(6) * * *

(i) *Calculation of rolling averages initially.* The carbon monoxide or hydrocarbon CEMS must begin recording one-minute average values by 12:01 a.m. and hourly rolling average values by 1:01 a.m., when 60 one-minute values will be available for calculating the initial hourly rolling average for those sources that come into compliance on the regulatory compliance date. Sources that elect to come into compliance before the regulatory compliance date must begin recording one-minute and hourly rolling average values within 60 seconds and 60 minutes (when 60 one-minute values will be available for calculating the initial hourly rolling average), respectively, from the time at which compliance begins.

* * * * *

(b) * * *

(5) * * *

(i) *Calculation of rolling averages initially.* Continuous monitoring systems must begin recording one-minute average values by 12:01 a.m., hourly rolling average values by 1:01 a.m.(e.g., when 60 one-minute values will be available for calculating the initial hourly rolling average), and twelve-hour rolling averages by 12:01 p.m.(e.g., when 720 one-minute averages are available to calculate a 12-hour rolling average), for those sources that come into compliance on the regulatory compliance date. Sources that elect to come into compliance before the regulatory compliance date must begin recording one-minute, hourly rolling average, and 12-hour rolling average values within 60 seconds, 60 minutes (when 60 one-minute values will be available for calculating the initial hourly rolling average), and 720 minutes (when 720 one-minute values will be available for calculating the initial 12-hour hourly rolling average) respectively, from the time at which compliance begins.

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301074; FRL–6751–7]

RIN 2070–AB78

Sulfentrazone; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of sulfentrazone *N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide and its major metabolite 3-hydroxymethyl sulfentrazone *N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide in or on horseradish and sugarcane. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on horseradish and sugarcane. This regulation establishes a maximum permissible level for combined residues of sulfentrazone in these food commodities. The tolerances will expire and are revoked on December 31, 2002.

DATES: This regulation is effective November 9, 2000. Objections and requests for hearings, identified by docket control number OPP–301074, must be received by EPA on or before January 8, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301074 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Meredith Laws, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703 305–9366; and e-mail address: laws.meredith@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311	Crop production Animal production Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301074. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for combined residues of the herbicide sulfentrazone, in or on horseradish and sugarcane at 0.1 and 0.05 part per million (ppm) respectively. These tolerances will expire and are revoked on December 31, 2002. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

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. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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 the 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 the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemptions for Sulfentrazone on Horseradish and Sugarcane and FFDCA Tolerances

Illinois submitted a section 18 request for the emergency use of sulfentrazone on horseradish to control annual broadleaf weeds. EPA reviewed the request and concluded that the situation was urgent and nonroutine because heavy rains, urbanization, and drainage canal problems led to flooding of fields during the spring of 1999 resulting in significant problems with yellow nutsedge and broadleaf weeds.

Louisiana submitted a section 18 request for the emergency use of sulfentrazone to control morning glories infesting sugarcane fields. EPA agrees that morning glory infestations may create emergency conditions for growers since the registered alternative herbicide is ineffective against late season infestations when used on a higher yielding sugarcane variety. Due to this variety's earlier lay-by, late season applications of soil herbicides are not possible. Additionally, morning glory vines can cause indirect economic costs to growers by disabling combine-type harvesters.

EPA has authorized under FIFRA section 18 the use of sulfentrazone on horseradish and sugarcane for control of annual broadleaf weeds in Illinois and morning glories in Louisiana, respectively. After having reviewed the 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 the combined residues of sulfentrazone in or on horseradish and sugarcane. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances 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 exemptions in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 2002, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on horseradish and sugarcane 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 these tolerances at the time of that application. EPA will take action to revoke these tolerances 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 horseradish or on sugarcane or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of sulfentrazone by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Illinois and Louisiana to use this pesticide on these crops 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 exemptions for sulfentrazone, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. 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 time-limited tolerances for combined residues of sulfentrazone in or on horseradish and sugarcane at 0.1 and 0.05 ppm, respectively. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is

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

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

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for sulfentrazone used for human risk assessment is shown in the following Table 1:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary females 13-50 years of age	NOAEL = 10.0 mg/kg/day UF = 100 Acute RfD = 0.10 mg/kg/day	FQPA SF = 10 aPAD = acute RfD/FQPA SF = 0.01 mg/kg/day	Rat Developmental LOAEL = 25 mg/kg/day based on decreased fetal weight and retarded skeletal development as evidenced by an increased number of litters with any variation and by decreased numbers of caudal vertebral and metacarpal ossification sites.
Acute Dietary general population including infants and children	NOAEL = 250 mg/kg/day UF = 100 Acute RfD = 2.5 mg/kg/day	FQPA SF = 10 aPAD = acute RfD/FQPA SF = 0.25 mg/kg/day	Acute Neurotoxicity Study in Rats LOAEL = 750 mg/kg/day based on increased incidences of clinical signs abdominal gripping, abdominogenital staining, and/or reddish- brown staining under the cage, FOB findings, and decreased motor activity which was reversed by Day 14 postdose. There was no evidence of neuropathology at the highest dose tested (2,000 mg/kg/day).

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Chronic Dietary all populations	NOAEL= 14.0 mg/kg/day UF = 100 Chronic RfD = 0.14 mg/kg/day	FQPA SF = 10 cPAD = chronic RfD/FQPA SF = 0.014 mg/kg/day	2-Gen. Repro. Study in Rats LOAEL = 33/44 mg/kg/day in males and females, respectively based on 1) decreased maternal body weight and/or body weight gain during gestation in both P and F1 generations, 2) reduced premating body weight gains in the second generation (F1 adults), 3) increased duration of gestation in both F1 and F2 dams, 4) reduced prenatal viability (fetal and litter), 5) reduced litter size, 6) increased number of stillborn pups, 7) reduced pup and litter postnatal survival, and 8) decreased pup body weights throughout gestation. In males, effects included decreased fertility in F1 generation and/or atrophy of the germinal epithelium of the testes, oligospermia and intratubular degeneration of the seminal product in the epididymis.

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.498) for the combined residues of sulfentrazone, in or on a variety of raw agricultural commodities. A permanent tolerance has been established for soybean, seed at 0.05 ppm. Time-limited tolerances have been established for cowpeas, lima beans, and sunflowers, with an expiration date of 12/30/00. Risk assessments were conducted by EPA to assess dietary exposures from sulfentrazone in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Two acute doses and endpoints were selected, one for the females 13+ years old population subgroup and another for the U.S. population and other subgroups (excluding females 13+ years old). Therefore, acute dietary exposure analyses were performed using two separate endpoints. Tolerance level residues and 100% crop treated were used for all commodities (Tier 1). As the acute analyses were Tier 1 assessments, acute risk estimates are shown at the 95th percentile.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tolerance level residues and 100% crop treated information were used for all commodities (Tier 1).

iii. *Cancer.* Sulfentrazone has been classified as a ''Group E'' chemical (not likely to be carcinogenic to humans via relevant routes of exposure). Therefore, no cancer dietary exposure risk analysis was performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for sulfentrazone in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of sulfentrazone.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides.

GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to sulfentrazone they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the EECs of sulfentrazone for acute exposures are estimated to be 12.5 parts per billion (ppb) for surface water and 21.8 ppb for ground water. The EECs for chronic exposures are estimated to be 12.0 ppb for surface water and 10.2 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Sulfentrazone is not registered for use on any sites that would result in residential exposure.

4. *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 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).

C. Safety Factor for Infants and Children

1. *Safety factor for infants and children*— i. *In general*. FFDCA section 408 provides that EPA shall apply an additional ten–fold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Developmental toxicity studies*— a. *Rats*. In the oral developmental study in rats, the maternal (systemic) NOAEL was 25 mg/kg/day, based on increased 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 LOAEL 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 33/44 mg/kg/day for males and females, respectively. The developmental (pup) NOAEL was 14/16 mg/kg/day based on 1) reduced prenatal viability (fetal and litter), 2) reduced litter size, 3) increased number of stillborn pups, 4) reduced pup and litter postnatal survival, and 5) decreased pup body weights throughout lactation at the LOAEL of 33/44 mg/kg/day. The reproductive NOAEL was 14/16 mg/kg/day, based on 1) increased duration of gestation in both F1 and F2 dams, 2) decreased fertility in F1 generation (males), and/or 3) 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.

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.

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. EPA determined that the 10X safety factor to protect infants and children should be retained. For acute dietary analysis, the FQPA SF was retained and is applicable to the U.S. population and all subgroups due to the increased susceptibility observed in the prenatal developmental studies. For chronic dietary analysis, the

FQPA safety factor was retained and is applicable for all populations due to the qualitative increased susceptibility observed in the 2-generation reproduction study.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD − (average food + chronic non-dietary, non-occupational exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to sulfentrazone in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP will reassess the potential impacts of sulfentrazone on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to sulfentrazone will occupy <1% of the aPAD for the U.S. population, 6% of the aPAD for females 13 years and older, <1% of the aPAD for all infants (<1 year old) and <1% of the aPAD for children (1-6 years old). In addition, despite the potential for acute dietary exposure to sulfentrazone in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of sulfentrazone in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2.

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO SULFENTRAZONE

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females, 13-50 years old	0.01	6	12.5	21.8	284
U.S. population (including infants and children)	0.25	<1	12.5	21.8	8,700
Children (1-6 years old) and all infants (1 year old)	0.25	<1	12.5	21.8	2484

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to sulfentrazone from food will utilize 2% of the cPAD for the U.S. population, 4% of the cPAD for all infants (< 1 year old) and 6 % of the cPAD for children (1-6 years old). There are no residential uses for sulfentrazone that result in chronic residential exposure to sulfentrazone. In addition, despite the potential for chronic dietary exposure to sulfentrazone in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of sulfentrazone in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO SULFENTRAZONE

Population Subgroup	cPAD (mg/kg)	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S Population	0.014	2	4.0	10.2	478
Children (1-6 years old)	0.014	6	4.0	10.2	132
Children (Females 13-50 years old)	0.014	2	4.0	10.2	412
Males (13-19 years old)	0.014	3	4.0	10.2	477

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

Sulfentrazone is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

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

Sulfentrazone is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

5. *Aggregate cancer risk for U.S. population*. Because sulfentrazone is not a carcinogen, a cancer aggregate risk assessment was not conducted.

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

V. Other Considerations

A. 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 a petition for a sulfentrazone tolerance on soybeans. A petition method validation (PMV) was successfully completed by the Agency's Analytical Chemistry Laboratory. 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 is 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, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no Codex, Canandian or Mexican residue limits for sulfentrazone on horseradish and sugarcane. Therefore, no compatibility problems exist for the proposed tolerances.

C. Conditions

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 labels pertaining to these emergencies are the same as those on the label for soybeans. Therefore, additional rotational crop data are not necessary for this action.

VI. Conclusion

Therefore, the tolerances are established for combined residues of sulfentrazone, in or on horseradish and sugarcane at 0.1 and 0.05 ppm, respectively.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301074 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before January 8, 2001.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP–301074, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental

Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408. 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); 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 or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 petition under FFDCA section 408, such as the tolerance/exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

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 to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 25, 2000.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

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

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

2. Section 180.498 is amended by alphabetically adding the commodities to the table in paragraph (b) to read as follows:

§ 180.498 Sulfentrazone; tolerances for residues.

* * * * *

(b)* * *

Commodity	Parts per million	Expiration/Revocation Date
* * * * *	*	*
Horseradish, Roots	0.1	12/31/02
* * * * *	*	*
Sugarcane	0.05	12/31/02
* * * * *	*	*

* * * * *

[FR Doc. 00–28714 Filed 11–8–00; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–6898–2]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final deletion of the Superfund Site from the National Priorities List (NPL).

SUMMARY: EPA Region 5 announces the deletion of the Ilada Energy Company Site (Site) from the National Priorities List (NPL) and requests public comment on this action. The NPL constitutes appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substance Pollution Continency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended, (CERCLA). EPA and the Illinois Environmental Protection Agency (IEPA) have determined that the Site poses no significant threat to public health or the environment and, therefore, further remedial measures pursuant to CERCLA are not appropriate.

DATES: This ''direct final'' action will be effective January 8, 2001, unless EPA receives dissenting comments by December 11, 2000. If written dissenting comments are received, EPA will publish a timely withdrawal of the rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Comments may be mailed to Jon Peterson, Remedial Project Manager, or Gladys Beard, Associate Remedial Project Manager, U.S. Environmental Protection Agency, Superfund Division, U.S. EPA, Region 5, 77 W. Jackson Blvd., (SR–6J), Chicago, IL 60604. Requests for comprehensive information on this Site is available through the public docket which is available for viewing at the Site Information Repositories at the following locations: U.S. EPA Region 5, Administrative Records, 77 W. Jackson Blvd., Chicago, IL 60604, Illinois Environmental Protection Agency, 1021 North Grand Avenue East, Springfield, Illinois 62794 and Cape Girardeau Public Library, 711 N. Clark, Cape Girardeau, MO 63701.

FOR FURTHER INFORMATION CONTACT: Jon Peterson at (312) 353–1264, email *peterson.jon@epa.gov* or Gladys Beard (SR–6J), U.S. Environmental Protection Agency, 77 W. Jackson, Chicago, II, (312) 886–7253, FAX (312) 886–4071, e-mail beard.gladys@epa.gov

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Environmental Protection Agency (EPA) Region 5 announces the deletion of the Ilada Energy Company Site, East Girardeau, Illinois from the National Priorities List (NPL), appendix B of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR part 300. EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and maintains the NPL as the list of these sites. EPA and the State of Illinois have determined that the remedial action for the Site has been successfully executed. EPA will accept comments on this action for thirty days after publication of this action in the **Federal Register**.

Section II of this notice explains the criteria for deleting sites from the NPL. Section III discusses the procedures that EPA is using for this action. Section IV discusses the history of the Ilada Energy Company Site and explains how the Site meets the deletion criteria. Section V states EPA's action to delete the Site from the NPL unless dissenting comments are received during the comment period.

II. NPL Deletion Criteria

Section 300.425(e) of the NCP provides that Sites may be deleted from, or recategorized on the NPL where no further response is appropriate. In making a determination to delete a Site from the NPL, EPA shall consider, in consultation with the state, whether any of the following criteria has been met:

(i) Responsible parties or other persons have implemented all appropriate response actions required;

(ii) All appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

(iii) The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, taking of remedial measures is not appropriate.

Even if the Site is deleted from the NPL, where hazardous substances, pollutants, or contaminants remain at the Site above levels that allow for unlimited use and unrestricted exposure, EPA's policy is that a subsequent review of the Site will be conducted at least every five years after the initiation of the remedial action at the Site to ensure that the Site remains protective of public health and the environment. In the case of this Site, EPA will conduct a Five-Year Review in the year of 2005. As explained below, the Site meets the NCP's deletion criteria (i) listed above. If new information becomes available which indicates a need for further action, EPA may initiate remedial actions. Whenever there is a significant release from a site deleted from the NPL, the site shall be restored to the NPL without the application of the Hazard Ranking System (HRS).

III. Deletion Procedures

The following procedures were used for the intended deletion of the Site:

(1) All appropriate responses under CERCLA have been implemented and no further action by EPA is appropriate; (2) The State has concurred with the proposed deletion decision; (3) A notice has been published in the local newspaper and has been distributed to appropriate federal, state, and local officials and other interested parties announcing the commencement of a 30-day dissenting public comment period on EPA's Direct Final Action to Delete; and, (4) All relevant documents have been made available for public review in the local Site information repositories. EPA is requesting only dissenting comments on the Direct Final Action to Delete.

For deletion of the Site, EPA's Regional Office will accept and evaluate public comments on EPA's Final Notice before making a final decision to delete. If necessary, the Agency will prepare a Responsiveness Summary, responding to each significant comment submitted during the public comment period. Deletion of the Site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. The NPL is designed primarily for informational purposes and to assist Agency management. As mentioned in section II of this document, § 300.425(e)(3) of the NCP states that the deletion of a Site from the NPL does not preclude eligibility for future response actions.