should be banned on agricultural crops, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that these trifloxystrobin tolerances are safe. The commenter has provided no information supporting a contrary conclusion.

D. Revisions to Petitioned-For Tolerances

The Agency is establishing the tolerance value on flax seed as requested but with the addition of a significant figure based on current practice and establishing a tolerance on grain, aspirated fractions using the commodity definition that is consistent with common commodity vocabulary currently used by the Agency. Also, based upon the relevant field trial and processing studies, EPA is modifying the tolerance in/on aspirated grain fractions to 10 ppm, not 15 ppm as proposed by the registrant. This is due to differences in how the Agency and the registrant each calculated the processed commodity residues for aspirated grain fractions.

V. Conclusion

Therefore, a tolerance is established for residues of trifloxystrobin, including its metabolites and degradates, in or on flax, seed at 0.40 ppm, and the existing tolerance for grain, aspirated fractions is amended from 5.0 ppm to 10 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance and amends a tolerance 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), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). 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: December 19, 2019.

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 § 180.555, add alphabetically the entry ''Flax, seed'' and revise the entry for ''Grain, aspirated fractions'' in the table in paragraph (a) to read as follows:

§ 180.555 Trifloxystrobin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Flax, seed	0.40
* * * * *	
Grain, aspirated grain fractions	10
* * * * *	

* * * * *

[FR Doc. 2019–02523 Filed 2–14–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0420; FRL–9983–89]

Trifluralin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of trifluralin in or on rosemary fresh leaves, rosemary dried leaves, and rosemary oil. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 15, 2019. Objections and requests for hearings must be received on or before April 16, 2019, 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–2017–0420, 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 Goodis, 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–2017–0420 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 April 16, 2019. 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–2017–0420, 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 October 23, 2017 (82 FR 49020) (FRL–9967–37), 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 7E8580) by IR–4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide trifluralin a,a,a-trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine in or on rosemary, fresh leaves at 0.1 parts per million (ppm); rosemary, dry leaves at 0.1 ppm; and rosemary, oil at 2.18 ppm. That document referenced a summary of the petition prepared by Gowan Company, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the level at which the tolerance is being established for rosemary oil, and modified the significant figures and commodity definitions used to be in line with Agency policy. The reason for these changes are explained in Unit IV.C.

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 trifluralin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with trifluralin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as

the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The primary target organs are the kidney and the liver in rats and dogs for trifluralin. Liver effects include increased liver weights and changes in clinical chemistry parameters. In the kidneys, tubular hyaline casts, minimal cortical tubular epithelial regeneration were observed microscopically, and an increased incidence of progressive glomerulonephritis was seen.

In the rat developmental toxicity study, developmental effects (increased resorptions and wavy ribs) occurred in the presence of less severe maternal effects (decreases in body weight gain, clinical signs, and changes in organ weights). In the 2-generation reproduction study, offspring effects (decreased fetal, neonatal and litter viability) were observed at a dose level where there was less severe maternal toxicity (decreased body weight, body weight gain and food consumption). However, the concern was low since clear NOAELs/LOAELs were established for maternal and developmental toxicities and the doses selected for overall risk assessment would address the concerns seen in these studies. A 21-day dermal toxicity study in the rat showed no systemic toxicity at the limit dose of 1,000 mg/kg/day; dermal effects included sub-epidermal inflammation and ulcerations at 200 mg/kg/day. A rabbit 21-day dermal toxicity study also did not show any systemic toxicity at 1,000 mg/kg/day; dermal effects observed at the LOAEL (100 mg/kg/day) included erythema, edema, and/or scaling and fissuring. A 30-day inhalation exposure to rats with trifluralin at 1,000 mg/m ^{3} resulted in increased methemoglobin and bilirubin, as well as dyspnea and ruffled fur. Trifluralin is not a neurotoxicant and does not appear to be an immunotoxicant.

In male rats, trifluralin was associated with increased incidence of thyroid follicular cell combined adenoma, papillary adenoma, cystadenoma, and carcinoma tumors. It has been classified as ''Group C, possible Human Carcinogen.'' Extensive testing showed, however, that trifluralin is neither mutagenic nor genotoxic, and does not inhibit the polymerization of microtubules in mammalian cells.

Specific information on the studies received and the nature of the adverse effects caused by trifluralin 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 the document titled ''*Trifluralin: Human Health Draft Risk Assessment for Registration Review and a Proposed Section 3 Use of Trifluralin on Rosemary*'' on pages 52–59 in docket ID number EPA–HQ–OPP–2017–0420.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for trifluralin used for human risk assessment is discussed in Unit II.B. of the final rule published in the **Federal Register** of July 31, 2013 (78 FR 46267) (FRL–9393–5).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to trifluralin, EPA considered exposure under the petitioned-for tolerances as well as all existing trifluralin tolerances in 40 CFR 180.207. EPA assessed dietary exposures from trifluralin 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 trifluralin. In estimating acute dietary exposure, EPA used 2003–2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA conducted an unrefined assessment using tolerance level residues, 100 percent crop treated (PCT), and default Dietary Exposure Evaluation Model (DEEM) processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used 2003–2008 food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, the chronic dietary exposure and risk estimates are somewhat refined and assumed tolerance-level residues for the majority of commodities, PCT data for some existing uses, and DEEM default processing factors. Pesticide Data Program (PDP) monitoring data were used for carrots, potatoes, bell peppers, non-bell peppers, tomatoes, tomato paste, oranges, orange juice, grapes, grape juice, raisins, corn syrup, and wheat flour.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data is not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that trifluralin should be classified as a possible human carcinogen and a linear approach has been used to quantify cancer risk since no mode of action data are available.

The aggregate cancer risk assessment for adults takes into account exposure estimates from dietary consumption of trifluralin from food, residential and drinking water sources. Exposures from residential uses are based on the lifetime average daily dose and assume an exposure period of 5 days per year and 50 years of exposure in a lifetime. Dietary exposure assumptions were

quantified using the same estimates as discussed in Unit III.C.1.ii., Chronic exposure.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition c:* Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows:

The chronic and cancer dietary exposure and risk assessments incorporated the following trifluralin average percent crop treated estimates: Almonds 2.5%; apricots 2.5%; asparagus 20%; barley 1%; beans, green 25%; broccoli 5%; Brussels sprouts 2.5%; cabbage 40%; canola 2.5%; cantaloupes 25%; carrots 30%; cauliflower 5%; celery 2.5%; chicory 20%; corn 1%; cotton 30%; cucumbers 2.5%; dry beans/peas 10%; grapefruit 2.5%; grapes 2.5%; honeydews 30%; lemons 2.5%; nectarines 2.5%; oranges 2.5%; peaches 1%; peanuts 5%; peas, green 10%; pecans 1%; peppers 20%; plums/prunes 1%; potatoes 2.5%; pumpkins 5%; sorghum 2.5%; soybeans 2.5%; squash 2.5%; sugar beets 2.5%; sugarcane 5%; sunflowers 5%; tomatoes 55%; walnuts 1%; watermelons 15%; and wheat 1%. For the remaining commodities, EPA assumed 100% crop treated.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models as well as monitoring data in the dietary exposure analysis and risk assessment for trifluralin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of trifluralin. The estimated drinking water concentrations (EDWCs) were calculated using a Total Toxic Residues (TTR) exposure modeling method, where trifluralin and its major degradates of concern (TR–4, TR–6, TR–7, TR–14, and TR–15) were combined. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Pesticide in Water Calculator (PWC), the estimated drinking water concentrations (EDWCs) of trifluralin for acute exposures are estimated to be 57 parts per billion (ppb) for surface water and 1.0 ppb for ground water; for chronic exposures for non-cancer assessments are estimated to be 15 ppb for surface water and 1.0 ppb for ground water; and for chronic exposures for cancer assessments are estimated to be 4.4 ppb for surface water and 1.0 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 57 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 15 ppb was used to assess the contribution to drinking water. For the cancer dietary risk assessment, the water concentration of value 4.4 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).

Trifluralin is currently registered for the following uses that could result in residential exposures: lawns, golf courses, vegetable and ornamental gardens. EPA assessed residential exposure using the following assumptions: For residential handlers, all registered trifluralin product labels with residential use sites (*e.g.,* lawns, ornamental and vegetable gardens) require that handlers wear specific clothing (*e.g.,* long sleeve shirt/long pants) and/or use personal protective equipment (PPE) except for one label. Therefore, EPA has assumed that only that one product is intended for homeowner use and has conducted a quantitative residential handler assessment based on the use sites and application rates as provided on the label. The quantitative exposure/risk assessment developed for residential handlers is based on the following scenarios: Applying granules via push-type spreader, spoon, cup, hand dispersal, and shaker can to residential vegetable and ornamental gardens.

Although a non-cancer dermal risk assessment was not performed due to the lack of an adverse effect in the non-cancer dermal study, dermal exposure was estimated for the residential handler cancer risk assessment because dermal exposure does contribute to the overall cancer risk for trifluralin.

There is the potential for post-application exposure for individuals exposed as a result of being in an environment that has been previously treated with trifluralin. For the residential post-application scenarios, all registered trifluralin product labels with residential use sites (*e.g.,* turf/lawns and ornamental and vegetable gardens) were considered for quantitative assessment. Although there is the potential for dermal exposure to adults and children, a quantitative non-cancer dermal risk assessment was not conducted since no non-cancer dermal hazard was identified. The quantitative

non-cancer exposure/risk assessment for residential post-application exposures is based on the following scenario: Incidental oral (hand to mouth, object to mouth, and soil ingestion) exposure for children (1 to <2) from granular formulations applied to turf.

Episodic granular ingestion for children is a potential exposure pathway for granular formulations; however, this exposure scenario could not be assessed because an acute dietary endpoint for general population, including infants and children, was not selected due to no effect attributable to a single (or few) day(s) oral exposure observed in animal studies.

Although a non-cancer dermal risk assessment was not performed due to the lack of an adverse effect in the non-cancer dermal study, dermal exposure was estimated for the residential post-application cancer risk assessment because dermal exposure does contribute to the overall cancer risk for trifluralin. Inhalation exposure is expected to negligible.

The worst-case residential exposure scenario used in the adult non-cancer aggregate assessment reflects inhalation exposure from applications to gardens via hand dispersal.

The worst-case residential exposure used in the adult cancer aggregate assessment reflects dermal exposure from post-application exposure from liquid applications to treated gardens.

The worst-case residential exposure used in the children 1<2 years old aggregate assessment reflects hand-to-mouth exposures from post-application exposure to turf applications.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.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.''

Based on a review of the toxicological database for trifluralin and the other dinitroanilines (benfluralin, butralin, ethalfluralin, fluazinam, flumetralin, oryzalin, pendimethalin, and prodiamine), the Agency has determined that although trifluralin shares some chemical and/or toxicological characteristics (*e.g.,* chemical structure or apical endpoint) with these other dinitroanilines, the toxicological database does not support a testable hypothesis for a common mechanism of action. No further data are required to determine that no common mechanism of toxicity exists for trifluralin and the other dinitroanilines and no further cumulative evaluation is necessary for trifluralin. For additional details, refer to the document titled ''*Dinitroanilines: Screening Analysis of Toxicological Profiles to Consider Whether a Candidate Common Mechanism Group Can Be Established*'' in docket ID number EPA–HQ–OPP–2017–0420 in *www.regulations.gov.*

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.* There was evidence of increased qualitative susceptibility in the rat developmental toxicity study, where fetal developmental effects (increased resorptions and wavy ribs) occurred in the presence of less severe maternal effects (decreases in body weight gain, clinical signs, and changes in organ weights); however, the concern was low since clear NOAELs/LOAELs were established for maternal and developmental toxicities. There was also a low concern for the qualitative susceptibility observed in the rat reproduction study since the dose-response was also well characterized; there was a clear NOAEL/LOAEL for maternal and developmental toxicities; and the effects were seen at a high-dose level (295/337 mg/kg/day). Offspring viability was not adversely affected in the two other 2-generation studies with trifluralin at dose levels up to 100 and 148 mg/kg/day. Similarly, there are no residual uncertainties for pre- and postnatal toxicity since the doses selected for overall risk assessment will address the concerns seen in these 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 trifluralin is complete.

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

iii. As noted in section D.2., there was evidence of increased qualitative susceptibility in the rat developmental toxicity study, however, the concern was low for the reasons outlined in that section; furthermore, there was also a low concern for the qualitative susceptibility observed in the rat reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on a refined risk assessment that incorporated some PCT and anticipated residue information. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to trifluralin in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by trifluralin.

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 trifluralin will occupy less than 1% of the aPAD for females 13–49 years old, the only population group of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to trifluralin from food and water will utilize 3.7% of the

cPAD for all infants less than 1 year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of trifluralin is not expected.

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

Trifluralin is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to trifluralin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 24,000 for adults and 15,000 for children 1 to less than 2 years old. Because EPA's level of concern for trifluralin is a MOE of 100 or below, these MOEs are not of concern.

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

An intermediate-term adverse effect was identified; however, trifluralin is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no 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 intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for trifluralin.

5. *Aggregate cancer risk for U.S. population.* A cancer aggregate assessment was conducted for trifluralin since it is classified as a ''Group C, Possible Human Carcinogen'' with a Q^{1}* of 2.96 × 10–3 $(mg/kg/day)^{-1}$ based upon male rat thyroid follicular cell combined adenoma, papillary adenoma, cystadenoma, and carcinoma tumor rate in human equivalents. The cancer aggregate risk assessment combines food and drinking water exposures with dermal and inhalation exposure from post-application exposure from treated gardens. The resulting aggregate cancer risk estimate for adults is 1.5×10^{-6}.

EPA generally considers cancer risks (expressed as the probability of an increased cancer case) in the range of 1 in 1 million (or 1×10^{-6}) or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the logarithmic scale; for example, risks falling between 3×10^{-7} and 3×10^{-6} are expressed as risks in the range of 10^{-6}. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6}. This is particularly the case where some conservatism is maintained in the exposure assessment. EPA has concluded the cancer risk for all existing trifluralin uses and the uses associated with the tolerances established in this action fall within the range of 1×10^{-6} and are thus negligible.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to trifluralin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography (GC) with electron capture detection (ECD)) 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.

The Codex has not established a MRL for trifluralin on rosemary.

C. Revisions to Petitioned-For Tolerances

EPA is establishing a tolerance of 3.0 ppm for residues of trifluralin in rosemary oil rather than the proposed value of 2.18 ppm based on Codex rounding classes. For the other tolerances that vary from what the petitioner requested, EPA is establishing tolerance values to conform to current Agency practices on significant figures.

V. Conclusion

Therefore, tolerances are established for residues of trifluralin, including its metabolites and degradates, in or on rosemary, dried leaves at 0.10 ppm; rosemary, fresh leaves at 0.10 ppm; and rosemary, oil at 3.0 ppm.

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), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). 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: December 21, 2018.

Donna S. Davis,

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:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.207:

■ a. Revise the introductory text of paragraph (a).

■ b. Add alphabetically the entries for ''Rosemary, dried leaves''; ''Rosemary, fresh leaves''; and ''Rosemary, oil'' to the table in paragraph (a).

The revision and additions read as follows:

§ 180.207 Trifluralin; tolerances for residues.

(a) *General.* Tolerances are established for residues of trifluralin, 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 trifluralin (2,6-dinitro-N,N-dipropyl-4-(trifluoromethyl)benzenamine).

Commodity	Parts per million
* * * * *	
Rosemary, dried leaves	0.10
Rosemary, fresh leaves	0.10
Rosemary, oil	3.0
* * * * *	

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[FR Doc. 2019–02535 Filed 2–14–19; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 36

[CC Docket No. 80–286, FCC No. 18–182]

Jurisdictional Separations and Referral to the Federal-State Joint Board

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission amends its part 36 jurisdictional separations rules by extending for up to six years the freeze of separations category relationships and allocation factors that it originally adopted in 2001. As a result, the freeze will remain in effect until the earlier of December 31, 2024, or the completion of comprehensive reform of the part 36 jurisdictional separations rules. The Commission also amends its part 36 jurisdictional separations rules by providing rate-of-return carriers that elected to freeze their separations category relationships in 2001 a one-time opportunity to unfreeze and update those relationships so that they can categorize their costs based on current circumstances.

DATES: These rules are effective February 15, 2019, except for the amendment to 47 CFR 36.3(b) which is delayed. The Commission will publish a document in the **Federal Register** announcing the effective date.

ADDRESSES: Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Marvin Sacks, Pricing Policy Division of the Wireline Competition Bureau, at (202)–418–2017 or via email at *Marvin.Sacks@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a final rule summary of the Commission's Report and Order, released December 17, 2018. A full-text version of this document can be obtained from the following internet address: *https://www.fcc.gov/document/fcc-extends-jurisdictional-separations-freeze-six-years.*

Synopsis

I. Introduction

1. In 1970, when monopoly rate-of-return local exchange carriers (LECs) provided telephone services primarily over circuit-switched, voice networks, the Commission codified its jurisdictional separations rules. Those rules required each LEC to divide its cost of providing service between the interstate and intrastate jurisdictions in a manner reflecting each jurisdiction's relative use of the LEC's network. In an era when the Commission and its State counterparts set virtually all telephone rates based on actual costs, the separations rules helped ensure that each LEC had the opportunity to recover its expenses and earn a reasonable return on its investments.

2. Today, phone companies deliver voice, data, and video services that are increasingly being provided over internet Protocol-based networks. New digital technologies blur the lines between interstate and intrastate communications, making last century's jurisdictional separations rules inadequate and outmoded vis-à-vis their