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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0297; FRL-10004-03]

Flutriafol; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flutriafol in or on multiple commodities which are identified and discussed later in this document. Cheminova A/S on behalf of FMC Corporation 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-2018-0297, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703)

305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing 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-2018-0297 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 docket ID number EPA-HQ-OPP-2018-0297, 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 July 24, 2018 (83 FR 34968) (FRL-9980-31), 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 8F8661) by Cheminova A/S, on behalf of FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104. 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 alfalfa, forage at 15.0 parts per million (ppm); alfalfa, hay at 50 ppm; barley, grain at 1.5 ppm; barley, hay at 7.0 ppm; barley, straw at 8.0 ppm; corn, sweet, forage at 9.0 ppm; corn, sweet kernels plus cobs with husks removed at 0.03 ppm; corn, sweet, stover at 8 ppm; rice, bran at 0.4 ppm; rice, grain at 0.5 ppm; rice, hulls at 1.5 ppm; rice, straw at 0.9 ppm. Although the Agency's document did not expressly include the following, the petition also requested the removal of the following tolerances upon establishment of the petitioned-for tolerances: existing tolerances for inadvertent or indirect residues of flutriafol in corn, sweet, forage at 0.09 ppm; corn, sweet, kernels plus cobs with husks removed at 0.01 ppm; and corn, sweet, stover at 0.07 ppm. That document referenced a summary of the petition prepared by Cheminova A/S on behalf of FMC Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is issuing some tolerances that vary from what the petitioner requested. The reason for these changes are explained in Unit IV.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 prenatal 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.

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 "Human Health Risk Assessment in Support of a Section 3 Registration for Application to Alfalfa, Barley, Sweet Corn, Rice (as a Rotated Crop), Turf, and Ornamentals at 18" in docket ID number EPA-HQ-OPP-2018-0297.

B. Toxicological Points of Departure/Levels of Concern

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

uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides*.

A summary of the toxicological endpoints for flutriafol used for human risk assessment is shown in Table 1 of this unit.

Table 1. 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 to 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	Chronic RfD = 0.05 mg/kg/day	Chronic toxicity – dog LOAEL = 20 mg/kg/day based on adverse liver findings (increased

	UF_H = 10X FQPA SF = 1X	cPAD = 0.05 mg/kg/day	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-term (1 to 30 days)	Dermal (or oral) study NOAEL = 7.5 mg/kg/day (dermal absorption factor = 15% UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC for MOE = <100	Developmental toxicity – rabbit 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.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to 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) 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 (ROC) for risk assessment, and 100 percent crop treated (PCT). Since adequate processing studies have been submitted that indicate that residues do not concentrate as a result of processing at levels which would require a tolerance in or on apple juice (translated to pear juice), grape juice, dried prunes, and tomato puree, the Agency's 2018 default processing factors for these commodities were reduced to 1. In addition, the Agency used a processing factor of 1 for raisin and tomato paste since those existing tolerances already account for the concentration of residues during the processing of the RACs, i.e., grape and tomato, into those processed commodities. 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 NHANES/WWEIA conducted from 2003-2008. As to residue levels in food, for the chronic analysis EPA assumed the same residue estimates as that used in the acute assessment excluding wheat, apple, and grape, where average field-trial residues were assumed and apple and grape where screening-level usage analysis (SLUA) percent crop treated estimates were assumed (100 PCT assumed for the remaining crops). The

chronic analysis also incorporated refinements to the livestock residue estimates through incorporation of median residues for selected commodities in calculation of the dietary burden estimates (100 PCT assumed) and through the incorporation of average residues from the feeding study. The Agency used the same processing factors for the chronic dietary assessment as it used for the acute assessment.

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

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

• Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The acute analysis assumed 100 PCT for all commodities. For the chronic analysis, the Agency used PCT for the following uses: apple 15%; grape 5%; and raisin 1%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding up to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the

percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which flutriafol may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for 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), Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM5-VVWM) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of flutriafol for acute exposures are estimated to be 29.5 parts per billion (ppb) for surface water and 630 ppb for ground water. For chronic exposure assessments, the EDWCs are estimated to be 5.8 ppb for surface water and 540 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 630 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 540 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 currently registered for the following uses that could result in residential exposures: golf course turf. EPA assessed residential exposure using the following assumptions: Residential handler exposure is not expected as result of the golf course use. There is the potential for post-application exposure for individuals exposed as a result of being in an environment that has been previously treated with flutriafol (i.e. golf courses). The quantitative exposure/risk assessment for residential post-application exposures is based on the following scenario:

• Dermal exposures for children (6 to < 11 years old), children (11 to < 16 years old), and adults contacting residues deposited on turf resulting from broadcast golf course applications.

These lifestages are not the only lifestages that could be potentially exposed for these post-application scenarios; however, the assessment of these lifestages are considered health protective for the exposures and risks for any other potentially exposed lifestages.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide*.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or

revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to flutriafol and any other substances. Although the conazole fungicides (triazoles) produce 1,2,4 triazole and its acid-conjugated metabolites (triazolylalanine and triazolylacetic acid), 1,2,4 triazole and its acid-conjugated metabolites do not contribute to the toxicity of the parent conazole fungicides (triazoles). The Agency has assessed the aggregate risks from the 1,2,4 triazole and its acid-conjugated metabolites (triazolylalanine and triazolylacetic acid) separately. The new uses of flutriafol are not expected to quantitatively alter the dietary exposure estimates used in the most recent aggregate risk assessment for the common triazole metabolites. The most recent triazole aggregate risk assessment (*Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address New Section 3 Registrations For Use of Difenoconazole and Mefentrifluconazole*; DP451447, dated May 15, 2019) can be found at *https://www.regulations.gov* at docket ID number EPA-HQ-OPP-2018-0002. Flutriafol does not appear to produce any other toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that flutriafol has a common mechanism of toxicity with other substances.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity

and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There is evidence of increased quantitative and qualitative prenatal and postnatal susceptibility for flutriafol in rats. 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, decreased number of live fetuses, complete litter resorptions and increased post-implantation loss were observed. Under current practices, these effects are considered both maternal and developmental effects, and it is unknown whether the effects occurred from toxicity to maternal animals or the fetuses. In the two-generation reproduction studies, effects in the offspring [decreased litter size and percentage of live births (increased pup mortality) and liver toxicity] was observed at the same dose as systemic toxicity in 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 uncertainty factors (UFs) to account for neurotoxicity. Signs of neurotoxicity were reported in the acute and subchronic neurotoxicity studies at the highest dose tested only. In the acute neurotoxicity study, 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. There is evidence of increased quantitative and qualitative susceptibility in developmental and reproduction toxicity studies; however, there concern is low based on the following:

• Clear NOAELs and LOAELs were established for effects in the fetuses/offspring.

• 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 to 49) as well as all other short-term and intermediate-term exposure scenarios.

• The acute reference dose for females 13 to 49 is 1,000-fold lower than the dose at which quantitative susceptibility in the first developmental rat study was observed.

• The chronic reference dose is greater than 300-fold lower than the doses 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 somewhat refined in that the chronic analysis used some average field trial residue data as well as some percent crop treated information. 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 69% 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 75% of the cPAD for all infants <1 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of 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 currently registered for uses that could result in short-term

residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to flutriafol.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 380 for adults, 500 for youth ages 11 to < 16 years old, and 160 for children ages 6 to < 11 years old. Because EPA's level of concern for flutriafol is an MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, flutriafol is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for 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 based on validation data were provided as part of the magnitude residues studies. In addition, the QuECHERS method has been shown to support and 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 Codex MRLs established for residues of flutriafol in/on the proposed commodities.

C. Revisions to Petitioned-For Tolerances

Based on the analysis of available field trial data and the Organization for Economic Co-

operation and Development (OECD) tolerance calculation procedure, EPA is establishing higher tolerance levels for residues in/on alfalfa forage and hay than what the petitioner proposed as it appears the petitioner averaged the residues from the two cuttings for both commodities. EPA used the higher residues of the two cuttings as this represents a worst-case scenario. Based on the increased dietary burden from new additional feed commodities (i.e., alfalfa forage and hay), EPA calculates that the established tolerances for residues of flutriafol in/on fat, liver, and meat byproducts, except liver of cattle, goat, horse, and sheep; eggs; and fat and meat byproducts of poultry need to be increased to avoid adulteration of those commodities. In accordance with 40 CFR 180.6, EPA is increasing those tolerances in this rulemaking.

EPA is not recommending tolerances for rice hulls or rice straw as these commodities are no longer considered to be significant feed items or for rice bran as it is lower than the rice, grain (RAC) tolerance. Finally, EPA is expressing tolerance values to be consistent with OECD's rounding class practice.

V. Conclusion

Therefore, tolerances are established for residues of flutriafol, (±)- α- (2- fluorophenyl- α- (4- fluorophenyl)- 1*H*- 1,2,4- triazole- 1- ethanol), in or on alfalfa, forage at 20 parts per million (ppm); alfalfa, hay at 70 ppm; barley, grain at 1.5 ppm; barley, hay at 7 ppm; barley, straw at 8 ppm; corn, sweet, forage at 9 ppm; corn, sweet kernels plus cobs with husks removed at 0.03 ppm; corn, sweet, stover at 8 ppm; rice, grain at 0.5 ppm. Based on the increased dietary burden from the new additional feed commodities, that agency is revising the following established tolerances of flutriafol in or on cattle, fat at 0.2 parts per million (ppm); cattle, liver at 1.5 ppm; cattle, meat byproducts, except liver at 0.08 ppm; egg at 0.02 ppm; goat, fat at 0.2 ppm; goat, liver at 1.5 ppm; goat, meat byproducts, except liver at 0.08 ppm; horse, fat at 0.2 ppm;

horse, liver at 1.5 ppm; horse, meat byproducts, except liver at 0.08 ppm; poultry, fat at 0.02 ppm; poultry, meat byproducts at 0.02 ppm; sheep, fat at 0.2 ppm; sheep, liver at 1.5 ppm; sheep, meat byproducts, except liver at 0.08 ppm. Also, this regulation removes established tolerances for inadvertent or indirect residues of flutriafol in corn, sweet, forage at 0.09 ppm; corn, sweet, kernels plus cobs with husks removed at 0.01 ppm; and corn, sweet, stover at 0.07 ppm the entries for the tolerances contained in paragraph (d) of §180.629. These tolerances are superseded and no longer necessary with the establishment of the new tolerances for sweet corn commodities.

VI. Statutory and Executive Order Reviews

This action establishes and modifies tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances 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: January 23, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In § 180.629:

a. In the table in paragraph (a):

i. Add alphabetically the entries for “Alfalfa, forage”; “Alfalfa, hay”; “Barley, grain”; “Barley, hay”; and “Barley, straw”;

ii. Revise the entries for “Cattle, fat”; “Cattle, liver”; and “Cattle, meat byproducts, except liver”;

iii. Add alphabetically the entries for “Corn, sweet, forage”; “Corn, sweet, kernel plus cob with husk removed”; and “Corn, sweet, stover”; and

iv. Revise the entries for “Egg”; “Goat, fat”; “Goat, liver”; “Goat, meat byproducts, except liver”; “Horse, fat”; “Horse, liver”; “Horse, meat byproducts, except liver”; “Poultry, fat”; “Poultry, meat byproducts”; “Sheep, fat”; “Sheep, liver”; and “Sheep, meat byproducts, except liver”; and

b. In paragraph (d):

i. In the introductory text, remove “table below” and “specified below” and add in their places “table 2 to this paragraph (d)” and “specified in table 2 to this paragraph (d),” respectively; and

ii. Revise the table.

The revisions and additions read as follows:

§ 180.629 Flutriafol; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * * * *	
Alfalfa, forage	20
Alfalfa, hay	70
* * * * * * *	
Barley, grain	1.5
Barley, hay	7
Barley, straw	8
* * * * * * *	
Cattle, fat	0.2
Cattle, liver	1.5
Cattle, meat byproducts, except liver	0.08
* * * * * * *	
Corn, sweet, forage	9
Corn, sweet, kernel plus cob with husk removed	0.03
Corn, sweet, stover	8
* * * * * * *	
Egg	0.02
* * * * * * *	
Goat, fat	0.2
Goat, liver	1.5
Goat, meat byproducts, except liver	0.08
* * * * * * *	
Horse, fat	0.2
Horse, liver	1.5
Horse, meat byproducts, except liver	0.08
* * * * * * *	
Poultry, fat	0.02
Poultry, meat byproducts	0.02
* * * * * * *	
Sheep, fat	0.2
Sheep, liver	1.5
Sheep, meat byproducts, except liver	0.08
* * * * * * *	

* * * * *

(d) * * *

Table 2 to Paragraph (d)

Commodity	Parts per million
Rice, grain	0.5

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