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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.

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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 February 14, 2020. Objections and

requests for hearings must be received on or before April 14, 2020, 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](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](mailto: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

April 14, 2020. 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

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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](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, (()-[alpha]-(2-fluorophenyl-[alpha]-

(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](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

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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](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

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Point of departure

Exposure/scenario and uncertainty/ RfD, PAD, LOC for Study and toxicological effects

safety factors risk assessment

----------------------------------------------------------------------------------------------------------------

Acute dietary (Females 13 to 49 NOAEL = 7.5 mg/kg/ Acute RfD = 0.075 Developmental study--rabbit.

years of age). day mg/kg/day LOAEL = 15 mg/kg/day based on

UFA = 10X........... aPAD = 0.075 mg/kg/ decreased number of live fetuses,

UFH = 10X........... day. complete litter resorptions and

FQPA SF = 1X........ increased post-implantation loss.

----------------------------------------------------------------------------------------------------------------

Acute dietary (General population NOAEL = 250 mg/kg/ Acute RfD = 2,5 mg/ Neurotoxicity screening battery--

including infants and children). day kg/day rat.

UFA = 10X........... aPAD = 2.5 mg/kg/ LOAEL = 750 mg/kg/day based on

UFH = 10X........... day. decreased body weight, body-

FQPA SF = 1X........ 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 Chronic toxicity--dog.

UFA = 10X........... mg/kg/day LOAEL = 20 mg/kg/day based on

UFH = 10X........... cPAD = 0.05 mg/kg/ adverse liver findings (increased

FQPA SF = 1X........ 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) LOC for MOE = <100 Developmental toxicity--rabbit.

study NOAEL = 7.5 LOAEL = 15 mg/kg/day based on

mg/kg/day (dermal decreased number of live fetuses,

absorption factor = complete litter resorptions and

15% increased post-implantation loss.

UFA = 10X...........

UFH = 10X...........

FQPA SF = 1X........

----------------------------------------------------------------------------------------------------------------

Cancer (Oral, dermal, inhala- Classification: ``Not likely to be Carcinogenic to Humans''

tion). 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.

UFA = extrapolation from animal to human (interspecies). UFH = potential variation in sensitivity among

members of the human population (intraspecies).

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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.

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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](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

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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](mailto: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,

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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,

()[hyphen][alpha][hyphen](2[hyphen]fluorophenyl[hyphen][alpha][hyph

en](4[hyphen]fluorophenyl)[hyphen]1H[hyphen]1,2,4[hyphen]triazole[hyphen

]1[hyphen]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 Sec. 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]

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

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

0

2. In Sec. 180.629:

0

a. In the table in paragraph (a):

0

i. Add alphabetically the entries for ``Alfalfa, forage''; ``Alfalfa,

hay''; ``Barley, grain''; ``Barley, hay''; and ``Barley, straw'';

0

ii. Revise the entries for ``Cattle, fat''; ``Cattle, liver''; and

``Cattle, meat byproducts, except liver'';

0

iii. Add alphabetically the entries for ``Corn, sweet, forage'';

``Corn, sweet, kernel plus cob with husk removed''; and ``Corn, sweet,

stover''; and

0

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

0

b. In paragraph (d):

0

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

0

ii. Revise the table.

The revisions and additions read as follows:

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Sec. 180.629 Flutriafol; tolerances for residues.

(a) \* \* \*

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Parts per

Commodity million

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\* \* \* \* \*

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

\* \* \* \* \*

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\* \* \* \* \*

(d) \* \* \*

Table 2 to Paragraph (d)

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Parts per

Commodity million

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Rice, grain................................................. 0.5

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[FR Doc. 2020-02035 Filed 2-13-20; 8:45 am]

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