12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

XI. 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: November 9, 2015.

Susan Lewis,

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 § 180.960, add alphabetically the following polymer to the table to read as follows:

§ 180.960 Polymers; exemptions from the requirement of a tolerance.

* * * * *

Polymer	CAS No.
* * * * *	
2-Propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene, minimum number average molecular weight (in amu), 2,000	52831–04–6.
* * * * *	

[FR Doc. 2015–29466 Filed 11–17–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0179; FRL–9933–61]

Flutriafol; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerances for residues of flutriafol in or on hop, dried cones. Cheminova A/S, c/o Cheminova, Inc. requested this tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). Additionally, tolerances are being removed that were inadvertently returned from an earlier Final rule.

DATES: This regulation is effective November 18, 2015. Objections and requests for hearings must be received on or before January 19, 2016, 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–2015–0179, 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: Susan Lewis, 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–2015–0179 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 January 19, 2016. 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–2015–0179, 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 and This Action

In the **Federal Register** of April 22, 2015 (80 FR 22466) (FRL–9925–79), 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 4F8294) by Cheminova Inc., c/o Cheminova A/S, 1600 Wilson Blvd., Suite 700, Arlington, VA 22209–2510. The petition requested that 40 CFR 180.629 be amended by establishing tolerances for residues of the fungicide flutriafol, ((±)-α-(2-fluorophenyl)-α-(4-fluorophenyl)-1H–1,2,4-triazole-1-ethanol), in or on hops, dried cones at 20 parts per million (ppm). That document referenced a summary of the petition prepared by Cheminova Inc., c/o Cheminova A/S, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing. For purposes of accuracy, the Agency notes that a harmless error was made in the notice of filing publication and is correcting that misstatement here: The petition was actually filed by Cheminova A/S, c/o Cheminova, Inc.

Additionally, in the **Federal Register** of February 4, 2015 (80 FR 5946) (FRL–9922–06) EPA established tolerances for residues of flutriafol, in or on several commodities, including cotton, gin byproducts at 6.0 ppm and cotton, undelinted seed at 0.50 ppm. When establishing the general tolerances in paragraph (a) for cotton, gin byproducts at 6.0 ppm and cotton, undelinted seed at 0.50 ppm, EPA inadvertently forgot to remove the existing tolerances for cotton, gin byproducts at 0.02 ppm and cotton, undelinted seed at 0.01 ppm from the table in paragraph (d) for *Indirect or inadvertent residues.* These indirect tolerances were made redundant by the establishment of the tolerances in the *General* section at a higher level for the same commodities. Therefore, EPA is removing the cotton, gin byproducts and cotton, undelinted seed tolerances established in § 180.629(d).

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for flutriafol including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with flutriafol 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. Consistent with the mammalian toxicity profiles of the other triazole fungicides, the prevalent adverse effects following oral exposure to flutriafol were in the liver. Effects consisted of increases in liver enzyme release (alkaline phosphatase), liver weights, and histopathology findings (hepatocyte vacuolization to centrilobular hypertrophy and slight increases in hemosiderin-laden Kupffer cells, minimal to severe fatty changes, and bile duct proliferation/cholangiolar fibrosis). Progression of toxicity occurred with time as some effects were only observed at chronic durations.

Slight indications of effects in the hematopoietic system were sporadically seen in all species consisting of slight anemia, increased platelets, white blood cells, neutrophils, and lymphocytes. The effects in the neurotoxicity screening batteries were observed only at higher doses and were considered secondary effects (decreased motor activity and hindlimb grip strength, ptosis, lost righting reflex, hunched posture, and ataxia). Flutriafol showed no evidence of dermal toxicity, or immunotoxicity. Flutriafol showed no evidence of carcinogenicity in rodents or *in vitro.*

There is evidence of increased quantitative and qualitative pre- and postnatal susceptibility for flutriafol in rats and rabbits. In the first of two rat developmental toxicity studies, developmental effects (delayed ossification or non-ossification of the skeleton in the fetuses) were observed at a lower dose than that where maternal effects were observed. In the second rat developmental study, developmental effects (external, visceral, and skeletal malformations; embryo lethality; skeletal variations; a generalized delay in fetal development; and fewer live fetuses) were more severe than the decreased food consumption and body-weight gains observed in the dams at the same dose. For rabbits, intrauterine deaths occurred at a dose level that also caused adverse effects in maternal animals. In the 2-generation reproduction studies, effects in the offspring decreased litter size and percentage of live births (increased pup mortality) and liver toxicity can be attributed to the systemic toxicity of the parental animals (decreased body weight and food consumption and liver toxicity) observed at the same dose.

Flutriafol is categorized as having high oral acute toxicity in the mouse. It is categorized as having low acute toxicity via the oral, dermal and inhalation routes in rats. Flutriafol is minimally irritating to the eyes and is not a dermal irritant. Flutriafol was not shown to be a skin sensitizer when tested in guinea pigs.

Flutriafol is considered to be ''Not likely to be Carcinogenic to Humans'' based on the results of the carcinogenicity studies in rats and mice. The results of the rat chronic toxicity/carcinogenicity study and the mouse carcinogenicity study are negative for carcinogenicity. All genotoxicity studies on flutriafol showed no evidence of clastogenicity or mutagenicity.

Specific information on the studies received and the nature of the adverse effects caused by flutriafol as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of June 6, 2014 (79 FR 32666) (FRL–9910–38).

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 the NOAEL and the LOAEL are identified. 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 flutriafol used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of June 6, 2014.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to flutriafol, EPA considered exposure under the petitioned-for tolerances as well as all existing flutriafol tolerances in 40 CFR 180.629. EPA assessed dietary exposures from flutriafol 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 flutriafol. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) Nationwide Health and Nutrition Examination Survey, What We Eat In America (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in food, EPA made the following assumptions for the acute exposure assessment: Tolerance-level residues or tolerance-level residues adjusted to account for the residues of concern for risk assessment and 100 percent crop treated (PCT). Since adequate processing studies have been submitted which indicate that tolerances for residues in/on apple juice, grape juice, dried prunes, and tomato puree are unnecessary and since tolerances for residues in/on raisin and tomato paste tolerances are established, the DEEM (ver. 7.81) default processing factors for these commodities were reduced to 1. The DEEM (ver. 7.81) default processing factors were retained for the remaining relevant commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA conducted from 2003–2008. As to residue levels in food, EPA made the following assumptions for the chronic exposure assessment: Tolerance-level residues or tolerance-level residues adjusted to account for the residues of concern for risk assessment and 100 PCT. Since adequate processing studies have been submitted which indicate that tolerances for residues in/on apple juice, grape juice, dried prunes, and tomato puree are unnecessary and since tolerances for residues in/on raisin and tomato paste tolerances are established, the DEEM (ver. 7.81) default processing factors for these commodities were reduced to 1. The DEEM (ver. 7.81) default processing factors were retained for the remaining relevant commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that flutriafol does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for flutriafol. Tolerance-level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for flutriafol in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of flutriafol. 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 First Index Reservoir Screening Tool (FIRST), and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of flutriafol for acute exposures are estimated to be 15.9 parts per billion (ppb) for surface water and 193 ppb for ground water.

For chronic exposures assessments the EDWC's are estimated to be 5.39 ppb for surface water and 165 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 193 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 165 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). Flutriafol is not registered for any specific use patterns that would result in residential exposure.

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

Flutriafol is a member of the triazole-containing class of pesticides. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events. In conazoles, however, a variable pattern of toxicological responses is found; some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects

from substances found to have a common mechanism of toxicity, see EPA's Web site at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

Triazole-derived pesticides can form the metabolite 1,2,4-triazole (T) and two triazole conjugates triazolylalanine (TA) and triazolylacetic acid (TAA). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, EPA conducted an initial human-health risk assessment for exposure to T, TA, and TAA resulting from the use of all current and pending uses of any triazole-derived fungicide as of September 1, 2005. The risk assessment was a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (*e.g.,* use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (*i.e.,* high-end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X Food Quality Protection Act (FQPA) safety factor (SF) for the protection of infants and children. The assessment included evaluations of risk for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment can be found in the propiconazole reregistration docket at *http://www.regulations.gov*. Docket ID Number EPA–HQ–OPP–2005–0497.

The most recent update to that aggregate human health risk assessment for free traizoles and its conjugates was conducted on April 9, 2015. This assessment considered all proposed/registered triazole derived pesticides uses with the resulting risk less than the Agency's level of concern. An update to the aggregate human health risk assessment for free triazoles and its conjugates may be found in this current docket, docket ID number EPA–HQ–OPP–2015–0179–0014 entitled, ''Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address The New Section 3 Registrations for Use of Propiconazole on Tea, Dill, Mustard Greens, Radish, and Watercress; Use of Difenoconazole on Globe Artichoke, Ginseng and Greenhouse Grown Cucumbers and Conversation of the Established Foliar Uses/Tolerances for Stone Fruit and Tree Nut Crop Groups to Fruit, Stone, Group 12–12 and the Nut, Tree, Group 14–12.; and Use of Flutriafol on Hops.''

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 SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The potential impact of *in utero* and perinatal flutriafol exposure was investigated in three developmental toxicity studies (two in rats, one in rabbits) and 2 multi-generation reproduction toxicity studies in rats. In the first of two rat developmental toxicity studies, increased quantitative susceptibility was observed with developmental effects (delayed ossification or non-ossification of the skeleton in the fetuses) seen at a lower dose than maternal effects. In the second rat developmental study, a qualitative susceptibility was noted. Although developmental toxicity occurred at the same dose level that elicited maternal toxicity, the developmental effects (external, visceral, and skeletal malformations; embryo lethality; skeletal variations; a generalized delay in fetal development; and fewer live fetuses) were more severe than the decreased food consumption and body-weight gains observed in the dams. For rabbits, there was in increased qualitative fetal susceptibly. Intrauterine deaths occurred at a dose level that also caused adverse effects in maternal animals. In the 2-generation reproduction studies, a qualitative susceptibility was also seen. Effects in the offspring decreased litter size and percentage of live births (increased pup mortality) and liver toxicity can be attributed to the systemic toxicity of the parental animals (decreased body weight and food consumption and liver toxicity).

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 flutriafol is complete.

ii. There is no indication that flutriafol is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. Signs of neurotoxicity were reported in the acute and subchronic neurotoxicity studies at the highest dose only; however, these effects were primarily seen in animals that were agonal (at the point of death) and, thus, are not indicative of neurotoxicity. In addition, there was no evidence of neurotoxicity in any additional short-term or long-term toxicity studies in rats, mice, and dogs.

iii. There are no concerns or residual uncertainties for prenatal and/or postnatal toxicity. Although there is evidence for increased quantitative and qualitative susceptibility in the prenatal study in rats and rabbits and the 2-generation reproduction study rats, there are no concerns for the offspring toxicity observed in the developmental and reproductive toxicity studies for the following reasons: (1) clear NOAELs and LOAELs were established in the fetuses/offspring for each of these studies; (2) the dose-response for these effects are well-defined and characterized; (3) developmental endpoints are used for assessing acute dietary risks to the most sensitive population (females 13–49 years old) as well as all other short and intermediate-term exposure scenarios; (4) the acute reference dose for females 13–49 is 1,000 fold lower than the dose at which quantitative susceptibility in the first developmental rat study was observed; and (5) the chronic reference dose is greater than 300-fold lower than the dose at which the offspring effects were observed in the 2-generation reproduction studies.

iv. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to flutriafol in drinking water. These assessments will not underestimate the exposure and risks posed by flutriafol.

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 flutriafol will occupy 39% of the aPAD for females 13–49 years, the population group receiving the greatest % aPAD.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to flutriafol from food and water will utilize 96% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for flutriafol.

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). Because there is no short-term residential exposure, and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for flutriafol.

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). 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 short-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 flutriafol.

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

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 flutriafol residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology gas chromotography/nitrogen-phosphorus detector (GC/NPD) for the proposed tolerances is available to enforce the tolerances recommended herein 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 flutriafol.

V. Conclusion

Therefore, tolerances are established for residues of flutriafol, ((±)-α-(2-fluorophenyl)-α-(4-fluorophenyl)-1H-1,2,4-triazole-1-ethanol), in or on hop, dried cones at 20 ppm. Additionally, the tolerances for cotton, gin byproducts, and cotton, undelinted seed established in 180.629(d) are being removed.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal**

Register. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 10, 2015.

Susan Lewis,

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 § 180.629:

■ a. Add alphabetically the commodity ''Hop, dried cones'' to the table in paragraph (a).

■ b. Remove the commodities ''Cotton, gin byproducts,'' and ''Cotton, undelinted seed'' from the table in paragraph (d).

The addition reads as follows:

§ 180.629 Flutriafol; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Hop, dried cones	20
* * * * *	

* * * * *

[FR Doc. 2015–29462 Filed 11–17–15; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 171, 172, 173, 174, and 179

[Docket No. PHMSA–2012–0082 (HM–251)]

RIN 2137–AE91

Hazardous Materials: Enhanced Tank Car Standards and Operational Controls for High-Hazard Flammable Trains

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Response to appeals.

SUMMARY: On May 8, 2015, the Pipeline and Hazardous Materials Safety Administration, in coordination with the Federal Railroad Administration (FRA), published a final rule entitled ''Hazardous Materials: Enhanced Tank Car Standards and Operational Controls for High-Hazard Flammable Trains,'' which adopted requirements designed to reduce the consequences and, in some instances, reduce the probability of accidents involving trains transporting large quantities of Class 3 flammable liquids. The Hazardous Materials Regulations provide a person the opportunity to appeal a PHMSA action, including a final rule. PHMSA received six appeals regarding the final rule, one of which was withdrawn. This document responds to the five remaining appeals submitted by the Dangerous Goods Advisory Council (DGAC), American Chemistry Council (ACC), Association of American Railroads (AAR), American Fuel & Petrochemical Manufacturers (AFPM), and jointly the Umatilla, Yakama, Warm Springs, and Nez Perce tribes (Columbia River Treaty Tribes) and the Quinault Indian Nation (Northwest Treaty Tribes).

DATES: November 18, 2015.

ADDRESSES: You may find information on this rulemaking and the associated appeals (Docket No. PHMSA–2012–0082) at the Federal eRulemaking Portal: *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ben Supko, (202) 366–8553, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration or Karl Alexy, (202) 493–6245, Office of Safety Assurance and Compliance, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Table of Contents of Supplementary Information

I. Background

Under 49 CFR 106.110–106.130,[1] a person may appeal a PHMSA action, including a final rule. Appeals must reach PHMSA no later than 30 days after the date PHMSA published the regulation. On May 8, 2015, PHMSA, in coordination with FRA, published a final rule entitled ''Hazardous Materials: Enhanced Tank Car Standards and Operational Controls for High-Hazard Flammable Trains'' (HM–251, 80 FR 26644) (the final rule). The final rule adopted requirements designed to reduce the consequences and, in some instances, reduce the probability of, accidents involving trains transporting large quantities of flammable liquids. The final rule defines certain trains transporting large volumes of flammable liquids as ''high-hazard flammable trains'' (HHFT)[2] and regulates their operation in terms of enhanced tank car designs, speed restrictions, braking systems, and routing. In response to the final rule, PHMSA received six appeals, one of which was withdrawn. The five active appeals were submitted by the DGAC, ACC, AAR, AFPM, and jointly the Columbia River Treaty Tribes and the Northwest Treaty Tribes.

Section 106.130 requires PHMSA to notify those who appeal, in writing, of the action on the appeal, within 90 days after the date that PHMSA published the action being appealed. Based on the final rule's publication date of May 8, 2015, PHMSA was required to provide a response or notice of delay by August 6, 2015. On August 6, 2015, PHMSA posted a notice of delay on its Web site and subsequently published that notice in the **Federal Register** on August 10, 2015 (Notice 15–14; 80 FR 47987).[3]

This document summarizes and responds to the appeals of the DGAC,

[1] All references to sections of the regulations in this document refer to title 49 CFR.

[2] HHFT ''means a single train transporting 20 or more loaded tank cars of a Class 3 flammable liquid in a continuous block or a single train carrying 35 or more loaded tank cars of a Class 3 flammable liquid throughout the train consist.'' § 171.8.

[3] *http://www.phmsa.dot.gov/pv_obj_cache/pv_obj_id_79961459E55D0ADB8FF510CF4A93EC93E3A00000/filename/Notice_No_15_14_Delay_in_Appeals.pdf*