

seq., 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).

Since tolerances and exemptions that are established in accordance with sections 408(e) and 408(l)(6) 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

**VIII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: April 1, 2010.

**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 180.614 is amended by revising paragraph (b) to read as follows:

**§ 180.614 Kasugamycin; tolerances for residues.**

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of kasugamycin, 3-O-[2-amino-4-[(carboxyiminomethyl)amino]-2,3,4,6-tetraoxy- $\alpha$ -D-arabino-hexopyranosyl]-D-chiro-inositol in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Apple	0.05	12/31/12

\* \* \* \* \*

[FR Doc. 2010-8133 Filed 4-13-10; 8:45 am]

**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2009-0134; FRL-8818-9]**

**Thifensulfuron methyl; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of thifensulfuron methyl in or on safflower, seed. Interregional Research Project Number 4

(IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective April 14, 2010. Objections and requests for hearings must be received on or before June 14, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0134. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6463; e-mail address: [madden.barbara@epa.gov](mailto:madden.barbara@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 those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide 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 Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/oppts> and select "Test Methods and Guidelines."

#### *C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0134 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before June 14, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2009-0134, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

#### **II. Petition for Tolerance**

In the **Federal Register** of April 8, 2009 (74 FR 15971) (FRL- 8407-4), 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 9F7523) by IR-4, 500 College Rd. East, Suite 201 W, Princeton, NJ 08540. 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 safflower, seed at 0.05 parts per million (ppm). That notice referenced a summary of the petition prepared on behalf of IR-4 by E.I. DuPont de Nemours, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

#### **III. Aggregate Risk Assessment and Determination of Safety**

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...."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in

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 for the petitioned-for tolerance for residues of thifensulfuron methyl on safflower seed at 0.05ppm. EPA's assessment of exposures and risks associated with thifensulfuron methyl 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.

Thifensulfuron methyl has mild to low acute toxicity when administered via the oral, inhalation and dermal routes of exposure. It has moderate to low toxicity with respect to eye and skin irritation and is not a dermal sensitizer. Most findings in the submitted studies related to decreases in body weights, body weight gains, or organ weights (a reflection of the lower body weights compared with control weights). There were increased liver weights in male dogs and increased thyroid/parathyroid weights in female dogs. There were no gross or histopathological changes reported in any of the studies.

In the rat developmental study, there were no maternal effects at the highest dose tested (HDT). The rabbit developmental study showed a decrease in maternal body weights at the HDT. There were no developmental effects at the HDT. In the 2-generation rat reproduction study there were no parental, reproductive or offspring effects. There was an increase in quantitative susceptibility in the rat developmental study, based on decreased mean fetal body weights, and an increase in the incidence of small renal papillae (only at the highest dose level).

Thifensulfuron methyl is classified as "not likely to be carcinogenic to humans," based on acceptable chronic/carcinogenicity studies in rats and mice at doses that are considered to be adequate, and not excessive for the determination of carcinogenic potential. The available mutagenicity studies *in vivo* and *in vitro* show that thifensulfuron methyl is neither mutagenic nor clastogenic.

Neurotoxicity was not observed in the submitted guideline studies. There were

no acute or subchronic neurotoxicity studies available for review. There were also no immunotoxicity studies submitted for review. Immunotoxicity was observed as a decrease in spleen weight in the subchronic rat study. However, this effect was only noted in males, and only at the mid-level dose of 177 mg/kg. The lack of response at the high-level dose, the occurrence in a single sex, the availability of a clear NOAEL, and the absence of immunotoxic effects in the remainder of the database reduce EPA's concern for immunotoxicity.

Specific information on the studies received and the nature of the adverse effects caused by thifensulfuron methyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document "Thifensulfuron Methyl.

Human Health Risk Assessment for the Proposed Food/Feed Use of the Herbicide (Associated with Regional Section 3 Registration) on Safflower," pp. 9-10 in docket ID number EPA-HQ-OPP-2009-0134.

*B. Toxicological Points of Departure/ Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest

dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level – generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) – and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for thifensulfuron methyl used for human risk assessment is shown in the table of this unit.

TABLE —SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THIFENSULFURON METHYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/ Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13 - 50 years of age)	NOAEL = 159 milligrams/kilograms/day (mg/kg/day) UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Acute RfD = 1.59 mg/kg/day aPAD = 1.59 mg/kg/day	Developmental Oral Toxicity-Rat. LOAEL = 725 mg/kg/day based on decreased mean body weight and increased incidence of small renal papillae
Acute dietary (General population including infants and children)	Not applicable.		There were no single dose effects appropriate for acute exposure assessment for the general population.
Chronic dietary (All populations)	NOAEL= 4.3 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF 1x	Chronic RfD = 0.043 mg/kg/day cPAD = 0.043mg/kg/day	Carcinogenicity oral toxicity in mice. LOAEL = 128 mg/kg/day based on decreased body weight and body weight gain.
Cancer (Oral)	Not likely to be a human carcinogen, based on the lack of evidence of carcinogenicity in rats and mice.		

UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). UF<sub>L</sub> = use of a LOAEL to extrapolate a NOAEL. UF<sub>S</sub> = use of a short-term study for long-term risk assessment. UF<sub>DB</sub> = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to thifensulfuron methyl, EPA considered exposure under the petitioned-for tolerance as well as all existing thifensulfuron methyl tolerances in 40 CFR 180.439. EPA assessed dietary exposures from thifensulfuron methyl in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and 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. No such effect was identified for thifensulfuron methyl for the general population. However, EPA identified potential acute effects (decreased mean body weight, and increased incidence of small renal papillae) from pre-natal exposure and thus is assessing exposure and risk for the population subgroup, females 13 – 49 years old.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels

in food, EPA used tolerance-level residues, DEEM default processing factors for all processed commodities and assumed 100 percent crop treated (PCT) for all commodities covered by existing or proposed tolerances.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used tolerance-level residues, DEEM default processing factors for all processed commodities and assumed 100 PCT for all commodities covered by existing or proposed tolerances.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has classified thifensulfuron methyl as “not likely to be carcinogenic to humans”. Therefore, a quantitative exposure assessment to evaluate cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue or PCT information in the dietary assessment for thifensulfuron methyl. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for thifensulfuron methyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of thifensulfuron methyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of thifensulfuron methyl for acute exposures are estimated to be 4.429 parts per billion (ppb) for surface water and 0.0972 ppb for ground water and for chronic exposures for non-cancer assessments are estimated to be 1.5 ppb for surface water and .0972 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 4.429 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 1.5 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Thifensulfuron methyl is not registered for any specific use patterns 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.”

EPA has not found thifensulfuron methyl to share a common mechanism of toxicity with 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 assumed that thifensulfuron methyl does not have 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 EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

#### D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicology database for thifensulfuron methyl includes rat and rabbit prenatal developmental toxicity studies and a 2-generation reproduction toxicity study in rats. There was evidence of increased quantitative susceptibility in the rat developmental toxicity study. At the HDT, decreased mean fetal weights, and an increase in incidence of small renal papillae were observed in the absence of maternal toxicity. There was no indication of pre- or post-natal susceptibility in the rabbit developmental or rat reproduction studies.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for thifensulfuron methyl is complete except for immunotoxicity, acute neurotoxicity and subchronic neurotoxicity testing. Recent changes to

40 CFR part 158 make acute and subchronic neurotoxicity testing (OPPTS Guideline 870.6200) and immunotoxicity testing (OPPTS Guideline 870.7800) required for pesticide registration; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA.

Neurotoxicity was not observed in any of the studies up to the HDT, nor is there any expectation of neurotoxicity based on the mechanism of action. Furthermore, the toxicity database for thifensulfuron methyl does not indicate that the immune system is the primary target organ. Immunotoxicity was observed as a decrease in spleen weight in the subchronic rat study. However, this effect was only noted in males, and only at the mid-level dose of 177 mg/kg. The lack of response in the high-level dose, the occurrence in a single sex, the availability of a clear NOAEL, and the absence of immunotoxic effects in the remainder of the database reduces EPA’s concern for immunotoxicity. The overall weight of evidence suggests that thifensulfuron methyl does not directly target the immune system, and this finding (decrease in spleen weight) may be due to secondary effects of a primary toxicity. Therefore, the Agency does not believe that conducting the acute and subchronic neurotoxicity, and the immunotoxicity studies will result in a lower point of departure than the currently selected endpoints for overall risk assessment, and therefore, a database uncertainty factor is not needed to account for the lack of these studies.

ii. There is no indication that thifensulfuron methyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is evidence that thifensulfuron methyl results in increased susceptibility in *in utero* rats in the prenatal developmental studies and in young rats in the 2-generation reproduction study; therefore, a degree of concern analysis was performed to determine the level of concern for the effects observed when considered in the context of all available toxicity data and to identify any residual concerns after establishing toxicity endpoints and traditional UF’s to be used in the thifensulfuron methyl risk assessment. In considering the overall toxicity profile and the endpoints and doses selected for the thifensulfuron methyl risk assessment, EPA characterized the degree of concern for the susceptibility observed in the rat developmental and

2-generation reproductive studies as low and determined that there are no residual uncertainties for prenatal and/or postnatal toxicity because:

a. The only missing toxicity data for thifensulfuron methyl are the newly required neurotoxicity and immunotoxicity studies; however, no additional UF is needed in the absence of these studies because there is no evidence to indicate that thifensulfuron methyl targets the nervous system or the immune system. Further, EPA has concluded a developmental neurotoxicity study is not required.

b. There are clear NOAELs and LOAELs for the developmental and offspring effects noted in the rat developmental toxicity and in the 2-generation reproduction toxicity studies and the doses and endpoints have been selected from these studies for risk assessment for the relevant exposed populations, i.e., pregnant females and children.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on conservative assumptions, including 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to thifensulfuron methyl in drinking water. These assessments will not underestimate the exposure and risks posed by thifensulfuron methyl.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to thifensulfuron methyl will occupy less than 1% of the aPAD for females (ages 13 – 49), the population subgroup receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to thifensulfuron methyl from food and water will utilize 1% of the cPAD for children (ages 3 –

5), the population subgroup receiving the greatest exposure. There are no residential uses for thifensulfuron methyl.

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

A short and intermediate-term adverse effect was identified; however, thifensulfuron methyl is not registered for any use patterns that would result in short or intermediate-term residential exposure. Short and intermediate-term risk is assessed based on short and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the point of departure used to assess short and intermediate-term risk), no further assessment of short or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short and intermediate-term risk for thifensulfuron methyl.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, thifensulfuron methyl is not expected to pose a cancer risk to humans.

5. *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, or to infants and children from aggregate exposure to thifensulfuron methyl residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

The following adequate enforcement methodology is available to enforce the tolerance expression: Two High Pressure Liquid Chromatography (HPLC) photo-conductivity detection methods. The methods 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](mailto:residuemethods@epa.gov).

##### *B. International Residue Limits*

There are no CODEX, Canadian or Mexican maximum residue limits (MRLs) established for residues of thifensulfuron methyl on safflower.

##### *C. Revisions to Petitioned-For Tolerances*

EPA revised the tolerance expression in paragraph (a) to clarify:

1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of thifensulfuron methyl not specifically mentioned; and

2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

#### **V. Conclusion**

Therefore, a 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 safflower, seed at 0.05 ppm.

#### **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by

Congress in the preemption provisions of section 408(n)(4) of FFDCFA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

## VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: April 1, 2010.

**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. In § 180.439, revise paragraph (a) introductory text and paragraph (c) to read as follows:

#### § 180.439 Thifensulfuron methyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of thifensulfuron methyl, including its metabolites and degradates, in or on the commodities listed in the following table [below]. Compliance with the tolerance levels specified in the following table [below] is to be determined by measuring only thifensulfuron methyl (methyl 3-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino] sulfonyl]-2-thiophenecarboxylate).

(c) *Tolerances with regional registrations.* Tolerances are established for residues of thifensulfuron methyl, including its metabolites and degradates, in or on the commodities listed in the following table [below]. Compliance with the tolerance levels specified in the following table [below] is to be determined by measuring only thifensulfuron methyl (methyl 3-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino] sulfonyl]-2-thiophenecarboxylate).

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

[FR Doc. 2010-8135 Filed 4-13-10; 8:45 am]

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## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 2, 90, and 95

[WP Docket No. 07-100, FCC 10-36]

#### PLMR Licensing; Frequency Coordination and Eligibility Issues

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** In this document, the Federal Communications Commission (Commission) considers rule changes to certain of its rules that were addressed in a previous decision in this proceeding. In that decision, the Commission proposed various changes to its rules regarding PLMR licensing, including frequency coordination and eligibility issues. This proceeding is part of our continuing effort to provide clear and concise rules that facilitate new

wireless technologies, devices and services, and are easy for the public to understand.

**DATES:** Effective May 14, 2010.

#### FOR FURTHER INFORMATION CONTACT:

Rodney P. Conway, at [Rodney.Conway@FCC.gov](mailto:Rodney.Conway@FCC.gov), Wireless Telecommunications Bureau, (202) 418-2904, or TTY (202) 418-7233.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's *Second Report and Order* ("Second R&O") in WP Docket No. 07-100, FCC 10-36, adopted on March 3, 2010, and released March 10, 2010. In a *Notice of Proposed Rulemaking and Order (NPRM and Order)* published at 72 FR 32582, June 13, 2007, in this proceeding, the Commission proposed various changes to its rules regarding PLMR licensing, including frequency coordination and eligibility issues. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street, SW., Washington, DC 20554. The complete text may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC 20554. The full text may also be downloaded at: <http://www.fcc.gov>. Alternative formats are available to persons with disabilities by sending an e-mail to [fcc504@fcc.gov](mailto:fcc504@fcc.gov) or by calling the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

1. Part 90 contains the rules for both the Private Land Mobile Radio (PLMR) Services and certain Commercial Mobile Radio Services (CMRS). PLMR licensees generally do not provide for-profit communications services. Some examples of PLMR licensees are public safety agencies, businesses that use radio only for their internal operations, utilities, transportation entities, and medical service providers. CMRS licensees, by comparison, do provide for-profit communications services, such as paging and Specialized Mobile Radio services that offer customers communications that are interconnected to the public switched network.

2. *Frequency Coordination and Related Matters.* Applications for new and modified part 90 stations generally require frequency coordination before the application is submitted to the Commission, but certain types of applications are exempt from the frequency coordination requirement because they do not "have an impact on near-term frequency selections." The *NPRM* sought comment on whether to permit licensees to forgo frequency