

rule is not a "major rule" as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 10, 2001.

**Peter Caulkins,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.205 is amended as follows:

i. By alphabetically adding the commodities artichoke, globe; corn, field, forage; corn, field grain; corn, field stover; corn, pop, grain; corn, pop, stover; endive; pea, dry; and persimmon to the table in paragraph (a).

ii. By removing the entries for corn grain, corn fodder, and corn forage from the table in paragraph (a).

iii. By removing the entries for corn flour, corn fodder, corn forage, corn grain and peas (dry) from the table in paragraph (b).

#### § 180.205 Paraquat; tolerances for residues.

(a) *General.* \* \* \*

| Commodity                 | Parts per million |   |   |      |
|---------------------------|-------------------|---|---|------|
| * * *                     | *                 | * | * | *    |
| Artichoke, globe .....    | *                 | * | * | 0.05 |
| * * *                     | *                 | * | * | *    |
| Corn, field, forage ..... |                   |   |   | 3.0  |
| Corn, field, grain .....  |                   |   |   | 0.1  |
| Corn, field, stover ..... |                   |   |   | 10.0 |
| * * *                     | *                 | * | * | *    |
| Corn, pop, grain .....    |                   |   |   | 0.1  |
| Corn, pop, stover .....   |                   |   |   | 10.0 |
| * * *                     | *                 | * | * | *    |
| Endive .....              | *                 | * | * | 0.05 |
| * * *                     | *                 | * | * | *    |
| Pea, dry .....            | *                 | * | * | 0.3  |
| * * *                     | *                 | * | * | *    |
| Persimmon ..              | *                 | * | * | 0.05 |
| * * *                     | *                 | * | * | *    |

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[FR Doc. 01-23606 Filed 9-20-01; 8:45 am]

BILLING CODE 6560-50-S

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP-301173; FRL-6801-8]

RIN 2070-AB78

#### Sulfosate; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of sulfosate (the trimethylsulfonium salt of glyphosate, also known as glyphosate-trimesium) in or on cotton, gin by-products, cotton undelinted seed, dried shelled pea and bean (except soybean) subgroup, edible podded legume vegetable subgroup, fruiting vegetable group, grain sorghum forage, grain sorghum grain, grain sorghum stover, leaves of root and tuber vegetable (except radish) subgroup, pistachio, radish roots, radish tops, succulent shelled pea and bean subgroup, sweet corn forage, sweet corn kernels plus cob with husks removed, sweet corn stover, tuberous vegetable and corn subgroup, and vegetable root (except radish) subgroup. This regulation increases tolerances in wheat bran, wheat grain, wheat hay, wheat shorts, wheat straw, and poultry meat by-products. Zeneca Ag. Products, now Syngenta Crop Protection, requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

**DATES:** This regulation is effective September 21, 2001. Objections and requests for hearings, identified by docket control number OPP-301173 must be received by EPA on or before November 20, 2001.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301173 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 703-305-5697; and e-mail address: tompkins.jim@epa.gov.

#### SUPPLEMENTARY INFORMATION:

#### I. General Information

##### A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

| Categories | NAICS Codes                    | Examples of Potentially Affected Entities                                             |
|------------|--------------------------------|---------------------------------------------------------------------------------------|
| Industry   | 111<br>112<br>311<br><br>32532 | Crop production<br>Animal production<br>Food manufacturing<br>Pesticide manufacturing |

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

##### B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>. A frequently updated electronic version of 40 CFR part 180 is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_00/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html), a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301173. The official record consists of the documents specifically referenced in this action, and other

information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

## II. Background and Statutory Findings

In the **Federal Register** of April 8, 1999 (64 FR 17171) (FRL-60712-), September 16, 1999 (64 FR 50280) (FRL-6089-3), and July 13, 2000 (65 FR 43326) (FRL-6592-9), EPA issued a notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of "a" pesticide petition (PP) for a tolerance by Zeneca Ag. Products, now Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419. This notice included a summary of the petition prepared by Zeneca Ag. Products, the registrant. There were no comments received in response to these notices of filing.

The petition announced in the April 8, 1999 notice requested that 40 CFR 180.489 be amended by establishing a tolerance for residues of the herbicide sulfosate, sulfonium, trimethyl-salt with *N*-(phosphonomethyl)glycine (1:1), in or on fruiting vegetables (except cucurbits) group at 0.05 parts per million (ppm); the edible-podded legume vegetables subgroup at 0.5 ppm (of which no more than 0.3 ppm is trimethylsulfonium (TMS)), the succulent shelled pea and bean subgroup at 0.2 ppm (of which no more than 0.1 ppm is TMS); the dried shelled pea and bean (except soybean) subgroup at 6 ppm (of which no more than 1.5 ppm is TMS); in cattle, goat, hog, sheep, and horse kidney at 3.5 ppm; in cattle, goat, hog, sheep, and horse meat by-products, except liver and kidney, at 2.5 ppm; and to increase the tolerance in cattle, goat, hog, sheep, and horse fat to 0.2 ppm; in cattle, goat, hog, sheep, and horse meat to 0.6 ppm; in cattle, goat, hog, sheep, and horse liver to 0.75 ppm; in milk to 1.1 ppm; in poultry liver to 0.1 ppm; in poultry

meat by-products to 0.25 ppm; in or on soybean seed to 21 ppm (of which no more than 13 ppm is TMS); in soybean hulls to 45 ppm (of which no more than 25 ppm is TMS); and in aspirated grain fractions to 1,300 ppm (of which no more than 720 ppm is TMS). The above proposed crop group and crop subgroup were changed to reflect regulations under 40 CFR 180.41(c).

The petition announced in the September 16, 1999 notice requested that 40 CFR 180.489 be amended by establishing a tolerance for residues of the herbicide sulfosate in or on wheat grain at 10 ppm (of which no more than 2.5 ppm is TMS); wheat hay at 1 ppm (of which no more than 0.5 ppm is TMS); wheat straw at 90 ppm (of which no more than 40 ppm is TMS); wheat bran at 30 ppm (of which no more than 6 ppm is TMS); and wheat shorts at 20 ppm (of which no more than 5 ppm is TMS); and to increase the tolerance in poultry meat by-products to 0.5 ppm and in milk to 2 ppm.

The petition announced in the July 13, 2000 notice requested that 40 CFR 180.489 be amended by establishing a tolerance for residues of the herbicide sulfosate in or on cotton gin by-products at 120 ppm of which no more than 35 ppm is TMS; cotton, undelinted seed at 40 ppm (of which no more than 10 ppm is TMS); leaves of root and tuber vegetables group (except radish) at 0.25 ppm (of which no more than 0.2 ppm is TMS); pistachio at 0.05 ppm; potato flakes at 2 ppm (of which no more than 1.5 ppm is TMS); radish roots at 16 ppm (of which no more than 15 ppm is TMS); radish tops at 10 ppm (of which no more than 8 ppm is TMS); root vegetables subgroup (except radish) at 0.15 ppm (of which no more than 0.1 ppm is TMS); sorghum grain at 35 ppm (of which no more than 15 ppm is TMS); sorghum forage at 0.2 ppm (of which no more than 0.1 ppm is TMS); sorghum stover at 140 ppm (of which no more than 60 ppm is TMS); sweet corn forage at 20 ppm (of which no more than 5 ppm is TMS); sweet corn, kernels + cob with husks removed at 0.15 ppm (of which no more than 0.1 ppm is TMS); sweet corn stover at 165 ppm (of which no more than 65 ppm is TMS); tuberous and corm vegetables subgroup at 1 ppm (of which no more than 0.5 ppm is TMS); and to increase the tolerance in poultry meat by-products to 0.5 ppm and in milk to 2 ppm.

EPA has determined that existing tolerances for cattle, goat, hog, sheep, horse, and milk are adequate to account for existing raw agricultural commodities (RACs) and the other proposed RACs listed above based on calculation of the maximum theoretical

dietary burden (MTDB); therefore, new tolerances are not being established for cattle, goat, hog, sheep, horse, and milk. The proposed separate tolerance for poultry liver at 0.1 ppm is not needed because it is covered by the tolerance for poultry meat by-products that is being established at 0.5 ppm; therefore, a tolerance is not being established for poultry liver. EPA has determined that a tolerance is not needed for potato flakes because sulfosate does not concentrate in potato flakes; therefore, a tolerance is not being established for potato flakes. EPA has determined that the appropriate tolerance for leaves of root and tuber vegetables group (except radish) is 0.30 ppm instead of the proposed tolerance of 0.25 ppm, and that the appropriate tolerance for sweet corn stover is 170 ppm instead of the proposed tolerance of 165 ppm. Tolerances were previously established for the soybean commodities and aspirated grain fractions in the **Federal Register** notice dated June 11, 1999 (64 FR 31505) (FRL-6086-6).

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action.

EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of sulfosate on cotton, gin by-products at 120 ppm (of which no more than 35 ppm is TMS), cotton, undelinted seed at 40 ppm (of which no more than 10 ppm is TMS), pea and bean, dried shelled (except soybean), subgroup (6C) at 6.00 ppm (of which no more than 1.5 ppm is TMS), vegetable, legume, edible podded subgroup (6A) at 0.50 ppm (of which no more than 0.3 ppm is TMS), vegetable, fruiting group (8) at 0.05 ppm, sorghum, grain, forage at 0.20 ppm (of which no more than 0.10 ppm is TMS), sorghum, grain, grain at 35 ppm (of which no more than 15 ppm is TMS), sorghum, grain, stover at 140 ppm (of which no more than 60 ppm is TMS), vegetable, leaves of root and tuber (except radish) group (2) at 0.30 ppm (of which no more than 0.20 ppm is TMS), pistachio at 0.05 ppm, radish, roots at 16 ppm (of which no more than 15 ppm is TMS), radish, tops at 10 ppm (of which no more than 8.0 ppm is TMS), pea and bean, succulent shelled subgroup (6B) at 0.20 ppm (of

which no more than 0.10 ppm is TMS), corn, sweet, forage at 20 ppm (of which no more than 5.0 ppm is TMS), corn, sweet, kernels plus cob with husks removed at 0.15 ppm (of which no more than 0.10 ppm is TMS), corn, sweet, stover at 170 ppm (of which no more than 65 ppm is TMS), vegetable, tuberous and corm subgroup (1C) at 1.0 ppm (of which no more than 0.50 ppm is TMS), and vegetable, root (except radish) subgroup (1A) at 0.15 ppm (of which no more than 0.10 ppm is TMS). This regulation increases tolerances in wheat, bran at 30 ppm (of which no more than 6.0 ppm is TMS), wheat, grain at 10 ppm (of which no more than 2.5 ppm is TMS), wheat, hay at 1.0 ppm (of which no more than 0.50 ppm is TMS), wheat, shorts at 20 ppm (of which no more than 5.0 ppm is TMS), wheat, straw at 90 ppm (of which no more than 40 ppm is TMS), and poultry meat by-products at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

#### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity,

completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by sulfosate is discussed in Unit II.A. of the **Federal Register** document published on September 11, 1998 (63 FR 48597) (FRL-6026-6). Please note that this unit included a typographical error. In the discussion of the feeding carcinogenicity study in mice, "79" should have been "7.9" in the following phrase: "In addition, there was increased incidence of white matter degeneration in the lumbar region of the spinal cord (males only) (2, 3, 4, 79% response, controls to high dose)." The nature of these toxic effects is also discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

| Guideline No. | Study Type                                  | Results                                                                                                                                                                                          |
|---------------|---------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 870.3100      | 90-Day oral toxicity - rat                  | NOAEL = 36 mg/kg/day (males)<br>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<br>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<br>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) | <i>Systemic</i><br>NOAEL = 1,000 mg/kg/day (highest dose tested (HDT))<br>LOAEL not established                                                                                                  |
| 870.3200      | 21-Day dermal toxicity - rat (formulation)  | NOAEL = 250 mg/kg/day<br>LOAEL = 1,000 mg/kg/day, based on sciatic nerve findings                                                                                                                |

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

| Guideline No. | Study Type                                            | Results                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|---------------|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 870.3700      | Prenatal developmental toxicity - rat                 | <p><i>Maternal</i><br/> NOAEL = 100 mg/kg/day<br/> 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</p> <p><i>Developmental</i><br/> NOAEL = 100 mg/kg/day<br/> LOAEL = 333 mg/kg/day, based on decreased fetal body weight</p>                                                                                                                                                                                                                                                                                                                                                               |
| 870.3700      | Prenatal developmental toxicity - rabbit              | <p><i>Maternal</i><br/> NOAEL = 40 mg/kg/day<br/> 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</p> <p><i>Developmental</i><br/> NOAEL = 40 mg/kg/day<br/> 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</p>                                                                |
| 870.3800      | 2-Generation reproduction and fertility effects - rat | <p><i>Systemic</i><br/> NOAEL = 150 ppm (6/8 mg/kg/day for males/females)<br/> 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 2,000 ppm and a decrease in body weights and body weight gains during the premating period at 2,000 ppm</p> <p><i>Reproductive/developmental</i><br/> NOAEL = 150 ppm (6/8 mg/kg/day for males/females)<br/> LOAEL = 800 ppm (35/41 mg/kg/day for males/females), based on decreased litter size in F1a and F2b litters at 2,000 ppm and on decrease in mean pup weights during lactation in second litters at 800 ppm and in all litters at 2,000 ppm</p> |
| 870.4100      | Chronic toxicity - dog                                | <p>NOAEL = 10 mg/kg/day<br/> LOAEL = 50 mg/kg/day, based on salivation and emesis, and hydrocephalus and support from shorter term studies also with these findings</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

| Guideline No. | Study Type                                                               | Results                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|---------------|--------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 870.4200      | Carcinogenicity - mouse                                                  | NOAEL = 1,000 ppm (118/159 mg/kg/day for males/females)<br>LOAEL is 8,000 ppm (991/1,341 mg/kg/day for males/females), based on decreased body weight and 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)<br>There was no evidence of carcinogenicity in this study at doses tested |
| 870.4300      | Chronic toxicity/carcinogenicity - rat                                   | NOAEL = > 1,000 ppm (41.8/55.7 mg/kg/day, males/females) HDT<br>LOAEL = > 1,000 ppm (41.8/55.7 mg/kg/day, males/ females)<br>No evidence of carcinogenicity                                                                                                                                                                                                                                                                                    |
| 870.5100      | Gene mutation/bacteria Ames <i>Salmonella typhimurium</i>                | Not mutagenic in TA1535, TA1537, TA1538, TA98, and TA100 tested with and without metabolic activation                                                                                                                                                                                                                                                                                                                                          |
| 870.5100      | Gene mutation/bacteria Ames <i>Salmonella typhimurium</i>                | Not a mutagen up to 40 µl/plate with TA1535, TA1537, TA98, and TA100 strains of <i>Salmonella typhimurium</i> in either the standard plate assay or the preincubation assay with and without the metabolic activation                                                                                                                                                                                                                          |
| 870.5275      | Cytogenetics sex link recessive - <i>drosophila melanoga</i>             | Not mutagenic in SLRL test                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 870.5300      | Gene Mutation/ <i>In vitro</i> 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/ <i>In vitro</i> 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 µl/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                                                                                                                                      |

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

| Guideline No.      | Study Type                                                                                                                                                                                             | Results                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 870.5300           | Gene mutation/ <i>In vitro</i> assay in mammalian cells-mouse lymphoma<br>Cytogenetics/ <i>In vitro</i> - mouse<br>(A) 870.5375<br>Chromosomal aberration<br>(B) 870.5900<br>Sister chromatid exchange | Positive mutagenicity observed at the thymidine locus under S-9 rat liver metabolic activation<br>(A) Chromosomal Aberration Assay: Under the standard test procedure positive clastogenic effect was observed at the concentration of 5 $\mu$ l/ml under the nonactivation assay and at the concentrations of 3 to 5 $\mu$ l/ml under the activation assay<br>(B) Sister Chromatid Exchange Assay: Under the standard test procedure, the test compound was a positive inducer of SCE at the concentration of 5 $\mu$ l/ml under the nonactivation assay and at the concentrations of 3 to 5 $\mu$ l/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 $\mu$ l/ml. 3/20/87 Addendum: Not a clastogen in these assays with and without metabolic activation under the pH adjusted test condition (PH 7.4) at concentrations of 4 through 10 $\mu$ l/ml |
| 870.5375           | Cytogenetics/ <i>In vitro</i> 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 <i>In vitro</i> CHO                                                                                                                                                                       | Increased chromosomal aberrations in activation assay at 6–8 $\mu$ l/ml. No increase in sister chromatid exchanges with S-9 metabolic activation (1–8 $\mu$ l/ml).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 870.5385           | Cytogenetics/rat bone marrow                                                                                                                                                                           | Not clastogenic in the rat bone marrow cells                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 870.5395           | Cytogenetics/ <i>In vivo</i> mouse micronucleus assay                                                                                                                                                  | Failed to induce significant increase in the number of PCE containing micronuclei                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 870.5375, 870.5900 | Cytogenetics/ <i>In vitro</i> CHO                                                                                                                                                                      | Not a clastogen in these assays with and without metabolic activation under the pH adjusted test condition (pH 7.4 to 7.6)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Other              | BALB/3T cells transformation assay                                                                                                                                                                     | Negative responses at 0.313, 0.625, 1.25, 2.50, and 5.0 $\mu$ l/ml in the BALB/3T cells transformation assay                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 870.6100           | Acute neurotoxicity - hen                                                                                                                                                                              | NOAEL = 500 mg/kg<br>LOAEL = 5,000 mg/kg based on diarrhea, changes in comb appearance, early decreased food consumption, and a decrease in egg production                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

| Guideline No. | Study Type                                       | Results                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|---------------|--------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 870.6200      | Acute neurotoxicity screening battery - rat      | NOAEL = 100 mg/kg<br>LOAEL = 300 mg/kg based on mortality, neurologic signs and decreased body weight and food consumption                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 870.6200      | Subchronic neurotoxicity screening battery - rat | NOAEL= 600 ppm (47.6/54.4 mg/kg/day for males/females)<br>LOAEL = 2,000 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 870.7485      | 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 C <sup>14</sup> sulfosate was rapidly excreted: IV treated male and females eliminated 90% of the administered dose in urine. Absorption of C <sup>14</sup> -sulfosate was incomplete by the oral route: Most groups eliminate 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 <sup>14</sup> CO <sub>2</sub> elimination. Tissue C <sup>14</sup> residues were < 0.32% of administered dose. Carcass C <sup>14</sup> residues were < 2.2% of administered dose (mostly in bones, 3–7 ppm in low dose rats and 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. |

*B. Toxicological Endpoints*

The toxicological endpoints for sulfosate are discussed in Unit II. B. of

the **Federal Register** document published on September 11, 1998 (63 FR 48597).

A summary of the toxicological endpoints for sulfosate used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR SULFOSATE FOR USE IN HUMAN RISK ASSESSMENT<sup>1</sup>.

| 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<br>UF = 100<br>Acute RfD = 1 mg/kg/day | FQPA SF = 3X<br>aPAD = aRfD ÷ FQPA SF<br>= 0.33 mg/kg/day | Acute neurotoxicity - rat<br>LOAEL = 300 mg/kg/day based on mortality, decreased body weight and food consumption, and neurotoxicity. |

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR SULFOSATE FOR USE IN HUMAN RISK ASSESSMENT<sup>1</sup>.—Continued

| Exposure Scenario                 | Dose Used in Risk Assessment, UF                                | FQPA SF* and Endpoint for Risk Assessment                  | Study and Toxicological Effects                                                                                                                                                                                |
|-----------------------------------|-----------------------------------------------------------------|------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Chronic dietary (all populations) | NOAEL= 25 mg/kg/day<br>UF = 100<br>Chronic RfD = 0.25 mg/kg/day | FQPA SF = 3X<br>cPAD = cRfD ÷ FQPA SF<br>= 0.083 mg/kg/day | Subchronic toxicity (capsule) - dog<br>Subchronic toxicity (gavage) - dog<br>Chronic toxicity - dog<br>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.

\*\*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

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.489) for the residues of sulfosate, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from sulfosate in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. The Dietary Exposure Evaluation Model (DEEM<sup>TM</sup>) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Tolerance level residues, DEEM default processing factors, and 100% crop treated (CT) information for all commodities. For acute dietary risk estimates, EPA's level of concern is for exposure at greater than 100% of the acute population adjusted dose (aPAD). The acute exposure estimates at the 95<sup>th</sup> 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 EPA's level of concern for the general U.S. population and all population subgroups.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM<sup>TM</sup> analysis evaluated the individual food consumption as reported by respondents in the USDA

1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tolerance level residues for all commodities, DEEM default processing factors, and %CT information for some commodities (oranges, grapefruit, soybeans, corn, peaches, and wheat). This procedure represents an over-estimation of dietary exposure, since tolerance level residue values were used for all commodities. For chronic dietary risk estimates, EPA's level of concern is for exposure at greater than 100% chronic population adjusted dose (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 analysis indicate that the chronic dietary risk estimates associated with the existing and proposed uses of sulfosate do not exceed EPA's level of concern for the U.S. population and all population subgroups.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To

provide for the periodic evaluation of the estimate of percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows.

For the acute analysis, tolerance level residues and 100% CT were used. For the chronic analysis, PCT information was used for oranges (1% CT), grapefruit (10% CT), soybeans (1% CT), corn (10% CT), peaches (1% CT), and wheat (1% CT). For corn, peaches, and wheat, which have PCT estimates of zero, a value of 1% CT was used in the analysis. For all crops other than oranges, grapefruit, soybeans, corn, peaches, and wheat, 100% CT was used, and tolerance level residues were used for all crops.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into



account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which sulfosate may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for sulfosate in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of sulfosate.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum PC coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to sulfosate they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW model, EECs of total sulfosate for acute exposures are estimated to be 125.5 ppb for surface water and 0.328 ppb for ground water. The EECs for chronic exposures are estimated to be 27.8 ppb for surface water and 0.328 ppb for ground water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Sulfosate is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

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. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, sulfosate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that sulfosate has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide

Tolerances (62 FR 62961, November 26, 1997).

#### *D. Safety Factor for Infants and Children*

1. *Safety factor for infants and children—In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* Prenatal and postnatal sensitivity is discussed in Unit II.E.1.iv. of the **Federal Register** document published on September 11, 1998 (63 FR 48597).

3. *Conclusion.* With the exception of the requested developmental neurotoxicity study, there is a complete toxicity data base for sulfosate and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The determination of the 3x safety factor for infants and children is discussed in Unit II.E.1.i. of the **Federal Register** document published on September 11, 1998 (63 FR 48597).

#### *E. Aggregate Risks and Determination of Safety*

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water

are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes

with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to sulfosate will occupy 33% of the aPAD for the U.S. population, up to 18% of the aPAD for females 13 years and older, 50% of the aPAD for all infants (< 1 year old) and 55% of the aPAD for children 1–6 years old. In addition, there is potential for acute dietary exposure to sulfosate in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO SULFOSATE

| Population Sub-group       | aPAD (mg/kg) | %aPAD (Food) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Acute DWLOC (ppb) |
|----------------------------|--------------|--------------|-------------------------|------------------------|-------------------|
| U.S. population            | 0.33         | 3            | 125.5                   | 0.328                  | 7,900             |
| All infants (< 1-year old) | 0.33         | 50           | 125.5                   | 0.328                  | 1,700             |
| Children (1–6 years old)   | 0.33         | 55           | 125.5                   | 0.328                  | 1,500             |
| Children (7–12 years old)  | 0.33         | 36           | 125.5                   | 0.328                  | 2,100             |
| Females (13–50 years old)  | 0.33         | 18           | 125.5                   | 0.328                  | 8,200             |
| Males (13–19 years old)    | 0.33         | 28           | 125.5                   | 0.328                  | 8,500             |
| Males (20 + years old)     | 0.33         | 18           | 125.5                   | 0.328                  | 9,600             |
| Seniors (55 + years old)   | 0.33         | 15           | 125.5                   | 0.328                  | 9,900             |

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to sulfosate from food will utilize 19% of the cPAD for the U.S. population, 47% of the cPAD for all

infants (< 1 year old) and 60% of the cPAD for children 1–6 years old. There are no residential uses for sulfosate that result in chronic residential exposure to sulfosate. In addition, there is potential for chronic dietary exposure to sulfosate

in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO SULFOSATE

| Population Subgroup        | cPAD mg/kg/day | %cPAD (Food) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Chronic DWLOC (ppb) |
|----------------------------|----------------|--------------|-------------------------|------------------------|---------------------|
| U.S. population            | 0.083          | 19           | 27.8                    | 0.328                  | 2,400               |
| All infants (< 1 year old) | 0.083          | 47           | 27.8                    | 0.328                  | 440                 |
| Children (1–6 years old)   | 0.083          | 60           | 27.8                    | 0.328                  | 340                 |
| Children (7–12 years old)  | 0.083          | 34           | 27.8                    | 0.328                  | 560                 |
| Females (13–50 years old)  | 0.083          | 12           | 27.8                    | 0.328                  | 2,300               |
| Males (13–19 years old)    | 0.083          | 21           | 27.8                    | 0.328                  | 2,300               |
| Males (20+ years old)      | 0.083          | 12           | 27.8                    | 0.328                  | 2,600               |

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO SULFOSATE—Continued

| Population Subgroup     | cPAD mg/<br>kg/day | %cPAD<br>(Food) | Surface<br>Water EEC<br>(ppb) | Ground<br>Water EEC<br>(ppb) | Chronic<br>DWLOC<br>(ppb) |
|-------------------------|--------------------|-----------------|-------------------------------|------------------------------|---------------------------|
| Seniors (55+ years old) | 0.083              | 11              | 27.8                          | 0.328                        | 2,600                     |

3. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to sulfosate residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Analytical enforcement methodology for sulfosate is discussed in Unit III.B. of the **Federal Register** document published on September 11, 1998 (63 FR 48597).

Adequate enforcement methodology (e.g; gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

##### B. International Residue Limits

There are no Codex, Canadian or Mexican tolerances or maximum residue limits for residues of sulfosate in the subject commodities. Therefore, a compatibility issue is not relevant to the proposed tolerances.

##### C. Conditions

EPA is imposing requirements of the following studies as conditions of registration: A developmental neurotoxicity study (DNT) in the rat (OPPTS Guideline No. 870.6300) (previously imposed and in progress) and a 28-day inhalation toxicity study. The DNT study in the rat is required based on the weight-of-the-evidence concerns for neurotoxicity in the mouse oncogenicity study, the subchronic and chronic dog studies, the 21-day dermal toxicity study in rats, and acute and subchronic neurotoxicity studies in the rat. Signs of neurotoxicity due to sulfosate included function observational battery (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. The 28-day inhalation toxicity study is required to provide further characterization of inhalation risk. 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.

#### V. Conclusion

Therefore, the tolerance is established for residues of sulfosate, sulfonium, trimethyl-salt with N-(phosphonomethyl)glycine (1:1), in or on cotton, gin by-products at 120 ppm (of which no more than 35 ppm is TMS), cotton, undelinted seed at 40 ppm (of which no more than 10 ppm is TMS), pea and bean, dried shelled except soybean), subgroup (6C) at 6.00 ppm (of which no more than 1.5 ppm is TMS), vegetable, legume, edible podded subgroup (6A) at 0.50 ppm (of which no more than 0.3 ppm is TMS), vegetable, fruiting group (8) at 0.05 ppm, sorghum, grain, forage at 0.20 ppm (of which no more than 0.10 ppm is TMS), sorghum, grain, grain at 35 ppm (of which no more than 15 ppm is TMS), sorghum, grain, stover at 140 ppm (of which no more than 60 ppm is TMS), vegetable, leaves of root and tuber (except radish) group (2) at 0.30 ppm (of which no more than 0.20 ppm is TMS), pistachio at 0.05 ppm, radish, roots at 16 ppm (of which no more than 15 ppm is TMS), radish, tops at 10 ppm (of which no more than 8.0 ppm is TMS), pea and bean, succulent shelled subgroup (6B) at 0.20 ppm (of which no more than 0.10 ppm is TMS), corn, sweet, forage at 20 ppm (of which no more than 5.0 ppm is TMS), corn, sweet, kernels plus cob with husks removed at 0.15 ppm (of which no more than 0.10 ppm is TMS), corn, sweet, stover at 170 ppm (of which no more than 65 ppm is TMS), vegetable, tuberous and corm subgroup (1C) at 1.0 ppm (of which no more than 0.50 ppm is TMS), and vegetable, root (except radish) subgroup

(1A) at 0.15 ppm (of which no more than 0.10 ppm is TMS). This regulation increases tolerances in wheat, bran at 30 ppm (of which no more than 6.0 ppm is TMS), wheat, grain at 10 ppm (of which no more than 2.5 ppm is TMS), wheat, hay at 1.0 ppm (of which no more than 0.50 ppm is TMS), wheat, shorts at 20 ppm (of which no more than 5.0 ppm is TMS), wheat, straw at 90 ppm (of which no more than 40 ppm is TMS), and poultry meat by-products at 0.05 ppm.

#### VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

##### A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-301173 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 20, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing

is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is

described in Unit I.B.2. Mail your copies, identified by docket control number OPP-301173, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov). Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

#### *B. When Will the Agency Grant a Request for a Hearing?*

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

#### **VII. Regulatory Assessment Requirements**

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public

Law 104-4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with*

*Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

#### VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small

Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 12, 2001.

**Peter Caulkins,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.489 is amended by revising the introductory text of paragraph (a); revising the entries for poultry, mby, wheat bran, wheat grain, and wheat hay; and alphabetically adding commodities to the table in paragraph (a) to read as follows:

#### § 180.489 Sulfosate (Sulfonium, trimethyl-salt with *N*-(phosphonomethyl)glycine (1:1)); tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide sulfosate (sulfonium, trimethyl-salt with *N*-(phosphonomethyl)glycine (1:1)) as the sum of the residues of the trimethylsulfonium cation (TSM) and the *N*-(phosphonomethyl) glycine anion measured separately in or on the following raw and processed agricultural commodities.

| Commodity                                                                                                                                        | Parts per million |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| * * * *                                                                                                                                          | *                 |
| Corn, sweet, forage (of which no more than 5.0 ppm is TMS) .....                                                                                 | 20                |
| Corn, sweet, kernels plus cob with husks removed (of which no more than 0.10 ppm is TMS) .....                                                   | 0.15              |
| Corn, sweet, stover (of which no more than 65 ppm is TMS) .....                                                                                  | 170               |
| Cotton, gin by-products (of which no more than 35 ppm is TMS) .....                                                                              | 120               |
| Cotton, undelinted seed (of which no more than 10 ppm is TMS) .....                                                                              | 40                |
| * * * *                                                                                                                                          | *                 |
| Crop group 2: Leaves of root and tuber vegetables (human food or animal feed (except radish) group (of which no more than 0.20 ppm is TSM) ..... | 0.30              |
| Crop group 8: Fruiting vegetables (except cucurbits) group .....                                                                                 | 0.05              |
| Crop subgroup 1-A: Root vegetables (except radish) subgroup (of which no more than 0.10 ppm is TSM) .....                                        | 0.15              |
| Crop subgroup 1-C: Tuberous and corm vegetables subgroup (of which no more than 0.50 ppm is TSM) .....                                           | 1                 |
| Crop subgroup 6-A: Edible-podded legume vegetables subgroup (of which no more than 0.3 ppm is TSM) .....                                         | 0.5               |
| Crop subgroup 6-B: Succulent shelled pea and bean subgroup (of which no more than 0.1 ppm is TSM) .....                                          | 0.20              |
| Crop subgroup 6-C: Dried shelled pea and bean (except soybean and animal feeds) subgroup (of which no more than 1.5 ppm is TSM) .....            | 6.0               |
| Pistachio .....                                                                                                                                  | 0.05              |
| * * * *                                                                                                                                          | *                 |
| Poultry, meat byproduct .....                                                                                                                    | 0.50              |
| * * * *                                                                                                                                          | *                 |
| Radish, roots (of which no more than 15 ppm is TMS) .....                                                                                        | 16                |
| Radish, tops (of which no more than 8.0 ppm is TMS) .....                                                                                        | 10                |
| * * * *                                                                                                                                          | *                 |
| Sorghum, grain, forage (of which no more than 0.10 ppm is TMS) .....                                                                             | 0.20              |
| Sorghum, grain, grain (of which no more than 15 ppm is TMS) .....                                                                                | 35                |
| Sorghum, grain, stover (of which no more than 60 ppm is TMS) .....                                                                               | 140               |
| * * * *                                                                                                                                          | *                 |
| Wheat, bran (of which no more than 6.0 ppm is TMS) .....                                                                                         | 30                |
| Wheat, grain (of which no more than 2.5 ppm is TMS) .....                                                                                        | 10                |
| * * * *                                                                                                                                          | *                 |
| Wheat, hay (of which no more than 0.50 ppm is TMS) .....                                                                                         | 1.0               |
| Wheat, shorts (of which no more than 5.0 ppm is TMS) .....                                                                                       | 20                |

| Commodity                                                | Parts per million |
|----------------------------------------------------------|-------------------|
| Wheat, straw (of which no more than 40 ppm is TMS) ..... | 90                |

\* \* \* \* \*

[FR Doc. 01-23605 Filed 9-20-01; 8:45 am]  
BILLING CODE 6560-50-S

**GENERAL SERVICES  
ADMINISTRATION**

**41 CFR Parts 101-46 and 102-39**

[FPMR Amendment H-208]

RIN 3090-AH23

**Replacement of Personal Property  
Pursuant to the Exchange/Sale  
Authority**

**AGENCY:** Office of Governmentwide  
Policy, GSA.

**ACTION:** Final rule.

**SUMMARY:** The General Services Administration is revising the Federal Property Management Regulations (FPMR) by moving coverage on replacement of personal property pursuant to the exchange/sale authority into the Federal Management Regulation (FMR). A cross-reference is added to the FPMR to direct readers to the coverage in the FMR. The FMR is written in plain language to provide agencies with updated regulatory material that is easy to read and understand.

**EFFECTIVE DATE:** September 21, 2001.

**FOR FURTHER INFORMATION CONTACT:** Rick Bender, Personal Property Management Policy Division (MTP), 202-501-3448.

**SUPPLEMENTARY INFORMATION:**

**A. Background**

This final rule updates, streamlines, and clarifies FPMR part 101-46 and moves the part into the Federal Management Regulation (FMR). The rule is written in a plain language question and answer format. In this format, a question and its answer combine to establish a rule. This means the employee and the agency must follow the language contained in both the question and its answer.

Updates include:

1. A revised definition of "replacement."
2. A new provision regarding the fixed price sale of exchange/sale property to a State Agency for Surplus Property before conducting an exchange/sale with a non-Government entity.
3. Revised restrictions on types of personal property that are ineligible for

exchange/sale, including removal of large weapons, fire control equipment, and guided missiles belonging to the Department of Defense, and furniture belonging to any executive agency from the list of such property.

4. Clarified restrictions on the exchange/sale of combat material.
5. A revised requirement for documentation of exchange/sale transactions.
6. Revised accounting requirements for the proceeds from the sale of personal property under the exchange/sale authority.
7. A new annual reporting requirement for exchange/sale transactions.

**B. Executive Order 12866**

GSA has determined that this final rule is not a significant rule for the purposes of Executive Order 12866 of September 30, 1993.

**C. Regulatory Flexibility Act**

A regulatory flexibility analysis is not required under the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because there is no requirement that this final rule be published in the **Federal Register** for notice and comment.

**D. Paperwork Reduction Act**

The Paperwork Reduction Act does not apply because this final rule does not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public which require the approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.*

**E. Small Business Regulatory  
Enforcement Fairness Act**

This final rule is exempt from Congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.

**List of Subjects in 41 CFR Parts 101-46  
and 102-39**

Government property management.

For the reasons set forth in the preamble, GSA amends 41 CFR chapters 101 and 102 as follows:

**CHAPTER 101—[AMENDED]**

1. Part 101-46 is revised to read as follows:

**PART 101-46—REPLACEMENT OF  
PERSONAL PROPERTY PURSUANT  
TO THE EXCHANGE/SALE AUTHORITY**

**Authority:** Sec. 205(c), 63 Stat. 390 (40 U.S.C. 486(c)).

**§ 101-46.000 Cross-reference to the Federal Management Regulation (FMR) (41 CFR chapter 102, parts 102-1 through 102-220).**

For information on replacement of personal property pursuant to the exchange/sale authority previously contained in this part, see FMR part 39 (41 CFR part 102-39).

**CHAPTER 102—[AMENDED]**

2. Part 102-39 is added to subchapter B of chapter 102 to read as follows:

**PART 102-39—REPLACEMENT OF  
PERSONAL PROPERTY PURSUANT  
TO THE EXCHANGE/SALE AUTHORITY**

**Subpart A—General**

Sec.

- 102-39.5 How are the terms "I" and "you" used in this part?
- 102-39.10 What does this part cover?
- 102-39.15 Why should I use the exchange/sale authority?
- 102-39.20 What definitions apply to this part?
- 102-39.25 How do I request a deviation from this part?

**Subpart B—Exchange/Sale Considerations**

- 102-39.30 When should I not use the exchange/sale authority?
- 102-39.35 How do I determine whether to do an exchange or a sale?
- 102-39.40 When should I arrange for a reimbursable transfer of exchange/sale property to a Federal agency or other eligible organization, or sell such property to a State Agency for Surplus Property?
- 102-39.45 What prohibitions apply to the exchange/sale of personal property?
- 102-39.50 What conditions apply to the exchange/sale of personal property?
- 102-39.55 What exceptions apply to the conditions for exchange/sale in § 102-39.50?

**Subpart C—Exchange/Sale Methods and Reports**

- 102-39.60 What are the exchange methods?
- 102-39.65 What are the sales methods?
- 102-39.70 What are the accounting requirements for the proceeds of sale?
- 102-39.75 What information am I required to report?

**Authority:** 40 U.S.C. 486(c).