Commodity	Parts per million
Vegetable, leafy, except Brassica, group 4	5.0

(b) *Section 18 emergency exemptions.* [Reserved]

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

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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0277; FRL–7679–4]

Thifensulfuron Methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of thifensulfuron methyl in or on canola, seed; cotton, gin byproducts; cotton, undelinted seed; and flax, seed. E. I. DuPont de Nemours & Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). In addition, this regulatory action is part of the tolerancere assessment requirements of section 408 (q) of the Federal Food, Drug, and Cosmetic Act (FFDCA) 21 U. S. C. 346a (q), as amended by the Food Quality Protection Act (FQPA) of 1996. By law, EPA is required to reassess 100% of the tolerances in existence on August 2, 1996, by August 2006. This regulatory action will count for 10 reassessments toward the August 2006 deadline.

DATES: This regulation is effective September 17, 2004. Objections and requests for hearings must be received on or before November 16, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0277. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: James A. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of July 7, 2004 (69 FR 40920) (FRL–7364–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F6152) by E.I. DuPont de Nemours and Company, DuPont Agricultural Products, Barley Mill Plaza, Wilmington, DE 19880–0038. The petition requested that 40 CFR 180.439 be amended by establishing a tolerance for residues of the herbicide thifensulfuron methyl, (methyl-3-[[[[(4-methoxy-6-methyl-1, 3, 5, -triazin-2-yl)amino]carbonyl]amino]sulfonyl]-2-thiophenecarboxylate), in or on imazethapyr tolerant canola seed at 0.02 parts per million (ppm), cotton seed at 0.02 ppm, cotton gin trash at 0.02 ppm, and CDC triffid flax at 0.02 ppm. That notice included a summary of the petition prepared by E. I. DuPont de Nemours & Company, the registrant. There were no comments received in response to the notice of filing.

During the course of the review the Agency decided to correct the Company address and correct the listings for the commodities canola, cotton gin trash, cottonseed, and flax. The company address is changed to DuPont Crop Protection, Stine-Haskell Research Center, Newark, DE 19714. The listing of the commodities imazethapyr tolerant canola, cotton seed, cotton gin trash, and Crop Development Center (CDC) triffid flax are corrected to read canola, seed; cotton, gin byproducts; cotton, undelinted seed; and flax, seed; respectively.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in

residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

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 of FFDCA 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).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of thifensulfuron methyl on canola, seed at 0.02 ppm; cotton, gin byproducts at 0.02 ppm; cotton, undelinted seed at 0.02 ppm; and flax, seed at 0.02 ppm. EPA's assessment of 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 thifensulfuron methyl are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-day oral toxicity—rodents	NOAEL = 7 and 9 milligrams/kilogram/day (mg/kg/day) males and females, respectively LOAEL = 177(males) and 216(females) mg/kg/day based on decreased body weight, body weight gain and organ weight
870.3150	90-day oral toxicity—non-rodents	NOAEL = 37.5 mg/kg/day LOAEL = 187.5 mg/kg/day based on decreased body weight and actual weight in high dose males
870.3700	Prenatal developmental—rodents	Maternal NOAEL = 725 mg/kg/day Maternal LOAEL = could not be determined. No overt toxicity detected in dose tested Developmental NOAEL = 159 mg/kg/day Developmental LOAEL = 725 mg/kg/day based on decrease mean fetal body weight
870.3700	Prenatal developmental—nonrodents	Maternal NOAEL = 158 mg/kg/day Maternal LOAEL = 511 mg/kg/day based on decrease mean body weight Developmental NOAEL = 511 mg/kg/day Developmental LOAEL = could not be determined
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 175 (males) and 244 (females) mg/kg/day Parental/Systemic LOAEL = could not be determined Reproductive NOAEL = 180 (males) and 212 (females) highest dose tested (HDT) mg/kg/day Reproductive LOAEL = could not be determined Offspring NOAEL = 180 (males) and 212 (females) HDT mg/kg/day Offspring LOAEL = could not be determined
870.4100	Chronic toxicity—rodents	NOAEL = 20 (males) and 26 (females) mg/kg/day LOAEL = 120 (males) and 133 (females) mg/kg/day based on decreased body weight and body weight gain
870.4100	Chronic toxicity—dogs	NOAEL = 18.75 mg/kg/day LOAEL = 18.75 mg/kg/day based on increased liver weight in high dose males and increased thyroid/ parathyroid-to-body weight ratios in females at the high dose, and decreased body weight and body weight gain in females after week 22
870.4200	Carcinogenicity—rats	NOAEL = 20 (males) and 26 (females) mg/kg/da y LOAEL = 120 (males) and 133 (females) mg/kg/day based on decreased body weight and body weight gain No evidence of carcinogenicity
870.4300	Carcinogenicity—mice	NOAEL = 4.3 (females) and 979 (males) HDT mg/kg/da LOAEL = 750 mg/kg/day based on decrease in terminal body weights in the mid and high dose female mice. LOAEL could not be determined in males No evidence of carcinogenicity

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.5100	Gene mutation	Not mutagenic with or without metabolic activation in an *in vitro* bacterial gene mutation assay using *Salmonella typhimurium*
870.5300	Cytogenetics	Not mutagenic in the *in vitro* CHO/HPRT at concentrations up to 2,712 mg/L in Chinese hamster ovary cells
870.5375	Chromosomal aberrations	Did not induce cytogenetic damage in the bone marrow cells at a dose of 5,000 mg/kg
870.7485	Metabolism and pharmacokinetics	In the rat metabolism study most of the radioactivity (triazine 2-^{14}C was recovered in the urine and feces with almost tissue and carcass accumulation of radioactivity. Of the radioactivity eliminated in the urine and feces, most was parent compound with 5 minor metabolites

B. 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 level of concern (LOC). 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 intraspecies differences.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the '' default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). 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 thifensulfuron methyl used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR THIFENSULFURON METHYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13-50 years of age)	NOAEL = 158.9 mg/kg/day UF = 100 Acute RfD = 1.59 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD/ Special FQPA SF = 1.59 mg/kg/day	Developmental oral toxicity study in rats LOAEL = 725 mg/kg/day based on decreased mean fetal body weight and increase in the incidence of small renal papillae.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR THIFENSULFURON METHYL FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Chronic Dietary (All populations)	NOAEL= 20 mg/kg/day UF = 100 Chronic RfD = 0.20 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD/ Special FQPA SF = 0.20 mg/kg/day	Combined chronic/carcinogenicity oral toxicity in rats LOAEL = 120 (males) mg/kg/day based on decrease body weight and body weight gain.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.439) for the residues of thifensulfuron methyl, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from thifensulfuron methyl 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.

Dietary exposure estimates were conducted using the Lifeline model (Version 2.0) which incorporates consumption data from the USDA Continuing Surveys of Food Intakes by Individuals (CSFII), 1994–1996 and 1998. The 1994–1996, 1998 data are based on reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods as consumed are linked to EPA-defined food commodities using publicly available recipe translation files (developed jointly by USDA/ARS and EPA). Lifeline models individual dietary exposures over a season by selecting a new CSFII diary each day from a set of similar individuals, based on age and season attributes. Further information regarding the Lifetime model can be found at the following web site: *http://www.LifelineTMgroup.org.*

The following assumptions were used for the acute exposure assessments: Tolerance level residues, 100% crop treated (CT), and default processing factors. Percent crop treated (PCT) or anticipated residues were not used.

ii. *Chronic exposure.* Dietary exposure estimates were conducted using the Lifeline model (Version 2.0) which incorporates consumption data from the USDA Continuing Surveys of Food Intakes by Individuals (CSFII), 1994–1996 and 1998. The 1994–1996, 1998 data are based on reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods as consumed are linked to EPA-defined food commodities using publicly available recipe translation files (developed jointly by USDA/ARS and EPA). Lifeline models individual dietary exposures over a season by selecting a new CSFII diary each day from a set of similar individuals, based on age and season attributes. The Lifeline chronic dietary exposure estimate is based on an average daily exposure from a profile of 1,000 individuals over a one year period. Further information regarding the Lifetime model can be found at the following web site: *http://www.LifelineTMgroup.org.*

The following assumptions were used for the chronic exposure assessments: Tolerance level residues, 100% crop treated (CT), and default processing factors were used. Percent crop treated (PCT) or anticipated residues were not used.

iii. *Cancer.* Thifensulfuron methyl has no carcinogenic potential. It is classified as not likely to be carcinogenic to humans based on the lack of evidence of carcinogenicity in both the rat and the mouse studies. Therefore, a cancer risk quantitative assessment was not 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 thifensulfuron methyl 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 thifensulfuron methyl.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used 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 thifensulfuron methyl they are further discussed in the aggregate risk sections in Unit.III.E.

Based on the FIRST and SCI-GROW models, the EECs of thifensulfuron methyl for acute exposures are estimated to be 0.331 to 4.358 part per billion (ppb) for surface water and 0.00002 to 0.0003 ppb for ground water. The EECs for chronic exposures are estimated to be 0.047 to .618 ppb ppb for surface water and 0.00002 to 0.0003 ppb for ground water.

3. *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).

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

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to thifensulfuron methyl and any other substances and thifensulfuron methyl 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 thifensulfuron methyl 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 policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA 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 on toxicity and exposure unless EPA determines based on reliable data 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. The developmental rabbit and two generation reproductive toxicity studies suggest that there is no evidence of increased quantitative or qualitative susceptibility of the offspring after in utero or post-natal exposure to thifensulfuron methyl. However, the acceptable developmental toxicity study in rats revealed increased quantitative susceptibility of the fetus after in utero exposure. There are no residual uncertainties for pre and/ post natal toxicity because the developmental NOAEL serves as the basis for the acute dietary RfD. This RfD includes an uncertainty factor of 100 and adequately addresses the concern for residual uncertainty with the need for an additional FQPA factor.

3. *Conclusion*. There is a complete toxicity data base for thifensulfuron methyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The impact of thifensulfuron methyl on the nervous system has not been specifically evaluated in neurotoxicity studies. However, no neuropathology or neurotoxicity was seen in either acute, subchronic, chronic, or reproductive studies, and there are no concerns from potential developmental neurotoxicity. Therefore, neurotoxicity data are not required for thifensulfuron methyl. EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is removed because of the completeness of the toxicity and exposure database, because are no residual uncertainties for pre and/ post natal toxicity and because there are no concerns for potential developmental neurotoxicity.

E. 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 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 + residential 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 EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/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 ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide 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 residues of the pesticide in 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 thifensulfuron methyl will occupy <1% of the aPAD for the U.S. population, <1 % of the aPAD for females 13 years and older, <1% of the aPAD for all infants less than one year old, and <1% of the aPAD for for children 1–2 years old. In addition, there is potential for acute dietary exposure to thifensulfuron methyl in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO THIFENSULFURON METHYL

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppt)	Acute DWLOC (ppb)
U.S. Population	0.000514	<1	4.358	.0003	5,6000
All infants (<1 year old	0.000824	<1	4.358	.0003	16,000
Children 1–2 years old	0.000959	<1	4.358	.0003	16,000
Children 37–5 years old	0.000904	<1	4.358	.0003	16,000
Females 13–59 years old	0.000487	<1	4.358	.0003	48,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to thifensulfuron methyl from food will utilize <1 % of the cPAD for the U.S. population, <1% of the cPAD for all infants less than 1 year old, and <1% of the cPAD for children 3–5 years old. There are no residential uses for thifensulfuron methyl that result in chronic residential exposure to thifensulfuron methyl. In addition, there is potential for chronic dietary exposure to thifensulfuron methyl in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO THIFENSULFURON METHYL

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.000203	<1	.618	.0003	7,000
All Infants <1 year old	0.000240	<1	.618	.0003	2,000
Children 1–2 years old	0.000410	<1	.618	.0003	2,000
Children 3–5 years old	0.000466	<1	.618	.0003	2,000
Females 13–49 years old	0.000206	<1	.618	.0003	6,000

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).

Thifensulfuron methyl 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 do not exceed the Agency's level of concern.

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

Thifensulfuron methyl 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 do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Thifensulfuron methyl has no carcinogenic potential. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

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 thifensulfuron methyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology including liquid chromatography with a photoconductivity detector and high-performance liquid chromatography with UV detector (HPLC/UV) are available for enforcement of the reassessed tolerances. These methods are published in PAM II.

Adequate enforcement methodology liquid chromatography with detection via electospray mass spectoscopy (LC/MS) is available to enforce the tolerance expression for canola, flax, and cotton. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are currently no Codex maximum residue limits (MRLs) for thifensulfuron methyl, therefore no questions of compatibility exist. Mexico has established tolerances on wheat and barley at 0.05 ppm. Canada has established tolerances for tomato at 0.07 ppm, flax at 0.02 ppm, and canola at 0.02 ppm. the established Mexican tolerances for wheat and barley are compatible with the reassessed tolerances on barley, grain, and wheat, grain. Canadian MRLs on flax and canola are compatible with the proposed tolerances of canola, seed and flax, seed.

C. Conditions

There are no conditions of registration for either the reassessed tolerances or the tolerances for canola, cotton, and flax.

V. Conclusion

Therefore, the tolerance is established for residues of thifensulfuron methyl,

methyl-3-[[[[(4-methoxy-6-methyl-1, 3, 5, -triazin-2-yl)amino]carbonyl]amino]sulfonyl]-2-thiophenecarboxylate, in or on canola, seed at 0.02 ppm; cotton, gin byproducts at 0.02 ppm; cotton, undelinted seed at 0.02 ppm; and flax, seed at 0.02 ppm. This action results in the reassessment of 10 tolerances as follows: barley, grain at 0.05 ppm; barley, straw at 0.1 ppm; oat grain at 0.05 ppm; oat, straw at 0.1 ppm; soybean at 0.1 ppm; wheat, grain at 0.05 ppm; wheat, straw at 0.1 ppm and also three corn tolerances (corn, field, forage at 0.1 ppm; corn, field, grain at 0.05 ppm; and corn, field, stover at 0.10 ppm) which were inadvertently removed from 40 CFR 180. 439. On May 12, 2004 (69 FR 26348) (FRL–7358–5), EPA proposed to reinstate the three corn tolerances for thifensulfuron methyl in 40 CFR 180.439. In the near future, EPA intends to publish the reinstatement of the corn tolerances for thifensulfuron methyl in the **Federal Register**.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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 ID number OPP–2004–0277 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 November 16, 2004.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0277, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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 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).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or 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 petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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: September 10, 2004.

Lois Rossi,

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 180.439 is revised to read as follows:

§ 180.439 Thifensulfuron methyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide thifensulfuron methyl (methyl-3-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino] carbonyl] amino] sulfonyl]-2-thiophene carboxylate) in or on the following raw agricultural commodities:

Commodity	
Barley, grain	0.05
Barley, straw	0.10
Canola, seed	0.02
Cotton, gin byproducts	0.02
Cotton, undelinted seed	0.02
Flax, seed	0.02
Oat, grain	0.05
Oat, straw	0.10
Soybean	0.10
Wheat, grain	0.05
Wheat, straw	0.10

(b) *Section 18 emergency exemptions.* [Reserved]

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

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

[FR Doc. 04–20983 Filed 9–16–04; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 2

[ET Docket No. 03–201; FCC 04–165]

Unlicensed Devices and Equipment Approval

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction.

SUMMARY: On September 7, 2004 (69 FR 54027), the Commission published final rules in the Report and Order, which amended the rules for unlicensed devices and equipment approval. This document contains a correction to § 2.948(a)(2), which was inadvertently published incorrectly.

DATES: Effective October 7, 2004.

FOR FURTHER INFORMATION CONTACT: Neal McNeil, Office of Engineering and Technology, (202) 418–2408, TTY (202) 418–2989, e-mail: *Neal.McNeil@fcc.gov*.

SUPPLEMENTARY INFORMATION: The Federal Communications Commission published a document amending parts 2 and 15 of the Commission's rules in the **Federal Register** of September 7, 2004 (69 FR 54027). This document corrects the **Federal Register** as it appeared.

In FR Doc. 04–19745, published on September 7, 2004 (69 FR 54027), the Commission is correcting § 2.948(a)(2).

PART 2—[CORRECTED]

■ In rule FR Doc. 04–19745 published on September 7, 2004 (69 FR 54027) make the following correction:

■ On page 54033, in the third column correct § 2.948(a)(2) to read as follows:

§ 2.948 Description of measurement facilities.

(a) * * *

(2) If the equipment is to be authorized by the Commission under the certification procedure, the description of the measurement facilities shall be filed with the Commission's Laboratory in Columbia, Maryland. The data describing the measurement facilities need only be filed once but must be updated as changes are made to the measurement facilities or as otherwise described in this section. At least every three years, the organization responsible for filing the data with the Commission shall certify that the data on file is current. A laboratory that has been accredited in accordance with paragraph (d) of this section is not required to file a description of its facilities with the Commission's laboratory, provided the accrediting organization (or designating authority in the case of foreign laboratories) submits the following