BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0654 and EPA-HQ-OPP-2013-0655; FRL-9910-38]

Flutriafol; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes, amends, and removes tolerances for residues of flutriafol in or on multiple commodities which are identified and discussed later in this document. Cheminova A/S c/o Cheminova, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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-2013-0654 and EPA-HQ-OPP-2013-0655, 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: 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 the appropriate docket ID number, EPA-HQ-OPP-2013-0654 and/or EPA-HQ-OPP-2013-0655, for the pesticide petition of interest 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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 the appropriate docket ID number, EPA-HQ-OPP-2013-0654 and/or EPA-HQ-OPP-2013-0655, for the pesticide petition of interest by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 25, 2013 (78 FR 63938) (FRL-9901-96), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (*PP* 3F8156; EPA-HQ-OPP-2013-0654) and (*PP* 3F8174; EPA-HQ-OPP-2013-0655) by Cheminova A/S, c/o Cheminova, Inc., 1600 Wilson Blvd., Suite 700, Arlington, VA 22209-2510. The petitions requested that 40 CFR 180.629 amend the current established tolerances for residues of the fungicide flutriafol, including its metabolites and degradates, in or on corn, field, forage to 5 parts per million (ppm); corn, field, stover to 15 ppm; corn, pop, stover to 15 ppm (PP 3F8156). The petitions also requested that the 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide flutriafol, including its metabolites and degradates, in or on cattle, liver at 1.0 ppm; cattle, meat byproducts, except liver at 0. 10 ppm; cattle, muscle at 0.03 ppm; goat, liver at 1.0 ppm; goat, meat byproducts, except liver at 0.10 ppm; goat, muscle at 0.03 ppm; horse, liver at 1.0 ppm; horse, meat byproducts, except liver at 0.10 ppm; horse, muscle at 0.03 ppm; milk at 0.01 ppm; sheep, liver at 1.0 ppm; sheep, meat byproducts, except liver at 0.10 ppm; sheep, muscle

at 0.03 ppm (*PP* 3F8156); african tree nut at 0.015 ppm; almond, nutmeat at 0.6 ppm; almond, hulls at 15 ppm; brazil nut at 0.015 ppm; bur oak at 0.015 ppm; butternut at 0.015 ppm; cajon at 0.015 ppm; cashew at 0.015 ppm; castanha-do-maranhao at 0.015 ppm; coconut at 0.015 ppm; coquito nut at 0.015 ppm; dika nut at 0.015 ppm; guiana chestnut at 0.015 ppm; hazelnut at 0.015 ppm; heartnut at 0.015 ppm; hickory nut at 0.015 ppm; Japanese horse-chestnut at 0.015 ppm; macadamia nut at 0.015 ppm; mongongo nut at 0.015 ppm; monkey-pot at 0.015 ppm; pachira nut at 0.015 ppm; peanut, hay at 15 ppm; pecan at 0.015 ppm; sapucaia nut at 0.015 ppm; strawberry at 1.5 ppm; tomato, paste at 1.5 ppm; triticale, grain at 0.10 ppm; vegetable, cucurbit, Group 9 at 0.20 ppm; vegetable, fruiting, Group 8-10 at 0.60 ppm; walnut, black at 0.015 ppm; walnut, English at 0.015 ppm; wheat, forage at 30 ppm; wheat, grain at 0.10 ppm; wheat, hay at 15 ppm; and wheat, straw at 9 ppm (*PP* 3F8174). The documents referenced a summary of the petitions prepared by Cheminova, Inc., the registrant, which is available in the docket, *http://www.regulations.gov*. There was one comment received in response to the notice of filings and is discussed in Unit IV.D.

Based upon review of the data supporting the petitions, proposed tolerances for cattle, liver; cattle, meat by products, except liver; goat, liver; goat, meat by products, except liver; horse, liver; horse, meat by products, except liver; sheep, liver; and sheep, meat by products, except liver were lowered. The proposed tolerances for wheat, grain; pecan; african tree nut; brazil nut; bur oak, butternut, cajou; cashew; castanha-do-maranhao; coconut; coquito nut; dika nut; guiana chestnut; hazelnut; heartnut; hickory nut; japanese horse-chestnut; macadamia nut; mongongo nut; monkey-pot; pachira nut; sapucaia nut; walnut, black; walnut, english; vegetable, cucurbit, group 9; vegetable,

fruiting, group 8-10; cattle, muscle; goat, muscle; horse, muscle; and sheep, muscle were increased. A tolerance for triticale, grain is not needed and so is not being established. On the other hand, EPA has determined that tolerances are needed for hog, fat and hog, muscle and accordingly are being established. The established tolerances for cattle, meat by products; goat, meat by products; horse, meat by products; and sheep, meat by products are being removed. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 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.

Flutriafol has high oral acute toxicity in the mouse. It has 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.

Short-term, subchronic, and chronic toxicity studies in rats, mice, and dogs identified the liver as the primary target organ of flutriafol. Hepatotoxicity was first evident in the subchronic studies (rats and dogs) in the form of increases in liver enzyme release (alkaline phosphatase), and liver weights, and histopathology findings ranging from hepatocyte vacuolization to centrilobular hypertrophy and slight increases in hemosiderin-laden Kupffer cells. It is noteworthy that with chronic exposures there are no indications of progression of liver toxicity in any of the species tested. After over 1 year of exposure, hepatotoxicity in rats, dogs, and mice took the form of minimal to severe fatty changes; bile duct proliferation/cholangiolarfibrosis; hemosiderin accumulation in Kupffer cells; centrilobular hypertrophy, and increases in alkaline phosphatase release. Slight indications of effects in the hematopoietic system are

sporadically seen in the database. These effects were manifested in the form of slight anemia (rats and dogs) and increased platelet, white blood cell, neutrophil, and lymphocyte counts (mice). These effects, however, were minimal in severity.

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 most recent risk assessment, "Flutriafol: Human-Health Risk Assessment for Tolerances in/on Field Corn, Popcorn, Peanut, Wheat, Strawberries, Cucurbit, Vegetables, Fruiting Vegetables, and Tree Nuts," which can be found at http://*www.regulations.gov*, under document ID number EPA-HQ-OPP-2013-0654-0005 and EPA-HQ-2013-0655-0007.

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 flutriafol used for human risk assessment is shown in the following table.

Table--Summary of Toxicological Doses and Endpoints for Flutriafol 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 = 7.5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.075 mg/kg/day aPAD = 0.075 mg/kg/day	Developmental Study – rabbit LOAEL = 15 mg/kg/day based on decreased number of live fetuses, complete litter resorptions and increased post-implantation loss.

Acute dietary (General population including infants and children)	NOAEL = 250 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 2.5 mg/kg/day aPAD = 2.5 mg/kg/day	Neurotoxicity screening battery – rat LOAEL = 750 mg/kg/day based on decreased body weight, body-weight gain, absolute and relative food consumption, and clinical signs of toxicity in both sexes: dehydration, urine-stained abdominal fur, ungroomed coat, ptosis, decreased motor activity, prostration, limp muscle tone, muscle flaccidity, hypothermia, hunched posture, impaired or lost righting reflex, scant feces; in males: Red or tan perioral substance, chromodacryorrhea, chromorhinorrhea and labored breathing, and in females: Piloerection and bradypnea.
Chronic dietary (All populations)	NOAEL= 5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.05 mg/kg/day cPAD = 0.05 mg/kg/day	Chronic toxicity – dog LOAEL = 20 mg/kg/day based on adverse liver findings (increased liver weights, increased centrilobular hepatocyte lipid in the liver, and increases in alkaline phosphatase, albumin, and triglycerides), increased adrenal cortical vacuolation of the zona fasciculata, and marked hemosiderin pigmentation in the liver and spleen in both sexes; mild anemia (characterized by decreased hemoglobin, hematocrit, and red blood cell count) in the males; and initial body weight losses, decreased cumulative body-weight gains, and increased adrenal weights in the females.
Dermal short (1 to 30 days) and Intermediate (1-6 months) Term	NOAEL = 7.5 mg/kg/day [1]Dermal absorption factor = 21% UF_A = 10x UF_H = 10x	Occupational LOC for MOE = 100	Developmental toxicity –rabbit Developmental LOAEL = 15 mg/kg/day based on decreased number of live fetuses, complete litter resorptions, and increased post-implantation loss.

Inhalation short (1 to 30 days) and Intermediate (1-6 months) Term	NOAEL= 7.5 mg/kg/day Inhalation toxicity assumed to be equivalent to oral toxicity [2] Inhalation-absorption factor = 100% UF_A = 10x UF_H = 10x	Occupational LOC for MOE = 100	Developmental toxicity –rabbit Developmental LOAEL =15 mg/kg/day based on decreased number of live fetuses, complete litter resorptions, and increased post-implantation loss.
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the carcinogenicity studies in rats and mice.		

[1] Dermal absorption factor was derived from the dermal penetration study.
[2] Inhalation absorption factor is considered the worst-case scenario for inhalation exposure using an oral NOAEL.

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_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 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's (USDA) National 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/recommended, the default processing factors for these commodities were reduced to 1. The 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's (NHANES/WWEIA) conducted from 2003-2008 as well. As to the 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, dried prunes, grape juice, and tomato puree are unnecessary and since tolerances for residues in/on raisin and tomato paste tolerances are established/recommended, the default processing factors for these commodities were reduced to 1. The 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 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 flutriafol dietary exposure analysis and risk assessment. 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://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Food Quality Protection Act (FQPA), First Index Reservoir Screening Tool (FIRST), Pesticide Root Zone Model /Ground Water (PRZM/GW), the estimated drinking water concentrations (EDWCs) of flutriafol for acute exposures are estimated to be 40.55 parts per billion (ppb) for surface water and 310 ppb for ground water.

For chronic exposures for cancer assessments the EDWC's are estimated to be 4.03 ppb for surface water and 202 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute and chronic dietary risk assessment, the water concentration value of 310 ppb and 202 ppb, respectively, were 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 website at *http://www.epa.gov/pesticides/cumulative*.

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 (UFs)) 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 risks 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 and 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-2013-0295 entitled "Common Triazole Metabolites: Updated Dietary (Food + Water) Exposure and Risk Assessment to Address the Revised Tolerance for Residues of Fenbuconazole in Peppers." Based on the triazole residue estimates resulting from the proposed uses for flutriafol, a revised triazole risk assessment is unnecessary.

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 two multi-generation reproduction toxicity studies in rats. In the first of two rat developmental toxicity studies, a quantitative susceptibility was observed (delayed ossification or non-ossification of the skeleton in the fetuses) at a lower dose than maternal effects. In the second rat developmental study, a qualitative susceptibility was noted. Although the developmental toxicity occurred at the same dose level that elicited maternal toxicity, the developmental effects (external, visceral, and skeletal malformations; embryo lethality 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, 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 studies in rats, mice, and dogs, or in the 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 in rats, there are no concerns for the offspring toxicity observed in the developmental and reproductive toxicity studies for the following reasons:

• Clear NOAELs and LOAELs were established in the fetuses/offspring for each of these studies.

• The dose-response for these effects are well-defined and characterized.

• 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.

• 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. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to 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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to flutriafol will occupy 31% of the aPAD for females 13-49 years old, the population group receiving the greatest exposure.

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 51% of the cPAD for children (1-2 years old the population group receiving the greatest exposure. Because there are no residential uses for flutriafol, the chronic aggregate risk includes food and drinking water only.

3. *Short-term risk*. Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Since flutriafol is not registered for any use patterns that would result in residential exposure, the short- and intermediate-term aggregate risk is the sum of the risk from exposure to flutriafol through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, flutriafol is classified as "not likely to be carcinogenic to humans." EPA does not expect flutriafol to pose a cancer risk.

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 Chromatography/Nitrogen/Phosphorus detector (GC/NPD) for proposed tolerances) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch,

Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no Canadian or Mexican MRLs for flutriafol in/on the proposed commodities with the exception for peanut hay; dried chili peppers; sweet peppers; wheat straw; wheat grain and wheat bran. The Codex has established MRLs for flutriafol in or on dried chili peppers at 10 ppm; peanut, hay at 20 ppm; sweet peppers at 1 ppm; wheat, bran at 0.3 ppm; wheat, grain at 0.15 ppm; and wheat, straw at 8 ppm. Wheat, bran and wheat, grain MRLs are the same as the tolerances being established for flutriafol in the United States. The Agency is establishing tolerances for vegetable, fruiting, group 8-10 at 1.0 ppm to harmonize with the Codex sweet pepper MRL.

Harmonization of the peanut, hay and wheat, straw tolerances were determined to be unnecessary as these commodities do not normally enter international commerce.

C. Revisions to Petitioned-For Tolerances

Based on an analysis of feeding studies and on the livestock maximum reasonable dietary burdens, EPA is establishing tolerances for hog, fat and hog, muscle and establishing lower tolerances than those proposed by the petitioner for cattle, liver; cattle, meat by products, except liver; goat, liver; goat, meat by products, except liver; horse, liver; horse, meat by products, except liver; sheep, liver; and sheep, meat by products, except liver. For the same reason EPA is establishing higher tolerance than those proposed by the petitioner for cattle, muscle; goat, muscle; horse, muscle; and sheep, muscle.

EPA established higher tolerance than those proposed by the petitioner for African tree nut; brazil nut; bur oak, butternut, cajou; cashew; castanha-do-maranhao; coconut; coquito nut; dika nut; guiana chestnut; hazelnut; heartnut; hickory nut; Japanese horse-chestnut; macadamia nut; mongongo nut; monkey-pot; pachira nut; sapucaia nut; vegetable, cucurbit, group 9; walnut, black; walnut, english and wheat, grain based upon the analysis of residue levels from crop field trial data and the Organization for Economic Cooperation Development (OECD) tolerance calculation procedure. The proposed tolerance for triticale is unnecessary because triticale is covered by the wheat tolerances. As the petitioned for tolerances for liver and meat byproducts of cattle, goat, horse, and sheep, replace meat byproducts tolerances for cattle, goat, horse, and sheep, the latter tolerances are being removed.

D. Response to Comments

EPA received one comment to the Notice of Filing that stated, in part, that no residues or increase in residues should be allowed for flutriafol. No additional data was

provided by the commenter for Agency review. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by FFDCA section 408 states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework. As is the case with almost all conventional pesticides, numerous tests have been performed to study the toxicological effects of flutriafol. The various tests use doses that range from quite low to many times higher than virtually any member of the population of the United States could ever be exposed to. The highest doses are, in fact, deliberately chosen to try to elicit toxicological symptoms because a description of these symptoms and the dose levels at which they occur is one of the desired outcomes of the studies. Virtually any chemical (vitamins, for example) is toxic if taken in excessively large doses. Risk, however, is a function of the exposure levels that actually occur in the population in comparison to the threshold exposure level at which adverse symptoms begin to be elicited. For a toxicologically average person, if actual exposure is less than the adverse symptom exposure threshold, no such symptoms are expected to be seen. However, in order to make the reasonable certainty of no harm determination the Agency requires more assurance than this that the use of animals (instead of humans) for testing, variations in susceptibility among members of the U.S. population, greater sensitivity of infants and children, etc., has been accounted for in the risk assessment process. Therefore, safety factors are used in

conjunction with dosing levels at which no or only the first symptoms of exposure to the pesticide were seen to provide a substantial additional margin of safety. This mechanism helps assure that toxicological symptoms will not be elicited in members of the U.S. population by beneficial, labeled uses of the pesticide. The fact that very high doses of a pesticide cause toxicological symptoms is not, by itself, enough to make approval of uses of that pesticide unreasonable.

V. Conclusion

Therefore, tolerances are established for residues of flutriafol, in or on African tree nut at 0.02 ppm; Almond at 0.60 ppm; Almond hull at 15 ppm; Brazil nut at 0.02 ppm; Butternut at 0.02 ppm; Bur oak at 0.02 ppm; Cajou at 0.02 ppm; Cashew at 0.02 ppm; Castanha-Do-Maranhao at 0.02 ppm; Cattle, fat at 0.05 ppm; Cattle, liver at 0.80 ppm; Cattle, meat by products, except liver at 0.05 ppm; Cattle, muscle at 0.05 ppm; Coconut at 0.02 ppm; Coquito nut at 0.02 ppm; Corn, field, forage at 5.0 ppm; Corn, field, stover to 15 ppm; Corn, pop, stover to 15 ppm; Dika nut at 0.02 ppm; Guiana chestnut at 0.02 ppm; Goat, fat at 0.05 ppm; Goat liver at 0.80 ppm; Goat, meat byproducts, except liver at 0.05 ppm; Goat, muscle at 0.05 ppm; Hazelnut at 0.02 ppm; Heartnut at 0.02 ppm; Hickory nut at 0.02 ppm; Hog, fat at 0.01 ppm; Hog, muscle at 0.01 ppm; Horse, fat at 0.05 ppm; Horse, liver at 0.80 ppm; Horse, meat byproducts, except liver at 0.05 ppm; Horse, muscle at 0.05 ppm; Japanese horse-chestnut at 0.02 ppm; Macadamia nut at 0.02 ppm; Milk at 0.01 ppm; Mongongo nut at 0.02 ppm; Monkey-pot at 0.02 ppm; Pachira nut at 0.02 ppm; Peanut, hay at 15 ppm; Pecan at 0.02 ppm; Sapucaia nut at 0.02 ppm; Sheep, fat at 0.05 ppm; Sheep, liver at 0.80 ppm; Sheep, meat byproducts, except liver at 0.05 ppm; Sheep, muscle at 0.05 ppm; Strawberry at

1.5ppm; Tomato, paste at 1.5 ppm; Vegetable, cucurbit, group 9 at 0.30 ppm; Vegetable, fruiting, group 8-10 at 1.0 ppm; Walnut, black at 0.02 ppm; Walnut, English at 0.02 ppm; Wheat, bran at 0.30 ppm; Wheat, forage at 30 ppm; Wheat, germ at 0.25 ppm; Wheat, grain at 0.15 ppm; Wheat, hay at 15 ppm; and Wheat, straw at 9.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 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: June 2, 2014.

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 §180.629, revise the table in paragraph (a) to read as follows:

§ 180.629 Flutriafol; tolerances for residues.

(a) * * *

Commodity	Parts per million
African tree nut	0.02
Almond	0.60
Almond, hull	15
Banana [1]	0.30
Beet sugar	0.08
Brazil nut	0.02
Bur oak	0.02
Butternut	0.02
Cajou	0.02
Cashew	0.02
Castanha-do-maranhao	0.02
Cattle, fat	0.05
Cattle, liver	0.80
Cattle, meat byproducts, except liver	0.05
Cattle, muscle	0.05
Coconut	0.02
Coffee, green, bean [1]	0.15
Coffee, instant [1]	0.30
Coquito nut	0.02
Corn, field, forage	5.0
Corn, field, grain	0.01
Corn, field, refined oil	0.02
Corn, field, stover	15
Corn, pop	0.01
Corn, pop, stover	15
Dika nut	0.02
Fruit, pome, group 11-09	0.40
Fruit, stone, group 12-10	1.5
Goat, fat	0.05
Goat, liver	0.80

Goat, meat byproducts, except liver	0.05
Goat, muscle	0.05
Grain, aspirated fractions	2.2
Grape	1.5
Grape, raisin	2.4
Guiana chestnut	0.02
Hazelnut	0.02
Heartnut	0.02
Hickory nut	0.02
Hog, fat	0.01
Hog, muscle	0.01
Horse, fat	0.05
Horse, liver	0.80
Horse, meat byproducts, except liver	0.05
Horse, muscle	0.05
Japanese horse-chestnut	0.02
Macadamia nut	0.02
Milk	0.01
Mongongo nut	0.02
Monkey-pot	0.02
Pachira nut	0.02
Peanut	0.09
Peanut, hay	15
Pecan	0.02
Sapucaia nut	0.02
Sheep, fat	0.05
Sheep, liver	0.80
Sheep, meat byproducts, except liver	0.05
Sheep, muscle	0.05
Soybean, seed	0.35
Strawberry	1.5
Tomato, paste	1.5
Vegetable, cucurbit, group 9	0.30
Vegetable, fruiting, group 8-10	1.0
Walnut, black	0.02
Walnut, English	0.02
Wheat, bran	0.30
Wheat, forage	30
Wheat, germ	0.25
Wheat, grain	0.15
Wheat, hay	15
Wheat, straw	9.0

[1]There are no U.S. registrations as of October 22, 2013.

* * * * *

[FR Doc. 2014-13223 Filed 06/05/2014 at 8:45 am; Publication Date: 06/06/2014]