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 an MRL for CPPA.

VIII. Conclusion

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of CPPA. Therefore, EPA is establishing an exemption from the requirement of a tolerance for residues of CPPA in or on all food commodities when applied as a plant growth regulator and used in accordance with good agricultural practices.

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption from the requirement of a tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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 of 1995 (NTTAA) (15 U.S.C. 272 note).

X. 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: July 9, 2013.

Steven Bradbury,

Director, 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. Add § 180.1321to subpart D to read as follows:

§ 180.1321 Complex Polymeric Polyhydroxy Acids; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of complex polymeric polyhydroxy acids in or on all food commodities when applied as a plant growth regulator and used in accordance with good agricultural practices.

[FR Doc. 2013–18185 Filed 7–30–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0304; FRL–9393–5]

Trifluralin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of trifluralin in or on the oilseed crop group 20. Interregional Research Project Number 4 (IR–4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 31, 2013. Objections and requests for hearings must be received on or before September 30, 2013, 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–2012–0304, 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), EPA West

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: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; 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–2012–0304 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 September 30, 2013. 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–2012–0304, 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.htm.*

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 25, 2012 (77 FR 43562) (FRL–9353–6), 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 2E8011) by IR–4, 500 College Road East, Suite 201W., Princeton, NJ 08540. The petition requested that 40 CFR 180.207 be amended by establishing tolerances for residues of the herbicide trifluralin, (alpha, alpha, alpha-trifluoro-2,6-dinitro-*N,N*-dipropyl-*p*-toluidine), in or on oilseed, crop group 20 at 0.05 parts per million (ppm). That document referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with 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 kidney and the liver are the principal target organs for trifluralin in rats and dogs. In subchronic oral studies liver effects include increased liver weights and changes in clinical chemistry parameters. Kidney effects include decreased kidney weights, kidney and bladder tumors, increased blood urea nitrogen (BUN), increases in total protein, aspartate aminotransferase (AST) and lactate dehydrogenase (LDH) in the urine. Also, protein electrophoresis of urine samples showed α1-globulin and α2-globulin. Kidney effects also included tubular hyaline casts, minimal cortical tubular

epithelial regeneration, observed microscopically, and an increased incidence of progressive glomerulonephritis. In dogs exposed to trifluralin for 1 year, multifocal cortical tubular cytoplasmic pigment deposition was noted in the kidneys of both sexes. In the subchronic studies, blood effects such as lower hemoglobin levels and changes in clinical chemistry were reported in rats.

There was qualitative evidence of increased 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). Also qualitatively, there is an indication of increased sensitivity in the 2-generation reproduction study in the rat in that 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).

In male rats, trifluralin was associated with increased incidence of thyroid follicular cell combined adenoma, papillary adenoma, cystadenoma, and carcinoma tumors. Based on the available data, trifluralin has been classified as a 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. It is also not a neurotoxicant and does not appear to be an immunotoxicant.

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 Risk Assessment for the Establishment of Tolerances on Oilseed Crop Group 20*'' pages 43–55 in docket ID number EPA–HQ–OPP–2012–0304.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for trifluralin used for human risk assessment is shown in the following Table.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TRIFLURALIN 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 = 100 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 1.0 mg/kg/day. aPAD = 1.0 mg/kg/day	Developmental Toxicity Study Rat. LOAEL = 500 mg/kg/day, based on reduced ossification of the vertebrae and ribs; thickened, wavy or bent ribs; and increased total litter resorptions.
Acute dietary (General population including infants and children).	No endpoints identified from the available developmental toxicity studies (rat and rabbit) were appropriate for an acute dietary assessment for trifluralin in the general population, including infants and children.		
Chronic dietary (All populations)	NOAEL= 2.4 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.024 mg/kg/day. cPAD = 0.024 mg/kg/day	Chronic (capsule) Toxicity—Dog. LOAEL = 40 mg/kg/day, based on increased frequency of abnormal stool, decreased body weights and body weight gains, and decreased erythrocytes and hemoglobin and increased thrombocytes (males).
Incidental oral short-term (1 to 30 days).	NOAEL= 10 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	2-generation Reproduction Study in Rats. LOAEL = 32.5 mg/kg/day, based on decreased pup weights in both generations and increased relative to body liver weights in the F2b females.
Inhalation short-term (1 to 30 days).	Inhalation study NOAEL = 300 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	30-Day Inhalation Study—Rat. LOAEL = 1000 mg/m^3 (270 mg/kg/day), based on increased methemoglobin and bilirubin in females and the incidence of dyspnea and rufflerd fur in males and females.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TRIFLURALIN 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
Cancer (Oral, dermal, inhalation).	Classification: Possible Human Carcinogen $Q_1{}^* = 2.96 \times 10^{-3}$ (mg/kg/day)$^{-1}$		

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 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, PCT data for some existing uses, and DEEM default processing factors. Pesticide Data Program (PDP) monitoring data were used for carrot, orange, orange juice, pepper, potato, and tomato.

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 are 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 the general U.S. population 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 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 average PCT for existing uses as follows:

Almonds: 1%; asparagus: 20%; barley: 1%; green bean: 25%; broccoli: 10%; cabbage: 40%; canola: 2.5%; cantaloupe: 25%; carrot: 40%; cauliflower: 10%; celery: 2.5%; corn: 1%; cotton: 30%; cucumber: 2.5%; dry bean/pea: 10%; garlic: 5%; grapefruit: 1%; grape: 2.5%; honeydew: 20%; lemon: 1%; onion: 2.5%; orange: 1%; peach: 1%; peanut: 5%; pecan: 1%; pepper: 25%; pistachio: 2.5%; potato: 2.5%; pumpkin: 5%; sorghum: 1%; soybean: 5%; squash: 5%; sugarbeet: 2.5%; sugarcane: 5%; sunflower: 10%; tomato: 60%; walnut: 1%; watermelon: 10%; and wheat: 1%.

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%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which trifluralin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models 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. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of trifluralin and its major degradates TR–4 (α,α,α-trifluoro-5-nitro-*N*4,*N*4-dipropyl-toluene-3,4-diamine), TR–6 (*5*-trifluoromethyl-3-nitro-1,2-benzenediamine) and TR–15 (2-ethyl-7-nitro-5-(trifluoromethyl) benzimidazole) (the residues of concern in drinking water) for acute exposures are estimated to be 23.83 parts per billion (ppb) for surface water and 0.0275 ppb for ground water. For chronic exposures for non-cancer assessments they are estimated to be 1.97 ppb for surface water and 0.0275 ppb for ground water. And for cancer assessments are estimated to be 1.59 ppb for surface water and 0.0275 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 23.83 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 1.97 ppb was used to assess the contribution to drinking water. And for cancer dietary risk assessment, the water concentration of value 1.59 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 including vegetable gardens, turf, and ornamentals. EPA assessed residential exposure using the following assumptions: EPA evaluated residential handler inhalation exposures, which are considered short-term in duration. The handler assessment did not consider dermal exposures because a dermal endpoint was not identified; in three dermal toxicity studies (21/28 days in rabbits; 21/28 days in rats; and 31-days in rats), trifluralin was tested up to the limit dose (1000 mg/kg/day) and caused no systemic toxicity. Handler exposure scenarios evaluated include the following:

- Loading/applying granulars with a push-type spreader;
- loading/applying granulars using a spoon, measuring scoop, shaker can, or via hand;
- mixing/loading/applying liquids with a hose-end sprayer;
- mixing/loading/applying liquids with low pressure handwand sprayer;
- mixing/loading/applying liquids with backpack sprayer; and applying trifluralin impregnated fabric squares to soil.

In terms of cancer risk, the Agency considers all exposure to trifluralin, including the dermal and inhalation exposure expected for homeowners, to have an associated carcinogenic risk. Carcinogenic risk for homeowner applicators was assessed based on the application methods outlined above. An upper-end assumption was made that the users assessed will apply trifluralin each season, as labeled, with an assumed exposure period of 5 days per year for 50 years of their life. Specific methods (or scenarios) of application (spreader, sprayer, etc.) were assessed to demonstrate the full range of exposure due to method and area treated, although users are not expected to use one method for 50 years. Carcinogenic risk for homeowner applicators was assessed by combining dermal exposure (adjusted for an estimated 3% absorption based on ethalfluralin data) and inhalation exposure (100% absorption), calculating this exposure on a per day basis (''Lifetime Average Daily Dose'', in mg/kg/day), and then quantifying risk by multiplying the updated upper-bound carcinogenic potency factor (Q_1*) of 2.96×10^{-3} (mg/kg/day)$^{-1}$ by the combined exposure estimate.

There is the potential for post-application exposure for individuals exposed as a result of being in an environment (vegetable garden, golf course turf, turf) that has been previously treated with trifluralin. All residential exposures are considered to be short-term in duration (1–30 days). No acute dietary or short-term dermal points of departure have been selected for trifluralin; therefore; only incidental oral post-application non-cancer risk estimates for children 1<2 years old were evaluated. This lifestage is not the only lifestage that could be potentially exposed for these post-application scenarios; however, the assessment of this lifestage is health protective for the exposures and risk estimates for any other potentially exposed lifestage. Non-cancer post-application scenarios assessed are as follows: Incidental oral (hand to mouth, object to mouth, and soil ingestion) exposure from granular applications to turf.

Estimated post-application cancer risk for the general U.S. population includes infants and children; therefore, in accordance with Agency policy, a children's cancer risk estimate was not reported separately. For post-application cancer risk, the only adult post-application residential scenarios that are applicable are the following:

- Dermal exposure to residues on lawns
- Dermal exposure to golf course turf
- Dermal exposure in home vegetable gardens.

There may be post-application residential exposure scenarios for trifluralin which could be combined for purposes of an aggregate exposure assessment. Combinations for residential exposure scenarios should have a reasonable probability of occurring on a single day and the pest that an individual is attempting to

control must be considered. It is reasonable that an adult may treat their turf and garden on the same day.

The worst case residential exposure for use in the adult non-cancer aggregate assessment reflects residential handler inhalation exposure from applying granules by hand to pre-plant ornamentals.

The worst case residential exposure for use in the children 1<2 years old non-cancer aggregate assessment reflects hand-to-mouth short-term post-application exposures from granular application to residential turf.

And lastly, the worst case residential exposure for use in the cancer aggregate assessment reflects dermal and inhalation exposure from loading/applying granules with a belly grinder to pre-plant ornamentals.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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

EPA has not found trifluralin to share a common mechanism of toxicity with any other substances, and trifluralin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that trifluralin does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the 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 qualitative evidence of increased 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). Also qualitatively, there is an indication of increased sensitivity in the 2-generation reproduction study in the rat in that 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).

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

i. The toxicity database for trifluralin is complete except for immunotoxicity testing. In the absence of specific immunotoxicity studies, EPA has evaluated the available trifluralin toxicity data to determine whether an additional uncertainty factor is needed to account or potential immunotoxicity. There are no indications in the available studies that organs associated with immune function, such as the thymus, are affected by trifluralin and trifluralin does not belong to a class of chemicals (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Based on the above considerations in this unit, EPA does not believe that conducting the immunotoxicity study will result in a dose less than the point of departure already used in this risk assessment, and an additional database uncertainty factor (UF) for potential immunotoxicity does not need to be applied.

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. Although qualitative evidence of increased susceptibility was seen in the rat developmental toxicity study, and an indication of increased sensitivity in the 2-generation reproduction study in the rat in that offspring effects, the concern for these effects is low for the following reasons: (1) The dose response was well characterized; (2) the developmental effects were seen in the presence of maternal toxicity; (3) clear NOAELs/LOAELs were established for maternal and developmental toxicities; and (4) for the rats in the 2-generation reproduction study, the effects were seen at a high-dose level (295 milligrams/kilogram/day (mg/kg/day) for males and 337 mg/kg/day for females). Furthermore, 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. Finally, there are no residual uncertainties for pre-natal and post-natal toxicity since the doses selected for overall risk assessment are protective of the effects seen in these studies.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessment for females 13–49, the population identified as having potential acute exposure, was performed based on 100 PCT and tolerance-level residues. The chronic dietary exposure and risk estimates are somewhat refined and assumed tolerance level residues, some PCT data, and DEEM default processing factors. Pesticide Data Program (PDP) monitoring data were used for carrot, orange, orange juice, pepper, potato, and tomato. These refinements are based on reliable data and will not underestimate the exposure and risk to any population subgroups. 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 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 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-term, 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 subgroup 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 less than 1% of the cPAD for all population groups. 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 25,000 for adults and 26,000 for children. 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.* The aggregate cancer risk estimate from trifluralin residues in food, drinking water, and residential exposure is 1×10^{-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.

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 for the crops addressed in this document.

C. Revisions to Petitioned-For Tolerances

PA has revised the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of trifluralin not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of trifluralin, including its metabolites and degradates, in or on oilseed, crop group 20 at 0.05 ppm. Compliance with the tolerance level is to be determined by only trifluralin α,α,α-trifluoro-2,6-dinitro-*N,N*-dipropyl-*p*-toluidine, in or on the oilseed, crop group 20.

Also, due to the establishment of the tolerance on oilseed, crop group 20, the existing tolerances for rapeseed, seed; flax, seed; mustard, seed; sunflower, seed; safflower, seed; and cotton undelinted seed are removed as unnecessary.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children From Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 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 final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between

the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination With Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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 of 1995 (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: July 25, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.207:

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

■ b. Remove the commodities cotton undelinted seed; flax, seed; mustard, seed; rapeseed, seed; safflower, seed; and sunflower, seed in the table in paragraph (a).

■ c. Add alphabetically the following commodity to the table in paragraph (a).

The amendment 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 following table. Compliance with the tolerance levels specified in the following table is to be determined by only trifluralin α,α,α-trifluoro-2,6-dinitro-*N,N*-dipropyl-*p*-toluidine, in or on the commodity.

Commodity	Parts per million
* * * * *	
Oilseed, crop group 20	0.05
* * * * *	

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[FR Doc. 2013–18420 Filed 7–30–13; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0439 and EPA–HQ–OPP–2012–0514; FRL–9393–6]

Pyroxasulfone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyroxasulfone in or on multiple commodities which are identified and discussed later in this document. K–I Chemical U.S.A., Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 31, 2013. Objections and requests for hearings must be received on or before September 30, 2013, 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–2012–0439 and EPA–HQ–OPP–2012–0514, 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), EPA West 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: Lois Rossi, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; 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.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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–2012–0439 and EPA–HQ–OPP–2012–0514 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 September 30, 2013. Addresses for mail and hand delivery of objections