preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.,* v. *U.S. EPA,* 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

H. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

I. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major'' rule as defined by 5 U.S.C. 804(2).

J. Petitions for Judicial Review

Under Section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 22, 1999. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See Section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Note: Incorporation by reference of the Implementation Plan for the State of Oregon was approved by the Director of the Office of Federal Register on July 1, 1982.

Dated: August 23, 1999.

Chuck Findley,

Acting Regional Administrator, Region 10.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart MM—Oregon

2. Section 52.1970 is amended by adding paragraph (c) (128) to read as follows:

§ 52.1970 Identification of plan.

* * * * *

(c) * * *

(128) On June 1, 1995 the State of Oregon submitted to EPA an attainment plan for the Lakeview PM10 nonattainment area. This SIP revision is designed to bring about the attainment of the PM10 NAAQS in Lakeview and satisfy Federal requirements applicable to moderate PM10 nonattainment areas.

(i) Incorporation by reference.

(A) June 1, 1995 letter from the Director, Oregon Department of Environmental Quality, the Governor's designee, to Region 10 Regional Administrator, EPA, submitting the Lakeview, Oregon PM10 Control Plan.

(B) Revision to the Oregon State Implementation Plan: Lakeview, Oregon PM10 Control Plan; Appendix 3, Lakeview Detailed Emissions Inventories; Appendix 4, Ordinances and Commitments; Appendix 5, Demonstration of Attainment; Appendix 9, Woodburning Curtailment Survey Protocol; Appendix 10, Legal Description of Lakeview PM10 Nonattainment Area.

(C) Supporting regulations approved as part of the revision, state effective May 1, 1995: OAR 340–20–047; OAR 340–21–010, –012, –025, –200; OAR 340–30–043, –300, –310, –340; OAR 340–34–150, –200, –210.

[FR Doc. 99–24447 Filed 9–20–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300903; FRL–6097–8]

RIN 2070–AB78

Sulfentrazone; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of *N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl] phenyl] methanesulfonamide in or on sunflowers, lima beans, and cowpeas. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on sunflowers, lima beans, and cowpeas. This regulation establishes a maximum permissible level for residues of sulfentrazone in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The tolerances will expire and is revoked on December 30, 2000.

DATES: This regulation is effective September 21, 1999. Objections and requests for hearings must be received by EPA on or before November 22, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300903], must 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 identified by the docket control number, [OPP–300903], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic 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 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300903]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Jacqueline E. Gwaltney, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 278, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6792, gwaltney.jackie@epamail@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(l)(6) of the FFDCA, 21 U.S.C. 346a, is establishing a tolerance for residues of the herbicide *N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-y-l] phenyl] methanesulfonamide, in or on sunflowers, lima bean, and cowpeas at 0.1 part per million (ppm). This tolerance will expire and is revoked on December 30, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Findings

The FQPA (Public Law 104–170) was signed into law August 3, 1996. FQPA amends both the FFDCA, 21 U.S.C. 301 *et seq*., and the FIFRA, 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described in this preamble and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

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

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Sulfentrazone on Sunflowers, Lima Beans, and Cowpeas and FFDCA Tolerances

North Dakota claims that there is an emergency situation regarding herbicide resistant weeds, especially kochia that has seriously reduced sunflower yields in all production systems. They also claimed that reduced till and no-till farmers need an herbicide tool, such as sulfentrazone, that does not need to be incorporated and will allow efficient, cost-effective control of broadleaf weeds. Presently there is no such tool available. North Dakota requested the use of sulfentrazone in order to eliminate the emergency. EPA has authorized under FIFRA section 18 the use of sulfentrazone on sunflowers for control of kochia in North Dakota.

Tennessee claims that the hophorn beam coppperleaf has increased in recent years, and has become such an overwhelming pest that entire fields were abandoned in 1995. The fields in question constitute some of the most fertile agricultural land in West Tennessee, an area where farming and agriculturally-related businesses are the primary sources of income. The registered alternative, does not provide effective control for the entire season.

After having reviewed these submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of sulfentrazone in or on sunflowers, lima beans, and cowpeas. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 30, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on sunflowers, lima beans, and cowpeas after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time

of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether sulfentrazone meets EPA's registration requirements for use on sunflowers, lima beans, and cowpeas or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of sulfentrazone by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than North Dakota and Tennessee to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for sulfentrazone, contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of sulfentrazone and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues or residues of *N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-y-l] phenyl] methanesulfonamide on sunflowers at 0.1 ppm, and on bean, succulent seed with pod (lima beans & cowpeas) at 0.1 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by sulfentrazone are discussed in this unit.

B. Toxicological Endpoint

1. *Acute toxicity*. For the acute analysis, the EPA selected two endpoints, one for the Females 13+ population subgroup and another for the General population (including infants and children). For the Females 13+ population subgroup, a Reference dose (RfD) of 0.10 milligrams/kilograms/day (mg/kg/day) from a no observable adverse effect level (NOAEL) = 10.0 was established based on decreased fetal weight and retarded skeletal development seen in a developmental rat study at a lowest observable adverse effect level (LOAEL) of 25 mg/kg/day. For the General population (including infants and children), an RfD of 2.5 mg/kg/day (NOAEL = 250) was established from an acute neurotoxicity study in rats. This endpoint is based upon increased clinical signs (abdominal gripping, abdominogenital staining, and/or reddish-brown staining under the cage), EPA findings, and decreased motor activity (which were reversed by day 14 postdose) at a LOAEL of 750 mg/kg/day. An uncertainty factor (UF) of 100X was applied to account for both interspecies extrapolation 10X and intraspecies variability 10X.

2. *Chronic toxicity*. For the chronic analysis, the EPA selected an RfD of 0.14 mg/kg/day (NOAEL = 14.0) based on significant toxic effects observed primarily in the second generation animals in a 2–generation rat reproduction study at a LOAEL of 33/44 mg/kg/day in males and females, respectively. A UF of 100X was applied to account for both interspecies extrapolation 10X and intraspecies variability 10X.

3. *Carcinogenicity*. The Agency determined that sulfentrazone should be classified as a ''Group E'' chemical (not likely to be carcinogenic to humans via relevant routes of exposure). This weight of the evidence judgment was largely based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.498) for the combined residues of *N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl] phenyl] methanesulfonamide, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from sulfentrazone as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. An acute dietary risk assessment is required for sulfentrazone.

Since two endpoints were selected for risk assessment, the acute dietary analyses were conducted for two main population subgroups, the Females 13+ subgroup and the General population (including infants, children, and adult males (excluding Females 13+)). The acute RfDs for the Females 13+ subgroup and the General population are 0.10 mg/kg/day and 2.5 mg/kg/day, respectively. The acute population adjusted doses (aPADs) are 0.01 mg/kg/day (0.10 mg/kg/day ÷ 10 = 0.01 mg/kg/day) and 0.25 mg/kg/day (2.5 mg/kg/day ÷ 10 = 0.25 mg/kg/day) for the Females 13+ subgroup and the General population, respectively.

Separate Tier 1 acute dietary exposure analyses were performed using tolerance level residues and 100% crop treated (CT) information. Dietary exposures and associated acute risk for the Females 13+ population subgroup at the 95th percentile are shown in Table 1 below.

Table 1- Summary of Results of Acute DEEM Analysis for Sulfentrazone (Females 13+)

Subgroups Exposure	(mg/kg/day)	% aPAD
Females (13+, pregnant, not nursing).	0.000515	5.2
Females (13+, nursing).	0.000702	7.0
Females (13–19 years, not pregnant, not nursing).	0.000663	6.6
Females (20+ years, not pregnant, not nursing).	0.000501	5.0
Females (13–50 years).	0.000562	5.6

Dietary exposures and associated acute risk for the General population including infants and children at the 95th percentile are shown in Table 2 below. The other subgroups included in Table 2 represent the highest dietary exposures for their respective subgroups (i.e., children and the other General population subgroups higher than U.S. population).

Since the EPA determined to retain the factor of 10X, the PAD was used in this risk assessment. The PAD is equal to the acute or chronic RfD divided by the FQPA Safety Factor. Therefore, the Agency's level of concern is for values >100% PAD.

Table 2. - Summary of Results of Acute DEEM Analysis for Sulfentrazone (General Population Including Infants and Children)

Subgroups Exposure	(mg/kg/day)	%aPAD
U.S. Population (48 Contiguos States).	0.000901	<1
Non-Hispanic Blacks.	0.001016	<1
Non-nursing Infants (<1 year).	0.001599	<1
Children (1–6 years).	0.001513	<1

The %aPADs for the Females 13+ subgroup were <100%, and the highest was 7.0% for Females (13+/nursing). The %aPADs for the General population (including infants and children) were <100%, and the highest subgroups (as shown in Table 3) had %aPADs of <1%. For acute dietary risk, the Agency's level of concern is >100% aPAD. The results of the acute analyses indicate that the acute dietary risks associated with the existing and proposed uses of sulfentrazone are well below the Agency's current level of concern.

ii. *Chronic exposure and risk.* A chronic dietary risk assessment is required for sulfentrazone. The chronic RfD used for the chronic dietary analysis for sulfentrazone is 0.14 mg/kg/day. Therefore, the chronic population adjusted dose (cPAD) is 0.014 (0.14 mg/kg/day ÷ 10 = 0.014 mg/kg/day) for chronic dietary exposure for All Populations which include Infants and Children. The chronic dietary exposure analysis used mean consumption (3–day average) data. A Tier 1 chronic dietary exposure assessment was performed using tolerance level residues and 100% crop treated (CT) information for all commodities as well. Since the Agency determined to retain the factor of 10X, the PAD was used in this risk assessment. The PAD is equal to the acute or chronic RfD divided by the FQPA Safety Factor. Therefore, the Agency's level of concern is for values >100% PAD.

Chronic dietary exposures for the General population and other subgroups are presented in Table 3 below. The other subgroups included in Table 3 represent the highest dietary exposures for their respective subgroups (i.e., children, females, and the other General population subgroups higher than U.S. population).

Table 3. Summary of Results from Chronic DEEM Analysis of Sulfentrazone

Subgroups Exposure	(mg/kg/day)	% cPAD
U.S. Population (48 Contiguous States).	0.000343	2.4
Non-Hispanic Other Than Black or White.	0.000372	2.7
Non-nursing Infants (<1 year).	0.000778	5.6
Children (1–6 years)	0.000773	5.5
Females (13+, not pregnant or nursing).	0.000318	2.3
Males (13–19 years)	0.000382	2.7

The %cPADs for all subgroups were <100%, and the highest was 5.6% for non-nursing infants (<1 year) and children (1–6 years). The results of the chronic analysis indicate that the chronic dietary risk associated with the existing and proposed uses of sulfentrazone is well below the Agency's current level of concern.

2. *From drinking water.* Drinking Water Level of Comparison (DWLOC) is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption and body weights. Different populations will have different DWLOCs.

The Agency uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for pesticides, it is used as a point of comparison against conservative model estimates of a pesticide's concentration in water.

DWLOC values are not regulatory standards for drinking water. They do have an indirect regulatory impact through aggregate exposure and risk assessments.

EPA does not have monitoring data available to perform a quantitative drinking water risk assessment for sulfentrazone at this time. Thus, ground and surface water exposure estimates were used for sulfentrazone on sunflowers.

i. *Chronic exposure and risk.* Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfDs or acute dietary NOAELs) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause sulfentrazone to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with sulfentrazone in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

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

EPA does not have, at this time, available data to determine whether sulfentrazone has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, sulfentrazone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that sulfentrazone has a common mechanism of toxicity with other substances. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* Since there are no residential uses for sulfentrazone, the aggregate exposure only includes food and water.

From the acute dietary (food only) risk assessments, high-end exposure estimates were calculated for the two main subgroups, Females 13+ years and the General population. For the subgroup Females 13+, the percentages of the aPAD that will be utilized by acute dietary (food only) exposure to residues of sulfentrazone range from 5.7% for Females (20+ yrs, not pregnant, not nursing) to 7.9% for Females (13+, pregnant, not nursing). For the General population subgroup, which includes the U.S. population and the most highly exposed subgroups (non-Hispanic Blacks, non-nursing infants (<1 year), and children (1–6 years)), <1% of the aPAD is occupied by acute dietary food exposure. The low %aPADs calculated for the Female 13+ subgroup and the General population provide assurance that there is reasonable certainty that no harm will be caused to infants, children, or adults from acute aggregate exposure to sulfentrazone residues.

The maximum estimated concentrations of sulfentrazone in surface and ground water are less than the Agency's DWLOCs for sulfentrazone as a contribution to acute aggregate exposure. Therefore, OPP concludes with reasonable certainty that residues of sulfentrazone in drinking water do not contribute significantly to the acute aggregate human health risk at the present time considering the present uses and the uses proposed in this action.

The Agency bases this determination on a comparison of estimated concentrations of sulfentrazone in surface waters and ground waters to levels of comparison for sulfentrazone in drinking water. The estimates of sulfentrazone in surface and ground waters are derived from water quality models that use conservative assumptions regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of sulfentrazone on drinking water as a part of the acute aggregate risk assessment process.

2. *Chronic risk.* Since there are no residential uses for sulfentrazone, the aggregate exposure only includes food and water.

For the U.S. population, 2% of the cPAD is occupied by dietary (food) exposure. For the most highly exposed subgroups, non-nursing infants (<1 year) and children (1–6 years), 6% of the cPAD is occupied by dietary food exposure. The estimated average concentrations of sulfentrazone in surface and ground water are less than EPA's levels of comparison for sulfentrazone in drinking water as a contribution to chronic aggregate exposure. Therefore, EPA concludes with reasonable certainty that residues of sulfentrazone in drinking water do not contribute significantly to the chronic aggregate human health risk at the present time considering the present uses and uses proposed in this action.

EPA bases this determination on a comparison of estimated concentrations of sulfentrazone in surface waters and ground waters to levels of comparison for sulfentrazone in drinking water. The estimates of sulfentrazone in surface and ground waters are derived from water quality models that use conservative assumptions regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of sulfentrazone on drinking water as a part of the aggregate chronic risk assessment process.

3. *Short- and intermediate-term risk.* Since there are no residential uses or exposure scenarios, short- and intermediate-term aggregate risk assessments were not conducted.

4. *Aggregate cancer risk for U.S. population.* Sulfentrazone has been classified as a ''Group E'' chemical (not likely to be carcinogenic to humans via relevant routes of exposure) by the RfD/Peer Review Committee. Therefore, no cancer dietary exposure analysis was performed.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to sulfentrazone residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children* — i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of sulfentrazone, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies* — a. *Rats.* In EPA's oral developmental study in rats, the maternal (systemic) NOAEL was 25 mg/kg/day, based on increased relative spleen weights and splenic extramedullary hematopoiesis at the LOAEL of 50 mg/kg/day. The developmental (fetal) NOAEL was 10 mg/kg/day, based on decreased mean fetal weight and retardation in skeletal development as evidenced by increased numbers of litters with any variation and by decreased numbers of caudal vertebral and metacarpal ossification sites at the LOEL of 25 mg/kg/day.

In the dermal developmental study in rats, the maternal (systemic) NOAEL was ≧250 mg/kg/day and a LOAEL was not determined. The developmental (fetal) NOAEL was 100 mg/kg/day, based on decreased fetal weight and increased fetal variations (hypoplastic or wavy ribs, incompletely ossified lumbar vertebral arches, incompletely ossified ischia or pubes, and reduced numbers of thoracic vertebral and rib ossification sites) at the LOAEL of 250 mg/kg/day.

b. *Rabbits.* In the oral developmental toxicity study in rabbits, the maternal

(systemic) NOAEL was 100 mg/kg/day, based on increased abortions, clinical signs (decreased feces and hematuria), and reduced body weight gain during gestation at the LOAEL of 250 mg/kg/day. The developmental (pup) NOAEL was 100 mg/kg/day, based on increased resorptions, decreased live fetuses per litter, and decreased fetal weight at the LOAEL of 250 mg/kg/day.

iii. *Reproductive toxicity study — Rats.* In the 2–generation reproductive toxicity study in rats, the maternal (systemic) NOAEL was 14/16 mg/kg/day in males and females, respectively, based on decreased maternal body weight and/or body weight gain during gestation in both P and F1 generations, and reduced premating body weight gains in the second generation (F1 adults) at the LOAEL of 33/40 mg/kg/day for males and females, respectively. The developmental (pup) NOEL was 14/16 mg/kg/day based on: (a) Reduced prenatal viability (fetal and litter); (b) reduced litter size; (c) increased number of stillborn pups; (d) reduced pup and litter postnatal survival and; (e) decreased pup body weights throughout lactation at the LOAEL of 33/40 mg/kg/day. The reproductive NOAEL was 14/16 mg/kg/day, based on: (a) Increased duration of gestation in both F1 and F2 dams; (b) decreased fertility in F1 generation (males); and/or (c) atrophy of the germinal epithelium of the testes, oligospermia and intratubular degeneration of the seminal product in the epididymis at the LOAEL of 33/40 mg/kg/day.

iv. *Prenatal and postnatal sensitivity.* The toxicological data base for evaluating prenatal and postnatal toxicity for sulfentrazone is complete with respect to current data requirements. Based on the developmental and reproductive toxicity studies discussed above for sulfentrazone there appears to be prenatal and postnatal sensitivity. Based on the above, the Agency concludes that reliable data support use of a 1,000-fold margin/factor, to protect infants and children.

v. *Conclusion.* There is a complete toxicity data base for sulfentrazone and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk.* Acute RfD = 2.5 mg/kg/day. For acute dietary risk, the Agency recommended use of the NOAEL of 250 mg/kg/day with an uncertainty factor of 100, based on increased incidences of clinical signs (abdominal gripping, abdominogenital staining, and or/reddish-brown staining under the cage), EPA findings, and decreased motor activity which were reversed by day 14 post dose at a LOAEL of 750 mg/kg, from an acute neurotoxicity study in rats. There was no evidence of neuropathology at the high dose (2,000 mg/kg).

3. *Chronic risk.* RfD = 0.14 mg/kg/day. For chronic dietary risk assessment the Agency recommended use of the NOAEL of 14 mg/kg/day with an uncertainty factor of 100, based on: (a) Decreased maternal body weight and/or body weight gain during gestation in both P and F1 generations; (b) reduced premating body weight gains in the second generation (F1 adults); (c) increased duration of gestation in both F1 and F2 dams; (d) reduced prenatal viability (fetal and litter); (e) reduced litter size; (f) increased number of stillborn pups; (g) reduced pup and litter postnatal survival; (h) decreased pup body weights throughout lactation; (i) decreased fertility in F1 generation males; and (j) atrophy of the germinal epithelium of the testes, oligospermia and intratubular degeneration of the seminal product in the epididymis at the LOAEL of 33/44 mg/kg/day for males and females, respectively, from a 2–generation reproductive toxicity study in rats.

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

IV. Other Considerations

A. Metabolism in Plants and Animals

1. *Plants.* No plant metabolism study was submitted with this petition. However, the nature of the residue in soybeans and rotational crops is adequately understood. The residues of concern in soybeans are the parent plus the metabolite 3-hydroxymethyl sulfentrazone. The residues of concern in the rotational crops are the parent plus the metabolites 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone.

EPA translated the sunflower plant metabolism data in support of the use of sulfentrazone on lima beans and cowpeas. Due to the uncertainty of the nature of the residue of sulfentrazone in lima beans and cowpeas, the residues of concern will be the parent plus the metabolites 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone.

2. *Animals.* There will be no animal feed items associated with the proposed use provided that the label is modified to specify the following restriction: Do not allow livestock to graze on treated plants or feed treated plants or plant trash to livestock.

B. Analytical Enforcement Methodology

An analytical methodology for the determination of sulfentrazone, 3-desmethyl sulfentrazone, and 3-hydroxymethyl sulfentrazone residues in/on various matrices was submitted with the petition. A petition method validation (PMV) was successfully completed by Analytical Chemistry Laboratory (ACL). The Limit of Quantitation (LOQ) and Minimum Detection Limit (MDL) were determined to be 0.05 ppm and 0.005–0.025 ppm, respectively. EPA concluded that the method was suitable for enforcement purposes.

Adequate enforcement methodology (example - gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

C. International Residue Limits

There are no Codex, Canadian or Mexican residue limits established for sulfentrazone on lima beans and cowpeas. Therefore, no compatibility problems exist for the tolerances.

D. Rotational Crop Restrictions

Rotational field trial data for wheat, corn, rice and sorghum were submitted in support of a petition for a sulfentrazone tolerance on soybeans. Permanent tolerances have been established on cereal grains (excluding sweet corn) when planted in rotation with the primary crop soybeans. The suggested rotational crop restrictions on the section 18 label pertaining to this petition are the same as those on the label for soybeans. Therefore, additional rotational crop data are not necessary for this action.

V. Conclusion

Therefore, the tolerance is established for combined residues of *N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl] phenyl] methanesulfonamide in sunflowers, lima beans, and cowpeas at 0.1 ppm.

VI. 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(l)(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 govern 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 November 22, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (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). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (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 genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues 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 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.

VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300903] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, 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. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, 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 record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408 of the FFDCA. 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). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal

governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and 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 the rule in the **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: September 9, 1999.

James Jones,

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. In § 180.498, by revising the heading to paragraph (a); redesignating the existing paragraph (b) as paragraph (d) and revising the heading; adding a new paragraph (b); and adding and reserving paragraph (c) to read as follows:

§ 180.498 Sulfentrazone; tolerances for residues.

(a) *General.* * * *

(b) *Section 18 emergency exemptions.* Time limited tolerances are established for residues of the herbicide *N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-y-l] phenyl] methanesulfonamide, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance is specified in the following table. The tolerances expire and will be revoked by EPA on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Bean, succulent seed without pod (lima beans & cowpeas).	0.1	12/30/00
Sunflower	0.1	12/30/00

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

(d) *Indirect or inadvertent residues.*

* * * * *

[FR Doc. 99–24509 Filed 9–20–99; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: Modified base (1% annual chance) flood elevations are finalized for the communities listed below. These modified elevations will be used to calculate flood insurance premium rates for new buildings and their contents.

EFFECTIVE DATES: The effective dates for these modified base flood elevations are indicated on the following table and revise the Flood Insurance Rate Map(s) in effect for each listed community prior to this date.

ADDRESSES: The modified base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Matthew B. Miller, P.E., Chief, Hazards Study Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646–3461, or (e-mail) matt.miller@fema.gov.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes the final determinations listed below of the final determinations of modified base flood elevations for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Associate Director has resolved any appeals resulting from this notification.

The modified base flood elevations are not listed for each community in this notice. However, this rule includes the address of the Chief Executive