■ ii. Remove the entries for "Aronia berry"; "Buffalo currant"; "Bushberry subgroup 13B"; "Chilean guava"; "European barberry"; "Highbush cranberry"; "Honeysuckle, edible"; "Jostaberry"; "Juneberry"; "Lingonberry"; "Native currant"; "Salal"; and "Sea buckthorn" from the table in paragraph (a)(1);

■ iii. Alphabetically add commodities to the table in paragraph (a)(1); and

■ iv. Revise the introductory text of paragraph (a)(2).

The amendments read as follows:

**§ 180.574 Fluazinam; tolerances for residues.**

(a) * * * (1) Tolerances are established for residues of fluazinam (3-chloro-*N*-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine), including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only fluazinam.

| Commodity | Parts per million |
|---|---|
| Bushberry subgroup 13-07B | 7.0 |
| * * * | * * |
| Lettuce, head | 0.02 |
| Lettuce, leaf | 2.0 |
| Onion, bulb, subgroup 3-07A | 0.20 |
| * * * | * * |

(2) Tolerances are established for residues of fluazinam, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only fluazinam and its metabolite AMGT (3-[[4-amino-3-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]amino]-2-nitro-6-(trifluoromethyl) phenyl]thio]-2-(beta-D-glucopyranosyloxy) propionic acid).

* * * * *

[FR Doc. 2010–11302 Filed 5–11–10; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[EPA–HQ–OPP–2009–0184; FRL–8812–6]**

## Flutriafol; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes 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 apple at 0.20 ppm; soybean, seed at 0.35 ppm; and grain, aspirated fractions at 2.2 ppm; and cattle, goat, hog, horse and sheep liver at 0.02 ppm. Cheminova A/S, c/o Cheminova, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective May 12, 2010. Objections and requests for hearings must be received on or before July 12, 2010, 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:** EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0184. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

**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; e-mail 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 Access Electronic Copies of this Document?*

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Test Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, 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–2009–0184 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before July 12, 2010.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA

without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2009–0184, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

## II. Petition for Tolerance

In the **Federal Register** of April 8, 2009 (74 FR 15973) (FRL–8407–4), 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 7F7197) by Cheminova A/S, c/o Cheminova, Inc., 1600 Wilson Blvd., Arlington, VA 22209. The petition requested that 40 CFR 180 be amended by establishing tolerances for residues of the fungicide flutriafol in or on the following raw agricultural commodities: Apple at 0.2 parts per million (ppm); apple, wet pomace at 0.3 ppm; soybean at 0.3 ppm; soybean, aspirated grain fractions at 0.5 ppm; and liver (cattle, goat, hog, horse and sheep) at 0.01 ppm. That notice referenced a summary of the petition prepared by Cheminova A/S, c/o Cheminova Inc., the registrant, which is available to the public 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 has determined that tolerances are not needed for apple, juice; wet apple pomace; soybean meal; soybean hull; and soybean oil. Additionally, tolerances were increased for soybean seed; aspirated grain fractions; and cattle, goat, hog, horse and sheep liver. 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 the petitioned-for tolerances for residues of flutriafol including its metabolites and degradates in or on apple at 0.20 ppm; soybean, seed at 0.35 ppm; grain, aspirated fractions at 2.2 ppm; and cattle, goat, hog, horse and sheep liver at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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. 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 Apple and Soybean at page 20 in docket ID number EPA–HQ–OPP–2009–0184.

Flutriafol has low acute oral and inhalation toxicity. A 28–day dermal toxicity study did not reveal any signs of toxicity at the limit dose (1,000 mg/kg/day). Thus, flutriafol is not considered to be acutely toxic via the dermal route. 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.

The pattern of toxicity attributed to flutriafol exposure via the oral route includes hepatotoxicity, developmental toxicity (manifested as increased intrauterine death) at the same dose as parental toxicity, and generalized toxicity (body weight/body weight gains and food consumption decrements as well as slight anemia).

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 enzymes (alkaline phosphatase), liver weights, and histopathology findings ranging from hepatocyte vacuolation to centrilobular hypertrophy and slight increases in hemosiderin-laden Kupffer cells. With chronic exposures, there were no indications of progression of liver toxicity in either species. Neither the chronic/carcinogenicity study in rats nor the carcinogenicity study in mice revealed treatment-related increases in tumor incidences.

Slight indications of effects on red blood cells were sporadically seen in the database. These effects were manifested in the form of slight anemia and increased hemosiderin in the liver or spleen of rats and dogs. Increased platelet, white blood cell, neutrophil, and lymphocyte counts were also observed in one study in mice. However, these effects were minimal in severity, were not considered adverse, and were not observed in any other study or species.

### *B. Toxicological Endpoints*

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in

sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 can be found at *http://www.regulations.gov* in document Flutriafol. Human-Health Risk Assessment for Proposed Uses on Apple and Soybean at page 20 in docket ID number EPA–HQ–OPP–2009–0184.

*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 for soybean and apples. Tolerances have been previously established in 40 CFR 180.629 in or on soybean treated under section 18 of FIFRA. 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.

In conducting the acute dietary exposure assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, version 2.03) which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). The following assumptions were made for the acute exposure assessment: Tolerance-level residues, 100% crop treated (CT), and DEEM™ version 7.81 default processing factors were used.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used the DEEM™ software with DEEM-FCID™, version 2.03 which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII. The following assumptions were made for the chronic exposure assessment: Tolerance-level residues, 100% CT, and DEEM™ version 7.81 default processing factors were used.

iii. *Cancer*. The Agency classified flutriafol as "Not Likely to be Carcinogenic to Humans" based on the results of the carcinogenicity studies in rats and mice. All genotoxicity studies on flutriafol showed no evidence of clastogenicity or mutagenicity. Flutriafol is a member of a class of pesticides known as triazoles. Although several triazoles are carcinogenic, many are not and flutriafol has been adequately tested and found not to be carcinogenic in long-term studies in rats and mice. Structure-activity-relationship analysis indicates that flutriafol may have the potential to produce thyroid and/or liver tumors in rodents. However, in the rat and mouse carcinogenicity studies, there were no treatment-related increases in tumor incidence when comparing treated animals to controls.

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

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for flutriafol in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of flutriafol. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the First Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI-GROW) models, 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 4.8 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 5.7 ppb for surface water and 4.8 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 48.8 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 5.7 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Flutriafol is not registered for any specific use patterns that would result in residential exposure.

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

Flutriafol is a member of the triazole-containing class of pesticides. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism 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) 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.

The Agency completed an updated dietary risk assessment considering exposure to T, TA, and TAA based on established and proposed uses of triazole fungicides; however, this risk assessment did not include flutriafol uses. The resulting acute and chronic exposure to T, TA, and TAA were less than the Agency's level of concern (T: ≤36% aPAD and ≤54% cPAD; TA/TAA: 34% aPAD and ≤40% cPAD). The Agency concludes that revised T and TA/TAA dietary risk assessments are unnecessary for the following reasons: (1) Incorporation of the flutriafol uses resulted in negligible changes to the T and TA/TAA residue estimates incorporated into the previous dietary analyses and (2) the T and TA/TAA drinking water estimates incorporated into the previous dietary analyses assumed an annual fungicide application rate of 10.38 pound active ingredient/acre (lb ai/acre) for nonagricultural uses and 2.0 lb ai/acre for agricultural uses and the formation of T and/or TA/TAA at 30.7% of the applied rate. Since the annual application rate for flutriafol is ≤0.63 lb ai/acre and since all environmental degradates were identified at <10% total radioactive residue (TRR), a revised drinking water assessment was 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 a multigeneration reproduction toxicity study in rats. Only one of the rat developmental toxicity studies was acceptable. Qualitative susceptibility was noted in the acceptable rat developmental study and in the two-generation reproduction study.

In the acceptable rat developmental study, developmental toxicity (late resorptions, skeletal malformations and variations, decrease in fetal weights) occurred at the same dose level that elicited maternal toxicity (late resorptions, decreased food consumption, body weight gains). In rabbits, a decreased number of live fetuses were observed at the same dose that also caused adverse effects in maternal animals (complete litter resorptions, increased post-implantation loss, decreased body weight gain and food consumption).

In the two-generation reproduction study, effects in the offspring (decreased litter size and percentage of live births and liver toxicity) were observed at the same dose as parental toxicity (decreased body weight and food consumption and liver toxicity) and may be related to the systemic toxicity of the parents. There is no concern for the offspring toxicity observed in the developmental and reproductive toxicity studies for the following reasons: (1) the effects were seen in the presence of maternal/parental/systemic toxicity; (2) clear NOAELs and LOAELs were established in the fetuses/offspring; (3) the dose-response for these effects are well defined and characterized; and (4) 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.

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings.

- Except for an immunotoxicity study, the toxicological database is complete. In accordance with the revised part 158 an immunotoxicity study is required. In the case of flutriafol, there was no evidence of toxicity to the immune organs in any study in the database. Increased hemosiderin in the spleen was observed in rats or dogs. However, this was considered due to the storage of iron following the clearance of damaged erythrocytes from the blood and not to an immunotoxic effect. Increased platelet, white blood cell, neutrophil, and lymphocyte counts were also observed in one study in mice. However, these effects were minimal in severity, were not considered adverse, and were not observed in any other study or species. Therefore, they are not considered immunotoxic effects.

In addition, flutriafol does not belong to a class of chemicals (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Based on the above considerations, the Agency does not believe that conducting a special series OPPTS Harmonized Guideline 870.7800 immunotoxicity study will result in a point of departure lower than that used for overall risk assessment. Therefore an additional UFDB does not need to be applied.

- There are no concerns or residual uncertainties for pre- and/or post-natal toxicity. There is no evidence of quantitative susceptibility following *in utero* exposures to rats or rabbits and following pre- and post-natal exposures to rats for two generations. There is no concern for the offspring toxicity observed in the developmental and reproductive toxicity studies for the following reasons: (1) The effects were seen in the presence of maternal/parental systemic toxicity; (2) clear NOAELs and LOAELs were established in the fetuses/offspring; (3) the dose-response for these effects are well defined and characterized; and (4) 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.

• 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 is not required.

• The dietary exposure assessment is conservative in nature (utilized tolerance level residues and 100% CT were utilized).

• Conservative (protective) assumptions were used in the ground water and surface water modeling to assess exposure to flutriafol in drinking water.

• There are no proposed residential uses.

• Based on summaries of confined/field rotational crop studies submitted by the petitioner, the Agency determined that rotation of only soybean to a treated field was acceptable. The Agency is requesting that the petitioner submit a detailed version of these studies and views this requirement as confirmatory and, therefore, not requiring the application of additional uncertainty factors.

• Storage stability data for flutriafol and/or its metabolites in/on livestock and soybean commodities have been requested. Based on the available storage stability data, which did not result in the degradation of flutriafol or its metabolites in a variety of matrices, the Agency views these data as confirmatory and, therefore, not requiring the application of additional uncertainty factors.

*E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

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 3.7% 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 will utilize 4.6% of the cPAD for (children 1 to 2 years old) the population group receiving the greatest exposure. There are no proposed or existing residential uses of flutriafol. Therefore, chronic dietary exposure to flutriafol is not a concern to the Agency.

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 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*. For flutriafol there were no treatment-related increases in tumor incidence when comparing treated animals to controls in the rat and mouse carcinogenicity studies. Therefore, the human cancer risk from flutriafol is negligible.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to flutriafol residues.

## IV. Other Considerations

*A. Analytical Enforcement Methodology*

Adequate enforcement methodologies (multiresidue method (MRM) Protocol D for apples; GC/Nitrogen/Phosphorus detector (NPD) method for soybean seed and method ICIA AM00306 for ruminant liver) are available to enforce the tolerance expression. The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

*B. International Residue Limits*

There are no currently established Codex, Canadian, or Mexican maximum residue limits for flutriafol on apples and soybeans.

*C. Revisions to Petitioned-For Tolerances*

Based on the processing data, the Agency determined that apple juice, wet apple pomace, soybean meal, soybean hull, and soybean oil tolerances are unnecessary. However, a tolerance for grain, aspirated fractions at 2.2 is required. Based on the crop field trial data, livestock feeding study, and/or the tolerance calculator, EPA is recommending for higher tolerances than that proposed by the petitioner for soybean, seed; aspirated grain fractions, and liver (cattle, goat, hog, horse, and sheep).

## V. Conclusion

Therefore, tolerances are established for residues of flutriafol including its metabolites and degradates in or on apple at 0.20 ppm; soybean, seed at 0.35 ppm; grain, aspirated fractions at 2.2 ppm; cattle, goat, hog, horse and sheep liver at 0.02 ppm.

## VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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: April 28, 2010.

**Steven Bradbury,**

*Director, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

## PART 180—[AMENDED]

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

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

■ 2. Revise § 180.629 to read as follows:

**180.629 Flutriafol; tolerances for residues.**

(a) *General.* Tolerances are established for the 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 the following commodities. Compliance with the following tolerances is to be determined by measuring flutriafol only.

| Commodity | Parts per million |
|---|---|
| Apple | 0.20 |
| Cattle, liver | 0.02 |
| Goat, liver | 0.02 |
| Grain, aspirated fractions | 2.2 |
| Hog, liver | 0.02 |
| Horse, liver | 0.02 |
| Sheep, liver | 0.02 |
| Soybean, seed | 0.35 |

(b) *Section 18 tolerance* [Reserved].

(c) *Tolerances with regional registrations* [Reserved].

(d) *Indirect or inadvertent residues* [Reserved].

[FR Doc. 2010–11296 Filed 5–11–10; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[EPA–HQ–OPP–2009–0307; FRL–8822–7]**

## Clethodim; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of clethodim in or on the raw agricultural commodity artichoke, globe; bushberry subgroup 13-07B; caneberry subgroup 13-07A; and peach. This regulation additionally removes the existing tolerances on lettuce leaf and spinach, as they are covered by the leafy greens subgroup 4A and removes the tolerance for flax seed at 0.50 ppm because there is one for flax seed at 0.6 ppm. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective May 12, 2010. Objections and requests for hearings must be received on or before July 12, 2010, 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:** EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0307. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

**FOR FURTHER INFORMATION CONTACT:** Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *ertman.andrew@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: