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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0875; FRL-9348-8]

Flutriafol; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes and amends tolerances for residues of Flutriafol [((±)-α-(2-fluorophenyl)-α-(4-fluorophenyl)-1*H*-1,2,4-triazole-1-ethanol], including its metabolites and degradates 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-2010-0875, is available either electronically through *http://www.regulations.gov* or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, 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: Tamue L. Gibson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-9096; email address: *gibson.tamue@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding

the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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://ecfr.gpoaccess.gov/cgi/t/text/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-2010-0875 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0875, 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

● *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 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 December 15, 2010 (75 FR 78240) (FRL-8853-1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7771) by Cheminova A/S, c/o Cheminova, Inc. 1600 Wilson Blvd., Arlington, VA 22209. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide flutriafol, including its metabolites and degradates, in or on corn, field, forage at 4.0 ppm; corn, field, stover at 6.0 ppm; corn, field, grain at 0.01 ppm; corn, field, flour at 0.03 ppm; corn, field, oil at 0.07 ppm; corn, field, meal at 0.03 ppm; corn, pop, stover at 6.0 ppm; corn, pop, grain at 0.01 ppm; grape at 1.1 ppm; grape, raisin at 2.5 ppm; peanut at 0.08 ppm; peanut, hay at 18 ppm; fruit, pome (Crop Group 11) at 0.60 ppm; fruit, stone (Crop Group 12) at 0.80 ppm; beet, sugar, root at 1.5 ppm; beet, sugar, tops at 2.5 ppm;

beet, sugar, refined at 0.70 ppm; beet, sugar, molasses at 1.0 ppm; beet, sugar, dried pulp at 1.0 ppm; wheat, forage at 25 ppm; wheat, hay at 9.0 ppm; wheat, straw at 6.0 ppm; wheat, grain at 0.15 ppm; wheat, grain, bran at 0.20 ppm; wheat, grain, germ at 0.20 ppm; barley, hay at 9.0 ppm; barley, straw at 6.0 ppm; barley, grain at 0.15 ppm; barley, grain, bran at 0.20 ppm; buckwheat, grain at 0.15 ppm; oats, forage at 25 ppm; oats, hay at 9.0 ppm; oats, straw at 6.0 ppm; oats, grain at 0.15 ppm; oats, grain, bran at 0.20 ppm; rye, forage at 25 ppm; rye, straw at 6.0 ppm; rye, grain at 0.15 ppm; cattle, liver at 0.12 ppm; goat, liver at 0.12 ppm; horse, liver at 0.12 ppm; sheep, liver at 0.12 ppm; and milk at 0.02 ppm. The proposed tolerance for fruit, pome which is based on new field trial data for pears and previously submitted data for apples, will replace the current tolerance for apples at 0.20 ppm. That notice referenced a summary of the petition prepared by Cheminova A/S, c/o Cheminova, Inc, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, tolerances for corn, field, forage; corn, field, stover; corn, field, refined oil; and corn, pop, stover were lowered. Tolerances for corn, field, flour and corn, field, meal were not required. Established tolerances for apple; cattle, liver; goat, liver; hog, liver; horse, liver; and sheep, liver and established rotational crop tolerances for corn, field, forage; corn, field, stover; corn, field, grain; corn, field, refined oil; corn, pop; and corn, pop, stover are removed. The proposed tolerances for wheat, forage; wheat, hay; wheat, straw; wheat, grain; wheat, grain, bran; wheat, grain, germ; barley, hay; barley, straw; barley, grain; barley, grain, bran; buckwheat, grain; oat, forage; oat, hay; oat, straw; oat, grain; oat, grain, bran; rye,

forage; rye, straw; and rye, grain were withdrawn by the petitioner. Tolerances were previously established on November 9, 2011 for banana, grape, raisin; pome and stone fruit, sugar beets and for the rotational corn crops--sweet, field, and popcorn, and cotton. 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), 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 can be found at *http://www.regulations.gov* in document "Flutriafol: Human Health Risk Assessment for Proposed Uses on Corn, Grapes, Peanuts, Pome Fruit (Crop Group 11), Stone Fruit (Crop Group 12), Sugar Beets, Wheat, Barley, Triticale, Buckwheat, Oats, Rye, Teosinte, and Imported Bananas," at p. 40 in docket ID number EPA-HQ-OPP-2010-0875.

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	NOAEL = 250	Acute RfD = 2.5	Neurotoxicity screening

(General population including infants and children)	mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	mg/kg/day aPAD = 2.5 mg/kg/day	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	Chronic RfD = 0.05 mg/kg/day	Chronic toxicity-dog LOAEL = 20 mg/kg/day

	UF_A = 10x UF_H = 10x FQPA SF = 1x	cPAD = 0.05 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.
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the carcinogenicity studies in rats and mice.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection

Act Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. mg/kg/day = milligrams/kilogram/day

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) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). 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, 100 percent crop treated (PCT), and Dietary Exposure Evaluation Model (DEEM™) version 7.81 default processing factors were used.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. 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, 100 PCT, and DEEM™ version 7.81 default processing factors were used.

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 or tolerance-level residues adjusted upward to account for the residues of concern for risk assessment and 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) Food 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 48.8 parts per billion (ppb) for surface water and 310 ppb for ground water.

For chronic exposures for non-cancer assessments the EDWC's are estimated to be 5.70 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 dietary risk assessment, the water concentration value of 310 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 conazole (triazole) 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 (EPA, 2002). 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 several conjugated triazole metabolites. 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 and the conjugated triazole metabolites 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 FQPA 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 Identification (ID) Number EPA-HQ-OPP-2005-0497 and an updated assessment may be found in docket ID EPA-HQ-OPP-2011-0120 in the document entitled "Common Triazole Metabolites: Updated Dietary (Food + Water) Exposure and Risk Assessment to Address the Amended

metconazole Section 3 Registration to Add uses on Tuberous and Corm Vegetables (Group 1C) and Bushberry Subgroup 13-07B." The Agency has determined that the proposed application to field and popcorn will not result in residues of 1,2,4-triazole (T), triazolylalanine (TA), and triazolylacetic acid (TAA) greater than the estimates incorporated in the most recent assessment. Therefore, a revised triazole metabolite assessment is not needed.

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*. 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 multigenerational 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 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, 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 concern for neurotoxicity with flutriafol. 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. A developmental neurotoxicity study (DNT) is not required given these results.

iii. There are no residual uncertainties for pre- and/or post-natal toxicity. Though there is evidence for increased susceptibility in the prenatal studies 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:

a. Clear NOAELs and LOAELs were established in the fetuses/offspring;

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

c. Developmental endpoints are used for assessing acute dietary risks to the most sensitive population (females 13-49) as well as all other short- and intermediate-term exposure scenarios; and

d. The chronic reference dose is greater than 300-fold lower than the does 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 (or higher) 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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to flutriafol will occupy 24% 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 42% of the cPAD for all infants less than 1 year old the population group receiving the greatest exposure. There are no residential uses for flutriafol. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of flutriafol 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). Flutriafol is not registered for any use patterns that would result in short-term residential exposure. Therefore, the short-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. *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). Flutriafol is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to flutriafol through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

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 Chromatography/Nitrogen/Phosphorus detector (GS/NPD) method for proposed tolerances and method ICIA AM00306 for ruminant liver) are 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 MRLs for flutriafol; therefore, harmonization is not an issue.

C. Revisions to Petitioned-For Tolerances

Based on the analysis of the residue trial data and Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures, tolerances for corn, field, forage; corn, pop, stover; and corn, field, stover were lowered. Established rotational crop tolerances for corn, field forage; corn, field, stover; corn, field, grain; corn, field, refined oil; corn, pop; and corn, pop, stover are removed as they are superseded by tolerances for direct application to the growing crop. The established tolerance for apple is removed and superseded by the previously established higher tolerance for fruit, pome, group 11-09. The established tolerances for cattle; liver; goat, liver; hog, liver; horse, liver; and sheep, liver are replaced by tolerances for meat byproducts of cattle, goat, hog, horse, and sheep. Based on the results from the field corn processing study, tolerances for corn, field, flour and corn, field, meal are not needed. Tolerances for wheat, forage; wheat, hay; wheat, straw; wheat, grain; wheat, bran; wheat, germ; barley, hay; barley, straw; barley, grain; barley, grain, bran; buckwheat, grain; oat, forage; oat, hay; oat, straw; oat, grain; oat, grain, bran; rye, forage; rye, straw; rye, grain were withdrawn by the petitioner. Tolerances were previously established on November 9, 2011 for banana; grape; grape, raisin; pome and stone fruit; sugar beets and for the rotational crops, field and popcorn, and cotton.

V. Conclusion

Therefore, tolerances are established for residues of flutriafol, [((±)-α-(2-fluorophenyl)-α-(4-fluorophenyl)-1*H*-1,2,4-triazole-1-ethanol], including its metabolites and degradates, in or on corn, field, forage at 0.75 ppm; corn, field, stover at 1.5 ppm; corn, field, grain at 0.01 ppm; corn, field, refined oil at 0.02 ppm; corn, pop at 0.01 ppm; corn, pop, stover at 1.5 ppm; cattle, meat byproducts at 0.07 ppm; goat, meat byproducts at 0.07 ppm; hog, meat byproducts at 0.02 ppm; horse, meat byproducts at 0.07 ppm and sheep, meat byproducts at 0.07 ppm. This final rule deletes established tolerances for apple; cattle; liver; goat, liver; hog, liver; horse, liver; and sheep, liver. This final rule also deletes established rotational crop tolerances for corn, field, forage; corn, field, stover; corn, field, grain; corn, field, refined oil; corn, pop; and corn, pop, stover.

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) (Public Law 104-4).

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), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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 27, 2012.

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. Section 180.629 is amended as follows:

i. Remove the entries for "Apple"; "Cattle, liver"; "Goat, liver"; "Hog, liver"; "Horse, liver"; and "Sheep, liver" from the table to paragraph (a).

ii. Add alphabetically the entries for "Cattle, meat byproducts"; "Corn, field, forage"; "Corn, field, grain"; "Corn, field, refined oil"; "Corn, field, stover"; "Corn, pop"; "Corn, pop, stover"; "Goat meat byproducts"; "Hog, meat byproducts"; "Horse meat byproducts"; and "Sheep meat byproducts" to the table in paragraph (a).

iii. Remove the entries for "Corn, field, forage"; "Corn, field, grain"; "Corn, field, refined oil"; "Corn, field, stover"; "Corn, pop"; and "Corn, pop, stover" from the table in paragraph (d).

The added entries read as follows:

§ 180.629 Flutriafol; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Cattle, meat byproducts	0.07
Corn, field, forage	0.75
Corn, field, grain	0.01

Corn, field, refined oil	0.02
Corn, field, stover	1.5
Corn, pop	0.01
Corn, pop, stover	1.5
* * *	* *
Goat, meat byproducts	0.07
* * *	* *
Hog, meat byproducts	0.02
Horse, meat byproducts	0.07
* * *	* *
Sheep, meat byproducts	0.07
* * *	* *

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