

APPENDIX A: SUMMARY OF ACCEPTABLE DECISIONS, REFRIGERATION SECTOR—Continued  
[Acceptable Decisions]

End-use	Substitute	Decision	Comments
<b>Foam Sector—Acceptable Decisions</b>			
HCFCs Rigid polyurethane and polyisocyanurate laminated boardstock.	Saturated Light Hydrocarbons C3–C6.	Acceptable .....	Zero ODP and GWP but must adhere to VOC regulations. Flammable.
HCFCs Rigid polyurethane appliance.	HFC–134a .....	Acceptable .....	Non-flammable and low toxicity but may contribute to global warming.
Saturated Light Hydrocarbons C3–C6	Acceptable .....	Zero ODP and GWP but must adhere to VOC regulations. Flammable..	
	Carbon Dioxide .....	Acceptable .....	High thermal conductivity.

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**40 CFR Part 180****[OPP–300459; FRL–5591–9]****RIN AB–78****Sulfentrazone; Establishment of Tolerances****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** This document establishes tolerances for residues of the herbicide sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its major metabolite 3-hydroxymethyl sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide), in or on the raw agricultural commodity soybean seed at 0.05 ppm and for combined inadvertent residues of sulfentrazone, and its metabolites, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone [N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide] in cereal grains (excluding sweet corn) forage at 0.2 ppm, straw at 0.6 ppm, hay at 0.2 ppm, grain at 0.1 ppm, stover at 0.1 ppm, bran at 0.15 ppm and hulls at 0.30 ppm. FMC Corporation submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170) requesting the tolerances.

**EFFECTIVE DATE:** This regulation becomes effective March 10, 1997.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [PF–670/OPP–

300459], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled Tolerance Petition Fees and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the docket control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically to the OPP by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov.

Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number PF–670/OPP–300459. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

**FOR FURTHER INFORMATION CONTACT:** By mail: Joanne I. Miller, Product Manager (PM) 23, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 237, CM #2, 1921 Jefferson Davis

Hwy., Arlington, VA 22202, (703)-305-6224; e-mail: miller.joanne@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** In the Federal Register of November 6, 1996 (60 FR 57420) (FRL–5571–4), EPA issued a notice pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), announcing the filing of a pesticide tolerance petition by FMC Corporation, 1735 Market Street, Philadelphia, PA 19103. The petition requested to amend 40 CFR part 180 by establishing a tolerance for residues of the herbicide sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) in or on raw agricultural commodity soybean seed at 0.05 ppm and rotational crop tolerances in cereal grains from 0.1 to 0.5 ppm. There were no comments received in response to the notice of filing.

The data submitted in the petition and other relevant material have been evaluated. The toxicology data listed below were considered in support of these tolerances.

**I. Toxicological Profile**

1. A battery of acute toxicity studies placed technical sulfentrazone in Toxicity Categories III and IV. No evidence of sensitization was observed following dermal application in guinea pigs.

2. A 90-day subchronic toxicity study was conducted in rats, with dietary intake levels of 0, 3.3, 6.7, 19.9, 65.8, 199.3, or 534.9 mg/kg/day for males and 0, 4, 7.7, 23.1, 78.1, 230.5, or 404.3 milligrams/kilograms/day (mg/kg/day) for females respectively. No Observed Effect Levels (NOELs) of 19.9 mg/kg/day in males and 23.1 mg/kg/day in females were based on clinical anemia.

3. A 90-day subchronic feeding study was conducted in mice by dietary admix

at doses of 0, 10.3, 17.8, 60.0, 108.4, or 194.4 mg/kg/day for males and 0, 13.9, 29.0, 79.8, 143.6, or 257.0 mg/kg/day for females, respectively. NOELs of 60 mg/kg/day (males) and 79.8 mg/kg/day (females) were based on decreases in body weights and/or gains; decreased erythrocytes, hemoglobin and hematocrit values; and splenic microscopic pathology.

4. In a 90-day subchronic feeding study in dogs administered by dietary admix at doses of 0, 10, 28, or 57 mg/kg/day for males and 0, 10, 28, or 73 mg/kg/day for females, a NOEL of 28 mg/kg/day was determined for both males and females based on decreases in hemoglobin and hematocrit, elevated alkaline phosphatase levels, increased liver weights and microscopic liver as well as splenic changes.

5. A 12-month feeding study in dogs was dosed at levels of 0.0, 9.9, 24.9, or 61.2 mg/kg/day for male dogs and 0.0, 10.4, 29.6, or 61.9 mg/kg/day for female dogs in the control through high-dose groups, respectively, with a NOEL of 24.9 mg/kg/day for males and 29.6 mg/kg/day for females based on hematology effects and microscopic liver changes.

6. An 18-month feeding/carcinogenicity study in mice was conducted with dietary intake of 0, 46.6, 93.9, 160.5, or 337.6 mg/kg/day for males and 0, 58.0, 116.9, 198.0, or 407.1 mg/kg/day for females. A NOEL of 93.9 mg/kg/day in males and 116.9 mg/kg/day in females was based on decreases in hemoglobin and hematocrit. There were no treatment-related increases in tumors of any kind observed at any dose level.

7. In a 24-month chronic feeding/oncogenicity study in rats at dietary doses of 0, 24.3, 40.0, 82.8, or 123.5 mg/kg/day for males and 0, 20.0, 36.4, 67.0, or 124.7 mg/kg/day for females, an overall NOEL of 40.0 mg/kg/day in males and 36.4 mg/kg/day in females was based on hematology effects and reduced body weights. There was no evidence of an oncogenic response.

8. A prenatal oral developmental toxicity study in the rat with dose levels at 25.0 or 50.0 mg/kg/day established a maternal NOEL of 25 mg/kg/day based on decreased body weight gain, increased spleen weight, and microscopic changes in the spleen, and a fetal NOEL of 10 mg/kg/day was based on fetal death, reduced body weights, and alterations in skeletal development at higher doses.

9. A supplemental oral developmental toxicity study conducted in rats at oral dose levels of 25.0 and 50.0 mg/kg/day to test for cardiac effects at the request of the EPA, did not reveal any significant effects on fetal cardiac

development. The results of this study confirmed the maternal and fetal findings of the previously-conducted developmental study on sulfentazone in rats and did not alter the study conclusions.

10. In a dermal developmental study in the rat at doses of 0, 5, 25, 50, 100 and 250 mg/kg/day, a maternal (systemic) No Observed Adverse Effect Level (NOAEL) was established at 250 mg/kg/day. Significant treatment-related increases in the fetal and litter incidences of incompletely ossified lumbar vertebral arches, hypoplastic or wavy ribs, and incompletely ossified or nonossified ischia or pubes occurred at the high-dose (250 mg/kg/day). An additional significant increase in the high-dose fetal incidence of variations in the sternbrae (incompletely ossified or unossified) was not judged to be treatment-related. At 250 mg/kg/day, the mean numbers of thoracic vertebral and rib ossification sites were significantly decreased, a high-dose effect of treatment with sulfentazone consistent with the significant treatment-related hypoplasia observed in the skeletal evaluation of the ribs. Therefore, the developmental (fetal) Lowest Observed Effect Level (LOEL) is 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. The developmental (fetal) NOEL is 100 mg/kg/day.

11. A developmental toxicity study in rabbits was conducted at gavage dose levels of 0, 100, 250, or 375 mg/kg/day. Treatment-related incidences of decreased feces and hematuria were noted at 250 mg/kg/day or greater. In addition, at the 375 mg/kg/day dose level, five rabbits aborted. Significant reductions in mean body weight change were observed for the dosing period (GD 7-19) and for the study duration (GD 0-29, both before and after adjustment for gravid uterine weight) at the 250 and 375 mg/kg/day dose levels. Therefore, the maternal (systemic) LOEL is 250 mg/kg/day, based upon increased abortions, clinical signs (hematuria and decreased feces), and reduced body weight gain. The maternal (systemic) NOEL is 100 mg/kg/day. Skeletal evaluation in fetuses revealed dose- and treatment-related findings at the 375 mg/kg/day dose level. These included significant increases in both the fetal and litter incidences of fused caudal vertebrae (a malformation) and of partially fused nasal bones (a variation). In addition, at 375 mg/kg/day, significant treatment-

related reductions in ossification site averages were observed for metacarpals and both fore- and hindpaw phalanges. Therefore, the developmental (fetal) LOEL is 250 mg/kg/day, based upon increased resorptions, decreased live fetuses per litter, and decreased fetal weight. The developmental (fetal) NOEL is 100 mg/kg/day.

12. A two-generation reproduction study in the rat at dietary levels of 14, 33, or 46 mg/kg/day in males and 16, 40, or 56 mg/kg/day in females established a NOEL for systemic and reproductive/developmental parameters of 14 mg/kg/day for males and 16 mg/kg/day for females. The LOEL for systemic and reproductive/developmental parameters was 33 mg/kg/day for males and 40 mg/kg/day for females. Systemic effects were comprised of decreased body weight gains, while reproductive/developmental effect at the LOEL included degeneration and/or atrophy in the testes, with epididymal sperm deficits, in the second (F1) generation males. Male fertility in the F1 generation was reduced at higher doses; litter size, pup survival, and pup body weight for both generations were also effected at higher doses.

13. A supplemental two-generation rat reproduction study was conducted at dietary intake levels of 50, 100, 200, or 500 ppm with a NOEL for reproductive parameters of 200 ppm. This study confirmed the reproductive/developmental effects observed in the first two-generation reproductive toxicity study. It was the conclusion of the RfD/Peer Review Committee that, under the conditions of the studies reviewed, sulfentazone caused developmental and reproductive toxicity. The results of these studies elicited a high level of concern by the Committee, since the developmental toxicity studies demonstrated embryo/fetal toxicity at treatment levels that were not maternally toxic, and significant toxic effects were observed primarily in the second generation animals of the reproduction study. Because these animals had been exposed to sulfentazone *in utero*, the possibility that the observed reproductive toxicity resulted from a developmental and/or genotoxic mechanism was suggested.

14. A reverse gene mutation assay (*salmonella typhimurium*) yielded negative results, both with and without metabolic activation.

15. A mouse lymphoma forward gene mutation assay yielded negative results with equivocal results without activation.

16. A mouse micronucleus assay test was negative following intraperitoneal injection of 340 mg/kg.

17. In an acute neurotoxicity study in rats at gavage doses of 0, 250, 750, or 2,000 mg/kg, a NOEL of 250 mg/kg and a LOEL of 750 mg/kg were based upon increased incidences of clinical signs, Functional Observation Battery (FOB) findings, and decreased motor activity which were reversed by day 14 post-dose. There was no evidence of neuropathology.

18. A 90-day subchronic neurotoxicity study in the rat was conducted at dietary levels of 30, 150, or 265 mg/kg/day in males, and 37, 180, or 292 mg/kg/day in females, with a NOEL of 30 mg/kg/day in males and 37 mg/kg/day in females. The LOEL was 150 mg/kg/day for males and 180 mg/kg/day for females based on increased incidences of clinical signs, decreased body weights, body weight gains, and food consumption in females and increased motor activity in females at week 13. There were no neurohistopathological effects on the peripheral or central nervous system.

19. A metabolism study in rats indicated that approximately 84 to 104% of the orally administered dose of sulfentrazone was excreted in the urine, and that the pooled urinary radioactivity consisted almost entirely of 3-hydroxymethyl sulfentrazone. Pooled fecal radioactivity showed that the major metabolite consisted of 3-hydroxymethyl-sulfentrazone (1.26 to 2.55% of the administered dose). The proposed metabolic pathway appeared to be conversion of the parent compound mainly to 3-hydroxymethyl-sulfentrazone (excreted in urine and feces).

## II. Aggregate Exposures

1. *Food and feed uses.* The primary source for human exposure to sulfentrazone will be from ingestion of both raw and processed agricultural commodities from soybeans. A DRES chronic exposure analysis was performed using tolerance level residues and 100% crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. The chronic analysis showed that exposure from the proposed new tolerance, in/on soybeans, on cereal grains (excluding sweet corn), on bran of cereal grains, milk, eggs, and meat for children 1 to 6 years old (the subgroup with the highest exposure) would be 38.8% of the RfD. The exposure for the general U.S. population would be 16.7% of the RfD.

The analysis for sulfentrazone is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with sulfentrazone. Even without refinements, the chronic dietary risk exposure to sulfentrazone appears to be minimal for this petition.

2. *Potable water.* A ground water exposure estimate for sulfentrazone is based on findings from a voluntary prospective ground water study conducted in a sandy (worst case) site in North Carolina. Although this single ground water monitoring study was incomplete, enough data were collected to confirm that sulfentrazone leaches substantially to ground water in areas with sandy soils. Sulfentrazone was found in ground water at concentrations as high as 37 parts per billion (ppb) in shallow wells and 19 ppb in deeper wells. Residues in shallow ground water were highly persistent and only slowly dissipated, with little change in concentrations over a 1-year period, at which time sampling was terminated. The use of 37 ppb in estimating dietary exposure through ground water represents the worst case. The worst case is based on soil type (sandy) and a limited population that would obtain their drinking water from wells in this type of soil. However, HED feels that due to sulfentrazone's mobility ( $K_{oc} = 43$ ;  $K_d = 0.2-0.8$ ) and persistence ( $\approx 9$  year half life), over time the worst case values may be approached in more typical ground water settings. Using 37 ppb, the dietary exposure from potable water is 0.00105 mg/kg/day to adults and 0.0037 mg/kg/day for children 1 to 6 years old.

3. *Non-dietary uses.* Since the petition for use of sulfentrazone is limited to commercial soybean production, no non-dietary exposures are expected for the general population.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." While the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the capability to resolve the scientific issues concerning common mechanism of toxicity in a meaningful way. EPA is commencing a pilot process

to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will enable the Agency to apply common mechanism issues to its pesticide risk assessments. At present, however, the Agency does not know how to apply the information in its files concerning common mechanism issues to risk assessments, and therefore believes that in most cases there is no "available information" concerning common mechanism that can be scientifically applied to tolerance decisions. Where it is clear that a particular pesticide may share a significant common mechanism with other chemicals, or where it is clear that a pesticide does not share a common mechanism with other chemicals, a tolerance decision may be affected by common mechanism issues. The Agency expects that most tolerance decisions will fall into the area in between, where EPA cannot reasonably determine whether a pesticide does or does not share a common mechanism of toxicity with other chemicals (and, if so, how that common mechanism should be factored into a risk assessment). In such circumstances, the Agency will reach a tolerance decision based on the best, currently-available and usable information, without regard to common mechanism issues. However, the Agency will also revisit such decisions when the Agency determines how to apply common mechanism information to pesticide risk assessments.

In the case of sulfentrazone, EPA has determined that it does not now have the capability to apply the information in its files to a resolution of common mechanism issues in a manner that would be useful in a risk assessment. This tolerance determination therefore does not take into account common mechanism issues. The Agency will reexamine the tolerances for sulfentrazone, if reexamination is appropriate, after the Agency has determined how to apply common mechanism issues to its pesticide risk assessments.

## III. Determination of Safety for U.S. Population and Children

1. *The U.S. population.* Based on a NOEL of 14 mg/kg/day body weight (bwt)/day from a two-generation rat reproduction study that demonstrated histopathological findings in testes and epididymides of second generation males as an endpoint, and using an uncertainty factor of 1,000, the Agency has determined a reference dose (RfD) of 0.014 mg/kg bwt/day for this assessment of risk. The extra factor of 10 and the uncertainty factor of 1,000 is to provide

added protection for infants and children. Based on the available toxicity data and the available exposure data identified above, the proposed tolerances will utilize 16.7% of the RfD for the U.S. population. Including an estimated exposure of 37 ppb in potable water, and assuming the injection of two liters of water per day, the dietary exposure for the U.S. adult population is increased and utilizes approximately 25% of the RfD.

2. *Children (1 to 6 years old)*. Using the RfD of 0.014 mg/kg bwt/day, as described above, and a Theoretical Maximum Residue Contribution (TMRC) of 0.005437 mg/kg bwt/day determined for children (1 to 6 years old), the proposed tolerances will utilize 38.8% of the RfD. Including an estimated exposure of 37 ppb in potable water, and assuming the injection of 1 liter of water per day, the dietary exposure for children (1 to 6 years old) population is increased and utilizes approximately 65% of the RfD.

3. *Non-food uses*. There are no non-food uses of sulfentrazone registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended.

#### IV. Determination of Safety for Infants and Children

Risk to infants and children was determined by use of developmental toxicity studies in rats and a two-generation reproduction study in rats. The oral developmental toxicity studies resulted in a maternal NOEL of 25 mg/kg/day based on decreased body weight gain, increased spleen weight, and microscopic changes in the spleen, and a fetal NOEL of 10 mg/kg/day based on fetal death, reduced body weights, and alterations in skeletal development at higher doses. A dermal developmental toxicity study in rats resulted in a developmental (fetal) NOEL of 100 mg/kg/day based on decreased fetal body weight and increased incidences of fetal alterations, comprised primarily of skeletal variations and reductions in mean numbers of ossification sites. A two-generation reproduction study in rats resulted in a NOEL for systemic and reproductive/developmental parameters of 14 mg/kg/day for males and 16 mg/kg/day for females. The LOEL for systemic and reproductive/developmental parameters was 33 mg/kg/day for males and 40 mg/kg/day for females. Systemic effects were comprised of decreased body weight gains, and reproductive/developmental effects at the LOEL included degeneration and/or atrophy of the testes, with epididymal sperm deficits in the second (F1) generation males. Male fertility in the F1 generation was reduced at higher doses;

litter size, pup survival and pup body weight for both generations were also effected at higher doses.

FFDCA section 408 provides that EPA shall apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base, unless EPA determines that such an additional factor is not necessary to protect the safety of infants and children. Based on current data requirements, the data base relative to pre- and post-natal toxicity is complete. EPA has determined that the toxicology data profile for sulfentrazone contains clear, unequivocal evidence that this chemical causes developmental and reproductive toxicity. Based upon the available data and toxicity profile, the Agency RfD Peer Review Committee considered sulfentrazone to be a relatively potent reproductive/developmental toxicant, and determined that an additional 10-fold uncertainty factor for the protection of infants and children was warranted.

This decision was based upon the data described above. The following facts were considered in reaching this conclusion:

(1) The lowest NOEL for chronic exposure, which is used to determine the RfD, is based upon severe, irreversible reproductive/developmental effects, observed in the two-generation reproduction study in rats.

(2) Developmental toxicity was observed in the absence of maternal effects in the prenatal developmental toxicity studies in rats (developmental NOELs were lower than maternal NOELs). This apparent increased sensitivity of the fetuses occurred following administration of sulfentrazone by either the dermal or the oral route, both of which are relevant to human exposure.

(3) A steep dose-response curve exists for the reproductive and developmental endpoints of concern. The reproductive and/or developmental LOELs for the prenatal developmental toxicity studies in rats and the two-generation reproduction study are only approximately 2.5 times greater than the corresponding NOELs in each of these studies. The reproductive and developmental NOELs are extremely low (i.e., in the range of 10 to 13 mg/kg/day). Additionally, in the rat prenatal developmental toxicity and two-generation reproduction studies, the reproductive/developmental effects increase in incidence and/or severity at higher doses.

(4) The reproductive/developmental toxicity profile is consistent and reproducible, providing a large measure

of confidence in the endpoints and dose levels.

The percent of the RfD that will be utilized by the aggregate exposure to sulfentrazone for the most exposed subgroup would be 65% for children (1 to 6 years old). Therefore, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure.

#### V. Other Considerations

1. *Endocrine effects*. An evaluation of the potential effects on the endocrine systems of mammals has not been determined; however, no evidence of such effects were reported in the chronic or reproductive toxicology studies described above. There was no observed pathology of the endocrine organs in these studies. There is no evidence at this time that sulfentrazone causes endocrine effects.

2. *Metabolism in plants and animals*. The metabolism of sulfentrazone in plants and animals is adequately understood for the purposes of these tolerances. Crop residues found after the pre-emergence use were the major metabolites 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone. In rotational crops, sulfentrazone is metabolized via four different pathways: (i) Oxidation of the 3-methyl group to form 3-hydroxymethyl sulfentrazone, followed by further oxidation to form sulfentrazone carboxylic acid which is decarboxylated to 3-desmethyl sulfentrazone; (ii) hydrolysis of the trifluoromethyl group to form desdifluoromethyl sulfentrazone which is oxidized and decarboxylated to form desdifluoromethyl desmethyl sulfentrazone; (iii) hydrolysis of the sulfonamide group to form desmethylsulfonyl sulfentrazone; and (iv) scission of the phenyl and triazole rings to produce methyl triazole. The corresponding phenyl metabolites are believed to remain bound. In animal metabolism sulfentrazone *per se* was the predominant component of the residue. The metabolite 3-hydroxymethyl sulfentrazone was also identified. It was determined by EPA that a soybean tolerance based on the parent and 3-hydroxymethyl sulfentrazone is therefore appropriate.

3. *Analytical method*. There is a practical analytical method for detecting and measuring levels of sulfentrazone and its metabolites in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances. The proposed analytical method for determining residues is hydrolysis

followed by gas chromatographic separation. EPA will provide information on this method to the Food and Drug Administration. Because of the long lead time from establishing these tolerances to publication the enforcement methodology is being made available in the interim to anyone interested in pesticide enforcement when requested by mail from: Calvin Furlow, Public Response Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1130A, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-5937.

4. *International tolerances.* There are no Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs) for sulfentrazone.

5. *Data Gaps.* Data gaps currently exist for a 21-day dermal study in rabbits, *in vivo* cytogenetics dominant lethal assay in rats, a wheat processing study, additional rice field trials and residue data for sorghum aspirated grain fractions. Based on the toxicological data and the levels of exposure, EPA has determined that the proposed tolerances will be safe.

#### VI. Summary of Findings

The analysis for sulfentrazone using tolerance level residues shows the proposed uses on soybeans will not cause exposure to exceed the levels at which the Agency believes there is an appreciable risk. All population subgroups examined by EPA are exposed to sulfentrazone residues at levels below 100% of the RfD for chronic effects.

Based on the information cited above, the Agency has determined that the establishment of the tolerances by adding a new section to 40 CFR part 180 will be safe; therefore, the tolerances are established as set forth below.

#### VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a tolerance regulation issued by EPA under new section 408(e) and (1)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with

appropriate adjustments to reflect the new law.

Any person may, by May 9, 1997, file written objections to any aspect of this regulation (including the automatic revocation provision) and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

#### VIII. Public Docket

A record has been established for this rulemaking under docket control number PF-670/OPP-300459. A public version of this record, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operation Division (7506C), Office of Pesticide Programs, Environmental Protection Agency,

Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. EPA has also established a special record for post-FQPA tolerances which contains documents of general applicability. This record can be found in the same location.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing requests, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

#### IX. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), this action is not a "significant regulatory action" and since this action does not impose any information collection requirements subject to approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, or contain any "unfunded mandates" as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because tolerances established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent amendment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence that the RFA is inapplicable.

Pursuant to 5 U.S.C. 801(a)(1)(A), EPA submitted 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 General Accounting Office prior to publication of the rule in today's Federal Register. This 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: February 27, 1997.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

**PART 180—[AMENDED]**

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

Authority: 21 U.S.C. 346a and 371.

2. By adding § 180.498 to read as follows:

**§ 180.498 Sulfentrazone; tolerances for residues.**

(a) *Tolerance--general.* A tolerance is established for combined residues of the herbicide sulfentrazone N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide and its major metabolite 3-hydroxymethyl sulfentrazone N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide in or on the following raw agricultural commodity:

Commodity	Parts per million
Soybean, seed .....	0.05

(b) *Tolerances--inadvertent and indirect residues.* Tolerances are established for inadvertent and indirect combined residues of the herbicide sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its metabolites 3-hydroxymethyl sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and 3-desmethyl sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) in or on the following raw agricultural commodities when present therein as a result of the application of sulfentrazone to growing crops.

Commodity	Parts per million
Cereal Grains (excluding sweet corn), Bran .....	0.15
Cereal Grains (excluding sweet corn), Forage .....	0.2
Cereal Grains (excluding sweet corn), Grain .....	0.1
Cereal Grains (excluding sweet corn), Hay .....	0.2
Cereal Grains (excluding sweet corn), Hulls .....	0.30
Cereal Grains (excluding sweet corn), Stover .....	0.1
Cereal Grains (excluding sweet corn), Straw .....	0.6

[FR Doc. 97-5874 Filed 3-7-97; 8:45 am]

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**GENERAL SERVICES ADMINISTRATION****41 CFR Parts 302-1, 302-2, 302-3, 302-7, 302-8, 302-9, and 302-11**

[FTR Amendment 58]

RIN 3090-AG17

**Federal Travel Regulation; Authority for the Administrator of General Services To Issue Regulations; Authority To Waive Limitations on Relocation Allowances When an Employee Is Relocated To or From a Remote or Isolated Location; Technical Correction To Relocation Income Tax (RIT) Allowance**

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

**ACTION:** Final rule.

**SUMMARY:** This final rule amends the Federal Travel Regulation (FTR) to reflect the direct authority conferred by statute on the Administrator of General Services to issue regulations implementing subchapter II of chapter 57 of title 5, United States Code, and to authorize agencies to waive certain statutory and regulatory limitations for an employee relocating to or from a remote or isolated location. This amendment also makes a technical correction to the RIT allowance. The amendment implements statutory changes, and is intended to improve the treatment of an employee transferred to a remote or isolated location.

**DATES:** This final rule is effective March 22, 1997.

**Applicability:** This rule applies to an employee whose effective date of transfer (date the employee reports for duty at the new official station) is on or after March 22, 1997.

**FOR FURTHER INFORMATION CONTACT:**

Robert A. Clauson, Travel and Transportation Management Policy Division (MTT), Washington, DC 20405, telephone 202-501-0299.

**SUPPLEMENTARY INFORMATION:** On September 23, 1996, the President signed into law the Federal Employee Travel Reform Act of 1996 (Pub. L. 104-201). Section 1722 of the Act transfers from the President to the Administrator of General Services authority to issue regulations implementing subchapter II of chapter 57 of title 5, United States Code, unless otherwise specified in subchapter II. Previously, the Administrator had exercised implementation authority under E.O. 11609, 36 FR 13747, 3 CFR, 1971-1975 Comp., p. 586; E.O. 12466, 49 FR 7349, 3 CFR, 1984 Comp., p. 165; and E.O. 12522, 50 FR 26337, 3 CFR, 1985 Comp., p. 375. This amendment reflects the statutory change of authority.

Section 1722 of the Act also directs the Administrator to authorize heads of agencies or their designees to waive any limitation in subchapter II of chapter 57 of title 5, United States Code, or in any implementing regulation for an employee relocating to or from a remote or isolated location who otherwise would suffer hardship. This amendment implements the limitation waiver provisions of section 1722 of the Act.

This amendment also makes a technical correction to the RIT allowance. The withholding rate for supplemental wages was raised from 20 percent to 28 percent in 1995. This amendment modifies the withholding tax allowance (WTA) provisions to reflect the 28 percent withholding rate.

The General Services Administration has determined that this rule is not a significant regulatory action for the purposes of Executive Order 12866 of September 30, 1993. This final rule is not required to be published in the Federal Register for notice and comment. Therefore, the Regulatory Flexibility Act does not apply. This rule also is exempt from Congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.

List of Subjects in 41 CFR Parts 302-1, 302-2, 302-3, 302-7, 302-8, 302-9, and 302-11

Government employees, Income taxes, Relocation allowances and entitlements, Transfers.

For the reasons set out in the preamble, 41 CFR parts 302-1, 302-2, 302-3, 302-7, 302-8, 302-9, and 302-11 are amended to read as follows: