppm is TMS)
Sorghum, grain, forage	0.20 ppm (of which no more than 0.10 ppm is TMS)
Sorghum, grain, stover	140 ppm (of which no more than 60 ppm is TMS)
Corn, sweet, forage	20 ppm (of which no more than 5.0 ppm is TMS)
Corn, sweet, kernels plus cob with husks removed	0.15 ppm (of which no more than 0.10 ppm is TMS)
Corn, sweet, stover	170 ppm (of which no more than 65 ppm is TMS)
Poultry, meat byproducts	0.5 ppm

The existing toxicological database for sulfosate supports the establishment of permanent tolerances for residues of sulfosate in/on the commodities listed above. **However, the registration should be conditional until the petitioner has satisfactorily addressed the toxicology deficiencies listed below** (see Section 8.2).

Deficiencies/Data Needs

1) Chemistry

- Revised Section B to include:

Legumes: a restriction against application of sulfosate to beans and peas grown for feed.
Cotton: a maximum of two preharvest broadcast applications at up to 1.0 lb ai/A/application with a minimum retreatment interval of 7 days between the two preharvest applications.

- Revised Section F's to include:
  The HED recommended tolerance levels.
  The following commodity definitions: "Vegetable, fruiting, group," "Vegetable, legume, edible podded, subgroup," "Pea and bean, succulent shelled, subgroup," "Pea and bean, dried shelled, except soybean, subgroup," "Vegetable, root, except radish, subgroup" and "Vegetable, leaves of root and tuber, except radish, group," "Vegetables, tuberous and corm, subgroup," "Sorghum, grain, grain," "Sorghum, grain, forage," and "Sorghum, grain, stover," "Corn, sweet, stover," "Corn, sweet, kernel plus cob with husks removed," and "Corn, sweet, forage."

2) Toxicology

- Developmental neurotoxicity study in the rat (OPPTS Guideline No. 870. 6300), and

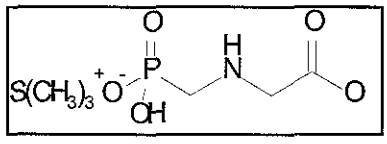
- 28-day inhalation toxicity study (OPPTS Guideline No. 870.3465) [The protocol for the existing 90-day inhalation toxicity study (OPPTS Guideline No. 870.3465) should be followed with the exposure (treatment) ending after 28 days, instead of 90 days.]

3) Occupational Exposure

- None

2.0. PHYSICAL/CHEMICAL PROPERTIES CHARACTERIZATION

Chemical Name:	Sulfonium, trimethyl-, salt with N-(phosphonomethyl)glycine (1:1)
Common Name:	Sulfosate
Trade Name:	Touchdown®
Chemical Type:	Herbicide
PC Code Number:	128501
CAS Registry No.:	81591-81-3
Empirical Formula:	$C_6H_{15}O_5SNP$
Molecular Weight:	244
Structure:	



3.0. HAZARD CHARACTERIZATION

Table 1. Acute Toxicity of Sulfosate Technical.

Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
870.1100	Acute Oral - rat	00126608	LD_{50} = 748 mg/kg	III
870.1200	Acute Dermal - rabbit	00126608	LD_{50} >2000 mg/kg	III
870.1300	Acute Inhalation - rat	00126609	LC_{50} >6.9 mg/L	IV
870.2400	Primary Eye Irritation - rabbit	00126608	Mild Irritation	III
870.2500	Primary Skin Irritation - rabbit	00126608	Mild Irritation	IV
870.2600	Dermal Sensitization - guinea pig	00154270	Slight Sensitizer	Not applicable

Table 2. Toxicity Profile of Sulfosate Technical.

Guideline No./ Study Type	Results
870.3100 90-Day oral toxicity rat	NOAEL = 36 mg/kg/day (males) LOAEL = 88 mg/kg/day (males), based on significant overall decrease in body weight gain of 22%.
870.3150 90-Day oral toxicity dog (Gavage)	NOAEL = 10 mg/kg/day LOAEL = 50 mg/kg/day, based on significant earlier onsets and increased incidence of salivation and emesis and hydrocephalus and/or dilated lateral ventricles (brain).
870.3150 90-Day oral toxicity dog (Capsule)	NOAEL = 25 mg/kg/day LOAEL = 50 mg/kg/day, based on salivation in both sexes, clinical signs of neurotoxicity in the females and possible treatment related signs (hydrocephalus) in one male.
870.3200 21-Day dermal toxicity rabbit (technical)	Systemic NOAEL = 1000 mg/kg/day (highest dose tested (HDT)). Systemic LOAEL not established

Guideline No./ Study Type	Results
870.3200 21-Day dermal toxicity rat (formulation)	NOAEL = 250 mg/kg/day LOAEL = 1000 mg/kg/day, based on sciatic nerve findings.
870.3700a Prenatal developmental toxicity rat	**Maternal** NOAEL = 100 mg/kg/day LOAEL = 333 mg/kg/day, based on decreased body weight, feed consumption and body weight gain along with increased incidences of salivation, chromorhinorrhea, and lethargy after dosing. **Developmental** NOAEL = 100 mg/kg/day. LOAEL = 333 mg/kg/day, based on decreased fetal body weight.
870.3700b Prenatal developmental toxicity rabbit	**Maternal** NOAEL = 40 mg/kg/day LOAEL = 100 mg/kg/day, based on 6 deaths in 17 pregnant does, 4 abortions in the 11 survivors along with decreased body weight, feed consumption and body weight gain. **Developmental** NOAEL = 40 mg/kg/day. LOAEL = 100 mg/kg/day, based on decreased number of live fetuses/doe for 7 surviving rabbits (5.4 versus 7.4 in controls), 4 rabbits aborted their litters. Having only 7 litters does not give a sufficiently higher number of animals to absolutely conclude that no developmental toxicity is occurring, particularly in light of the massive losses to death and abortions.
870.3800 Two-generation reproduction and fertility effects rat	**Systemic** NOAEL = 150 ppm (6/8 mg/kg/day for males/females). LOAEL = 800 ppm (35/41 mg/kg/day for males/females), based on a decrease in absolute and sometimes relative organ weights in both generations (thymus, heart, kidney and liver) at 800 and 2000 ppm and a decrease in body weights and body weight gains during the premating period at 2000 ppm. **Reproductive/developmental** NOAEL = 150 ppm (6/8 mg/kg/day for males/females). LOAEL = 800 ppm (35/41 mg/kg/day for males/females), based on decreased litter size in F1a and F2b litters at 2000 ppm and on decrease in mean pup weights during lactation in second litters at 800 ppm & in all litters at 2000 ppm.
870.4100b Chronic toxicity dog	NOAEL = 10 mg/kg/day LOAEL = 50 mg/kg/day, based on salivation and emesis, and hydrocephalus and support from shorter term studies also with these findings.

Guideline No./ Study Type	Results
870.4300 Chronic toxicity/ carcinogenicity rat	NOAEL = 1000 ppm (41.8/55.7 mg/kg/day, males/ females) (HDT) LOAEL >1000 ppm (41.8/55.7 mg/kg/day, males/ females) No evidence of carcinogenicity.
870.4200b Carcinogenicity mouse	NOAEL = 1000 ppm (118/159 mg/kg/day for males/females) LOAEL is 8000 ppm (991/1341 mg/kg/day for males/females), based on decreased body weight & food consumption (both sexes); increased incidence of white matter degeneration in lumbar bar region of spinal cord (males only); increased incidence of epithelial hyperplasia of duodenum (females only). There was no evidence of carcinogenicity in this study at doses tested.
870.6100 Acute neurotoxicity hen	NOAEL = 500 mg/kg. LOAEL = 5000 mg/kg based on diarrhea, changes in comb appearance, early decreased food consumption, and a decrease in egg production.
870.6200a Acute neurotoxicity screening battery rat	NOAEL = 100 mg/kg. LOAEL = 300 mg/kg based on mortality, neurologic signs and decreased body weight and food consumption.
870.6200b Subchronic neurotoxicity screening battery rat	NOAEL= 600 ppm (47.6/54.4 mg/kg/day for males/females). LOAEL = 2000 ppm (153.2/171 mg/kg/day for males/females) based on decreases in mean body weight, food consumption, food utilization and mean forelimb grip strength values.
870.5100 Gene mutation/bacteria Ames *Salmonella typhimurium*	Not mutagenic in TA1535, TA1537, TA1538, TA98, and TA100 Tested with and without metabolic activation.

Guideline No./ Study Type	Results
870.5100 Gene mutation/bacteria Ames *Salmonella typhimurium*	Not a mutagen up to 40 ul/plate with TA1535, TA1537, TA98, and TA100 strains of Salmonella typhimurium in either the standard plate assay or the preincubation assay with and without the metabolic activation.
870.5300 Gene Mutation/ *In vitro* assay in mammalian cells - mouse lymphoma	Mutagenic effect was observed under the standard test procedure with and without the metabolic activation at the concentrations tested (3.5 through 5.0 µl/ml).
870.5300 Gene mutation/ *In vitro* assay in mammalian cells - mouse lymphoma	Mutagenic in this assay with and without metabolic activation under the pH unadjusted test condition (pH 5.62-7.07) - through 5 ug/ml. 3/30/97 Addendum: Not a mutagen in this assay with and without metabolic activation under the pH adjusted test condition (pH 7.4) using 5-10 μl/ml concentrations.
870.5300 Gene mutation/ *In vitro* assay in mammalian cells - mouse lymphoma	Positive mutagenicity observed at the thymidine locus under S-9 rat liver metabolic activation.
870.5275 Cytogenetics sex link recessive - *drosophila melanoga*	Not mutagenic in SLRL test.

Guideline No./ Study Type	Results
Cytogenetics/ *In vitro* - mouse A) 870.5375 Chromosomal aberration B) 870.5900 Sister chromatid exchange	A) *Chromosomal Aberration Assay*: Under the standard test procedure positive clastogenic effect was observed at the concentration of 5 μl/ml under the nonactivation assay and at the concentrations of 3 to 5 μl/ml under the activation assay. B) *Sister Chromatid Exchange Assay*: Under the standard test procedure, the test compound was a positive inducer of SCE at the concentration of 5 μl/ml under the nonactivation assay and at the concentrations of 3 to 5 μl/ml under the activation assay. A and B) Clastogenic in these assays with and without metabolic activation under the pH unadjusted test condition (PH 5.62-7.07) at concentrations of 3 through 5 μl/ml. 3/20/87 Addendum: **Not a clastogen** in these assays with & without metabolic activation under the **pH adjusted** test condition (PH 7.4) at concentrations of 4 through 10 μl/ml.
870.5375 Cytogenetics/ *In vitro* CHO	Sister chromatid exchange not determined. **Positive for the induction of chromosomal aberration** in CHO cells in the absence (4 mg/ml) and presence (8,10,12 mg/ml) of S9 metabolic activation.
870.5375 Cytogenetics/ *In vitro* CHO	Increased chromosomal aberrations in activation assay at 6-8 μl/ml. No increase in sister chromatid exchanges with S-9 metabolic activation (1-8 μl/ml).
870.5375, 870.5900 Cytogenetics/ *In vitro* CHO	**Not a clastogen** in these assays with and without metabolic activation under the pH adjusted test condition (pH 7.4 to 7.6).
870.5395 Cytogenetics/ *In vivo* mouse micronucleus assay	Failed to induce significant increase in the number of PCE containing micronuclei.
870.5385 Cytogenetics/ rat bone marrow	Not clastogenic in the rat bone marrow cells.
Other BALB/3T cells transformation assay	Negative responses at 0.313, 0.625, 1.25,2.50, and 5.0 mg/ml in the BALB/3T cells transformation assay.

Guideline No./ Study Type	Results
870.7485 Metabolism and pharmacokinetics	Radiolabelled trimethylsulfonium ion is rapidly excreted unmetabolized in urine and feces; principal sites of localization of ion are adrenals, kidneys, bladder, liver, thyroid and stomach.
870.7485 Metabolism and pharmacokinetics	Intravenous (IV) or oral C14 sulfosate was rapidly excreted: IV treated male & females eliminated 90% of the administered dose in urine. Absorption of C14-sulfosate was incomplete by the oral route: Most groups eliminates 47-57% of the administered dose in the urine and 36-42% in the feces. Females treated with a high dose eliminated less in the urine (36% of dose) and more in the feces (54% of dose). Negligible 14CO2 elimination. Tissue C14 residues were < 0.32% of administered dose. Carcass C14 residues were < 2.2% of administered dose (mostly in bones, 3-7 ppm in low dose rats & 19-32 ppm in high dose rats). Most excreted radioactivity was unchanged anion (carboxymethylamino-methylphosphonate). One fecal metabolite was aminomethyl phosphonic acid. Several minor unidentified metabolites were recovered.

Hazard Characterization

Sulfosate (the trimethylsulfonium salt of glyphosate, also known as glyphosate-trimesium) is a 1:1 molar salt of N-(phosphonomethyl)glycine anion (PMG) and the trimethylsulfonium cation (TMS). In acute toxicity studies, sulfosate technical has low acute toxicity (Categories III and IV) via the oral, dermal, and inhalation routes. It is mildly irritating to the eyes and skin and it produces a weak dermal sensitization reaction in guinea pigs.

Sulfosate is a neurotoxic chemical which produces clinical findings such as salivation, tremors, emesis, and decreased activity in dogs and/or rats. TMS is the moiety responsible for neurotoxicity; there are no neurotoxic signs associated with glyphosate. Salivation was the most consistent sign. In one study, salivation stopped upon withdrawal of sulfosate and recurred upon reintroduction of treatment. Dogs appear to be the most sensitive species for these effects, with high intra-individual variability in sensitivity. Salivation and emesis occurred in both the subchronic and chronic toxicity studies in the dog at the same dose level (50 mg/kg/day). Hydrocephalus or dilated ventricles were observed in at least one animal at the highest dose tested (HDT) (50 mg/kg/day) in adult dogs in all the dog studies, following both 90-days (gavage or capsule) and one year of dosing. This finding was not seen in controls or low dose groups. Hydrocephaly and/or dilated ventricles in dogs of this age may have been due to inherent asymptomatic incidences in the beagle (Vullo et al., 1997), but it was noted that these animals were not supplied by the same breeding colony, and the incidences were only observed at the high dose levels across several studies. Therefore, these findings could not be dismissed. The toxicology data base provides no evidence that sulfosate has anticholinesterase activity, since

decreased cholinesterase activity in rats and dogs following subchronic and chronic exposures was not reported.

Acute neurotoxicity effects observed after a single dose of 300 mg/kg in the rat included ptosis, decreased activity, decreased splay reflex, upward curvature of spine, shaking, sides pinched in, signs of urinary incontinence, irregular breathing, hunched posture, abnormal or staggering gait, increased time to tail flick, decreased landing foot splay, decreased forelimb grip strength, decreased hindlimb grip strength, decreased motor activity. There was also death at this dose. In the subchronic rat neurotoxicity study, the decreased forelimb grip strength observed at 153 mg/kg/day, in females only, may also have been due to treatment.

Neuropathology was observed in the 21-day rat dermal study (sciatic nerve degeneration) at 1000 mg/kg using the sulfosate formulation, and the 2-year chronic mouse study (degeneration of the sciatic nerve, lumbar spinal root, and lumbar spinal white matter in males) at 991 mg/kg. Although these findings were previously discounted due to lack of supporting neuropathology data in the acute and subchronic neurotoxicity studies in rats, the overall neurotoxicity profile of the chemical indicated that the neuropathology could be a treatment-related effect of concern.

There is no indication of an increased susceptibility of fetuses or offspring in rats or rabbits after prenatal and/or postnatal exposure to sulfosate. In the prenatal developmental toxicity study in rats, evidence of developmental toxicity (decreased fetal body weight) was seen only in the presence of maternal toxicity (decreased body weight/gain, food consumption, salivation, chromorhinorrhea, and lethargy). In the developmental toxicity study in rabbits, developmental toxicity (decreased number of live fetuses/doe) was seen in the presence of maternal toxicity (death, abortions, decreased body weight, body weight gain and food consumption) at the highest dose level. In the two-generation reproduction study in rats, effects in the offspring (decreased litter size and pup weights) were observed only at or above treatment levels which results in evidence of parental toxicity (decreased absolute/relative organ weights, body weight and body weight gain). There are no data gaps for the assessment of effects of sulfosate following *in utero* exposure or the effects on young animals following early exposure (exception - developmental neurotoxicity).

Sulfosate is classified as a "not likely human carcinogen", based on the absence of tumorigenicity in two species of animals in two acceptable studies. Based on the available mutagenicity studies, there is no concern for mutagenicity. In some of the *in vitro* mutagenicity tests (forward mutation/mouse lymphoma cells, structural chromosomal aberrations/CHO cells) conducted in 1982, sulfosate induced a false positive mutagenic effect. A common feature of these tests was that the pHs of the test incubation media were acidic (pH 5.67-7.07) due to the addition of sulfosate. These positive results were no longer observed when the pH was readjusted to a more physiological level (pH 7.4) before the mutagenicity tests were conducted.

There are no metabolites of concern. Sulfosate is rapidly absorbed and excreted mainly as the unchanged parent compound.

The existing toxicity database for sulfosate is adequate for this Food/Feed use registration, except for the following studies: 1) a developmental neurotoxicity (DNT) study, and 2) a 28-day inhalation toxicity study in the rat. (See Section 6.0 Data Gaps for details).

3.1. FQPA Considerations

On **November 21, 2000**, the HED Hazard Identification Assessment Review Committee (HIARC) met to **reexamine** the acute dietary endpoint for females 13-50 years old, the cRfD, as well as the toxicological endpoints selected for use as appropriate in occupational/residential exposure risk assessments for sulfosate (Attachment 1, HED DOC. No. 014430). The potential for increased susceptibility of infants and children from exposure to sulfosate was **not** reevaluated at this meeting. On **May 20, 1999**, the HIARC reexamined the dermal endpoints and dermal absorption for sulfosate (HED DOC. No. 013577). The HIARC had previously met on **June 12, 1998** (document date June 25, 1998) to evaluate the neurotoxicity hazard assessment/characterization for sulfosate (HED DOC. No. 012652). This was a follow-up meeting to the HIARC meeting held on **March 26, 1998** to re-assess the RfDs established in 1994 as well as the toxicological endpoints selected for acute dietary and occupational/residential exposure risk assessments for sulfosate (HED DOC. No. 012594). The HIARC addressed the potential enhanced sensitivity of infants and children from exposure to sulfosate as required by the FQPA of 1996 at both the March 26, 1998 and June 12, 1998 meetings. The HIARC concluded the following:

- The data provided no indication of increased susceptibility in rats or rabbits from *in utero* and/or post natal exposure to sulfosate.

- Based upon a weight-of-the-evidence consideration of the nuerotoxicity of sulfosate, the Committee decided **to require the conduct of a developmental neurotoxicity study with sulfosate** to evaluate the potential for effects on functional development.

The HED FQPA SFC met on June 29, 1998 to re-evaluate the hazard and exposure data for sulfosate and recommend application of the FQPA SF (as required by FQPA of August 3, 1996) to ensure the protection of infants and children from exposure to this pesticide (Attachment 2). The FQPA SFC recommended that the 10X factor for increased susceptibility of infants and children should be **reduced to 3X** based on the need for a developmental neurotoxicity study in rats. There is no increased susceptibility to young rats or rabbits following *in utero* exposure in prenatal studies or in the postnatal study in rats, and the toxicology data base is complete. Additionally, the exposure assessments for sulfosate do not indicate a concern for potential risk to infants and children since: 1) the dietary exposure assessments are conservative resulting in an overestimate of dietary exposure; 2) data from modeling are used for the ground and surface source drinking water exposure assessments, resulting in estimates considered to be reasonable upper-bound concentrations; and 3) there are currently no registered residential uses for sulfosate. However, the FQPA SFC recommended that the FQPA SF should not be removed, but instead it should be reduced to 3X because of the concern for the overall neurotoxicity exhibited

in long-term studies in adult animals (mice, rats, and dogs). In mice, sulfosate induced degeneration of the sciatic nerve, lumbar spinal root and lumbar spinal white matter. In rats, degeneration of the sciatic nerve was seen following dermal applications. In dogs, hydrocephalus and/or dilated ventricles were observed following subchronic and chronic exposures. In addition, clinical signs indicative of neurotoxicity such as salivation, tremors, emesis, decreased activity were seen in rats and dogs.

The Committee determined that the FQPA SF (3X) is applicable for the following subpopulations: 1) acute dietary (all populations which include infants and children), and 2) chronic dietary (all populations which include infants and children).

3.2. Dose Response Assessment

The doses and toxicological endpoints selected for various exposure scenarios are summarized in Table 3.

Table 3. Summary of Toxicological Dose and Endpoints for Sulfosate for Use in Human Risk Assessment[1].

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Endpoint for Risk Assessment	Study and Toxicological Effects
Acute Dietary general population including infants and children	NOAEL = 100 mg/kg/day UF = 100 **Acute RfD** = 1 mg/kg/day	FQPA SF = 3X **aPAD** = aRfD / FQPA SF = **0.33 mg/kg/day**	Acute neurotoxicity - rat LOAEL = 300 mg/kg/day based on mortality, decreased body weight and food consumption, and neurotoxicity.
Chronic Dietary all populations	NOAEL= 25 mg/kg/day UF = 100 **Chronic RfD** = 0.25 mg/kg/day	FQPA SF = 3X **cPAD** = cRfD / FQPA SF = **0.083 mg/kg/day**	Subchronic toxicity (capsule) - dog Subchronic toxicity (gavage) - dog Chronic toxicity - dog LOAEL = 50 mg/kg/day based on salivation and emesis, clinical signs of neurotoxicity, and hydrocephalus.
Short-Term Dermal (1-7 days) (Occupational)	Dermal study adjusted[2] NOAEL= 167 mg/kg/day	LOC for MOE = 100 (occupational)	21-Day dermal toxicity - rat (formulation) adjusted LOAEL = 667 mg/kg/day based on sciatic nerve fiber degeneration.

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Endpoint for Risk Assessment	Study and Toxicological Effects
Intermediate-Term Dermal (1 week - several months) (Occupational)	Dermal study adjusted[2] NOAEL= 167 mg/kg/day	LOC for MOE = 100	21-Day dermal toxicity - rat (formulation) adjusted LOAEL = 667 mg/kg/day based on sciatic nerve fiber degeneration.
Short-Term Inhalation (1-7 days) (Occupational)	Oral study NOAEL= 25 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100	Subchronic toxicity (capsule) - dog Subchronic toxicity (gavage) - dog Chronic toxicity - dog LOAEL = 50 mg/kg/day based on salivation and emesis, clinical signs of neurotoxicity, and hydrocephalus.
Intermediate-Term Inhalation (1 week - several months) (Occupational)	Oral study NOAEL= 25 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100	Subchronic toxicity (capsule) - dog Subchronic toxicity (gavage) - dog Chronic toxicity - dog LOAEL = 50 mg/kg/day based on salivation and emesis, clinical signs of neurotoxicity, and hydrocephalus.
Cancer (oral, dermal, inhalation)	Cancer classification (Group E)	Risk Assessment not required	No evidence of carcinogenicity

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

[1] UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, LOC = level of concern, MOE = margin of exposure

[2]This is adjusted for the 40% a.i. in the formulation and put in terms of the technical which is 60% a.i.

Endpoint Selection Rationale and Discussion

Acute Dietary Endpoint: An aRfD of 1.0 mg/kg/day was established for the general population, including infants and children based on a developmental NOAEL of 100 mg/kg/day from an acute neurotoxicity study in the rat. An UF of 100 (10-fold for interspecies extrapolation and 10-fold for intraspecies variability) was applied to the NOAEL to derive the RfD. The LOAEL of 300 mg/kg was based on mortality, decreased body weight and food consumption, and neurotoxicity. This endpoint is appropriate for this risk assessment since it was observed after a single dose in the acute neurotoxicity study. **The FQPA SF of 3X is applicable for acute dietary risk assessment. Thus, the aPAD is 0.33 mg/kg/day.** [Neither a developmental toxicity endpoint resulting from a single exposure and related to an *in utero* effect nor a maternal toxicity endpoint resulting from a single exposure and relevant only to pregnant females was identified, therefore, a separate acute dietary RfD was not established for females 13-50 years old.]

Chronic Dietary Endpoint: The cRfD of 0.25 mg/kg/day was determined on the basis of two subchronic (capsule and gavage) dog toxicity studies and a chronic (gavage) dog toxicity study. An UF of 100 (10-fold for interspecies extrapolation and 10-fold for intraspecies variability) was applied to the NOAEL of 25 mg/kg/day to derive the RfD. The NOAEL of 25 mg/kg/day is based on salivation and emesis, clinical signs of neurotoxicity, and hydrocephalus seen at a LOAEL of 50 mg/kg/day. In the subchronic gavage study and the chronic gavage study, the dose levels selected (0, 2, 10, and 50 mg/kg/day), the NOAELs (10 mg/kg/day) and LOAELs (50 mg/kg/day), and the effects seen at the LOAEL (salivation, emesis and hydrocephalus) were similar in both studies. Since a similar endpoint of equal severity was observed, these studies were evaluated using a single dose-response curve. In the subchronic capsule study (doses: 0, 10, 25, and 50 mg/kg/day), the NOAEL was 25 mg/kg/day and the LOAEL was also 50 mg/kg/day, based on salivation in both sexes, clinical signs of neurotoxicity in females and possible-treatment related signs (hydrocephalus) in one male. The higher NOAEL of 25 mg/kg/day from the subchronic capsule study was used to establish the chronic RfD because the capsule study had a smaller dose spread than the gavage studies. No additional UF (for use of a subchronic NOAEL) is needed because there is no increase in severity of effects over time in the chronic study as compared to the subchronic studies. **The FQPA SF of 3X is applicable for chronic dietary risk assessment. Thus, the cPAD is 0.083 mg/kg/day.**

Carcinogenicity: The HED/RfD Committee (document dated 26-JUL-1994) has classified sulfosate as a "Group E" - no evidence of carcinogenicity in male and female rats as well as in male and female mice. A cancer risk assessment is not required.

Short- and Intermediate Term Dermal Endpoints: The short- and intermediate-term dermal endpoints were chosen from a 21-day dermal toxicity study in the rat using the formulation product. The adjusted NOAEL/LOAEL is 167/667 mg/kg/day based on sciatic nerve fiber degeneration. The NOAEL and LOAEL have been adjusted to the 60% technical since the study being used was conducted on a 40% formulation.

NOAEL x 0.40 ÷0.60 = (250 mg/kg/day) (0.4) ÷ (0.6) = 167 mg/kg/day
LOAEL x 0.40 ÷0.60 = (1000 mg/kg/day) (0.4) ÷ (0.6) = 667 mg/kg/day

In the study with the formulation product, the NOAEL was 250 mg/kg/day and the LOAEL was 1000 mg/kg/day based on minimal sciatic nerve fiber degeneration of unstated severity. The database also included a 21-day dermal toxicity study with the technical product in the rabbit. In the study with the technical product, the NOAEL for systemic toxicity was 1000 mg/kg/day (Limit-Dose), the highest dose tested; a LOAEL was not established. Although the study used for risk assessment is conducted with the formulation, it is considered appropriate since the neurotoxic potential of sulfosate in the rat has been demonstrated in other studies.

Long-term Dermal Endpoint: The long-term dermal endpoint was determined on the basis of two subchronic (capsule and gavage) dog toxicity studies and a chronic (gavage) dog toxicity study. The NOAEL was 25 mg/kg/day based on salivation and emesis, clinical signs of neurotoxicity, and hydrocephalus seen at a LOAEL of 50 mg/kg/day. See the "chronic RfD" for details. Since an oral route was used, a dermal absorption factor of 23% should be used for route-to-route extrapolation. (See Memo, J. Kidwell, 1/02/01, HED Doc. No. 014430 for more details on dermal absorption.) However, since the uses under consideration in the current risk assessment do not include long-term dermal exposure, a long-term dermal risk assessment was not performed.

Short-, Intermediate-, and Long-term Inhalation Endpoints: The short-, intermediate-, and long-term inhalation endpoints were determined on the basis of two subchronic (capsule and gavage) dog toxicity studies and a chronic (gavage) dog toxicity study. The NOAEL was 25 mg/kg/day based on salivation and emesis, clinical signs of neurotoxicity, and hydrocephalus seen at a LOAEL of 50 mg/kg/day. See the "chronic RfD" for details. Since an oral route was used, a inhalation absorption factor of 100% was used for route-to-route extrapolation for short- and intermediate-term inhalation assessments. However, since the uses under consideration in the current risk assessment do not include long-term inhalation exposure, a long-term inhalation risk assessment was not performed.

MOE for Occupational/Residential Risk Assessments: The level of concern for MOEs for dermal and inhalation occupational exposure risk assessment is less than 100. There are no proposed or registered residential uses at this time.

3.3 Endocrine Disruption

EPA is required under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific bases for

including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA has authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, sulfosate may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

4.0. EXPOSURE ASSESSMENT

Residue chemistry data pertaining to the proposed uses of sulfosate were submitted and reviewed by HED in the following memos: *Wheat* - (Memos, D217440, G. Kramer, 1/8/01 and D259191, J. Tyler, 1/8/01); *Fruiting Vegetables (Except Cucurbits)* - (Memos, D243450, J. Rowell, 9/21/98 and D257947, G. Kramer, 7/30/99), and (Memo, D273122, J. Tyler, 3/7/01); *Edible-Podded Legume Vegetables Subgroup, Succulent Shelled Pea And Bean Subgroup, and Dried Shelled Pea and Bean (Except Soybean) Subgroup* - (Memos, D259252, G. Kramer, 9/24/99 and D243368, G. Kramer, 5/17/99) and (Memo, D273123 , J. Tyler, 3/7/01); *Sweet Corn, Cotton, Grain Sorghum, Root and Tuber Vegetables, Pistachios* - (Memo, D263247, J. Tyler, 2/13/01). The occupational exposure memo for the proposed uses of sulfosate are provided in the following memos: (Memos, D269398, M. Dow, 1/6/01 and D272496, M. Dow, 1/29/01).

4.1. Summary of Proposed and Registered Uses

Syngenta provided copies of the following labels for use on wheat, fruiting vegetables (except cucurbits), legume vegetables, cotton, pistachios, sweet corn, grain sorghum, and root and tuber vegetables for the control of broadleaf and grass weeds: Touchdown® 5 (5 lb/gal SC/L formulation of sulfosate, EPA Reg. No. 10182-429), Touchdown® (6 lb/gal SC formulation of sulfosate, EPA Reg. No. 10182-324) and Touchdown® BTU (5 lb/gal SC formulation, EPA Reg. No. 10182-429).

Sulfosate is currently registered for control of annual and perennial weeds in bananas, citrus fruits, coffee, corn (field, pop, and seed), grapes, pome fruits, soybeans, stone fruits, tree nuts, and wheat using ground or aerial equipment. Sulfosate can be applied to these crops as preplant or preemergence broadcast applications, as a postemergence directed applications, directed spot applications, or a wiper/wick application. The use on soybeans also allows for a pre-harvest broadcast application as a harvest aid at up to 1 lb ai/A.

For broadcast and directed applications, the maximum single application rates specified for control of annual and perennial weeds are 2 and 4 lb ai/A, respectively. Spot applications may

be made using 0.4-3% v/v solutions (0.02-0.16 lb ai/gal solution), and wiper/wick applications may be made using a 1.25 lb ai/gallon solution. Retreatment intervals of 14-21 days are specified for postemergence spot applications. The maximum seasonal application rate is 8 lb ai/A/year.

Broadcast ground and aerial applications should be made in 3-40 and 3-15 gallons of water per acre, respectively, and applications may include a nonionic surfactant or wetting agent at up to 0.25% v/v. Applications through any type of irrigation system are prohibited.

The general use directions specify a restricted entry interval (REI) of 12 hours and prohibit the grazing or harvest of cover crops for feed. The label also specifies a 35-day rotational crop restriction for any crops not listed on the label. Table 4 summarizes the proposed use pattern of sulfosate.

Table 4. Proposed Use Patterns.

Crop	Application Rate (lb. ai/A)		PHI (days)	Instructions/Restrictions
	Per App.	Maximum		
Wheat	0.5-4.0	8 (preharvest application - 1)	forage and hay - 14 grain and straw - 56	Applications: preemergent and preharvest applications at the hard dough stage, and spot treatments using a spray solution of up to 3% ai.
Legumes and Fruiting Vegetables	0.25-4 (directed sprays -2; preharvest to dried legumes - 1)	8	preharvest application - 7 preplant/preharvest: edible podded legumes - 50 succulent shelled peas and beans - 58 fruiting vegetables - 28	Applications: multiple broadcast applications before, during, or after planting prior to crop emergence on the following vegete seed, and preharvest applications to dried legumes. The preharvest applications to dried beans, dried lentils, and dried peas are to be made when the crop has 30% or less grain moisture content. For fruiting vegetables, do not plant within 3 days of application Directed sprays should be made after plants are 6 inches tall. Do not apply harvest aid to vegetable crops grown for seed.
Sweet Corn	0.5-4.0	8		Applications: broadcast preplant, at planting, or preemergence applications.
Cotton	0.5-4.0 (preharvest - 0.5-2.0)	8	preharvest or wiper/ wick application - 7	Applications: preplant or preemergence broadcast, postemergence directed spot, and broadcast preharvest (after bolls have matured). Do not make preharvest application to cotton grown for seed. Spot applications must be made prior to boll opening.

Crop	Application Rate (lb. ai/A)		PHI (days)	Instructions/Restrictions
	Per App.	Maximum		
Sorghum	0.5-4.0 (preharvest - 0.5-2.0)	8	grain or stover following postemergence spot treatment - 28 grain following preharvest application - 7	Applications: preplant or preemergence broadcast, postemergence directed spot, and broadcast preharvest (on grain sorghum after majority of seed heads have matured). Do not make preharvest applications to sorghum grown for seed.
Pistachios	0.5-4	8	20	Applications: directed applications to orchard floors. Minimum retreatment interval not specified.
Root and Tuber Vegetables	0.5-4	8	Not specified	Applications: broadcast preplant, at planting, or preemergence applications. Minimum retreatment interval not specified.

Conclusions:

Wheat: The amended label adequately delineates the proposed use pattern for wheat.

Fruiting Vegetables (Except Cucurbits): The amended label adequately delineates the proposed use pattern for fruiting vegetables.

Edible-Podded Legume Vegetables Subgroup, Succulent Shelled Pea And Bean Subgroup, and Dried Shelled Pea and Bean (Except Soybean) Subgroup: The specimen labels adequately delineate the proposed use pattern for sulfosate on beans (all types), catjang, guar, lentils (all types), lupines (all types), peas (all types), and soybean (immature seed). However, the proposed labels must be modified to include a restriction against application of sulfosate to beans and peas grown for animal feed. **A revised Section B should be submitted.**

Sweet Corn, Cotton, Grain Sorghum, Root and Tuber Vegetables, Pistachios: The amended label adequately delineates the proposed use pattern for sulfosate on pistachios, root and tuber vegetables, and sweet corn. However, the proposed grain sorghum use directions should be amended to include a statement prohibiting the use of sulfosate on sweet sorghum or forage sorghum. In addition, the proposed use directions for cotton should be amended to specify a maximum of two preharvest broadcast applications at up to 1.0 lb ai/A/application with a minimum retreatment interval of 7 days between the two preharvest applications. **A revised Section B should be submitted.**

4.2. Dietary Exposure/Risk Pathway

4.2.1 Residue Profile

Background

Tolerances for sulfosate have been established for the following crops or commodities [40 CFR §180.489(a)]: almond hulls, aspirated grain fractions, bananas (import only), citrus fruits, field and pop corn, grapes, pome fruits, prunes, raisins, soybeans, stone fruits, tree nuts, wheat, eggs, milk, and meat, kidney, meat byproducts (except kidney), and fat of poultry and livestock.

Syngenta (formerly Zeneca Ag Products) has submitted petitions for a Section 3 registration and permanent tolerances for residues of sulfosate in or on cotton, root and tuber vegetables, pistachio, grain sorghum, sweet corn, wheat, fruiting vegetables (except cucurbits), edible-podded legume vegetables, succulent shelled pea and beans, and dried shelled pea and beans (except soybeans).

Residue Profile

Nature of the Residue

Plants: No new metabolism studies were submitted with these petitions. 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, G. Otakie, 12/7/93), corn (DP Barcode D171509, F. Griffith, 9/30/92) and soybeans (DP Barcode D208740, G. Kramer, 4/4/95). HED concluded that the parent ions are the residues of regulatory concern for sulfosate in these crops; these data will be translated other crops (DP Barcode D211742, G. Kramer, et al., 2/9/95). 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:

> raw agricultural commodity (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 trimethylsulfonium cation (TMS) and y is the maximum expected total of TMS and N-(phosphonomethyl)glycine anion (PMG).

Livestock: Sulfosate metabolism studies in livestock 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 Barcode D205472, G. Kramer, 4/4/95). HED concluded that the

parent ions are the residues of regulatory concern for sulfosate in meat, milk, and eggs.

Enforcement Methods

Plants: Enforcement of the proposed tolerances requires two enforcement methods: one method for PMG (RR 92-042B RES) and one method for TMS (RR93-105B RES). Method validation and successful Petition Method Validation (PMV) of the revised methods RR 92-042B RES and RR 93-105B RES have been completed by the Analytical Chemistry Lab (ACL) (DP Barcode D215869, G. Kramer, 7/6/95; DP Barcode D219447, G. Kramer, 1/23/96). Both methods have been submitted to the Food and Drug Administration (FDA) for inclusion in Pesticide Analytical Manual (PAM) II (DP Barcodes D248046 and D248047, G. Kramer).

Livestock: Enforcement of the proposed tolerances requires two enforcement methods: one method for PMG (RR 93-104B RES) and one method for TMS (RR93-100B RES). Method validation and successful PMV of Methods RR 93-104B and RR 93-100B have been completed by the ACL (DP Barcode D225926, G. Kramer 5/13/96; DP Barcode D221382, G. Kramer, 1/22/96). The methods were revised to incorporate revisions required by HED, and revised methods (RR 93-104B RES and RR 93-100B RES) were approved by HED 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 (DP Barcodes D248043 and D248045, G. Kramer).

Multiresidue Method: 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 inclusion in PAM I (Memo, S. Koepke, 10/29/90).

Magnitude of the Residue - Crop Field Trials

Wheat: Adequate residue field trial data in support of the proposed preharvest use on wheat have been submitted.

Fruiting Vegetables (Except Cucurbits): Adequate residue field trial data in support of the proposed use on the fruiting vegetable (except cucurbits) crop group have been submitted. The correct commodity definition is "Vegetable, fruiting, group." **The petitioner should submit a revised Section F.**

Edible-Podded Legume Vegetables Subgroup (Crop Subgroup 6-A): The submitted residue field data are adequate to support the proposed preemergence use on the edible podded legume vegetables subgroup. The correct commodity definition is "Vegetable, legume, edible podded, subgroup." **The petitioner should submit a revised Section F.**

Succulent Shelled Pea And Bean Subgroup (Crop Subgroup 6-B): The submitted residue field trial data are adequate to support the proposed preemergence use of sulfosate on the succulent

shelled pea and bean subgroup. The correct commodity definition is "Pea and bean, succulent shelled, subgroup." **The petitioner should submit a revised Section F.**

Dried Shelled Pea and Bean (Except Soybean) Subgroup (Crop Subgroup 6-C): The submitted residue field data in support of the proposed use on the dried shelled pea and bean (except soybean) subgroup are adequate. **If the petitioner modifies the product labels to prohibit use of sulfosate grown on animal feed,** then no data pertaining to cowpea forage and hay or field pea vines and hay will be required to support this petition. The correct commodity definition is "Pea and bean, dried shelled, except soybean, subgroup." **The petitioner should submit a revised Section F.**

Cotton: Adequate residue field trial data in support of the proposed use on cotton have been submitted.

Root Vegetables (Crop Group 1A) and Leaves of Root and Tuber Vegetables (Crop Group 2): Adequate residue field trial data in support of the proposed use on root vegetables and the leaves of root and tuber vegetables have been submitted. The correct commodity definitions are "Vegetable, root, except radish, subgroup" and "Vegetable, leaves of root and tuber, except radish, group." **The petitioner should submit a revised Section F**.

Tuberous and Corm Vegetables (Crop Group 1C): Adequate residue field trial data in support of the proposed use on tuberous and corm vegetables have been submitted. The correct commodity definition is "Vegetables, tuberous and corm, subgroup." **The petitioner should submit a revised Section F.**

Pistachio: No residue data on pistachios were submitted with the current petition. However, the existing sulfosate residue data on almonds, pecans, and walnuts, which reflect the same use pattern as proposed for pistachios, will be translated to support a separate 0.05 ppm tolerance for residues in/on pistachios.

Grain Sorghum: Adequate residue field trial data in support of the proposed use on grain sorghum have been submitted. The aspirated grain fractions (AGF) data submitted for grain sorghum are adequate and indicate that the combined residues of PMG and TMS in/on AGF derived from grain sorghum grain are significantly less (maximum of 151 ppm) than the established 1300 ppm tolerance for AGF, which is based on data from soybeans (DP Barcode D243318, 4/23/99, G. Kramer). Therefore, no change in the AGF tolerance is required. The correct commodity definitions are "sorghum, grain, grain," "sorghum, grain, forage," and "sorghum, grain, stover." **The petitioner should submit a revised Section F.**

Sweet Corn: Adequate residue field trial data in support of the proposed use on sweet corn have been submitted. The correct commodity definitions are "corn, sweet, stover," "corn, sweet, kernel plus cob with husks removed," and "corn, sweet, forage." **The petitioner should submit a revised Section F.**

Conclusions: The submitted residue data support the establishment of permanent tolerances for residues of sulfosate in/on the following commodities:

Wheat, grain	10 ppm (of which no more than 2.5 ppm is TMS)
Wheat, straw	90 ppm (of which no more than 40 ppm is TMS)
Wheat, hay	1.0 ppm (of which no more than 0.50 ppm is TMS)
Vegetable, fruiting, group	0.05 ppm
Vegetable, legume, edible podded, subgroup	0.50 ppm (of which no more than 0.3 ppm is TMS)
Pea and bean, succulent shelled, subgroup	0.20 ppm (of which no more than 0.1 ppm is TMS)
Pea and bean, dried shelled, except soybean, subgroup	6.00 ppm (of which no more than 1.5 ppm is TMS)
Cotton, gin byproducts	120 ppm (of which no more than 35 ppm is TMS)
Cotton, undelinted seed	40 ppm (of which no more than 10 ppm is TMS)
Pistachio	0.05 ppm
Radish, roots	16 ppm (of which no more than 15 ppm is TMS)
Radish, tops	10 ppm (of which no more than 8.0 ppm is TMS)
Vegetable, root, except radish, subgroup	0.15 ppm (of which no more than 0.10 ppm is TMS)
Vegetable, tuberous and corm, subgroup	1.0 ppm (of which no more than 0.50 ppm is TMS)
Vegetable, leaves of root and tuber, except radish, group	0.30 ppm (of which no more than 0.20 ppm is TMS)
Sorghum, grain, grain	35 ppm (of which no more than 15 ppm is TMS)
Sorghum, grain, forage	0.20 ppm (of which no more than 0.10 ppm is TMS)
Sorghum, grain, stover	140 ppm (of which no more than 60 ppm is TMS)
Corn, sweet, forage	20 ppm (of which no more than 5.0 ppm is TMS)
Corn, sweet, kernels plus cob with husks removed	0.15 ppm (of which no more than 0.10 ppm is TMS)
Corn, sweet, stover	170 ppm (of which no more than 65 ppm is TMS)

Magnitude of the Residue in Processed Commodities

Wheat: HED has concluded that the appropriate tolerance is 30 ppm (of which no more than 6.0 ppm is TMS) for bran and 20 ppm (of which no more than 5.0 ppm is TMS) for shorts. These results support the proposed tolerances on wheat processed commodities.

Fruiting Vegetables (Except Cucurbits): The magnitude of residue in processed commodities from tomatoes is adequately understood. HED has concluded that the establishment of tolerances for these processed commodities is not necessary.

Cotton: Tho cotton processing study is adequate and indicates that the combined residues of PMG and TMS do not concentrate in cotton hulls, meal, or refined oil. Separate tolerances for cotton processed fractions are not required.

Root and Tuber Vegetables: The potato processing study is adequate and indicates that the combined residues of PMG and TMS do not concentrate in wet peel and concentrate only slightly in flakes (1.7x) and chips (1.1x). Based on the combined highest average field trial (HAFT) residues of <0.37 ppm from the potato field trials and the observed concentration factors for flakes and chips, the maximum expected combined residues of PMG and TMS in potato flakes and chips would be 0.63 and 0.41 ppm, respectively. As these residue levels are below the 1 ppm tolerance proposed for the potato RAC, separate tolerances for residues in potato flakes

and chips are not required. **A revised Section F should be submitted with the tolerance for potato, flakes deleted.**

The submitted sugar beet processing study is adequate and indicates that detectable levels of sulfosate residues are not likely to occur in commodities processed from sugar beets treated in accordance with the proposed use directions. Therefore, no tolerances are required for sulfosate residues in sugar beet processed commodities.

Magnitude of the Residue in Meat, Milk, Poultry and Eggs (MMPE)

Ruminants: An adequate ruminant feeding study has been previously reviewed. Based on a calculated maximum theoretical dietary burden (MTDB) of 438 ppm for cattle and the results of the earlier feeding study, the current 1.5 ppm tolerance for milk and the tolerances for residues in fat (0.5 ppm), kidneys (6.0 ppm), and meat byproducts, except kidney (1.5 ppm), and meat (1.0 ppm) of cattle, goats, hogs, horses, and sheep are adequate. The proposed tolerance increase for residues in milk is not necessary. **A revised Section F should be submitted with the proposed tolerance increase for milk deleted.**

Poultry: An adequate poultry feeding study has been previously reviewed. Based on a calculated MTDB of 37 ppm for poultry and the results of the earlier feeding study, the current 0.05 ppm tolerance for eggs and the 0.05 ppm tolerances for residues in poultry fat and meat are adequate. **The tolerance for residues in poultry meat by products should be increased to 0.5 ppm as proposed by the petitioner.**

Magnitude of the Residue in Rotational Crops

HED 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 8.0 lbs. a.i./A (DP Barcode D209543, 4/21/95, G. Kramer). No additional rotational crop data are required to support these petitions.

International considerations

No Codex limits or Canadian and Mexican Maximum Residue Limits (MRLs) have been established for the proposed uses. Therefore, harmonization is not an issue with these petition. The International Residue Limit Status (IRLS) sheet is attached (Attachment 3).

4.2.2 Dietary Exposure Analysis

The dietary exposure analyses for sulfosate were performed using DEEM™ (version 7.075) (Memo, J.Tyler, 2/28/01; Barcode D271947) (See Attachment 4). The DEEM™ analyses evaluated the individual food consumption as reported by respondents in the USDA 1989-92 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated

exposure to the chemical for each commodity. For acute dietary risk assessments, the entire distribution of single day food consumption events is combined with a single residue level (deterministic analysis) to obtain a distribution of exposure in mg/kg. For chronic dietary risk assessments, the three-day average of consumption for each sub-population is combined with residues in commodities to determine average exposure in mg/kg/day.

HED notes that there is a degree of uncertainty in extrapolating exposures for certain population subgroups which may not be sufficiently represented in the consumption surveys, (e.g., nursing infants). Therefore, risks estimated for these subpopulations were included in representative populations having sufficient numbers of survey respondents (*e.g.*, all infants or females, 13-50 years old). Thus, the population subgroups listed in Table 5 include those subgroups having sufficient numbers of survey respondents in the CSFII food consumption survey to be considered statistically reliable.

Acute Dietary

The conservative, deterministic acute dietary exposure analysis for sulfosate was performed using tolerance level residues, DEEM default processing factors, and 100% CT information for all commodities (Attachment 4). For acute dietary risk estimates, HED's level of concern is >100% aPAD. The acute exposure estimates at the 95th percentile were <100% of the aPAD for the general U.S. population and all subgroups, with children 1-6 years old as the highest exposure estimate at 55% of the aPAD. The results of the analysis indicate that the acute dietary risk estimates associated with the existing and proposed uses of sulfosate do not exceed HED's level of concern for the general U.S. population and all population subgroups.

Table 5. Summary of Results from Acute DEEM™ Analyses of Sulfosate at the 95th Percentile.

Subgroups	Exposure (mg/kg/day)	% aPAD
U.S. Population (total)	0.108394	33
All Infants (< 1 year old)	0.166415	50
Children 1-6 years old	0.183192	55
Children 7-12 years old	0.118676	36
Females 13-50 years old	0.059479	18
Males 13-19 years old	0.091213	28
Males 20+ years old	0.059255	18
Seniors 55+ years old	0.050393	15

Chronic Dietary

The partially refined Tier 2 chronic dietary analysis for sulfosate was performed using tolerance level residues for all commodities, DEEM default processing factors, and %CT information for some commodities (oranges, grapefruit, soybeans, corn, peaches, and wheat. Crops (wheat, corn, and peaches) that BEAD had estimated at 0% CT were rounded up to 1% CT (Attachment 4).

However, this procedure still represents an over-estimation of dietary exposure, since tolerance level residue values were used for all commodities. Further refinements would entail the use of anticipated residues (ARs) and/or monitoring data for some commodities. For chronic dietary risk estimates, HED's level of concern is >100% cPAD. The chronic exposure estimates were <100% of the cPAD for the general U.S. population and all subgroups, with children 1-6 years old as the most highly exposed population subgroup at 60% of the cPAD. The results of the analyses indicate that the chronic dietary risk estimates associated with the existing and proposed uses of sulfosate do not exceed HED's level of concern for the U.S. population and all population subgroups.

Table 6. Summary of Results from Chronic DEEM ™ Analysis of Sulfosate.

Subgroups	Exposure (mg/kg/day)	% cPAD
U.S. Population (total)	0.015940	19
All Infants (< 1 year old)	0.039004	47
Children 1-6 years old	0.049736	60
Children 7-12 years old	0.027764	34
Females 13-50 years old	0.009911	12
Males 13-19 years old	0.016992	21
Males 20+ years old	0.009775	12
Seniors 55+ years old	0.009290	11

4.3 Water Exposure/Risk Pathway

EFED provided a drinking water assessment for sulfosate (Memo, D263248, P. Jennings and T. Nguyen, 1/30/01,) (Attachment 5). The EECs were based on a the maximum application of 8.0 lb ai/acre. Trimesium and glyphosate free acid were modeled as separate chemical species because each mole of glyphosate trimesium produces one mole of glyphosate free acid and one mole of trimesium. For risk assessment purposes, the EEC for total sulfosate (glyphosate free acid and trimesium) was reported. Additionally, the crop with the highest surface water EEC was used for purposes of this risk assessment.

Environmental Fate Properties

Upon contact with water, sulfosate disassociates to glyphosate free acid and to the counter cation, trimesium. No data on monitored concentrations of glyphosate free acid or trimesium in surface water were found. Based on the evolution of carbon dioxide, the major degradate of trimesium, this half-life of trimesium is estimated to range from 2 to 3 weeks. No other environmental fate data are available from EFED.

EECs/Monitoring Results

Surface Water

The maximum acute and chronic surface water EECs for the total residue (glyphosate free acid and trimesium) were estimated by the surface water Tier 1 model GENEEC version 1.2. For surface water resources, the maximum acute EEC was 125.5 μg/L (ppb) and the 56-day chronic EEC was 83.5 μg/L. HED interim policy allows the 56-day GENEEC value to be divided by 3 to obtain a value for chronic risk assessment calculations (HED SOP 99.5, 8/1/99). Therefore, a surface water value of **27.8** μg/L (ppb) will be used for chronic risk assessment.

Ground Water

The predicted ground water EEC of the total residue (glyphosate free acid and trimesium) using the ground water Tier 1 model SCI-GROW was 0.328 μg/L (ppb) which can be considered as an acute and chronic value.

4.4 Residential Exposure/Risk Pathway

There are no products containing sulfosate registered for residential use or that may be applied by commercial applicators to residential sites. Therefore, there is no assessment of residential exposure.

4.4.1 Non-occupational Off-Target Exposure

This assessment for sulfosate reflects the Agency's current approaches for completing residential exposure assessments based on the guidance provided in the *Draft: Series 875-Occupational and Residential Exposure Test Guidelines, Group B-Postapplication Exposure Monitoring Test Guidelines*, the *Draft: Standard Operating Procedures (SOPs) for Residential Exposure Assessment*, and the *Overview of Issues Related to the Standard Operating Procedures for Residential Exposure Assessment* presented at the September 1999 meeting of the FIFRA Scientific Advisory Panel (SAP). The Agency is, however, currently in the process of revising its guidance for completing these types of assessments. Modifications to this assessment shall be incorporated as updated guidance becomes available. This will include expanding the scope of the residential exposure assessments by developing guidance for characterizing exposures from other sources already not addressed such as from spray drift; residential residue track-in; exposures to farm worker children; and exposures to children in schools.

5.0. AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION

Aggregate exposure risk assessments were performed for the following: acute aggregate exposure (food + drinking water) and chronic aggregate exposure (food + drinking water). Short- and intermediate-term and cancer aggregate risk assessments were not performed because

there are no registered or proposed residential non-food uses and sulfosate is not carcinogenic, respectively.

A DWLOC is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. A DWLOC will vary depending on the toxic endpoint, drinking water consumption, body weights, and pesticide uses. Different populations will have different DWLOCs. HED uses DWLOCs in the risk assessment process to assess potential concern for exposure associated with pesticides in drinking water. DWLOC values are not regulatory standards for drinking water.

HED has calculated DWLOCs for acute and chronic exposure to sulfosate in surface and ground water (See Tables 8a and 8b). To calculate the DWLOC for acute exposure relative to an acute toxicity endpoint, the acute dietary food exposure (from DEEM™) was subtracted from the aPAD to obtain the acceptable acute exposure to sulfosate in drinking water. To calculate the DWLOC for chronic exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DEEM™) was subtracted from the cPAD to obtain the acceptable chronic exposure to sulfosate in drinking water. DWLOCs were then calculated using the default body weights and drinking water consumption figures listed in Table 7 below.

Table 7. Default Body Weight and Drinking Water Consumption Figures.

DEEM Population	Body Weights (kg)	Drinking Water Consumption (liters/day)
U.S. Population/48 States	70	2
Females 13-50 years old	60	2
Infants/children	10	1

Calculation for acute and chronic exposures:

$$DWLOC\ (\mu g/L) = \frac{water\ exposure\ (mg/kg/day)\ x\ body\ weight\ (kg)}{consumption\ (L/day)\ x\ 0.001\ mg/\mu g}$$

5.1. Acute Risk

5.1.1 Aggregate Acute Risk Assessment

Acute aggregate risk estimates are below HED's level of concern. The conservative, deterministic acute dietary exposure analysis for sulfosate was performed using DEEM default processing factors, tolerance level residues, and 100% CT information for all commodities. The acute exposure estimates at the 95th percentile were <100% of the aPAD for the general U.S.

population and all subgroups, with children 1-6 years old, having the highest exposure estimate of 55% of the aPAD. Thus, the acute dietary risk associated with the proposed uses of sulfosate does not exceed HED's level of concern (>100% aPAD). The surface and ground water EECs were used to compare against back-calculated DWLOCs for aggregate risk assessments. For the acute scenario, the DWLOC is 1500 ppb for children 1-6 years old. For ground and surface water, the EECs for sulfosate are less than HED's DWLOCs for sulfosate in drinking water as a contribution to acute aggregate exposure (Table 8a). Therefore, HED concludes with reasonable certainty that residues of sulfosate in drinking water do not contribute significantly to the acute aggregate human health risk at the present time.

5.1.2 Acute DWLOC Calculations

The DWLOCs for the acute scenario is listed in Table 8.

Table 8. DWLOC and Aggregate Risk Tables.

Table 8a. Acute DWLOC Calculations.

Population Subgroup	Acute Scenario					
	aPAD mg/kg/day	Acute Food Exp mg/kg/day	Max Acute Water Exp mg/kg/day[1]	Ground Water EEC (*ppb*)	Surface Water EEC (*ppb*)[2]	Acute DWLOC (μg/L)[3]
U.S. Population	0.33	0.108394	0.22494	0.328	125.5	7900
All Infants (< 1 year old)	0.33	0.166415	0.16692	0.328	125.5	1700
Children 1-6 years old	0.33	0.183192	0.15014	0.328	125.5	1500
Children 7-12 years old	0.33	0.118676	0.21466	0.328	125.5	2100
Females 13-50 years old	0.33	0.059479	0.27385	0.328	125.5	8200
Males 13-19 years old	0.33	0.091213	0.24212	0.328	125.5	8500
Males 20+ years old	0.33	0.059255	0.27408	0.328	125.5	9600
Seniors 55+ years old	0.33	0.050393	0.28294	0.328	125.5	9900

[1] Maximum acute water exposure (mg/kg/day) = [(acute PAD (mg/kg/day) - acute food exposure (mg/kg/day)]

[2] The crop producing the highest EEC was used.

[3] Acute DWLOC(μg/L) = $\frac{\text{[maximum acute water exposure (mg/kg/day) x body weight (kg)]}}{\text{[water consumption (L/day) x } 10^{-3} \text{ mg/}\mu\text{g]}}$

5.2. Chronic Aggregate Risk

5.2.1 Aggregate Chronic Risk Assessment

Chronic aggregate risk estimates are below HED's level of concern. A partially refined chronic dietary analysis for sulfosate was performed using tolerance level residues for all commodities, DEEM default processing factors, and %CT information for some commodities (oranges, grapefruit, soybeans, corn, peaches, and wheat. Crops (wheat, corn, and peaches) that BEAD had estimated at 0% CT were rounded up to 1% CT. However, this analysis is still an over-estimation of dietary exposure, since tolerance level residue values were used for all commodities. Further refinements would entail the use of ARs and/or monitoring data for some commodities. The chronic exposure estimates were <100% of the cPAD for the general U.S. population and all subgroups, with children 1-6 years old being the most highly exposed population subgroup with 60% of the cPAD. Thus, the chronic dietary risk associated with the proposed uses of sulfosate does not exceed HED's level of concern (>100% cPAD). The surface and ground water EECs were used to compare against back-calculated DWLOCs for aggregate risk assessments. For the chronic scenario, the DWLOCs are 330 ppb for children 1-6 years old. For ground and surface water, the EECs for sulfosate are less than HED's DWLOCs for sulfosate in drinking water as a contribution to chronic aggregate exposure (Table 8b). Therefore, HED concludes with reasonable certainty that residues of sulfosate in drinking water do not contribute significantly to the chronic aggregate human health risk at the present time.

5.2.2 Chronic DWLOC Calculations

The DWLOCs for the chronic scenario are listed in Table 8.

Table 8. DWLOC and Aggregate Risk Tables Continued.

Table 8b. Chronic DWLOC Calculations.

Population Subgroup	Chronic Scenario					
	cPAD mg/kg/day	Chronic Food Exp mg/kg/day	Max Chronic Water Exp mg/kg/day[1]	Ground Water EEC (*ppb*)	Surface Water EEC (*ppb*)[2]	Chronic DWLOC (μg/L)[3]
U.S. Population	0.083	0.015940	0.06739	0.328	27.8	2400
All Infants (< 1 year old)	0.083	0.039004	0.04433	0.328	27.8	440
Children 1-6 years old	0.083	0.049736	0.03360	0.328	27.8	340
Children 7-12 years old	0.083	0.027764	0.05557	0.328	27.8	560

Table 8b. Chronic DWLOC Calculations.						
Population Subgroup	Chronic Scenario					
	cPAD mg/kg/day	Chronic Food Exp mg/kg/day	Max Chronic Water Exp mg/kg/day[1]	Ground Water EEC (*ppb*)	Surface Water EEC (*ppb*)[2]	Chronic DWLOC (μg/L)[3]
Females 13-50 years old	0.083	0.009911	0.07342	0.328	27.8	2300
Males 13-19 years old	0.083	0.016992	0.06634	0.328	27.8	2300
Males 20+ years old	0.083	0.009775	0.07356	0.328	27.8	2600
Seniors 55+ years old	0.083	0.009290	0.07404	0.328	27.8	2600

[1] Maximum Chronic Water Exposure (mg/kg/day) = [Chronic PAD (mg/kg/day) - Chronic Dietary Exposure (mg/kg/day)]

[2]The crop producing the highest EEC was used.

[3]Chronic DWLOC(μg/L) = [maximum chronic water exposure (mg/kg/day) x body weight (kg)]
[water consumption (L/day) x 10^{-3} mg/μg]

6.0. CUMULATIVE RISK

EPA does not have, at this time, available data to determine whether sulfosate has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that sulfosate has a common mechanism of toxicity with other substances.

On this basis, the petitioner must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether sulfosate shares a common mechanism of toxicity with any other substance and, if so, whether any tolerances for sulfosate need to be modified or revoked.

7.0 OCCUPATIONAL EXPOSURE

Syngenta, (formerly, Zeneca Ag Products, Zeneca Inc.), has submitted petitions 5F4554, 7F4853, 9F6032 and 7F4876 to register the 5.0 pound active ingredient/gallon, liquid, emulsifiable concentrate, nonselective foliar systemic herbicide sulfosate for new uses on podded, leguminous, fruiting vegetables and wheat - (PLFW); and on cotton, sorghum, root and tuberous vegetables (CSRTV). There is also a proposed use on sweet corn. Sulfosate may be applied by air or ground depending upon crop and stage of crop growth.

For the PLFW, sulfosate may be broadcast applied before transplanting or before, during or after planting but prior to crop emergence if direct seeded; shielded or hooded directed sprays

(eggplant, ground cherry, pepino, peppers, tomatillo, and tomato only).

For wheat, sulfosate may be applied before, during, or after planting, but before crop emergence, as a spot spray, preharvest and postharvest.

Sulfosate may be applied as a preharvest aid to dried beans (all), catjang, guar, dried lentils (all), dried peas (all) and to wheat (Touchdown 5 booklets TOU429.RSG-06 1699 and TOU429.RSC-102898). The rate of application as a harvest aid is the same at 1.6 pints of Touchdown 5 per Acre, applied as a broadcast spray by air or ground.

When applied as a harvest aid to the PLFW vegetables, applications must be made at least 7 days preharvest. As a preharvest aid for wheat, applications must occur 14 days before harvest for forage, 21 days before hay harvest, and 7 days before grain and straw harvest. Table 9 presents a summary of the proposed new uses.

The proposed label for the CSRTV is Touchdown® 5 Herbicide (document TOU429.RSF-061199). It may be applied aerially or by ground (**"shielded/hooded application"** are new ground deliveries added to the label). For cotton, sorghum and the root and tuber vegetables, it may be applied broadcast before, during or after planting but **prior to crop emergence** and is for control of annual, perennial and woody plant weed species. For cotton and sorghum, shielded/hooded, spot treatments or wiper/wick applications may be made prior to harvest. It may also be used as a preharvest desiccant for cotton and sorghum. For cotton, spot applications must be made prior to boll opening and preharvest wiper/wick applications must be made 7 days prior to harvest. For sorghum, wiper/wick and spot applications must be made 28 days prior to harvest of grain or stoker. Sorghum preharvest applications must be made at least 7 days prior to harvest. Sulfosate may be applied for chemical fallow land and "postharvest" uses. Applications for the proposed uses should be made in 3-30 gallons of water/A by ground or 3-15 gallons of water/A by air. The maximum application rate is 4.0 pounds of active ingredient per acre with two applications at the maximum rate possible per year. A number of herbicides may be tank mixed with sulfosate.

The proposed labeling for sweet corn (Touchdown 5 Booklet TOU429.RSF-061199) lists the same directions as it does for Field Corn, Popcorn and Seed Corn which are currently registered uses. Applications are to be made "before, during, or after planting but before **crop emergence**; spot spray; and post harvest" (emphasis added).

Table 9. Use Pattern Summary for Proposed Uses of Sulfosate on Podded, Leguminous & Fruiting Vegetables and Wheat and Cotton, Sorghum and Root & Tuberous Vegetables.	
Formulation	48.6%; 5 lb a.i./gal liquid
Use Sites	podded, leguminous & fruiting vegetables, wheat; cotton sorghum, root & tuberous vegetables, sweet corn
Pests	annual, perennial and woody plant weed spp.
Application methods	aerial, ground (broadcast, spot, wiper/wick, shielded/hooded) pre-emergence and for certain pre-harvest aids
Maximum application rate	4.0 lb a.i./A
Frequency/Timing	two/season at maximum rate of 4.0 lb a.i./A
PHI	**cotton:** spot app's prior to boll opening; preharvest and wiper/wick app's 7 day PHI **sorghum:** preharvest 7 day PHI; spot/wiper/wick 28 day PHI for grain or stoker **root/tuberous vegetables:** pre-emergence applications only PLF vegetables - 7 days; wheat - 14 days (forage), 21 days (hay), 7days (grain or straw)
REI	acute tox categories III and IV; WPS REI - 12 hr
Manufacturer	Syngenta, formerly Zeneca Ag

Based on the proposed use patterns, commercial applicators are expected to have short-term and possibly intermediate-term exposures. Grower/applicators are expected to have short-term exposures. This document presents estimated exposures for Mixer/Loaders supporting aerial application, for private, grower application and for private, grower, combined mixer, loader, and applicator.

An MOE of 100 is adequate to ensure protection for handler exposures to sulfosate via the dermal and inhalation routes. All MOE's are greater than 104 and therefore are not of concern to HED. Based on the proposed use patterns, only short- and intermediate-term exposures are expected. Therefore, no long-term exposure assessment was performed. Sulfosate is classified as a Group E, "not likely human carcinogen". Therefore, no cancer assessment is required.

In the document "SULFOSATE - Fourth Report of the Hazard Identification Assessment Review Committee" (HIARC) (Memo, J. Kidwell, 2 January 2001; HED Doc. No. 014430), the

committee identified dermal and inhalation toxicological endpoints of concern for short- and intermediate-term exposures. A NOAEL of 167 mg a.i./kg bw/day (for short-term and intermediate-term dermal exposure) was established based on sciatic nerve fiber degeneration seen in a 21 day dermal toxicity study in the rat (MRID 4315102). Short- (st) and intermediate-term (it) inhalation endpoints (NOAEL) of 25 mg a.i./kg bw/day were identified and were based on subchronic toxicity (capsule) - dog; subchronic toxicity (gavage) - dog; and chronic toxicity - dog studies based on salivation and emesis, clinical signs of neurotoxicity, and hydrocephalus.

7.1 Occupational Handler Exposure

No chemical specific data were available to assess potential exposures to workers from the proposed uses. Therefore, this exposure assessment was conducted using data available in the Pesticide Handler's Exposure Database (PHED) Surrogate Table (v1.1., 1998). HED has estimated exposure and risk resulting from the use of sulfosate on cotton and wheat. Cotton and wheat are expected to represent high-end scenarios in terms of acres treated per day. In certain agricultural areas, contiguously planted acres of cotton and wheat are expected to exceed the other proposed new uses of sulfosate.

The proposed label(s) direct applicators and other handlers "must wear: long sleeved shirt and long pants, socks and shoes, and waterproof gloves." When handlers use closed systems, or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, the handler PPE requirements may be reduced or modified as specified in the WPS.

Table 10 summarizes HED's exposure estimates for mixer/loaders in support of commercial aerial application, for private (i.e., grower) ground applicators and for private mixer, loader, applicators of sulfosate. Estimates of exposure to mixer/loaders are presented for cotton or wheat acreage treated aerially and acreage treated by ground applicators or mixer/loader/applicators. An assessment of aerial applicators is not presented. The unit exposures for pilots is much lower than the mixer/loaders supporting aerial application. If MOE's for aerial mixer/loaders are acceptable, by default, MOE's for pilots will be acceptable. HED believes that acres treated for any of the proposed vegetables listed earlier in this document, will not exceed those presented for cotton and wheat. The estimates of exposure and risk for cotton and wheat are believed to represent the highest exposures of all handlers of sulfosate for use on the crops proposed in this document. The estimates of exposure are based on the maximum label rate of application i.e., 4.0 lb a.i./acre. The rate of application for use as a pre-harvest desiccant (i.e., "harvest aid") is 1.0 lb a.i./acre. Therefore HED believes that exposures that might result from the use of sulfosate as a harvest aid, will not exceed the handler exposures for pre-emergence applications estimated in this document.

Table 10. Handler Exposures to Sulfosate (Touchdown 5® Herbicide).

Job Function	AR (lbs ai/Acre)	Unit[1] Exposure (mg/lb ai)	Acres/ Day[2]	Average Dermal Daily Dose (ADD)[3] (mg/kg/day)	Average Inhalation Daily Dose (ADD)[3] (mg/kg/day)	Dermal MOE[4]	Inhalation MOE[4]
Aerial mixer/loader	4.0	D 0.023d[1a]	1200	1.6	0.08	104	300
		I 0.0012[1a]					
Groundboom applicator	4.0	D 0.014[1b]	200	0.16	0.0085	1044	2.9K
		I 0.00074[1b]					
Groundboom Mix/Load/App	4.0	D 0.057[1c]	200	0.65	0.015	257	1.6K
		I 0.0013[1c]					

[1] Pesticide Handlers Exposure Database (PHED) v. 1.1 Surrogate Exposure Table

a. For Mixer/Loader, Open Pour, All Liquids, Single layer of clothing **with** gloves; page 17; High Confidence Data for Dermal and Inhalation.

b. For Applicator, Ground-boom, Open Cab, Single layer of clothing **NO** gloves; page 28; High Confidence Data for Dermal (D) and Inhalation (I).

c. For Mixer/Loader/Applicator, Liquid-Open Pour, Ground-boom Open Cab, Single layer clothing **with** gloves, page 44; Medium Confidence

Dermal Data/High Confidence Inhalation Data.

[2] Acres/Day from Science Advisory Council for Exposure Policy No. 9 Revised 5 July 2000.

[3] Average Daily Dose (ADD) = Unit Exposure * AR * Acres/Day ÷ 70 kg body weight

[4] Margin of Exposure (MOE) = No Adverse Effect Level (NOAEL) ÷ ADD where dermal (short and intermediate term) NOAEL = 167 mg ai/kg bw/day; short-term and intermediate-term inhalation NOAELs = 25 mg a.i./kg bw/day.

The MOEs are **104** and greater for all handling activities. Therefore, since HED's level of concern for sulfosate is for MOEs less than 100, exposure to handlers is below the level of concern.

7.2 Occupational Postapplication

There are no post-application, manual labor, cultural activities associated with the pre-emergence applications of sulfosate to wheat or the podded, leguminous or fruiting vegetables. There are also no known manual labor post-application activities associated with shielded or hooded directed sprays. There are no manual post-application activities associated with the pre-harvest crop dessication uses on wheat, dried beans (all), catjang, dried lentils (all), dried lupines (all), and dried peas (all).

For the proposed use of sulfosate on sweet corn, all sulfosate applied to sweet corn will be applied prior to crop emergence. No, post-application exposure to agricultural workers is expected.

There are no post-application, manual labor, cultural activities associated with the pre-emergence applications of sulfosate to cotton, sorghum or any of the root/tuberous vegetables. There are also no known manual labor post-application activities associated with shielded/hooded, spot,

wiper or wick applications to cotton or sorghum pre-harvest. Finally, there are no manual post-application activities associated with the pre-harvest crop dessication uses on cotton or sorghum. Therefore, there is no assessment of post-application exposure.

7.3 Restricted Entry Interval (REI)

Based on sulfosate's Toxicological Category classifications of III and IV, the appropriate interim WPS REI is 12 hours.

7.4 Incidents

The OPP REFS Incident Data Reporting System (09/00) lists four unconfirmed incidents reported by Zeneca.

8.0. DATA NEEDS/LABEL REQUIREMENTS

8.1 Chemistry

- Revised Section B to include:
  - Legumes: a restriction against application of sulfosate to beans and peas grown for animal feed.
  - Cotton: a maximum of two preharvest broadcast applications at up to 1.0 lb ai/A/application with a minimum retreatment interval of 7 days between the two preharvest applications.
- Revised Section F's to include:
  - The HED recommended tolerance levels.
  - The following commodity definitions: "Vegetable, fruiting, group," "Vegetable, legume, edible podded, subgroup," "Pea and bean, succulent shelled, subgroup," "Pea and bean, dried shelled, except soybean, subgroup," "Vegetable, root, except radish, subgroup" and "Vegetable, leaves of root and tuber, except radish, group," "Vegetables, tuberous and corm, subgroup," "Sorghum, grain, grain," "Sorghum, grain, forage," and "Sorghum, grain, stover," "Corn, sweet, stover," "Corn, sweet, kernel plus cob with husks removed," and "Corn, sweet, forage."

8.2 Toxicology

- *Developmental neurotoxicity study in the rat.* The DNT study in the rat is required based on the weight-of-the-evidence concerns for neurotoxicity in the mouse oncogenicity study, the gavage dog studies, 21-day dermal toxicity study in rats, and acute and subchronic neurotoxicity studies in the rat. Signs of neurotoxicity due to sulfosate included FOB effects in the rat neurotoxicity studies, and treatment-related chemical signs of salivation and emesis in the dog. There were also concerns for hydrocephalus in all dog studies (at least one dog/study at the high dose, none in

controls) and possible treatment related histopathology in the mouse carcinogenicity and 21-day dermal rat studies.

- *28-day inhalation toxicity study*. This study was requested by HIARC for further characterization of inhalation risk assessments. Due to the potential for inhalation exposure, there is concern for toxicity by the inhalation route. The 28-day inhalation toxicity study would give a dose and endpoint examined via the route of exposure of concern (i.e., route specific study) and thus would avoid using an oral study and route-to-route extrapolation. The protocol for the existing 90-day inhalation toxicity study (OPPTS 870.3465) should be followed with the exposure (treatment) ending after 28 days, instead of 90 days.

8.3 Occupational

- None

Attachment 1: Hazard Identification Assessment Review Committee Report
Attachment 2: FQPA Safety Factor Committee Report
Attachment 3: IRLS Form
Attachment 4: Dietary Exposure Analyses
Attachment 5: Drinking Water Assessment for Sulfosate
Attachment 6: Incident Report

cc (with attachments): D. Vogel (RAB1), J. Kidwell (RAB1), J. Tyler (RAB1), M. Dow (RAB1)
RDI: RAB1 Toxicologists (1/23/01), RAB1 Chemists (2/27/01), ORE (11/3/01), Team (3/8/01), Branch (3/14/01), G. Herndon, Acting BSS (3/20/01)
D.Vogel:806S:CM#2:(703)305-0874:7509C:RAB1

ATTACHMENT 1 - HIARC Report
(*Available Electronically*)

ATTACHMENT 2 - FQPA Safety Factor Committee Report (*Available Electronically*)

ATTACHMENT 3 - Codex Form

INTERNATIONAL RESIDUE LIMIT STATUS			
Chemical Name: Sulfosate	Common Name:	X Proposed tolerance □ Reevaluated tolerance □ Other	Date: 12/7/00; 2/28/00
Codex Status (Maximum Residue Limits)		U. S. Tolerances	
X No Codex proposal step 6 or above □ No Codex proposal step 6 or above for the crops requested		Petition Number: 9F6032, 5F4554, 7F4876, 7F4853 DP Barcode: Other Identifier:	
Residue definition (step 8/CXL):N/A		Reviewer/Branch: Jennifer R. Tyler	
		Residue definition: 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 LOQ (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 TMS) = y ppm, where x is the maximum expected residue of TMS and y is the maximum expected total of TMS and PMG.	

Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		Cotton, gin byproducts	120 ppm (of which no more than 35 ppm is TMS)
		Cotton, undelinted seed	40 ppm (of which no more than 10 ppm is TMS)
		Leaves of Root and tuber Vegetables Group, except Radish	0.25 ppm (of which no more than 0.2 ppm is TMS)
		Milk	2.0 ppm
		Pistachio	0.05 ppm
		Potato, flakes	2.0 ppm (of which no more than 1.5 ppm is TMS)
		Poultry, mbyp	0.5 ppm
		Radish, roots	16 ppm (of which no more than 15 ppm is TMS)
		Radish, tops	10 ppm (of which no more than 8 ppm is TMS)
		Root Vegetables, except Radish	0.15 ppm (of which no more than 0.1 ppm is TMS)
		Sorghum, grain	35 ppm (of which no more than 15 ppm is TMS)
		Sorghum, forage	0.2 ppm (of which no more than 0.1 ppm is TMS)
		Sorghum, stover	140 ppm (of which no more than 60 ppm is TMS)
		Sweet corn, forage	20 ppm (of which no more than 5 ppm is TMS)
		Sweet corn, kernels + cob with husks removed (K+CWHR)	0.15 ppm (of which no more than 0.1 ppm is TMS)
		Sweet corn, stover	165 ppm (of which no more than 65 ppm is TMS)

Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		Tuberous and Corm Vegetables Subgroup	1 ppm(of which no more than 0.5 ppm is TMS)
		Wheat, grain	10 ppm (of which no more than 2.5 ppm is TMS)
		Wheat, straw	90 ppm (of which no more than 40 ppm is TMS)
		Wheat, hay	1.0 ppm (of which no more than 0.50 ppm is TMS)
		Vegetable, fruiting, group	0.05 ppm
		Vegetable, legume, edible podded, subgroup	0.50 ppm (of which no more than 0.3 ppm is TMS)
		Pea and bean, succulent shelled, subgroup	0.20 ppm (of which no more than 0.1 ppm is TMS)
		Pea and bean, dried shelled, except soybean, subgroup	6.00 ppm (of which no more than 1.5 ppm is TMS)

Limits for Canada	Limits for Mexico
X No Limits □ No Limits for the crops requested	X No Limits □ No Limits for the crops requested
Residue definition: N/A	Residue definition:N/A

Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)

Notes/Special Instructions:
S.Funk, 12/12/00

ATTACHMENT 4: Acute and Chronic Dietary Exposure Analyses *(Available Electronically)*

014507

ATTACHMENT 5: Drinking Water Assessment for Sulfosate (*Available Electronically)*

13544

013754

Chemical:	**Sulfosate**
PC Code:	**128501**
HED File Code	**14000 Risk Reviews**
Memo Date:	**03/20/2001**
File ID:	**TX014507**
Accession Number:	**412-02-0006**

HED Records Reference Center
12/04/2001