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).

V. 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: November 10, 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), 346(a) and 371.

2. Section 180.1207 is added to subpart D to read as follows:

§ 180.1207 N-acyl sarcosines and sodium N-acyl sarcosinates; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the following substances when used as inert ingredients (surfactants) at levels not to exceed 10% in pesticide formulations containing glyphosate:

Name	CAS Reg. No.
N-acyl sarcosines.	
N-cocoyl sarcosine mixture ...	68411-97-2
N-lauroyl sarcosine	97-78-9
N-myristoyl sarcosine	52558-73-3
N-oleoyl sarcosine	110-25-8
N-stearoyl sarcosine	142-48-3
Sodium N-acyl sarcosinates.	
N-cocoyl sarcosine sodium salt mixture	61791-59-1
N-methyl-N-(1-oxo-9-octodecenyl) glycine	3624-77-9
N-methyl-N-(1-oxododecyl) glycine	137-16-6
N-methyl-N-(1-oxooctadecyl) glycine	5136-55-0
N-methyl-N-(1-oxotetradecyl glycine	30364-51-3

[FR Doc. 99–31545 Filed 12–3–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300931; FRL–6384–1]

RIN 2070–AB78

Tetraconazole [(+/-)-2-(2,4-dichlorophenyl)-3-(1H-1,2,4-triazol-1-yl) propyl 1, 1,2,2-tetrafluoroethyl ether]; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of tetraconazole in or on sugar beets, and sugar beet-related commodities, and for secondary residues of triazole on animal commodities from livestock fed sugar beet by-products. This action is in response to EPA's granting of an emergency exemption under provisions of section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act, authorizing use of the pesticide on sugar beets. This regulation establishes maximum permissible levels for residues of tetraconazole [(+/-)-2-(2,4-dichlorophenyl)-3-(1*H*-1,2,4-triazol-1-yl) propyl 1, 1,2,2-tetrafluoroethyl ether] in the effected food commodities. The tolerances will expire and will be revoked on December 31, 2001.

DATES: This regulation is effective December 6, 1999. Objections and requests for hearings, identified by docket control number OPP–300931, must be received by EPA on or before February 4, 2000.

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'' section. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300931 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: David Deegan, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: 703–308–9358; and e-mail address: deegan.dave@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	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing 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 in the ''FOR FURTHER INFORMATION CONTACT'' section.

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'' 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–300931. 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, Crystal 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 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for residues of the fungicide tetraconazole, in or on sugar beet at 0.10 part per million (ppm), 6.0 ppm in sugar beet top, 0.20 ppm in sugar beet dried pulp, 0.30 ppm in sugar beet molasses, 0.050 ppm in milk, 0.030 ppm in cattle, meat and meat byproducts except kidney and liver, 0.20 ppm in kidney, 6.0 ppm in liver, and 0.60 ppm in fat. These tolerances will expire and are revoked on December 31, 2001. 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(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 Federal Insecticide, Fungicide, and Rodenticide Act (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 Exemption for Tetraconazole on Sugar beets and FFDCA Tolerances

The Red River Valley, shared by North Dakota and Minnesota, is the leader in U.S. sugar beet production, representing approximately 45% of planted acreage and 50% of tonnage produced annually. *Cercospora* leafspot began to present a problem to sugarbeet growers in the early 1980's. Growers at that time preferred benzimidazole fungicides (benomyl and thiophanate methyl) which were registered. Within a few years, resistance was shown to have developed toward these compounds (also, since then sugar beets was dropped from the thiabendazole label). During approximately the following 17 years, growers have employed a variety of chemical classes in the control of *C. beticola*. Triphenyltin hydroxide (Fentin Hydroxide, TPTH) provided reliable control of *cercospora* between about 1983 and 1994. In 1994, resistance was documented and use very quickly dropped off as use was no longer recommended as a sound control practice. There continues to be some limited use of the benzimidazole fungicides, but they are no longer recommended for stand-alone use, nor for more than one application per year. There are currently ethylenebisdithiocarbamate (EBDC) fungicides registered for this use (Mancozeb, maneb) that do work effectively when applied at full label rates. However, label restrictions preclude mancozeb being used for season-long control, leaving significant acreage unprotected during the final month of growth. A final alternative, copper hydroxide, is less effective than mancozeb and is not preferred or recommended. The applicants stated that without approval of the use of tetraconazole to control *cercospora* on sugar beets, losses to growers could approach and exceed 17% of net revenue. After having reviewed the submission, EPA concurs that emergency conditions exist for these states. EPA has authorized under FIFRA section 18 the use of tetraconazole on sugar beets for control of *Cercospora* leafspot in North Dakota and Minnesota.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of tetraconazole in or on sugar beets. 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 exemption 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 be revoked on December 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on sugar beets 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-setting action 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 tetraconazole meets EPA's registration requirements for use on sugar beets, or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for

registration of tetraconazole 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 North Dakota and Minnesota 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 tetraconazole, contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

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 tetraconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of tetraconazole on sugar beets at 0.10 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 tetraconazole are discussed in this unit.

B. Toxicological Endpoint

1. *Acute toxicity*. Acute Reference Dose (RfD) = 0.05 milligrams/kilogram/day (mg/kg/day). For acute dietary risk assessment, EPA used the no observed adverse effect level (NOAEL) of 5 mg/kg/day, based on decreased maternal body weight and food consumption at the lowest observed adverse effect level (LOAEL) of 22.5 mg/kg/day, from the developmental study in rats. Due to the severity of pup effects in rat reproduction study, an additional FQPA safety factor of three has been applied to the acute and chronic RfD calculations. The percent of acute and chronic RfD utilized should not exceed 33%. This risk assessment will evaluate acute dietary risk to all population subgroups.

2. *Short- and intermediate-term toxicity.* For short-term Margin of Exposure (MOE) calculations, EPA used the NOAEL of 5 mg/kg/day, based on decreased maternal body weight and food consumption at the LOAEL of 22.5 mg/kg/day, from the developmental study in rats.

For intermediate-term MOE calculations, EPA used the NOAEL of 0.8 mg/kg/day 10 ppm from the 90-day oral feeding study in rats. At the LOAEL of 4.1 mg/kg/day 60 ppm, there were increased liver weights and associated changes in liver pathology observed as minimal centrilobular hepatocyte enlargement.

3. *Chronic toxicity*. EPA has established the RfD for tetraconazole at 0.005 mg/kg/day. This RfD is based on a 2-year chronic toxicity/carcinogenicity study in rats with a NOAEL of 0.5 mg/kg/day 10 ppm and an uncertainty factor of 100 based on osseous hypertrophy of skull bones at the LOAEL of 3.9 mg/kg/day 80 ppm. Due to the severity of pup effects in the rat reproduction study, an additional FQPA safety factor of three has been applied to the acute and chronic RfD calculations. The percent of acute and chronic RfD utilized should not exceed 33%.

4. *Carcinogenicity*. Tetraconazole has not been classified with respect to carcinogenic potential by EPA. However, based on the tumorigenic results in the mouse carcinogenicity study, EPA has made an initial determination that a Q1* should be determined based on the male mouse benign liver tumors, excluding the highest dose. The Q1* is 0.037 $(mg/kg/day)^{-1}$.

C. Exposures and Risks

1. *From food and feed uses.* Because EPA has never registered any other uses of tetraconazole, there are no other tolerances for food or feed items that have been established prior to this action. The current action being taken to establish time-limited tolerances to support an authorized emergency exemption use of tetraconazole represent the total potential exposure to this chemical. Risk assessments were conducted by EPA to assess dietary exposures and risks from tetraconazole 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. The acute dietary (food only) risk assessment used the Anticipated Residue Contribution (ARC). The high-end exposure estimate (food only) of 0.002231 mg/kg/day, represents 13% of the Population Adjusted Dose (PAD) for children 1-6 years of age. This should be viewed as a partially refined risk estimate; refinement using anticipated residue values and percent crop-treated (PCT) data in conjunction with Monte Carlo analysis would result in a lower acute dietary exposure estimate.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, EPA incorporated anticipated residue values.The emergency exemption tetraconazole time-limited tolerances result in an ARC that is equivalent to the following percentages of the RfD:

	Exposure mg/kg/day	% PAD
U.S. Population (48 Contiguous States) ..	0.000068	4.0%
Hispanics	0.000097	5.7%
Non-Hispanic Blacks	0.000082	4.8%
Children (1-6 years old)	0.000153	9.0%

The subgroups listed above are: (1) The U.S. population (48 contiguous states); (2) those for children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 contiguous states).

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

2. *From drinking water.* Because tetraconazole is a new and unregistered chemical, EPA does not currently have adequate data with which to model

upper-level screening concentrations due to consumption of drinking water. Therefore, EPA is not able to determine if concentrations of residues of tetraconazole in drinking water would exceed the drinking water level of concern (DWLOC) estimates. However, because both the cancer risk and the non-cancer risk dietary estimates determined by EPA are sufficiently low that it is EPA's best scientific judgement that, for this pesticide tolerance setting action, a conclusion can be made that there is ''a reasonable certainty of no harm'' that will result from possible water-borne residues of tetraconazole. Additionally, there are no residential uses, nor any other type of currently registered use, of tetraconazole. Due to the limited amounts of exposure to residues of tetraconazole anticipated to result from this emergency exemption use, and because of the conservative nature of this risk assessment, EPA believes that any potential exposure to residues of tetraconazole from drinking water will not result in levels of exposure that exceed margins of safety identified in this risk assessment.

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 tetraconazole to exceed the RfD if the tolerances being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with tetraconazole 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. *From non-dietary exposure.* There are currently no other registered uses of tetraconazole. The only exposure to residues of tetraconazole would result from the subject emergency exemptions, and are described in detail throughout this document.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Tetraconazole is a member of the conazole class of pesticides. Other members of this class include hexaconazole, and propiconazole. All of the conazoles demonstrate carcinogenicity in animal studies. 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 tetraconazole 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, tetraconazole 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 tetraconazole 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. *Chronic risk.* Using the ARC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to tetraconazole from food will utilize 4% of the cPAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children up to 6 years of age. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to tetraconazole in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

2. *Aggregate cancer risk for U.S. population*. Tetraconazole produced statistically significant increases in male and female mouse liver adenomas and carcinomas. Based on a determination of the Q1* for this tolerance setting action only, the Q1* was determined to be 3.7 x 10^{-2} based on benign tumors in males with the exclusion of the high dose group.

The cancer risk for the U.S. population is, without adjustment, 2.5 x 10^{-6}. Because this is an emergency exemption use of tetraconazole, it is considered appropriate to divide the cancer risk by a factor of 14 [5 years for potential emergency exemption use/70 years lifetime = 1/14].

The adjusted cancer risk for the U.S. population is 1.8 x 10^{-7} and this adjusted cancer risk is below EPA's level of concern.

3. *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 tetraconazole 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 tetraconazole, 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 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 the developmental study in rats, the maternal (systemic) NOAEL was 5 mg/kg/day, based on decreased body weight and decreased food consumption at the LOAEL of 22.5 mg/kg/day. The developmental (fetal) NOAEL was 22.5 mg/kg/day, based on visceral changes, supernumerary ribs, and delayed ossification at the LOAEL of 100 mg/kg/day.

b. *Rabbits.* In the developmental toxicity study in rabbits, the maternal (systemic) NOAEL was 15 mg/kg/day, based on decreased weight gain and decreased food consumption at the LOAEL of 30 mg/kg/day. The developmental (fetal) NOAEL was 30 mg/kg/day highest dose tested (HDT).

iii. *Reproductive toxicity study*— *Rats.* In the 2-generation reproductive toxicity study in rats, the maternal (systemic) NOAEL was 0.7 mg/kg/day, based on dystocia, delayed vaginal opening, and increased liver weight at the LOAEL of 5.9 mg/kg/day. The developmental (pup) NOAEL was 0.7 mg/kg/day, based on increased time to observation of balanopreputial skin fold and liver weight at the LOAEL of 5.9 mg/kg/day. At the high dose of 35.5 mg/kg/day, there was a decrease in the mean number of live pups per litter on lactation days 0 and 4 (precull) in the presence of significant maternal toxicity.

iv. *Prenatal and postnatal sensitivity.* The toxicological data base for evaluating prenatal and postnatal toxicity for tetraconazole is complete with respect to current data requirements. Based on the developmental and reproductive toxicity studies discussed above, for tetraconazole there does appear to be an extra sensitivity for prenatal or postnatal effects. EPA has therefore concluded that, for purposes of this tolerance-setting action, the FQPA safety factor of 10 be reduced to three for both the acute and chronic dietary estimates, and be applied to all population subgroups.

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

2. *Acute risk.* The acute dietary (food only) risk assessment used the ARC. The high-end exposure estimate (food only) of 0.002231 mg/kg/day, represents 13% of the PAD for children ages 1-6 years. As stated earlier, this should be viewed as a partially refined risk estimate; refinement using anticipated residue values and PCT data in conjunction with Monte Carlo analysis would result in a lower acute dietary exposure estimate.

3. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to tetraconazole from food will utilize 9% of the RfD for children ages 1-6 years. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to tetraconazole in drinking water exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

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 tetraconazole residues.

V. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residue in sugar beet is adequately understood for the purpose of this tolerance action only. Ten-week old potted sugar beet plants in an outdoor field were treated with tetraconazole labeled with carbon-14 in the triazole ring at 100g/ha, and were then re-treated twice more at 21-day intervals. Samples of root and leaf were collected 0, 20, 41, and 76 days after the first treatment. The total radioactive residue (TRR) found in the root was always <0.01 ppm. TRRs in the leaf were 1.6, 1.9, 3.1, and 1.3 ppm, respectively. Over 90% of the TRR in beet leaf was extractable. The main residue was identified as tetraconazole, declining from 94-95% TRR (day 0 and 20) to 81% on day 41 and 54% on day 76. The TRR in the root was not characterized. The residue of concern is the parent compound, tetraconazole, in beet root and leaf.

The nature of the residue in the goat is adequately understood for the purpose of this tolerance action only. Upon dosing a lactating goat for 5 consecutive days with radiolabled tetraconazole (in phenyl and triazole rings), liver retained the highest radioactivity and muscle contained the lowest radioactivity. Tetraconazole was found to be the major residue in the liver and fat, and triazole was the major residue in milk, muscle and kidney.

B. Analytical Enforcement Methodology

An enforcement method for sugar beet and livestock commodities is not available. However, a method for measuring tetraconazole in beet root and top is available (MRID 44751314), and for measuring tetraconazole in livestock commodities is available (MRID 44751316). The registrant needs to conduct independent laboratory validation before these methods can be tested in EPA laboratories as enforcement methods.

To request information on the above referenced measuring methods, please contact: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

C. Magnitude of Residues

Residues of tetraconazole are not expected to exceed 6.0 ppm in sugar beet top, 0.10 ppm in roots, 0.20 ppm in dry pulp, 0.30 ppm in molasses, and 0.012 ppm in refined sugar as a result of the authorized emergency exemption use. Time-limited tolerances should be established on sugar beet top, root, pulp, and molasses.

Sugar beet tops, dry pulp, and molasses may be fed to cattle as a result of the authorized use. Secondary residues in animal commodities are not expected to exceed 0.050 ppm in milk, 6.0 ppm in liver, 0.60 ppm in fat, 0.20 ppm in kidney, and 0.030 ppm in muscle of cattle as a result of use authorized under these emergency exemptions. Time-limited tolerances should be established at these levels on milk, meat, meat byproducts, kidney, liver, and fat of cattle.

D. International Residue Limits

There are no CODEX MRLs, Canadian or Mexican tolerances established.

E. Rotational Crop Restrictions

Crops other than sugar beet should not be grown within 120 days following the last application of tetraconazole.

VI. Conclusion

Therefore, the tolerances are established for residues of tetraconazole in sugar beet roots at 0.10 ppm, 6.0 ppm in sugar beet top, 0.20 ppm in sugar beet dried pulp, 0.30 ppm in sugar beet molasses, 0.050 ppm in milk, 0.030 ppm in cattle meat and meat byproducts except kidney and liver, 0.20 ppm in cattle kidney, 6.0 ppm in cattle liver, and 0.60 ppm in cattle fat.

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–300931 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 February 4, 2000.

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, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Room M3708, 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, 401 M St., SW., 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, 401 M St., SW., 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. of this preamble, 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. of this preamble. Mail your copies, identified by the docket number OPP–300931, 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 or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. of this preamble. 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 5.1/6.1 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 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 General Accounting Office

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: November 4, 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. 346a, 321(q) and 371.

2. Section 180.557 is added to read as follows:

§ 180.557 Tetraconazole; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the fungicide tetraconazole [(+/-)-2-(2,4-dichlorophenyl)-3-(1*H*-1,2,4-triazol-1-yl) propyl 1, 1,2,2-tetrafluoroethyl ether] in connection with the use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and be revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Beet, sugar, dried pulp.	0.20	12/31/01
Beet, sugar, molasses.	0.30	12/31/01
Beet, sugar, roots.	0.10	12/31/01
Beet, sugar, tops.	6.0	12/31/01
Cattle, fat	0.60	12/31/01
Cattle, kidney	0.20	12/31/01
Cattle, liver	6.0	12/31/01
Cattle, meat	0.030	12/31/01
Cattle, meat byproducts; except kidney and liver.	0.030	12/31/01
Milk	0.050	12/31/01

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

(d) *Indirect or inadvertent residues.* [Reserved]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–6483–6]

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

AGENCY: Environmental Protection Agency.

ACTION: Notice of deletion of the Baxter/Union Pacific Railroad Tie Treating Site, Laramie, Wyoming from the National Priorities List (NPL).

SUMMARY: The U.S. Environmental Protection Agency (EPA) announces the deletion of the Baxter/Union Pacific Railroad Tie Treating Site (Site) in Laramie, Wyoming, from the National Priorities List (NPL). The NPL is appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substance Contingency Plan (NCP), promulgated by EPA pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. EPA, in consultation with the State of Wyoming, has determined that the Site meets the criteria of the Resource Conservation and Recovery Act (RCRA) Deferral Policy, making it eligible for delisting pursuant to § 300.425 of the NCP. The Site is currently being addressed under RCRA, with permits and orders in place to ensure Site contamination is cleaned up.

EFFECTIVE DATE: December 6, 1999.

FOR FURTHER INFORMATION CONTACT: Dennis Jaramillo, U.S. Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Mail code: 8ENF–T, Denver, CO 80202, telephone (303) 312–6203.

SUPPLEMENTARY INFORMATION: The Site to be deleted from the NPL is: The Baxter/Union Pacific Railroad Tie Treating Plant Site, in Laramie, Wyoming.

A Notice of Intent to Delete for this Site was published on September 23, 1999 (64 FR 51496). The closing date for comments on the Notice of Intent to Delete was October 26, 1999. Five comments were received during the comment period, all in support of the proposed deletion. In response, EPA would like to thank all those who commented. EPA now publishes this Notice of Deletion as the final step in removing the site from the NPL.

EPA identifies sites that present a significant risk to public health and the environment and maintains the NPL as