### VIII. Congressional Review Act

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 10, 2003.

**Debra Edwards,**

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

■ Therefore, 40 CFR part 180 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 180.414 is amended as follows:

■ a. By revising the commodities cattle, goat, hog, horse, and sheep meat byproducts in the table in paragraph (a).

■ b. By revising the commodities onion, dry bulb and onion, green in the table in paragraph (a).

■ c. By alphabetically adding commodities in the table in paragraph (a).

■ d. By removing and reserving paragraph (c).

**§ 180.414 Cyromazine; tolerances for residues.**

(a) * * *

| Commodity | Parts per million |
|---|---|
| * * * | * * |
| Broccoli | 1.0 |
| Cabbage, abyssinian | 10.0 |
| Cabbage, seakale | 10.0 |
| * * * | * * |
| Cattle, kidney | 0.2 |
| Cattle, meat byproducts, except kidney | 0.05 |
| * * * | * * |
| Garlic, bulb | 0.2 |
| Garlic, great-headed, bulb | 0.2 |
| * * * | * * |
| Goat, kidney | 0.2 |
| * * * | * * |
| Goat, meat byproducts, except kidney | 0.05 |
| Hanover salad, leaves | 10.0 |
| * * * | * * |
| Hog, kidney | 0.2 |
| * * * | * * |
| Hog, meat byproducts, except kidney | 0.05 |
| * * * | * * |
| Horse, kidney | 0.2 |
| * * * | * * |
| Horse, meat byproducts, except kidney | 0.05 |
| * * * | * * |
| Leek | 3.0 |
| * * * | * * |
| Onion, dry bulb | 0.2 |
| Onion, green | 3.0 |
| Onion, potato | 3.0 |
| Onion, tree | 3.0 |
| Onion, welsh | 3.0 |
| * * * | * * |
| Rakkyo, bulb | 0.2 |
| Shallot, bulb | 0.2 |
| Shallot, fresh leaves | 3.0 |
| * * * | * * |
| Sheep, kidney | 0.2 |
| * * * | * * |
| Sheep, meat byproducts, except kidney | 0.05 |
| * * * | * * |
| Turnip, greens | 10.0 |
| Vegetable, brassica, leafy, group 5, except broccoli | 10.0 |
| * * * | * * |

* * * * * *

(c) *Tolerances with regional registrations.* [Reserved]

* * * * * *

[FR Doc. 03–24012 Filed 9–23–03; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[OPP–2003–0270; FRL–7324–5]**

### Sulfentrazone; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of the herbicide sulfentrazone and its metabolites in or on asparagus; bean, lima, succulent; cabbage; corn, field, forage; corn, field, grain; corn, field, stover; horseradish, roots; pea and bean, dried shelled, except soybean, subgroup 6C; peanut; peanut, meal; peppermint, tops; potato; spearmint, tops; sugarcane, cane; sugarcane, molasses; and sunflower, seed. EPA is also deleting certain sulfentrazone tolerances that are no longer needed as result of this action. The Interregional Research Project Number 4 and FMC Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective September 24, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0270, must be received on or before November 24, 2003.

**ADDRESSES:** Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703)308–9368; e-mail address: *jamerson.hoyt@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:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any 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 Copies of this Document and Other Related Information?*

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0270. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. 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*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

## II. Background and Statutory Findings

In the **Federal Register** of March 7, 2003 (68 FR 11096) (FRL–7290–1), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petitions (PP 0E6149, 1E6311, 2E6405, 2E6498, and 2E6500) by the Interregional Research Project Number 4 (IR-4), and 681 U.S. Highway #1 South, North Brunswick, NJ 08902, and PP 0F6116 and 2F6391 by FMC Corporation, Agricultural Products Group, 1735 Market Street, Philadelphia, PA 19103. That notice included a summary of the petitions prepared by FMC Corporation, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.498 be amended by establishing tolerances for combined residues of the herbicide sulfentrazone, [*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-ylphenylmethansulfonoamide and its metabolites HMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol- 1-yl)phenyl)methanesulfonamide) and DMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide), in or on food commodities as follows: Sunflower, seed at 0.2 parts per million (ppm) (PP 0E6149); horseradish, roots at 0.2 ppm (PP 1E6311); cabbage at 0.2 ppm (PP 1E6311); peppermint, tops and spearmint, tops at 0.3 ppm (1E6311); potato at 0.1 ppm (PP 2E6405); bean, lima, succulent at 0.15 ppm (PP 2E6498); asparagus at 0.15 ppm (2E6500); peanut nutmeat and its processed parts at 0.2 ppm and sugarcane and its processed parts at 0.1 ppm (PP 0F6116); corn, field forage at 0.25 ppm (PP 2F6391); corn, field stover at 0.35 ppm (PP 2F6391); pea and bean, dried shelled, except soybean, subgroup 6C at 0.15 ppm (PP 2F6391). Pesticide petitions 0F6116, 2F6391 and 2E6405 were subsequently amended to propose tolerances for peanut at 0.20 ppm; peanut, meal at 0.40 ppm; sugarcane, cane at 0.15 ppm; sugarcane, molasses at 0.20 ppm; corn, field, forage at 0.20 ppm; corn, field, grain at 0.15 ppm; corn, field, stover at 0.30 ppm and potato at 0.15 ppm. EPA is also deleting several time-limited tolerances established in connection with section 18 emergency exemption under 40 CFR 180.498(b) that are no longer needed, as a result of this action. The deletions to 40 CFR 180.498(b) are as follows:

1. Delete horseradish, roots at 0.1 ppm; replace with horseradish, roots at 0.20 ppm.

2. Delete pea, dry, seed at 0.10 ppm; replace with pea and bean, dried shelled, except soybean, subgroup 6C at 0.15 ppm.

3. Delete potato at 0.10 ppm; potato, granules/flakes at 0.20 ppm; and potato, wet peel at 0.15 ppm; replace with potato at 0.15 ppm.

4. Delete sugarcane at 0.05 ppm; replace with sugarcane, cane 0.15 ppm and sugarcane, molasses at 0.20 ppm.

5. Delete sunflower at 0.1 ppm; replace with sunflower, seed at 0.20 ppm.

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) of the FFDCA 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) of the FFDCA 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 of the FFDCA 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) of the FFDCA, 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) of the

FFDCA, for tolerances for combined residues of sulfentrazone and its major metabolites on asparagus at 0.15 ppm; bean, lima, succulent at 0.15 ppm; cabbage at 0.20 ppm; corn, field, forage at 0.20 ppm; corn, field, grain at 0.15 ppm; corn, field, stover at 0.30 ppm; horseradish, roots at 0.20 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 0.15 ppm; peanut at 0.20 ppm; peanut, meal at 0.40 ppm; peppermint, tops at 0.30 ppm; potato at 0.15 ppm; spearmint, tops at 0.30 ppm; sugarcane, cane 0.15 ppm; sugarcane, molasses 0.20 ppm; and sunflower, seed at 0.20 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances 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 sulfentrazone are discussed in Table 1 of this unit 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 rodents (rats) | NOAEL = 19.9 milligrams/kilogram/day (mg/kg/day) for males and 23.1 mg/kg/day for females<br>LOAEL = 65.8 mg/kg/day for males and 78.1 mg/kg/day for females based on clinical signs of anemia (reduced hematocrit, hemoglobin, mean cell volume, and mean cell hemoglobin values during treatment) |
| 870.3100 | 90–Day oral toxicity rodents (mice) | NOAEL = 60 mg/kg/day for males and 79.8 mg/kg/day for females<br>LOAEL = 108.4 mg/kg/day for males and 143.6 mg/kg/day for females based on decreased body weights, body weight gains, red blood cells, hemoglobin, hematocrit, and severity of splenic micropathology (increased incidence and severity of extramedullary hematopoiesis) |
| 870.3150 | 90–Day oral toxicity in nonrodents (dogs) | NOAEL = 28 mg/kg/day<br>LOAEL = 57 mg/kg/day for males and 73 mg/kg/day for females based on decreased body weights (7-10%) and body weight gains during first 5 weeks of study; decreased hemoglobin, hematocrit, mean cell volume, mean cell hemoglobin and mean cell hemoglobin concentration, and increased absolute liver weights and alkaline phosphatase levels, and microscopic changes in the liver and spleen (pigmented sinusoidal microphages in the liver, swollen centrilobular hepatocytes and pigmented reticuloendothelial cells in the spleen) |
| 870.3200 | 21/28–Day dermal toxicity | Systemic and dermal NOAEL = 1,000 mg/kg/day, highest dose tested (HDT) |
| 870.3700 | Prenatal developmental in rodents (rats) | Maternal<br>NOAEL = 25 mg/kg/day<br>LOAEL = 50 mg/kg/day based on increased relative splenic extramedullary hematopoiesis<br>Developmental<br>NOAEL = 10 mg/kg/day<br>LOAEL = 25 mg/kg/day based on decreased mean fetal weights, and retardation in skeletal development evidenced by an increased number of litters with any variation and by decreased number of caudal vertebral and metacarpal ossification sites |

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

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.3700 | Prenatal developmental in rodents (rats) | *Maternal*<br>NOAEL = 250 mg/kg/day<br>LOAEL was not established.<br>*Developmental*<br>NOAEL = 100 mg/kg/day<br>LOAEL = 250 mg/kg/day based on decreased fetal body weight; increased incidence of fetal variations: hypoplastic or wavy ribs, incompletely ossified lumbar vertebral arches, and incompletely ossified ischia or pubis; and reduced number of thoracic vertebral and rib ossification sites |
| 870.3700 | Prenatal developmental in non-rodents (rabbits) | *Maternal*<br>NOAEL = 100 mg/kg/day<br>LOAEL = 250 mg/kg/day based on increased abortions, clinical signs (hematuria and decreased feces), and reduced body weight gain<br>*Developmental*<br>NOAEL = 100 mg/kg/day<br>LOAEL = 250 mg/kg/day based on increased resorptions, decreased live fetuses per litter, and decreased fetal weights |
| 870.3800 | 2–Generation reproduction and fertility effects (rats) | *Parental/Systemic*<br>NOAEL = 14 mg/kg/day for males and 16 mg/kg/day for females<br>LOAEL = 33 mg/kg/day for males and 40 mg/kg/day for females based on decreased maternal body weight/body weight gain during gestation in both generation (P and F1) and reduced premating body weight gain in second generation (F1) males<br>*Reproductive*<br>NOAEL = 14 mg/kg/day for males and 16 mg/kg/day for females<br>LOAEL = 33 mg/kg/day for males and 40 mg/kg/day for females based on increased duration of gestation in females and degeneration and/or atrophy of the germinal epithelium of the testes and oligospermia and intratubular degenerated seminal material in the epididymis of F1 males<br>*Offspring*<br>NOAEL = 14 mg/kg/day for males and 16 mg/kg/day for females<br>LOAEL = 33 mg/kg/day for males and 40 mg/kg/day for females based on reduced prenatal viability (fetal and litter), reduced litter size, increased number of stillborn pups, reduced pup and litter postnatal survival and decreased pup body weights throughout lactation |
| 870.3800 | Reproduction and fertility effects (rat) Nonguideline | *Parental/Systemic*<br>NOAEL = 20 mg/kg/day<br>LOAEL = 51 mg/kg/day (F1 females) based on decrease in pre-mating body weight gain (10%)<br>*Offspring and Reproductive*<br>NOAEL = 16 mg/kg/day<br>LOAEL = 40 mg/kg/day based on reduced gestation day 20 fetal weights; decreased postnatal day 0, 4 and 7 pup weights; decreased pup survival; delayed vaginal patency; reduced epididymal, prostate, and testicular weights<br>Additional information supports the conclusions reached in the 2-generation reproduction study in rats |

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

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.4100 | Chronic toxicity dogs | NOAEL = 24.9 mg/kg/day for males and 29.6 mg/kg/day for females<br>LOAEL = 61.2 mg/kg/day for males and 61.9 mg/kg/day for females based on compensated normochromic microcytosis |
| 870.4200 | Carcinogenicity mice | NOAEL = 93.9 mg/kg/day for males and 116.9 mg/kg/day for females<br>LOAEL = 160.5 mg/kg/day for males and 198.0 mg/kg/day for females based on dose-related decreases in hemoglobin and hematocrit by study termination<br>No evidence of carcinogenicity |
| 870.4300 | Combined chronic toxicity/carcinogenicity rats | NOAEL = 40 mg/kg/day for males and 36.4 mg/kg/day in females<br>LOAEL = 82.2 mg/kg/day for males and 67 mg/kg/day for females based on dose-related decreased body weights (11 and 19%), body weight gains (13 and 26%), food consumption (13 and 19%), hemoglobin, hematocrit, mean cell volume, and mean cell hemoglobin. Increased nucleated red blood cells and reticulocytes in bone of females at 124.7 mg/kg/day<br>No evidence of carcinogenicity |
| 870.5100 | Gene mutation | No evidence of compound-induced cytotoxicity was evident in *Salmonella typhimurium* strains TA1535, TA1538, TA1537, TA98 and TA100 either in presence or in absence of S9 activation. The positive controls induced the expected mutagenic responses in the appropriate tester strain.<br>Sulfentrazone was considered not mutagenic under any test condition. |
| 870.5300 | *In vitro* mammalian cell gene mutation assay (mouse lymphoma) | In a forward gene mutation assay, sulfentrazone at precipitating levels was equivocally positive in the absence of S9 activation. This response was not repeated at doses up to 1,800 μg/ml in the presence of S9 activation. |
| 870.5395 | Mammalian erythrocyte micronucleus test | The test was negative in mice administered single intraperitoneal doses of 85 to 340 mg/kg. The 340 mg/kg dose was estimated to be approximately 80% of the $LD_{50}$. No evidence of a cytotoxic effect on the target organ and no significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow cells. |
| 870.5450 | Dominant lethal assay- rodent | There were no significant difference from negative controls in the proportion of early dead: total implants, and (total) dead: total implants. Based on the results, sulfentrazone is considered negative for inducing dominant lethal mutations in pre-meiotic, meiotic, and post-meiotic germ cells of male rats under conditions of this assay up to the estimated MTD. |
| 870.6200 | Acute neurotoxicity screening battery | NOAEL = 250 mg/kg/day<br>LOAEL = 750 mg/kg/day based on increased incidence of clinical signs, FOB findings, and decreased motor activity which was reversed by day 14 postdose. No evidence of neuropathology at any dose tested. |

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

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.6200 | Subchronic neurotoxicity screening battery | NOAEL = 30 mg/kg/day for males and 37 mg/kg/day for females<br>LOAEL = 150 mg/kg/day for males and 180 mg/kg/day for females based on increased incidence of clinical signs; decreased body weight, body weight gains, and food consumption in females; and increased motor activity in females. At 5,000 ppm, included increased mortality; decreased body weights, and body weight gains in males; decreased hindlimb grip strength and increased tail flick latency in males at week 8; distended bladders with red fluid and enlarged spleen.<br>No evidence of neuropathology at 2,500 and 5,000 ppm. |
| 870.7485 | Metabolism and pharmacokinetics (rats) | Sulfentrazone (Phenyl -14C - sulfentrazone) was readily absorbed and 84 to 104% of the administered dose was excreted in urine and feces within 72 hours. There were no major sex differences in the pattern of excretion. Almost all the radioactivity in the urine was 3-hydroxy-methyl-F6285 (84 - 104% of the administered dose). In the feces, HMS accounted for 1.26 to 2.55% of the administered dose. The proposed metabolic pathway appeared to be conversion of the parent compound mainly to 3-hydroxymethyl-F6285 (excreted in the urine). A small amount of 3-hydroxymethyl-F6285 was also converted to 3-carboxylic acid-F6285 (excreted in the urine and feces). |

*B. Toxicological Endpoints*

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factors (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as $1 \times 10^{-6}$ or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer}$ = point of departure/exposures) is calculated. A summary of the toxicological endpoints for sulfentrazone used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR SULFENTRAZONE FOR USE IN HUMAN RISK ASSESSMENT

| Exposure Scenario | Dose Used in Risk Assessment, UF | FQPA SF* and Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Acute dietary (females 13-50 years of age) | NOAEL = 25 mg/kg/day<br>UF = 100<br>Acute RfD = 0.25 mg/kg/day | FQPA SF = 1X<br>aPAD = acute RfD/ FQPA SF = 0.25 mg/kg/day | Developmental toxicity study in rats<br>LOAEL = 50 mg/kg/day based on decreased live fetuses, and increased early resorptions |
| Acute dietary (general population including infants and children) | NOAEL = 250 mg/kg/day<br>UF = 100<br>Acute RfD = 2.5 mg/kg/day | FQPA SF = 1X<br>aPAD = acute RfD/ FQPA SF = 2.5 mg/kg/day | Acute neurotoxicity study in rats<br>LOAEL = 750 mg/kg/day based on increased incidence of clinical signs and FOB parameters and decreased motor activity. |
| Chronic dietary (all populations) | NOAEL= 14 mg/kg/day<br>UF = 100<br>Chronic RfD = 0.14 mg/kg/day | FQPA SF = 1X<br>cPAD = chronic RfD/ FQPA SF = 0.14 mg/kg/day | 2–Generation reproduction study<br>LOAEL = 33 mg/kg/day based on decreased body weight and body weight gains |
| Short-term (1 to 30 days) and intermediate-term (1 to 6 months) incidental oral | Offspring<br>NOAEL = 14 mg/kg/day | LOC for MOE = 100 (Residential) | 2–Generation reproduction study<br>LOAEL = 33 mg/kg/day based on decreased pup body weights during lactation in both generations |
| Short-term dermal (1 to 30 days), intermediate-term dermal (1 to 6 months) and long-term dermal (>6 months) | Dermal study NOAEL= 100 mg/kg/day (dermal absorption rate = 10%) | LOC for MOE = 100 (Residential) | Dermal developmental study in rats<br>LOAEL = 250 mg/kg/day based on decreased fetal body weight; increased incidences of fetal variations: hypoplastic or wavy ribs, incompletely ossified lumbar vertebral arches, and incompletely ossified ischia or pubes; and reduced number of thoracic vertebral and rib ossification sites |
| Short-term inhalation (1 to 30 days), intermdiate-term inhalation (1 to 6 months) and long-term inhalation (> 6 months) | Oral study NOAEL = 14 mg/kg/day (inhalation rate = 100% | LOC for MOE = 100 (Residential) | 2–Generation reproduction study<br>LOAEL = 33 mg/kg/day based on decreased body weight and body weight gains |
| Cancer (oral, dermal, inhalation) | Not applicable | Not applicable | No evidence of carcinogenicity in rats and mice |

*The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.498) for the combined residues of sulfentrazone, in or on soybean, seed at 0.05 ppm. Time-limited tolerances (set to expire on December 31, 2004) are established in connection with section 18 emergency exemptions for bean, succulent seed without pod at 0.1; horseradish, roots at 0.1 ppm; chickpea, seed at 0.10 ppm; pea, dry, seed 0.10 ppm; potato at 0.10 ppm; potato, wet peel at 0.15; flax, seed at 0.20 ppm; potato, granules/flakes at 0.20 ppm; strawberry at 0.60 ppm. Time-limited tolerances (set to expire on December 31, 2005) are established in connection with section 18 emergency exemptions for sugarcane at 0.05 ppm and sunflower at 0.1 ppm. Tolerances are also established for indirect or inadvertent residues in or on cereal grain (excluding sweet corn). Risk assessments were conducted by EPA to assess dietary exposures from sulfentrazone 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. In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM™) which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. Separate Tier I, acute dietary exposure assessments were performed for females 13 to 49 years old and for the general U.S. population (including infants and children) using tolerance-level residues and 100 percent crop treated (PCT).

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment EPA used the DEEM™ software with the Food Commodity Intake Database which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. An unrefined, Tier I chronic dietary exposure assessment was performed using tolerance-level residues and 100 PCT.

2. *Dietary exposure from drinking water.* Sulfentrazone and the degradate 3-carboxylic acid sulfentrazone are the residues of concern for the drinking-water risk assessment. Environmental

fate data suggest that sulfentrazone and 3-carboxylic acid sulfentrazone are persistent and mobile. Based on the structure similarity, 3-carboxylic acid sulfentrazone could potentially have similar toxicity as the parent.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for sulfentrazone 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 sulfentrazone.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentrations in Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop 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 unlikely that drinking water concentrations would 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 sulfentrazone, they are further discussed in the aggregate risk sections in Unit E.

Based on the FIRST and SCI-GROW models the EECs of sulfentrazone plus its major metabolite 3-carboxylic acid for acute exposures are estimated to be 35.8 parts per billion (ppb) for surface water and 26.0 ppb for ground water. The EECs for chronic exposures are estimated to be 7.8 ppb for surface water and 26.0 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). Sulfentrazone is proposed for use on use on turf by professional lawn care operators as a broadcast spray at a maximum application rate of 0.03 lbs active ingredient. Based on the proposed use pattern, potential residential/non-occupational post-application exposures include the following: Short-term oral turfgrass exposure (toddler hand-to-mouth, object-to-mouth); short-term dermal turfgrass exposure (adult and toddler) and short-term dermal golfer exposure (adult and adolescent). Incidental ingestion of soil is assumed to be negligible. Exposure over intermediate-term (1-6 months) or long-term (chronic, more than 6 months) exposure is not expected. Homeowner handler exposure is not expected since sulfentrazone will be applied by professional lawn care operators.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA 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 sulfentrazone has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to sulfentrazone and any other substances and sulfentrazone 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 sulfentrazone 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

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

1. *In general*. Section 408 of the FFDCA 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 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*. There is evidence of increased quantitative susceptibility following *in utero* exposure in the developmental-toxicity studies in rats via the oral and dermal routes, and there is evidence for increased qualitative susceptibility following prenatal and/or postnatal exposure in the 2–generation reproduction study in rats. A Degree of Concern Analysis was performed by EPA and it was concluded that concerns are low for the quantitative susceptibility of rat fetuses observed following oral and dermal exposures, the qualitative susceptibility of rabbit fetuses seen via the oral route, and the qualitative susceptibility seen in the 1- and 2-generation reproduction studies. The conclusion was based on the following:

- The dose-response was well characterized.
- There were clear NOAELs and LOAELs for developmental, offspring, maternal, and parental toxicities.
- The developmental effects in rabbits and the offspring effects in the rats were seen in the presence of maternal and parental toxicities, respectively.
- The parental reproductive and offspring effects were reproducible between the two reproductive studies.

3. *Conclusion*. There is a complete toxicity data base for sulfentrazone and

exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be reduced to 1X for the following reasons:

1. There are no residual uncertainties for prenatal and/or postnatal toxicities via the oral route since the doses selected for overall risk assessments would address the concerns for the developmental and offspring toxicities seen in the above mentioned studies.

2. There are no residual uncertainties for prenatal and/or postnatal toxicities via the dermal route since the dose/endpoint/study/species of concern was used for dermal-risk assessment.

3. The toxicology data base is complete.

4. The dietary (food) exposure assessment utilizes existing and proposed tolerance level residues and assumes 100% of crops treated with sulfentrazone. The assessment is based on reliable data and is not expected to underestimate exposure/risk.

5. Conservative assumptions are used in the drinking water models. The drinking water exposure assessment is not expected to underestimate exposure/risk.

6. The residential exposure assessment is based on conservative assumptions and is not expected to underestimate risk.

*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: 2 liter (L)/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 sulfentrazone will occupy <1% of the aPAD for the U.S. population, <1% of the aPAD for females 13 years and older, and <1% of the aPAD for children 1 to 2 years old, the population at greatest exposure. In addition, there is potential for acute dietary exposure to sulfentrazone in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 of this unit:

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

| Population Subgroup | aPAD (mg/kg) | % aPAD (Food) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Acute DWLOC (ppb) |
|---|---|---|---|---|---|
| U.S. population | 2.5 | <1 | 35.8 | 26 | 87,000 |
| Children (1 to 2 years old) | 2.5 | <1 | 35.8 | 26 | 25,000 |
| Females (13 to 49 years old) | 2.5 | <1 | 35.8 | 26 | 75,000 |

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to sulfentrazone from food will utilize 1% of the cPAD for the U.S. population, 1% of the cPAD for females 13 to 49 years old and 1 % of the cPAD for children, 3 to 5 years old, the population at greatest exposure. Based on the proposed use pattern for turf grass, chronic residential exposure to residues of sulfentrazone is not expected. In addition, there is potential for chronic dietary exposure to sulfentrazone and its degredate, 3-carboxylic acid sulfentrazone, 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 Table 4 of this unit:

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

| Population Subgroup | cPAD mg/kg/day | % cPAD (Food) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Chronic DWLOC (ppb) |
|---|---|---|---|---|---|
| U.S. population | 0.14 | 1 | 7.8 | 26 | 4,900 |
| Children (3 to 5 years old) | 0.14 | 1 | 7.8 | 26 | 1,400 |
| Females (13 to 49 years old) | 0.14 | 1 | 7.8 | 26 | 4,200 |

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Sulfentrazone is proposed for registration for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for sulfentrazone. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs ranging from 6,900 for the U.S. population to 3,200 for children 3 to 5 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of sulfentrazone in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO SULFENTRAZONE

| Population Subgroup | Aggregate MOE (Food + Residential) | Aggregate Level of Concern (LOC) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Short-Term DWLOC (ppb) |
|---|---|---|---|---|---|
| U.S. population | 6,900 | 100 | 7.8 | 26 | 4,900 |
| Children (3 to 5 years old) | 3,200 | 100 | 7.8 | 26 | 1,400 |
| Females (13 to 49 years) | 7,600 | 100 | 7.8 | 26 | 4,200 |

5. *Aggregate cancer risk for U.S. population*. There is no evidence of carcinogenicity to humans based on carcinogenicity studies in male and female rats and mice. The Agency concludes that pesticidal uses of sulfentrazone are not likely to pose a cancer hazard to humans.

6. *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 sulfentrazone residues.

## IV. Other Considerations

### *A. Analytical Enforcement Methodology*

An adequate enforcement method using gas chromatography (GC) for the determination of sulfentrazone, DMS, and HMS residues is available for enforcement. The method was forwarded to the Food and Drug Administration (FDA) for inclusion in Pesticide Analytical Method Volume II (PAM II). The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

### *B. International Residue Limits*

There are no established Codex, Canadian or Mexican maximum residue limits (MRLs) for residues of sulfentrazone in/on the subject commodities. Therefore, no compatibility problems exist for the tolerances established by this rule.

## V. Conclusion

Therefore, the tolerance is established for combined residues of sulfentrazone and its metabolites HMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide) and DMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide, in or on asparagus at 0.15 ppm; bean, lima, succulent at 0.15 ppm; cabbage at 0.20 ppm; corn, field, forage at 0.20 ppm; corn, field, grain at 0.15 ppm; corn, field, stover at 0.30 ppm; horseradish, roots at 0.20 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 0.15 ppm; peanut at 0.20 ppm; peanut, meal at 0.40 ppm; peppermint, tops at 0.30 ppm; potato at 0.15 ppm; spearmint, tops at 0.30 ppm; sugarcane, cane 0.15 ppm; sugarcane, molasses 0.20 ppm; and sunflower, seed at 0.20 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. 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 ID number OPP–2003–0270 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 24, 2003.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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*, 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 20460–0001.

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 20460–0001.

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.1. Mail your copies, identified by docket ID number OPP–2003–0270, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *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. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA 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 special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or 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 section 408(d) of the FFDCA, 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 section 408(n)(4) of the FFDCA. 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. Congressional Review Act

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 10, 2003.

**Debra Edwards,**

*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 180.498 is amended by redesignating existing paragraph (a) as (a)(1), by adding paragraph (a)(2), and in the table to paragraph (b) by removing the entries ''horseradish, roots''; ''pea, dry, seed''; ''potato''; ''potato, granules/flakes''; ''potato, wet peel''; ''sugarcane''; and ''sunflower, seed.''

### § 180.498 Sulfentrazone; tolerances for residues.

(a) *General.* (1) * * *

(2) Tolerances are established for combined residues of the herbicide sulfentrazone and its metabolites HMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol- 1-yl)phenyl)methanesulfonamide) and DMS (*N*-(2,4-dichloro-5-(4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl)phenyl)methanesulfonamide in or on the following food commodities:

| Commodity | Parts per million |
|---|---|
| Asparagus | 0.15 |
| Bean, lima, succulent | 0.15 |
| Cabbage | 0.20 |
| Corn, field, forage | 0.20 |
| Corn, field, grain | 0.15 |
| Corn, field, stover | 0.30 |
| Horseradish, roots | 0.20 |
| Pea and bean, dried shelled, except soybean, subgroup 6C | 0.15 |
| Peanut | 0.20 |
| Peanut, meal | 0.40 |
| Peppermint, tops | 0.30 |
| Potato | 0.15 |
| Spearmint, tops | 0.30 |
| Sugarcane, cane | 0.15 |
| Sugarcane, molasses | 0.20 |
| Sunflower, seed | 0.20 |

* * * * *

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