<table>
<thead>
<tr>
<th>Rule Number</th>
<th>Effective Date</th>
<th>EPA Approval Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix A, Hazardous Air Pollutants—Section 112(b) of the Clean Air Act.</td>
<td>2/18/11</td>
<td>8/29/12</td>
<td></td>
</tr>
</tbody>
</table>
your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0564, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http://www.epa.gov/dockets/contacts.htm.

II. Summary of Petitioned-for Tolerance

In the Federal Register of August 26, 2011 (76 FR 53372) (FRL–8884–9), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7885) by IR–4, 500 College Rd. East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.439 be amended to reflect the results of the studies submitted in support of this action. EPA reviewed the available scientific data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Thifensulfuron methyl has mild to moderate irritation and is not a dermal sensitiser. 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.

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 following Table.

### TABLE—SUMMARY OF TOXICOLOGICAL DOES AND ENDPOINTS FOR THIFENSULFURON METHYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT

<table>
<thead>
<tr>
<th>Exposure/Scenario</th>
<th>Point of departure and uncertainty/safety factors</th>
<th>RID, PAD, LOC for risk assessment</th>
<th>Study and toxicological effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dietary .......... (Females 13–50 years of age).</td>
<td>NOAEL = 159 mg/kg/day .... UF = 10X NOAEL = 4.3 mg/kg/day .... UF = 10X FQPA SF = 1X</td>
<td>aRfD = 1.59 mg/kg/day .... aPAD = 1.59 mg/kg/day</td>
<td>Developmental oral toxicity in rats. LOAEL = 725 mg/kg/day, based on an increased incidence of small renal papillae. Carcinogenicity oral toxicity in mice. LOAEL = 128 mg/kg/day, based on decreased body weight and body weight gain.</td>
</tr>
<tr>
<td>Chronic dietary .......... (All populations)</td>
<td>cUF = 10X cUF = 10X FQPA SF = 1X</td>
<td>cRfD = 0.043 mg/kg/day .... cPAD = 0.043 mg/kg/day</td>
<td></td>
</tr>
</tbody>
</table>

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RID = reference dose. UF = uncertainty factor. UF = extrapolation from animal to human (interspecies). UF = potential variation in sensitivity among members of the human population (intraspecies).

### 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 tolerances 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.

   Such effects were identified for thifensulfuron methyl. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance level residues for all commodities.

   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 assumed 100 PCT and tolerance level residues for all commodities.

   iii. **Cancer.** Based on the data summarized in Unit III.A., EPA has concluded that thifensulfuron methyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing 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. For chronic exposures for non-cancer assessments the EDWCs are estimated to be 1.5 ppb for surface water and 0.0972 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, termicidces, 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 Web site 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 Food Quality Protection Act (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 toxicity 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.
   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. Although there was evidence of increased quantitative susceptibility in the rat developmental study, the Agency’s degree of concern for the increased susceptibility is low because it was only observed in the rat developmental toxicity study and not seen in the rabbit developmental or reproduction studies, and was observed at doses considerably higher than the doses chosen for risk assessment; in addition, there was a clear NOAEL for the fetal effects, and therefore EPA’s risk assessment is protective of the potential susceptibility.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 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 13–49 years old, the only population subgroup of concern.

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 1.4% of the cPAD for children 3–5 years old, the population group 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 short- and intermediate-term 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 either short- and/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- and/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 POD used to assess short- and intermediate-term risk), no further assessment of short- and 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

Adverse enforcement methodology (liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Maps Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: residuermethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for thifensulfuron methyl in or on chicory roots and/or tops.

V. Conclusion

Therefore, tolerances are established for residues of thifensulfuron methyl, methyl-3-[[[14-methoxy-6-methyl-1,3,5-triazin-2-ylamino] carbonyl]amino]
sulfonyl]-2-thiophenecarboxylate, in or on chicory roots at 0.01 ppm and chicory tops at 0.01 ppm.)

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) 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 12899, 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 FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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) (Pub. L. 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: August 17, 2012.

Daniel J. Rosenblatt,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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


2. Section 180.439 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.439 Thifensulfuron methyl; tolerances for residues.

(a) * * *

Commodity Parts per million

| * | * | * | * | *
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chicory, roots</td>
<td>0.01</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chicory, tops</td>
<td>0.01</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

EPA Acting Director, Office of Pesticide Programs.