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 established MRLs for clothianidin in/on citrus fruits at 0.07 ppm. These MRLs are the same as the tolerance established for clothianidin in/on fruit, citrus, group 10–10 in the United States. The Codex has not established any MRLs for sulfoxaflor in/on sorghum commodities.

IV. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to petitions 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 FFDCA section 408(d), such as the tolerances 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 action 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA has submitted 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 the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 20, 2017.

Michael L. Goodis,

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 § 180.586, revise the table in paragraph (b) to read as follows:

§ 180.586 Clothianidin; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ revocation date
Fruit, citrus, group 10–10	0.07	12/31/20

■ 3. In § 180.668, revise the table in paragraph (b) to read as follows:

§ 180. 668 Sulfoxaflor; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ revocation date
Sorghum, forage ...	0.4	12/31/20
Sorghum, grain	0.3	12/31/20
Sorghum, stover ...	0.9	12/31/20

* * * * *

[FR Doc. 2017–25826 Filed 12–1–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0314; FRL–9969–13]

Ethofumesate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of ethofumesate in or on beet, sugar, molasses and beet, sugar, roots. In addition, this regulation eliminates tolerances for residues of ethofumesate that are superseded by the tolerances established by this final rule. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 4, 2017. Objections and requests for hearings must be received on or before February 2, 2018, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0314, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket)

in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 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–2016–0314 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 February 2, 2018. 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 (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2016–0314, 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 CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *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.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 20, 2016 (81 FR 47150) (FRL–9948–45), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E8472) by IR–4, IR–4 Project Headquarters, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.345 be amended by increasing the existing tolerance for the combined residues of the herbicide ethofumesate (2-ethoxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate) and its metabolites (2-hydroxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate and 2,3-dihydro-3,3-dimethyl-2-oxo-5-benzofuranyl methanesulfonate) both calculated as the parent compound, in or on beet, sugar, molasses from 0.5 to 2.5 parts per million (ppm); beet, sugar, refined sugar from 0.2 to 1.0 ppm; beet, sugar, roots from 0.3 to 1.5 ppm; and beet, sugar, tops from 4.0 to 30.0 ppm. That document referenced a summary of the petition prepared by Willowood USA, LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* One comment was received on the notice of filing. EPA's response to the comment is found in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing tolerances that differ from what the petitioner requested. The reasons for these changes are explained in Unit IV.D.

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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for ethofumesate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with ethofumesate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity database 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 liver is the main target organ in rats and dogs, and the major critical effects seen in oral studies are decreased body weight/body weight gain and hepatic toxicity in the rat, dog and/or rabbit. Mice are relatively insensitive to ethofumesate up to the limit dose following subchronic and chronic dietary exposure.

Ethofumesate did not demonstrate the potential to cause neurotoxicity in four species (rats, mice, dogs and rabbits).

Rats did not show evidence of developmental, maternal, or offspring toxicity or susceptibility in a three-generation reproduction study or any developmental or maternal toxicity in the developmental toxicity study. Although increased prenatal quantitative sensitivity (increased resorptions, increased post-implantation loss and incomplete ossification of the vertebral arches) was observed in the rabbit developmental toxicity study, the developmental toxicity no observed adverse effect levels (NOAELs) and lowest observed adverse effect levels (LOAELs) are well characterized. In maternal rabbits, effects included decreased body weight, increased mortality, abortions and complete litter resorption at levels in excess of the limit dose.

Ethofumesate is classified as ''Not Likely to be Carcinogenic to Humans'', based on bioassays in the rat and the mouse, combined with a lack of *in vitro* or *in vivo* mutagenicity supported by a battery of mutagenicity studies that showed no evidence of a mutagenic effect.

Specific information on the studies received and the nature of the adverse effects caused by ethofumesate 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, ''Ethofumesate. Human Health Risk Assessment for an Amended Use on Sugar Beets'' dated October 4, 2017 at pages 33–36 in docket ID number EPA–HQ–OPP–2016–0314.

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/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for ethofumesate used for human risk assessment is shown in the Table of this unit.

TABLE SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ETHOFUMESATE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–49 years of age).	NOAEL = 30 mg/kg/day. UF_A = 10x UF_H =10x FQPA SF = 1x Total UF = 100	Acute RfD = 0.30 mg/kg/day. aPAD = 0.30 mg/kg/day	Developmental toxicity study in rabbit. Developmental LOAEL = 300 mg/kg/day based on increased resorptions, post-implantation loss and incomplete ossification of the vertebral arches.
Acute Dietary General population including infants and children.	No appropriate acute endpoint identified for the general population including infants and children.		
Chronic dietary (Females 13–49 years of age).	NOAEL = 30 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x Total UF = 100	Chronic RfD = 0.30 mg/kg/day. cPAD = 0.30 mg/kg/day.	Developmental toxicity study in rabbit. Developmental LOAEL = 300 mg/kg/day based on increased resorptions, post-implantation loss and incomplete ossification of the vertebral arches.
Chronic Dietary, General population including infants and children.	NOAEL= 127 mg/kg/day. UF_A=10 UF_H=10 FQPA SF = 1X Total UF = 100	cRfD = 1.3 mg/kg/day. cPAD = 1.3 mg/kg/day.	Chronic oral toxicity/carcinogenicity study (rat). LOAEL = 469 mg/kg/day based on decreased body weight gain in females.

TABLE SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ETHOFUMESATE FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Incidental oral short-term (1 to 30 days) & intermediate-term (1 to 6 months) Infants and children only.	NOAEL= 190 mg/kg/ day. UF_A = 10x UF_H = 10x FQPA SF = 1x Total UF = 100	Residential LOC for MOE = 100.	90-day oral toxicity study (rats). LOAEL = 1900 mg/kg/day based on based on reduced body weight gain, microscopic lesions in the liver and kidney in male rats and reduced body weight/weight gain in females.
Dermal short-term (1 to 30 days) Females 13–49 years of age.	NOAEL = 30 mg/kg/ day. Dermal absorption rate (DAF) = 27% UF_A = 10x UF_H = 10x FQPA SF = 1x Total UF = 100	LOC for MOE = 100	Developmental toxicity study (rabbits). Developmental LOAEL = 300 mg/kg/day based on increased resorptions, post-implantation loss and incomplete ossification of the vertebral arches.
Dermal short-term General population including infants and children.	NOAEL= 190 mg/kg/ day. DAF rate = 27% UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-day oral toxicity study (rats). LOAEL = 1900 mg/kg/day based on reduced body weight gain, microscopic lesions in the liver and kidney in male rats and reduced body weight/weight gain in females.
Inhalation (short and intermediate) Females 13–49 years of age.	NOAEL= 30 mg/kg/ day. Inhalation & oral toxicity considered equivalent UF_A = 10x UF_H = 10x FQPA SF = 1x Total UF = 100	LOC for MOE = 100	Developmental toxicity study (rabbits). Developmental LOAEL = 300 mg/kg/day based on increased resorptions, post-implantation loss and incomplete ossification of the vertebral arches.
Inhalation (short and intermediate term) General population including infants and children.	NOAEL = 190 ..... Inhalation & oral toxicity considered equivalent UF_A = 10x UF_H = 10x FQPA SF = 1x Total UF = 100	LOC for MOE = 100	90-day oral toxicity study (rats). LOAEL = 1900 mg/kg/day based on reduced body weight gain, microscopic lesions in the liver and kidney in male rats and reduced body weight/weight gain in females.
Cancer (Oral, dermal, inhalation).	Classification: ''Not likely to be carcinogenic to humans''.		

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). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = 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 ethofumesate, EPA considered exposure under the petitioned-for tolerances as well as all existing ethofumesate tolerances in 40 CFR 180.345. EPA assessed dietary exposures from ethofumesate 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. Because no appropriate endpoint was identified for the general population including infants and children, a quantitative acute dietary exposure assessment was not conducted for these populations. Such effects were observed for the population subgroup females 13–49 years of age.

In estimating acute dietary exposure for females 13–49 years, EPA used food consumption information from the United States Department of Agriculture (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) from 2003 through 2008. As to residue levels in food, EPA used an unrefined determination based on tolerance-level residues, 100 percent crop treated (PCT) information for all commodities, and Dietary Exposure Evaluation Model (DEEM) 7.81 default processing factors, where available.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's 2003–2008 NHANES/ WWEIA. As to residue levels in food, EPA used an unrefined determination based on 100 PCT, tolerance-level residues for all commodities, and Dietary Exposure Evaluation Model

(DEEM) 7.81 default processing factors, where available.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that ethofumesate 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 percent crop treated (PCT) information.* The Agency did not use anticipated residue data or percent crop treated estimates.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for ethofumesate in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of ethofumesate. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Tier I: First Index Reservoir Screening Tool (FIRST) and Tier II: Pesticide Root Zone Model Ground Water (PRZM GW)/PWC, the estimated drinking water concentrations (EDWCs) of ethofumesate (parent compound only) for acute exposures are estimated to be 416 parts per billion (ppb) for surface water and 750 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 123 ppb for surface water and 695 ppb for ground water.

Modeled estimates of drinking water concentrations of ethofumesate for parent compound only, were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 750 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 695 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).

Ethofumesate is currently registered for the following uses that could result in residential exposures: ornamental lawns and turf (including golf courses, parks, cemeteries, and homeowner/commercial lawns). EPA assessed residential exposure using the following assumptions: All ethofumesate products are intended for either agricultural use or require professional application for ornamental turf. Although registered products are labeled for use on home lawns, residential handler exposures are not anticipated because the label language requiring personal protective equipment (PPE) and prohibiting the use of handheld equipment indicate that the product is not intended for homeowner use. Therefore, the Agency has not conducted a residential handler assessment.

There is potential for ethofumesate residential post-application exposure for individuals exposed as a result of being in an environment that has been previously treated. Residential post-application dermal (adults and children) and incidental oral (children only) exposures are anticipated from the registered turf uses. EPA conducted screening level calculations on the scenarios most likely to result in highest possible exposure. These scenarios are:

- For children 1 to <2 years old: incidental ingestion (hand-to-mouth), incidental ingestion (turf-to-mouth), incidental ingestion (soil-to-mouth), and dermal exposure
- for adults and youths (11 to <16 years old: dermal exposure (golfing, lawn mowing, etc.).

Post-application exposures were calculated by considering the potential sources of exposure then calculating dermal and/or incidental oral exposure and risks. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

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 ethofumesate and any other substances and ethofumesate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that ethofumesate 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/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

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 Safety Factor (FQPA 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.* There are no concerns or uncertainties for pre- and/or post-natal toxicity resulting from exposure to ethofumesate. There is no evidence that ethofumesate results in increased susceptibility in *in utero* exposure to ethofumesate in the prenatal developmental study in rats. Increased pre-natal quantitative susceptibility was observed in the rabbit developmental toxicity study. The Agency concluded, however, that there is no concern that the risk assessment will not adequately safeguard against potential pre- and post-natal toxicity because the developmental toxicity NOAELs/LOAELs are well characterized and are used as endpoints for risk assessment for the appropriate population subgroups.

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 ethofumesate is sufficiently complete and adequate for characterizing potential pre- and/or post-natal risks to infants and children. Available studies supporting this decision include developmental toxicity studies in rats and rabbits, and a three-generation reproduction study in rats.

Based on all available hazard and exposure data for ethofumesate, the Agency determined that the subchronic inhalation, acute and subchronic neurotoxicity, and the immunotoxicity

studies for ethofumesate were not necessary and waived those requirements. The existing ethofumesate database is extensive and adequately sufficient to permit a full assessment of risks associated with proposed new uses under consideration.

ii. There is no indication that ethofumesate is a neurotoxic chemical. Ethofumesate did not cause clear clinical or histopathological signs of neurotoxicity in four species tested (rats, rabbits, mice and dogs) as evaluated by the current studies within the database. In addition, there was no evidence of neurotoxicity observed in the toxicity databases of chemicals in the same class as ethofumesate. Therefore, EPA is not requiring a developmental neurotoxicity study nor incorporating an additional UFs to account for neurotoxicity.

iii. There is no evidence that ethofumesate results in increased susceptibility in *in utero* exposure to ethofumesate in the prenatal developmental study in rats. No rat developmental effects were seen at the highest dose tested (limit dose of 1000 mg/kg). There is, however, quantitative evidence for increased susceptibility following *in utero* exposure to ethofumesate in an adequate developmental toxicity study in the rabbit. At 300 mg/kg/day, no maternal toxicity was reported, but developmental toxicity was observed as increased resorptions, post-implantation loss and skeletal abnormalities (incomplete ossification of vertebral arches). However, the developmental toxicity NOAELs and LOAELs are well characterized and are used as endpoints for risk assessment for the appropriate population subgroups.

There was no quantitative or qualitative evidence of increased susceptibility in the three-generation reproduction study in rats with ethofumesate since maternal, reproductive and offspring toxicity were not observed at any dose tested up to 5000 ppm (397 and 463 mg/kg/day, males and females, respectively). Although a limit dose was not achieved and no maternal toxicity reported, a new study was not required because the highest dose tested was similar to the dose level that caused toxicity to rats in the chronic/carcinogenicity dietary study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary exposure analyses are unlikely to underestimate exposure. The acute and chronic dietary food and drinking water exposure assessments were performed based on 100 PCT information for all commodities, tolerance-level residues, and Dietary Exposure Evaluation Model (DEEM) 7.81 default processing factors where available. The dietary exposure analyses also assumed that all drinking water will contain ethofumesate at the highest EDWC levels modeled by EPA. The Agency used similarly conservative assumptions to assess post-application exposure of adults and children. The residential exposure estimates are based on EPA's 2012 Residential Standard Operations Procedures (SOPs). These assessments will not underestimate the exposure and risks posed by ethofumesate.

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 population-adjusted dose (aPAD) and chronic population-adjusted dose (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 ethofumesate will occupy 14% of the aPAD at the 95th percentile for females 13–49 years old, the only population subgroup for which an acute dietary endpoint attributable to a single exposure was identified.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure from food and drinking water only as chronic exposure from residential uses of ethofumesate is not expected, EPA identified separate chronic dietary endpoints for the general population, including infants and children, as well as for the population subgroup of females 13–49 years of age. Based on the input parameters and assumptions, the chronic dietary risk estimate for the U.S. population was determined to be 1.2% of the cPAD with the population subgroup of females 13–49 years having the highest risk estimate at 5.2% of the cPAD. EPA concluded that ethofumesate risk estimates for all population subgroups were below the level of concern of <100% of the cPAD.

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

Ethofumesate is currently registered for uses that could result in short-term residential exposure. Residential exposure to ethofumesate is not anticipated from the amended uses that are the subject of this regulatory action; however, it is anticipated from currently registered residential uses of ethofumesate. Residential exposures are only expected to be short-term in duration; however, since the point of departure is the same for short and intermediate-term exposures, the short-term aggregate is protective of any longer-term exposures.

Aggregate risk estimates (MOEs) were derived using recommended exposure scenarios including: For adults, dermal post-application exposure from high contact activities on treated turf; for children, including ages 11 to <16 years and 6 to <11 years, dermal post-application exposure from golfing on treated turf; and for children (1 to <2 years), combined dermal plus hand-to-mouth post-application exposure from high contact activities on treated turf.

EPA short-term aggregate risk calculations of aggregate MOEs, combining average food and drinking water, plus residential exposures (total exposure), ranged from 120 for females 13–49 years; to 430 for children 1 to <2 years; to 770 for adults, 20–49 years and significantly higher for population subgroups, children 6 to 11 years and youth 11 to <16 years. These short-term aggregate risk estimates are not of concern to EPA (*i.e.,* MOEs are ≥ 100).

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, ethofumesate 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 ethofumesate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method I in PAM Vol. II is listed as an adequate tolerance enforcement method for plants) is available to enforce the tolerance expression.

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;

email address: *residuemethods@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.

There are no Codex MRLs established for the residues of ethofumesate in/on any sugar beet raw agricultural or processed commodity.

C. Response to Comments

One commenter supported the tolerance action but expressed concerns about the need for additional data to assess the toxicity of ethofumesate to bioaccumulate and to contribute to obesity and diabetes. To the extent the commenter is concerned about impacts on aquatic life, earthworms, and other non-human organisms, this comment is outside the scope of review appropriate for a tolerance safety assessment under section 408 of the FFDCA. If the commenter is raising concerns about potential human harm, the Agency has considered all the available data and determined that the tolerances are safe; there is nothing in the toxicity database that would suggest toxicity concerns related to diabetes or obesity.

The octanol-water partition coefficient (log K_{ow}) for ethofumesate is 2.8. Compounds with log K_{ow} values less than three are unlikely to bioaccumulate substantially. Therefore, further assessment of the bioaccumulation of ethofumesate is not warranted at this time.

D. Revisions to Petitioned-For Tolerances

EPA is not increasing the existing tolerance for ''Beet, sugar, tops'' because it is unnecessary due to the fact that this commodity is no longer a significant livestock feed item or a recognized human food.

Although the petitioner requested an increase in the existing sugar, beet, refined sugar tolerance, EPA has determined that the tolerance is not needed because the limit established for the raw agricultural commodity (RAC) (beet, sugar, roots at 1.5 ppm) is sufficient to cover residues in this processed commodity (at 1.0 ppm).

In setting the sugar beet molasses tolerance, EPA used the empirical processing factor previously derived for determining the concentration of residues in this processed commodity, which results in a tolerance of 2.0 ppm rather 2.5 ppm as requested.

The tolerance expressions at 180.345 paragraphs (a) and (c) for ethofumesate are being revised to comply with current EPA policies and to accommodate updated tolerance enforcement methods that convert the NC 20645 (2-(2-hydroxy-5-methanesulfonyloxyphenyl) methylpropanoic acid) metabolite to NC9607 (3,3-dimethyl-5-[(methylsulfonyl)oxy]-2(3*H*)-benzofuranone) prior to quantitation.

V. Conclusion

Therefore, tolerances are established for residues of the herbicide ethofumesate in or on beet, sugar, molasses at 2.0 ppm and beet, sugar, roots at 1.5 ppm. Also, the tolerance for beet, sugar, refined is deleted because residues in that processed commodity are covered by the tolerance for beet, sugar, roots.

VI. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 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 action 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 26, 2017.

Michael Goodis,

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 § 180.345:
■ i. Revise the introductory text of paragraph (a);
■ ii. Remove the entry for ''Beet, sugar, refined sugar'' from the table in paragraph (a);
■ iii. Revise the entries for ''Beet, sugar, molasses'' and ''Beet, sugar, roots'' in the table in paragraph (a): and
■ iv. Revise the introductory text of paragraph (c) to read as follows:

§ 180.345 Ethofumesate; tolerances for residues.

(a) *General.* Tolerance are established for residues of the herbicide ethofumesate, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of ethofumesate, 2-ethoxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate, and its metabolites 2-hydroxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate, and 2,3-dihydro-3,3-dimethyl-2-oxo-5-benzofuranylmethanesulfonate, calculated as the stoichiometric equivalent of ethofumesate, in or on the following food commodities.

Commodity	Parts per million
* * * * *	
Beet, sugar, molasses	2.0
Beet, sugar, roots	1.5
* * * * *	

* * * * *

(c) *Tolerances with regional registrations.* Tolerances with a regional registration, as defined in § 180.1(l) are established for residues of the herbicide ethofumesate, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified is to be determined by measuring only the sum of ethofumesate, 2-ethoxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate, and its metabolites 2-hydroxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate, and 2,3-dihydro-3,3-dimethyl-2-oxo-5-benzofuranylmethanesulfonate, calculated as the stoichiometric equivalent of ethofumesate, in or on the raw agricultural commodities.

* * * * *

[FR Doc. 2017–25828 Filed 12–1–17; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 10 and 11

[PS Docket No. 15–91; PS Docket No. 15–94; FCC 17–143]

Wireless Emergency Alerts; Emergency Alert System

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) grants the petition filed by CTIA for reconsideration the Commission's recent decision to revise its Wireless Emergency Alert (WEA) rules and grants in part and denies in part the Competitive Carrier Association's (CCA) request for a waiver or extension of time. Specifically, the Commission extends the timeframe for compliance with the requirement in the *WEA Report and Order* that Participating CMS Providers provide ''clickable'' embedded references in WEA messages from 12 months to 30 months except for AT&T, Verizon, T-Mobile, Sprint and U.S. Cellular. This document also clarifies that the requirement for ''clickable'' embedded references encompass phone numbers and other types of embedded references, and that our embedded reference requirement applies to new devices as well as existing devices capable of supporting this feature through a software upgrade. Finally, this document denies CCA's request for a waiver or an extension of time for compliance with the geo-targeting requirements.

DATES: Effective December 4, 2017.

FOR FURTHER INFORMATION CONTACT: Gregory Cooke of the Public Safety and Homeland Security Bureau, Policy and Licensing Division, *gregory.cooke@fcc.gov,* (202) 418–2351.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order on Reconsideration in PS Docket No. 15–91, No. 15–94, FCC 17–143, released on November 1, 2017. The document is available for download at *https://apps.fcc.gov/edocs_public/attachmatch/FCC-17-143A1.pdf.* The complete text of this document is also available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Supplemental Regulatory Flexibility Analysis

1. This Supplemental Final Regulatory Flexibility Analysis (Supplemental FRFA) supplements the Final Regulatory Flexibility Analysis (FRFA) of the September 2016 *WEA Report and Order,* 81 FR 75710 (*WEA R&O*) to reflect the actions taken in this *Order on Reconsideration* and conforms to the RFA.

Need for, and Objective of, the Order

2. In the *WEA R&O,* we took advantage of the significant technological changes and improvements experienced by the mobile wireless industry since the passage of the Warning, Alert and Response Network (WARN) Act, and deployment of WEA to improve the utility of WEA as a life-saving tool. As pertinent to the *Order on Reconsideration* we adopt today, in the *WEA R&O* we adopted rules focused on improving WEA message content by narrowing the rules for the geo-targeting of alerts, requiring Participating Commercial Mobile Service (CMS) Providers to support embedded references (*i.e.,* URLs and phone numbers) included in WEA Alert Messages. In doing so, we set a deadline for compliance with the embedded reference requirement of one year (12 months).

3. In this *Order on Reconsideration,* we grant, to the extent described herein, CTIA's Petition for Reconsideration of the *WEA R&O* and CCA's Petition for Waiver, or in the Alternative, Extension of Time. In doing so, we deny CCA's request for a waiver or an extension of time for compliance with the *WEA R&O's* best approximates geo-targeting standard, as compliance with the best approximate geo-targeting is well within the capabilities of CCA's members; and we reconsider the deadline for compliance with the embedded reference requirement from one year (12 months) to 30 months for all