Commodity	Parts per million
* * * * *	
Fruit, citrus, group 10	0.03
* * * * *	
Grape	0.01
* * * * *	
Potato[1]	1.0
Potato, chips[1]	2.0
Potato, granules/flakes[1]	4.0
* * * * *	

[1] No U.S. registrations.

* * * * *

(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for residues of the herbicide fluazifop-P-butyl, including its metabolites and degradates, in or on the following commodities in the table. Compliance with the tolerance levels specified in the table below is to be determined by measuring only the sum of fluazifop-P-butyl, butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluazifop, (R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, calculated as the stoichiometric equivalent of fluazifop, in or on the commodity.

* * * * *

[FR Doc. 2011–1779 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0125; FRL–8860–1]

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. Additionally, this regulation deletes existing tolerances on commodities superseded by the establishment of crop subgroups. This regulation also deletes a time-limited tolerance on bean, succulent seed without pod (lima bean and cowpea), as the tolerance expired on December 31, 2007. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 2, 2011. Objections and requests for hearings must be received on or before April 4, 2011, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0125. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 305–7390; *e-mail address: nollen.laura@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://www.gpoaccess.gov/ecfr.*

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–2008–0125 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 April 4, 2011. 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–2008–0125, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays).

Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerances

In the **Federal Register** of March 12, 2008 (73 FR 13225) (FRL–3854–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E7308) by IR–4, 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 combined free and conjugated 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 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 *Brassica,* head and stem, subgroup 5A at 0.20 parts per million (ppm); *Brassica,* leafy greens, subgroup 5B at 0.35 ppm; melon, subgroup 9A at 0.10 ppm; vegetable, fruiting, group 8 at 0.05 ppm; okra at 0.05 ppm; pea, succulent at 0.05 ppm; flax at 0.05 ppm; strawberry at 0.05 ppm; and vegetable, tuberous and corn, subgroup 1C at 0.15 ppm. That notice referenced a summary of the petition prepared on behalf of IR–4 by FMC Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance levels for several commodities. Additionally, the EPA has assessed several additional fruiting vegetable commodities in order to establish the revised and expanded fruiting vegetable group 8–10. EPA has also revised the tolerance expression for all established commodities to be consistent with current Agency policy. 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of 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 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.

Sulfentrazone has 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. In a published, non-guideline developmental toxicity study in the rat (de Castro, *et al.,* 2007), several dose-dependent effects (delayed ear opening, decreased grip response and rearing frequency, and increased surface righting reflex reaction time) were reported in pups whose mothers were treated with sulfentrazone. However, this study had several shortcomings that limit its use for regulatory purposes.

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 document: "Sulfentrazone; REVISED Section 3 Registration Request to Add New Uses on: *Brassica,* Head and Stem, Subgroup 5A; *Brassica,* Leafy Greens, Subgroup 5B; Melon, Subgroup 9A; Fruiting

Vegetable, Group 8 and Okra; Pea, Succulent; Flax; Strawberry; and Tuberous and Corm Vegetable, Subgroup 1C. Human-Health Risk Assessment." pp. 51–56 in docket ID number EPA–HQ–OPP–2008–0125.

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 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) (a = acute, c = chronic) 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.*

The doses and toxicological endpoints selected for several exposure scenarios including the acute dietary endpoints for females 13–49 years old, the chronic dietary endpoint, and the short- and intermediate-term inhalation endpoint have been revised since the last risk assessment based on a re-evaluation of the toxicology database. The updated endpoints are protective of sulfentrazone's developmental toxicity, which was the critical effect in the database and observed via both the oral and dermal routes of exposure.

The acute dietary endpoint is based on increased gestation duration, reduced prenatal viability (fetal and litter), reduced litter size, increased number of stillborn pups, reduced postnatal survival (pups and litter), and pup body weight deficits throughout lactation in both generations of offspring observed in a 2-generation reproductive toxicity study in rats. The developmental effects were reported in the presence of mild maternal toxicity (slightly decreased body-weight gain, particularly in F_1 females). It has been EPA's practice to consider various forms of developmental toxicity such as reduced prenatal viability, reduced litter size, and increased number of stillborn pups as single-dose effects and, therefore, relevant for the acute dietary (females aged 13–49) exposure scenario, in order to protect against potential exposure of pregnant females. It should be noted that the fetal body weight deficits and retardation in skeletal development (including decreased numbers of caudal vertebral and metacarpal ossification sites) reported in the oral rat prenatal developmental toxicity study were also evaluated for this acute dietary endpoint. However, it was concluded that such effects are unlikely due to a single dose event and are more appropriate for a repeated-exposure scenario. Furthermore, EPA has not traditionally considered delays in ossification (and related fetal body weight deficits) to be single dose effects.

The chronic dietary endpoint is based on developmental toxicity (decreased fetal weights and delay in skeletal ossification) that was observed in the oral developmental toxicity study in the rat. This study provides the lowest NOAEL in the database, and the effects are similar to those observed in offspring (decreased body weight) at a slightly higher dose in the 2-generation reproduction study in rats. In addition, choice of the developmental toxicity study in the rat protects against exposure of women throughout their entire lifespan, which includes their childbearing years.

The short- and intermediate-term inhalation endpoints are based on developmental toxicity (decreased fetal weights, delay in skeletal ossification) that was observed in the oral developmental toxicity study in the rat. An oral study was chosen for this exposure scenario in the absence of an inhalation toxicity study. Assuming 100% absorption via the inhalation route, the oral developmental toxicity study protects pregnant women who might be exposed via inhalation against the critical effect observed in the sulfentrazone database, developmental toxicity.

The endpoints for the other exposure scenarios remain the same. A summary of the toxicological endpoints for sulfentrazone used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—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 milligrams/kilogram/ day (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 number 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= 10 mg/kg/ day. UF_A = 10x ..... UF_H = 10x ..... FQPA SF = 1x	Chronic RfD = 0.1 mg/kg/day. cPAD = 0.1 mg/kg/ day.	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.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SULFENTRAZONE FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL= 14 mg/kg/day. UF_A = 10x ..... UF_H = 10x ..... FQPA SF = 1x	LOC for MOE = 100.	2-Generation Reproduction Study—Rat, LOAEL = 33 mg/kg/day based on decreased pup body weights during lactation and reduced postnatal survival in both generations.
Dermal short-term (1 to 30 days) and intermediate-term. (1 to 6 months)	Dermal (or oral) study NOAEL = 100 mg/kg/day. 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 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.
Inhalation short-term (1 to 30 days).	Inhalation (or oral) study NOAEL= 10 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x ..... UF_H = 10x ..... FQPA SF = 1x	LOC for MOE = 100.	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.
Cancer (Oral, dermal, inhalation).	Sulfentrazone is classified as "not likely to be carcinogenic to humans."		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor.

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 13–49 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 and/or PCT information in the dietary assessment for sulfentrazone. Tolerance level residues and/or 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 (application by professional applicators only). 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 postapplication dermal exposure from contact with treated residential and recreational turf (home lawns and golf courses). Youths, ages 10–12 years old, were selected as a representative population to assess postapplication dermal exposure from contact with treated residential and recreational turf (home lawns and golf courses). Children, ages 3–6 years old, were selected as a representative population to assess for postapplication dermal and incidental oral (hand-to-mouth, object-to-mouth, soil ingestion and episodic ingestion of granules) exposure to residential turf/home lawns. As short- and intermediate-term points of departure are the same, the short-term assessment is considered protective of intermediate-term exposures. For children, however, while all three incidental oral exposures were aggregated for short-term exposures, the intermediate-term postapplication exposure scenario included only the soil ingestion incidental oral pathway, as this is the only pathway assumed to potentially result in intermediate-term exposures. 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 Web site 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 (10×) 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 10×, 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. Additionally, several dose-dependent effects were observed in rat pups whose mothers were treated with sulfentrazone in a published non-guideline rat developmental toxicity study.

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. That decision is based on the following findings:

i. The toxicity database for sulfentrazone is complete except for immunotoxicity testing. Recent changes to 40 CFR part 158 require immunotoxicity testing (OPPTS Test Guideline 870.7800) for pesticide registration. However, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA. The toxicology database for sulfentrazone does not show any evidence of treatment-related effects on the immune system; the overall weight of evidence is consistent with this chemical being a PPO inhibitor resulting in disruption of heme biosynthesis and subsequent effects on red blood cell dysfunction (*e.g.,* anemia). Unlike white blood cells (leukocytes) which are cells of the immune system, red blood cells function to deliver oxygen to body tissues and are not involved in eliciting an immune response. Furthermore, there is no indication in the sulfentrazone database of any effect on leukocyte counts (an indicator of immune function). Thus, the overall weight of evidence indicates that this chemical does not directly target the immune system. Sulfentrazone also does not belong to a class of chemicals (*e.g.,* the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Based on the above considerations, EPA does not believe that conducting a functional immunotoxicity study will result in a lower point of departure than that currently used for overall risk assessment. Therefore, an additional database UF to account for potential immunotoxicity does not need to be applied.

ii. The toxicity database for sulfentrazone does not trigger the need for a developmental neurotoxicity (DNT) study. There are no indications in any of the studies available that the nervous system is a target for sulfentrazone. The FOB findings were very non-specific signs of toxicity (perianal staining, colored tears) and motor activity changes only occurred at higher doses following acute exposure with rapid reversibility, also indicating general toxicity rather than specific neurotoxicity. The lack of neuropathological findings further supports the non-specific nature of the signs observed. In addition, there is a literature DNT study available for sulfentrazone. The only reliable effects seen in this study involved effects on physical and reflex development, which are known to be affected by body weight. Therefore, these effects are likely secondary to the effects (including body weight deficits) reported in the 2-generation reproductive toxicity study. EPA employed an independent statistical method to evaluate the literature DNT in an effort to determine if these effects were consistent with effects observed in other guideline studies at these same dose levels. The results of that analysis indicate that the results of the literature DNT study are consistent with what was observed in the rat 2-generation

reproduction study and that the studies used for risk assessment (NOAEL of 10 mg/kg/day from the developmental toxicity study in rat and the NOAEL of 14 mg/kg/day from the 2–generation reproduction study), are protective of the observations made at ≥25 mg/kg/day in the literature study for which a NOAEL was not attained. Based on the weight of evidence, there is no uncertainty related to developmental neurotoxicity.

iii. There is evidence of increased quantitative susceptibility following *in utero* exposure in the oral and dermal developmental toxicity studies in rats 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 aPAD and 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 <1% of the aPAD for the general population, including infants and children. For females 13–49 years old, the acute dietary exposure to sulfentrazone from food and water will occupy 2.3% of the applicable aPAD chosen for that population subgroup.

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 3.6% 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- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and 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 short- and intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to sulfentrazone.

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded the combined short- and intermediate-term food, water, and residential exposures result in aggregate MOEs of 310 for the general U.S. population; 450 for children 1–2 years old for short-term exposures; and 590 for children 1–2 years old for intermediate-term exposures. Because EPA's level of concern for sulfentrazone is a MOE of 100 or below, these MOEs are not of concern.

4. *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.

5. *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 U.N. 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, Canadian, or Mexican MRLs established for residues of sulfentrazone in or on the subject commodities.

C. Response to Comments

EPA received one comment to the Notice of Filing that had an objection to "the manufacture or sale" of sulfentrazone, citing the cruelty of animal testing as the main source of opposition. The Agency has received these same or similar comments from this commenter on numerous previous occasions. Please refer to the **Federal Register** of 70 FR 1349 (January 7, 2005) and 70 FR 37683 (June 30, 2005) for the Agency's previous responses to these and other similar comments.

D. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA revised the proposed tolerances for the following commodities: *Brassica,* leafy greens, subgroup 5B from 0.35 ppm to 0.40 ppm; melon, subgroup 9A from 0.10 ppm to 0.15 ppm; vegetable, fruiting, group 8 from 0.05 ppm to 0.15 ppm; okra from 0.05 ppm to 0.15 ppm; pea, succulent from 0.05 ppm to 0.15 ppm; flax from 0.05 ppm to 0.15 ppm; and strawberry from 0.05 ppm to 0.15 ppm. EPA revised the tolerance levels based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data.*

Additionally, EPA was petitioned for tolerances on fruiting vegetable group 8

and a separate tolerance on okra. In the **Federal Register** of December 8, 2010 (75 FR 76284) (FRL–8853–8), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA expanded and revised the existing fruiting vegetable crop group 8. Changes to crop group 8 included adding okra, cocona, African eggplant, pea eggplant, scarlet eggplant, goji berry, garden huckleberry, martynia, naranjilla, roselle, sunberry, bush tomato, currant tomato, and tree tomato; creating subgroups; revising the representative commodities; and naming the new crop group fruiting vegetable group 8–10. EPA indicated in the December 8, 2010 final rule as well as the earlier January 6, 2010 proposed rule (75 FR 807) (FRL–8801–2) that, for existing petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA has assessed and is establishing a tolerance on fruiting vegetable group 8–10.

Finally, the EPA has revised the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of sulfentrazone not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of the combined residues of free and conjugated forms 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, in or on *Brassica,* head and stem, subgroup 5A at 0.20 ppm; *Brassica,* leafy greens, subgroup 5B at 0.40 ppm; melon, subgroup 9A at 0.15 ppm; vegetable, fruiting, group 8–10 at 0.15 ppm; pea, succulent at 0.15 ppm; flax at 0.15 ppm; strawberry at 0.15 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.15 ppm. Additionally, this regulation deletes existing individual tolerances in or on cabbage at 0.20 ppm and potato at 0.15 ppm, and further deletes the time-limited tolerance for bean, succulent seed without pod (lima bean and cowpea) at 0.1 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of 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 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 section 408(d) of 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.

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 section 408(n)(4) of FFDCA. 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: January 14, 2011.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.498 is amended as follows:
■ i. Revise the introductory text of paragraph (a)(1);
■ ii. Revise the introductory text of paragraph (a)(2), remove the entries for "Cabbage" and "Potato" and add commodities to the table;
■ iii. Revise paragraph (b); and
■ iv. Revise the introductory text of paragraph (d), to read as follows:

§ 180.498 Sulfentrazone; tolerances for residues.

(a)(1) *General.* Tolerances 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 metabolite 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, calculated as the stoichiometric equivalent of sulfentrazone in or on the following commodities.

* * * * *

(2) Tolerances 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
* * * * *	
Brassica, head and stem, subgroup 5A	0.20
Brassica, leafy greens, subgroup 5B	0.40
* * * * *	
Flax	0.15
* * * * *	
Melon, subgroup 9A	0.15
Pea, succulent	0.15
* * * * *	
Strawberry	0.15
* * * * *	
Vegetable, fruiting, group 8–10	0.15
Vegetable, tuberous and corm, subgroup 1C	0.15

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of the free and conjugated forms of sulfentrazone, including its metabolites and degradates, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. 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. These tolerances expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ revocation date
Flax, seed	0.20	12/31/13
Strawberry	0.60	12/31/13

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for inadvertent and indirect 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 when present therein as a result of the application of sulfentrazone to growing crops.

* * * * *

[FR Doc. 2011–1898 Filed 2–1–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0796; FRL–8860–2]

Bispyribac-sodium; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of bispyribac-sodium in or on fish, freshwater. Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 2, 2011. Objections and requests for hearings must be received on or before April 4, 2011, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0796. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.