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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0758; FRL-9353-8]

Sulfentrazone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of sulfentrazone in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) and FMC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-0758 is available at *http://www.regulations.gov* or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please

review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9367; email address: *ertman.andrew@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide 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 Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0758 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0758, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you

consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 5, 2011 (76 FR 61647) (FRL-8890-5), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7890) by (IR–4), Rutgers, The State University of New Jersey, 500 College Road East, Suite 201–W., Princeton, NJ 08540. The petition requested that 40 CFR 180.498 be amended by establishing tolerances for 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-yl]phenyl]methanesulfonamide) and its metabolites 3-hydroxymethylsulfentrazone (*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 3-desmethyl sulfentrazone (*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 rhubarb at 0.2 parts per million

(ppm); turnip, roots at 0.2 ppm; turnip, tops at 0.7 ppm; and sunflower subgroup 20B at 0.2 ppm; ‘‘Tolerances with regional registrations’’ in or on wheat, forage at 0.45 ppm (Pacific Northwest only); wheat, hay at 0.20 ppm (Pacific Northwest only); wheat, grain at 0.20 ppm (Pacific Northwest only); wheat, straw at 1.4 ppm (Pacific Northwest only); and cowpea, succulent at 0.15 ppm (Tennessee only). In addition, the petition requested to amend the current tolerances in 40 CFR 180.498 in or on bean, lima, succulent at 0.15 ppm by removing the tolerance from the table in Section (a)(2) and adding the tolerance to Section (c) *Tolerances with regional registrations.* Upon approval of the aforementioned tolerance on the sunflower subgroup 20B, the petition additionally proposed to remove the established tolerance in or on the raw agricultural commodity sunflower, seed at 0.2 ppm. That notice referenced a summary of the petition prepared by FMC, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

In the **Federal Register** of July 6, 2011 (76 FR 39358) (FRL-8875-6), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7838) by FMC Corporation, 1735 Market St., Philadelphia, PA 19103. The petition requested that 40 CFR 180.498 be amended by establishing tolerances for 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-yl]phenyl]methanesulfonamide) and its metabolites 3-hydroxymethylsulfentrazone (*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 3-desmethyl sulfentrazone (*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 crop group 10-10 citrus fruit at 0.15 ppm; crop group 13–07 berry and small fruit at 0.15 ppm; crop group 14 tree nut and pistachio at 0.15 ppm; and crop group 18 non-grass animal feed (forage, fodder, straw, and hay): Alfalfa, forage at 5 ppm; alfalfa, hay at 20 ppm; alfalfa, seed at 3 ppm; clover, forage at 5 ppm; clover, hay at 20 ppm; and clover, seed at 3 ppm. That notice referenced a summary of the petition prepared by FMC, the registrant, which is available in the docket, *http://www.regulations.gov*. A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the tolerance levels for some commodities and is not establishing tolerances on alfalfa forage, hay, and seed and clover forage, hay, and seed. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of 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 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 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...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA 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 for sulfentrazone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with sulfentrazone 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.

Based on the results of acute toxicity studies in rats, sulfentrazone was classified as having low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is a mild eye irritant, but not a dermal irritant or sensitizer. Subchronic and chronic toxicity studies in rats, mice and dogs identified the hematopoietic system as the target of sulfentrazone. Protoporphyrinogen oxidase inhibition in the mammalian species may result in disruption of heme synthesis. In these studies, disruption of heme synthesis was observed at about the same dose levels across species, except in the case of mice, where the effects were seen at a slightly higher dose. The hematotoxicity occurred around the same dose level for short- through long-term exposure without increasing in severity.

In the oral and dermal rat developmental toxicity studies, decreased fetal body weights and reduced/delayed skeletal ossifications were noted at doses that were not maternally toxic. In rabbits, developmental effects such as decreased pup viability were observed at a maternally toxic dose (clinical signs, abortions and decreased body weight gains). In the 2-generation reproduction study in rats, offspring effects such as decreased body weights and decreased litter survival were observed at a maternally toxic dose (slightly decreased body weight gain).

In the acute neurotoxicity study, an increased incidence of clinical signs (staggered gait, splayed hind limbs, and abdominal gripping), changes in functional observation battery (FOB) parameters, and decreased motor activity were observed; however, complete recovery was observed within 14 days and there was no evidence of neuropathology. In the subchronic neurotoxicity study, clinical signs of toxicity, increased motor activity, and/or decreased body weights, body-weight gain, and food consumption were observed. There was no evidence of neuropathology in either study. A published, non-guideline developmental toxicity study in the rat (de Castro, *et al*., 2007) failed to demonstrate conclusively developmental neurotoxicity and contains several shortcomings that limit its use for regulatory purposes. Further, the reported offspring effects involving measures of physical and reflex development are likely secondary effects reflective of the poor general state of the offspring, as reported in the rat 2-generation reproductive toxicity study at similar dose levels.

No systemic toxicity was seen via the dermal route up to the limit dose in a 28-day dermal toxicity study in rabbits.

Preliminary review of a recently submitted 28-day rat immunotoxicity study suggests that sulfentrazone does not directly target the immune system; and, there is no evidence of immunotoxicity in the rest of the toxicity database for sulfentrazone.

Carcinogenicity studies in rats and mice showed no evidence of increased incidence of tumor formation due to treatment with sulfentrazone. Therefore, the EPA classified sulfentrazone as "not likely to be carcinogenic to humans." The available mutagenicity studies indicate that sulfentrazone is weakly clastogenic in the *in vitro* mouse lymphoma assay in the absence of S9 activation; however, the response was not evident in the presence of S9 activation. Sulfentrazone is neither mutagenic in bacterial cells, nor clastogenic in male or female mice *in vivo*. Specific information on the studies received and the nature of the adverse effects caused by sulfentrazone as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document titled *"*Sulfentrazone*:* Human-Health Risk Assessment for the Establishment of Sulfentrazone Tolerances in/on: Rhubarb, Turnip Roots and Tops, Sunflower Subgroup 20B, Succulent Cowpea, Succulent Lima Bean, Succulent Vegetable Soybean*,* Wheat (Spring), Citrus Fruit Group 10-10, Low-Growing Berry Group 13-07, Tree Nut Group 14, Pistachios, and Crop Group 18 Nongrass Animal Feeds *",* pp. 45-49 in docket ID number EPA-HQ-OPP-2011-0758.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold

below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for sulfentrazone used for human risk assessment is shown in the following table:

Table—Summary of Toxicological Doses and Endpoints for Sulfentrazone for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-49 years of age)	NOAEL = 14 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	Acute RfD = 0.14 mg/kg/day aPAD = 0.14 mg/kg/day	2-Generation Reproductive Toxicity Study - Rat Offspring Toxicity LOAEL = 33 (M) and 40 (F) mg/kg/day based on reduced prenatal viability (fetal & litter), reduced litter size, increased no. of stillborn pups, reduced pup

			and litter postnatal survival, and decreased pup body weights throughout lactation.
Acute dietary (General population including infants and children)	NOAEL = 250 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	Acute RfD = 2.5 mg/kg/day aPAD = 2.5 mg/kg/day	Acute Neurotoxicity Study - Rat 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 UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.14 mg/kg/day cPAD = 0.14 mg/kg/day	2-Generation Reproductive Toxicity Study - Rat Offspring Toxicity LOAEL = 33 (M) and 40 (F) mg/kg/day based on reduced prenatal viability (fetal & litter), reduced litter size, increased no. of stillborn pups, reduced pup and litter postnatal survival, and decreased pup body weights throughout lactation.
Short- (1-30 days) and Intermediate-Term (1-6 months) Incidental Oral	NOAEL = 14 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC for MOE = 100	2-Generation Reproduction Study - Rat Offspring LOAEL = 33 mg/kg/day based on decreased pup body weights and reduced postnatal survival in both generations.
Short- Term Dermal (1-30 days)	Dermal study NOAEL = 100 mg/kg/day (dermal absorption rate = 100% UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC for MOE = 100	Dermal Developmental Study - Rat LOAEL = 250 mg/kg/day based on decreased fetal body weight; increased incidences of fetal skeletal 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 (1-30 days)	Inhalation (or oral) study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10X UF_H = 10X FQPA SF = 10X	LOC for MOE = 1000	Prenatal Developmental Toxicity - Rat Developmental LOAEL = 25 mg/kg/day, based upon 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.

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies). M = male. F = female. FOB = functional observation battery.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to sulfentrazone, EPA considered exposure under the petitioned-for tolerances as well as all existing sulfentrazone tolerances in 40 CFR 180.498. EPA assessed dietary exposures from sulfentrazone in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and 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. Such effects were identified for sulfentrazone. EPA performed separate acute risk assessments for females 13 to 49 years old and for the general population, including infants and children, based on different endpoints and aPADs. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture

(USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance-level residues, dietary exposure evaluation model DEEM™ (ver. 7.81) default processing factors, and assumed 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA used tolerance-level residues, DEEM™ (ver. 7.81) default processing factors, and assumed 100 PCT for all commodities.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that sulfentrazone does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue or PCT information in the dietary assessment for sulfentrazone. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for sulfentrazone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of sulfentrazone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Sulfentrazone and 3-carboxylic acid sulfentrazone are the residues of concern in drinking water. Therefore, the First Index Reservoir Screening Tool (FIRST) model was used to estimate concentrations of sulfentrazone and 3-carboxylic acid sulfentrazone in

surface water, and the Screening Concentration in Ground Water (SCI-GROW) model was utilized to estimate concentrations in ground water. The estimated drinking water concentrations (EDWCs) of sulfentrazone and 3-carbyoxylic acid sulfentrazone for acute exposures are estimated to be 35.8 parts per billion (ppb) for surface water and 26.0 ppb for ground water**.** For chronic exposures for non-cancer assessments, EDWCs are estimated to be 7.8 ppb for surface water and 26.0 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 35.8 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 26.0 ppb was used to assess the contribution to drinking 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 currently registered for the following use that could result in residential exposures: Residential home lawns/turf and recreational turf, such as golf courses. EPA assessed residential exposure using the following assumptions: Adults were assessed for potential short-term dermal and inhalation handler exposure from applying sulfentrazone to residential turf/home lawns and for short-term post-application dermal exposure from contact with treated residential and recreational turf home lawns and golf courses. For adult handlers, dermal and inhalation exposures were aggregated for the short-term assessment. Because the level of concern for dermal exposures (MOEs less than 100) and inhalation exposure (MOEs less than 1,000) are different, a total

aggregate risk index (ARI) approach was used for adult handlers instead of the MOE approach. ARIs of less than 1 indicate risks are not of concern. Children, ages 11 < 16 years old and 6 < 11 years old, were assessed for post-application dermal exposure from contact with treated residential and recreational turf (home lawns and golf courses). Children, ages 1 < 2 years old, were assessed for post-application dermal and incidental oral (hand-to-mouth, object-to- mouth, soil ingestion and episodic ingestion of granules) exposure to residential turf/home lawns.

For the short-term exposure duration, the post-application exposure scenarios that were combined for children 1 < 2 years old are the dermal and hand-to-mouth scenarios. This combination should be considered a protective estimate of children's exposure to pesticides used on turf. For the intermediate-term exposure duration, the only potential post-application exposure scenario is soil ingestion. Chronic exposures are not expected and were not assessed.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of 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 has not found sulfentrazone to share a common mechanism of toxicity with 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 assumed that sulfentrazone does not have 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 EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There is evidence of increased quantitative susceptibility following *in utero* exposure in the oral and dermal rat developmental toxicity studies. Developmental effects, including decreased fetal body weights and reduced/delayed skeletal ossifications were observed at doses that were not maternally toxic. In the 2-generation reproduction study in rats, offspring effects such as decreased body weights and decreased litter survival were observed at a slightly maternally toxic dose (slightly decreased body weight gain), indicating possible slightly increased qualitative susceptibility.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for all scenarios except for inhalation exposure, where a 10X FQPA SF factor has been retained due to the lack of an appropriate inhalation study. That decision is based on the following findings:

i. The toxicity database for sulfentrazone is complete with the exception of a 28-day inhalation study in rats. A 10X FQPA SF has been retained for inhalation exposure scenarios due to this data gap.

ii. There is no indication that sulfentrazone is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional safety factors to account for neurotoxicity.

iii. There is evidence of increased quantitative susceptibility following *in utero* exposure in the oral and dermal developmental toxicity studies in rat and possible evidence of slightly increased qualitative susceptibility of offspring in the 2-generation rat reproduction study. However, concern is low because clear NOAELs have been identified for the effects noted in these studies and both of the developmental toxicity studies have been chosen for endpoint selection, thereby protecting the relevant human subpopulations from the noted effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to sulfentrazone in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well

as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by sulfentrazone.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to sulfentrazone will occupy 3.2% of the aPAD for females 13-49 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to sulfentrazone from food and water will utilize 4.2% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of sulfentrazone is not expected.

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

Sulfentrazone is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to sulfentrazone.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 280 for children 1-2 years old, and an ARI of 3.9 for the general U.S. population and adult males. Because EPA's level of concern for sulfentrazone is an MOE of 100 or below and/or and ARI of 1 or below, this MOE and ARI are not of concern.

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

Sulfentrazone is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to sulfentrazone.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 2,400 for children 1-2 years old, the only population subgroup of concern. Because EPA's level of concern for sulfentrazone is an MOE of 100 or below, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, sulfentrazone is not expected to pose a cancer risk 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 or to infants and children from aggregate exposure to sulfentrazone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography (GC)) is available to enforce the tolerance expression. The method has been forwarded for inclusion in the Pesticides Analytical Manual, Volume 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

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is

different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no Codex MRLs established for sulfentrazone on the subject crops in this rule**.**

C. Response to Comments

A comment was received objecting generally to the use of this chemical stating that the "…product should [sic] not be approved to be manufactured or sold anywhere on earth…" The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This comment appears to be directed at the underlying statute and not EPA's implementation of it; the commenter has made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-For Tolerances

The tolerances proposed in the petitions have been revised as follows: the rhubarb tolerance is being set at 0.15 ppm instead of 0.2 ppm; the turnip root tolerance is being set at 0.15 ppm instead of 0.2 ppm; the turnip top tolerance is being set at 0.60 ppm instead of 0.7 ppm; the wheat forage tolerance is being set at 0.50 ppm instead of 0.45 ppm; the wheat hay tolerance is being set at 0.30 instead of 0.20 ppm; the wheat grain tolerance is being set at 0.15 ppm instead of 0.20 ppm; the wheat straw tolerance is being set at 1.5 ppm instead of 1.4 ppm. EPA revised the tolerance levels

based on analysis of the residue field trial data and by using the organization for economic cooperation and development (OECD) tolerance calculation procedures.

Tolerances are not being established at this time for alfalfa forage, hay, and seed and clover forage, hay, and seed due to the need for additional residue data and a ruminant feeding study.

V. Conclusion

Therefore, tolerances are established for residues of sulfentrazone, (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its metabolites 3-hydroxymethylsulfentrazone (*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 3-desmethyl sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide), in section 180.498(a)(2) in or on rhubarb at 0.15 ppm; turnip roots at 0.15 ppm; turnip tops at 0.60 ppm; sunflower subgroup 20B at 0.20 ppm; citrus fruit group 10-10 at 0.15 ppm; low growing berry group 13-07 at 0.15 ppm; tree nut group 14 at 0.15 ppm; pistachio at 0.15 ppm; and section 180.498 (c) tolerances with regional registrations for wheat forage at 0.50 ppm; wheat hay at 0.30 ppm; wheat grain at 0.15 ppm; wheat straw at 1.5 ppm; and cowpea, succulent at 0.15 ppm.

In addition, the following tolerances are being removed as unnecessary in section 180.498(a)(2), sunflower seed, and strawberry, and in section 180.498(b), flax seed and strawberry.

Lastly, the tolerance for “bean, lima, succulent” is being moved from section 180.498(a)(2) to section 180.498(c).

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). 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.*, 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).

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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the

relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: July 3, 2012.

Lois Rossi,
Director, Registration Division, Office 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), 346a and 371.

2. Section 180.498 is amended by:

i. In the table to paragraph (a)(2), remove the entries for "bean, lima, succulent," "sunflower, seed," and "strawberry" , and add alphabetically new entries as shown below.

ii. Revise paragraphs (b) and (c).

The added and revised text read as follows:

§ 180.498 Sulfentrazone; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
* * * * *	
Berry, low growing, group 13-07	0.15
* * * * *	
Fruit, citrus, group 10-10	0.15
* * * * *	
Nut, tree, group 14	0.15
* * * * *	
Pistachio	0.15
Rhubarb	0.15
* * * * *	
Sunflower subgroup 20B	0.20
Turnip, roots	0.15
Turnip, tops	0.60
* * * * *	

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration are established for the combined residues of the free and conjugated forms of sulfentrazone, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) 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, calculated as the stoichiometric equivalent of sulfentrazone in or on the following commodities.

Commodity	Parts per million
Bean, lima, succulent	0.15
Cowpea, succulent	0.15
Wheat, forage	0.50
Wheat, grain	0.15
Wheat, hay	0.30
Wheat, straw	1.5

* * * * *

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