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 § 180.652, revise paragraph (a) to read as follows:

§ 180.652 Ethiprole; tolerances for residues.

(a) General. Tolerances are established for residues of ethiprole, 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 ethiprole, 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-(ethylsulfinyl)-1*H*-pyrazole-3-carbonitrile.

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Coffee, green bean [1]	0.1
Rice, grain [1]	1.7
Tea, dried [1]	30

[1] There are no U.S. registrations for this commodity as of June 28, 2019.

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[FR Doc. 2019–13546 Filed 6–27–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0002; FRL–9994–51]

Mefentrifluconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mefentrifluconazole in or on multiple commodities which are identified and discussed later in this document. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 28, 2019. Objections and requests for hearings must be received on or before August 27, 2019, 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–2018–0002, 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–2018–0002 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 August 27, 2019. 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–2018–0002, 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 May 18, 2018 (83 FR 23247) (FRL–9976–87), 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 7F8612) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, North Carolina 27709–3528. The petition requested to establish tolerances in 40 CFR part 180 for residues of the fungicide mefentrifluconazole (BAS 750 F); 2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1*H*-1,2,4-triazole-1-yl)propan-2-ol] in or on the following raw agricultural commodities: almond, hulls at 4 parts per million (ppm); barley, hay at 15 ppm; barley, straw at 30 ppm; cattle, fat at 0.3 ppm;

cattle, kidney at 0.2 ppm; cattle, liver at 0.5 ppm; cattle, meat at 0.09 ppm; cattle, muscle at 0.04 ppm; cereal grains crop group 15, except wheat and corn at 3 ppm; cherry subgroup 12–12A at 4 ppm; citrus, oil at 30 ppm; corn, aspirated grain fractions at 0.3 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 9 ppm; corn, sweet, forage at 6 ppm; corn, sweet, grain at 0.02 ppm; corn, sweet, stover at 6 ppm; foliage of legume vegetables, except soybean, crop subgroup 7A at 20 ppm; forages of cereal grains, crop group 16 at 4 ppm; goat, fat at 0.3 ppm; goat, kidney at 0.2 ppm; goat, liver at 0.5 ppm; goat, meat at 0.09 ppm; goat, muscle at 0.04 ppm; grape, raisin at 4 ppm; grapefruit subgroup 10–10C at 1 ppm; horse, fat at 0.3 ppm; horse, kidney at 0.2 ppm; horse, liver at 0.5 ppm; horse, meat at 0.09 ppm; horse, muscle at 0.04 ppm; legume vegetables (succulent or dried) crop group 6, except lentil at 0.1 ppm; lemon/lime subgroup 10–10B at 2 ppm; lentil, dry at 2 ppm; milk at 0.03 ppm; orange subgroup 10–10A at 1 ppm; peach subgroup 12–12B at 2 ppm; peanut at 0.01 ppm; peanut, hay at 30 ppm; plum prune, fresh at 4 ppm; plum subgroup 12–12C at 2 ppm; pome fruit crop group 11–10 at 1.5 ppm; poultry, eggs at 0.01 ppm; poultry, fat at 0.01 ppm; poultry, liver at 0.01 ppm; poultry, meat at 0.01 ppm; poultry, muscle at 0.01 ppm; poultry, skin at 0.01 ppm; rapeseed subgroup 20A at 1 ppm; rice, straw at 9 ppm; sheep, fat at 0.3 ppm; sheep, kidney at 0.2 ppm; sheep, liver at 0.5 ppm; sheep, meat at 0.09 ppm; sheep, muscle at 0.04 ppm; small fruit vine climbing, except fuzzy kiwifruit subgroup 13–07F at 1.5 ppm; sorghum, stover at 9 ppm; soybean, aspirated grain fractions at 5 ppm; soybean, forage at 4 ppm; soybean, hay at 15 ppm; soybean, seed at 0.3 ppm; sugar beet at 0.6 ppm; sugar beet, top at 9 ppm; swine, fat at 0.01 ppm; swine, liver at 0.01 ppm; swine, meat at 0.01 ppm; swine, skin at 0.01 ppm; tree nut crop group 14–12 at 0.06 ppm; tuberous and corm vegetables subgroup 1C at 0.02 ppm; wheat, aspirated grain fractions at 20 ppm; wheat, grain at 0.4 ppm; wheat, hay at 8 ppm; and wheat, straw at 30 ppm. That document referenced a summary of the petition prepared by BASF, the registrant, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing; however, they were not related to mefentrifluconazole.

Following revisions to that petition, EPA published another notice of filing, which supersedes the May 18, 2018 document. That document was published in the **Federal Register** of March 18, 2019 (84 FR 9735) (FRL–9989–90). The tolerances requested were the same, except for the following: (1) The new petition sought two new tolerances, one for residues on corn, pop, grain at 0.01 ppm and one for residues on grain, cereal, forage, fodder, and straw, group 16, stover at 9 ppm; and (2) the new petition dropped the request for the separate stover tolerances for corn, field, stover at 9 ppm; corn, sweet, stover at 6 ppm; and sorghum, stover at 9 ppm, as those would be subsumed in the group 16, stover tolerance. The amended summary of the petition prepared by BASF, the registrant, and referenced in that document, is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing; however, they were not related to mefentrifluconazole.

Based upon review of the data supporting the petition and under its authority in FFDCA section 408(d)(4)(A)(i), EPA is establishing tolerances that vary slightly from what the petitioner sought. The reason for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for mefentrifluconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with mefentrifluconazole 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.

The liver was the most consistent target organ across species, with mice being the most sensitive species. Following subchronic and chronic exposures, increased absolute and relative liver weights, and histopathological liver findings (subchronic: hypertrophy, cytoplasmic alteration, and necrosis in males; fatty change in females; chronic: diffuse and macrovesicular fatty changes) were observed in both sexes. Decreased cholesterol was also observed in the mouse subchronic toxicity studies (cholesterol was not measured in the mouse carcinogenicity study). Following oral exposures to rats, there were effects on liver function as evidenced by increased alkaline phosphatase (ALP), gamma-glutamyl transferase (GGT), and cholesterol, increased absolute and relative liver weights, and histopathological findings (hepatocellular hypertrophy (subchronic and chronic), multifocal necrosis (females; subchronic)). In dogs, liver effects included increased ALP, increased liver weights, and histopathological findings in the liver (hepatocellular hypertrophy, eosinophilic change, and subcapsular fibrosis). In the 90-day oral toxicity study in dogs, males were more sensitive than females; however, in the 1-year toxicity study, effects were observed at the same dose for both sexes. The toxicity was also shown to progress, with greater increases in ALP along with fibrosis being observed in the chronic study. Other effects included increased white blood cell (WBC) counts in mice following subchronic exposures. In addition, increased adrenal gland weights were noted in male rats following subchronic exposures and in female rats, dogs, and mice following chronic exposures; however, corresponding histopathological findings (eosinophilic cytoplasmic change) were only noted in the adrenal glands of female mice in the carcinogenicity study. An in vitro human recombinant aromatase assay

conducted with mefentrifluconazole indicates that it has the potential to interact with the aromatase enzyme.

There was no evidence of increased quantitative or qualitative fetal susceptibility in the developmental toxicity studies in rats and rabbits or offspring susceptibility in the two-generation reproduction toxicity studies in rats. In the developmental toxicity study in rats, fetal effects (increased placental weight, decreased fetal weight, increased incidence of dilated renal pelvis) occurred at the same dose as maternal effects (increased placental weight). In the developmental toxicity study in rabbits, no maternal or developmental effects were seen up to the highest dose tested (25 mg/kg/day); 50 mg/kg/day was established as the maximum tolerable dose (MTD) for non-pregnant female rabbits in the range-finding studies. In the two-generation reproduction study in rats; offspring effects (decreased pup body weight, increased total litter loss and litters containing pup death during post-natal day (PND) 1–4, and increased incidence of dilated renal pelvis) occurred at the same dose as those eliciting parental toxicity (changes in clinical chemistry parameters (increased ALP, GGT, triglycerides, cholesterol), increased relative liver weights, histopathological findings in the liver, and increased total litter loss and litters containing pup death during PND 1–4). Reproductive toxicity (decreased implantation sites per dam in the F1 generation maternal animals) was observed at the same dose causing parental and offspring effects.

In the acute neurotoxicity study in rats, unsteady gait, increased foot splay, and decreased motor activity were observed at 2,000 mg/kg (no-observed-adverse-effect-level (NOAEL) = 600 mg/kg) for both sexes. However, there is no other evidence of neurotoxicity in the database. In addition, there were no treatment-related histopathological findings in the central or peripheral nervous system in the toxicological database.

Mefentrifluconazole was categorized as having low acute toxicity via the oral, dermal, and inhalation routes (Toxicity Categories III–IV). It is a not an eye or skin irritant (Toxicity Category IV), but it is a dermal sensitizer.

M750F022 is a metabolite that was identified as a residue of concern in the livestock metabolism studies and has a hydroxyl group instead of the triazole ring as a result of cleavage. In the available rat metabolism data, M750F022 was not found at significant amounts; however, it is a proposed intermediate for several metabolites that were observed in the study. Additional toxicological studies were performed, which demonstrated that M750F022 was of low acute toxicity by the oral route in rats. There was no genotoxic concern identified in three in vitro genotoxicity assays. In a 28-day oral toxicity study in mice, the liver was identified as the target organ. M750F022 showed considerably lower potential for aromatase inhibition than the parent, mefentrifluconazole, in an in vitro aromatase inhibition assay. Based on these studies, M750F022 is not considered to be a greater toxicological concern than mefentrifluconazole.

Specific information on the studies received and the nature of the adverse effects caused by mefentrifluconazole as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document titled ''*Mefentrifluconazole. Human Health Risk Assessment for the Section 3 Registration Action of the New Active Ingredient on Non-Residential Turf, Sod Farms, Ornamentals, Commercial and On-Farm Seed Treatment; and Pome Fruit, Crop Group 11–10; Stone Fruit, Crop Group 12–12; Tree Nuts, Crop Group 14–12; Cereal Grains, Crop Group 15; Legume Vegetables, Crop Group 6; Foliage of Legume Vegetables, Crop Group 7; Citrus Fruit, Crop Group 10–10; Small Fruit Vine Climbing, Except Fuzzy Kiwifruit Subgroup 13–07F; Soybeans; Peanuts; Sugar Beet; Rapeseed Subgroup 20A; and Tuberous and Corm Vegetables Subgroup 1C*'' on pages 50–57 in docket ID number EPA–HQ–OPP–2018–0002.

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 mefentrifluconazole used for human risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MEFENTRIFLUCONAZOLE 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 13–50 years of age).	NOAEL = 73 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	Acute RfD = 0.73 mg/kg/day. aPAD = 0.73 mg/kg/day	Two-Generation Reproduction Toxicity Study. LOAEL = 194 mg/kg/day based on decreased implantations per dam.
Acute dietary (General population including infants and children).	No appropriate toxicological effect attributable to a single dose was observed. Therefore, a dose and endpoint were not identified for this risk assessment.		

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MEFENTRIFLUCONAZOLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Chronic dietary (All populations)	NOAEL= 3.5 mg/kg/ day. UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.035 mg/kg/day. cPAD = 0.035 mg/ kg/day	Mouse Carcinogenicity Study. LOAEL = 9.1 mg/kg/day based on increased liver weights and histopathological findings in the liver (both sexes).
Incidental/Adult oral short-term (1–30 days).	NOAEL = 11 mg/kg/ day. UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC for MOE = 100	Subchronic Toxicity—Mouse. LOAEL = 58 mg/kg/day increased total white blood cell (WBC) counts, decreased cholesterol levels, increased absolute and relative liver weights, and histopathological liver findings.
Dermal short-term (1 to 30 days) and intermediate-term (1–6 months).	Oral study NOAEL = 11 mg/kg/day (dermal absorption factor = 15.6%). UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC for MOE = 100	Subchronic Toxicity—Mouse. LOAEL = 58 mg/kg/day increased total WBC counts, decreased cholesterol levels, and histopathological liver findings.
Cancer (Oral, dermal, inhalation).	Classification: ''Not likely to be Carcinogenic to Humans'' based on the absence of treatment-related tumors in two adequate rodent carcinogenicity studies.		

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 mefentrifluconazole, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from mefentrifluconazole 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.

No such effects were identified in the toxicological studies for the general population for mefentrifluconazole; therefore, a quantitative acute dietary exposure assessment for the general population is unnecessary.

However, such effects were identified for mefentrifluconazole for females 13 to 49 years old. In estimating acute dietary exposure, EPA used 2003–2008 food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA conducted an unrefined acute dietary exposure and risk assessment assuming 100 percent crop treated (PCT), default processing factors, and tolerance-level residues for all food commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used 2003–2008 food consumption data from the USDA's NHANES/ WWEIA. As to residue levels in food, EPA conducted a partially refined chronic dietary exposure and risk assessment assuming 100 PCT, empirical processing factors (when available), and average field-trial residues for some commodities.

iii. *Cancer.* A cancer dietary exposure and risk assessment was not conducted for mefentrifluconazole as it was classified as ''Not likely to be Carcinogenic to Humans'' based on the absence of treatment-related tumors in two adequate rodent carcinogenicity studies.

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.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for mefentrifluconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of mefentrifluconazole. 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 Pesticide in Water Calculator (PWC), the estimated drinking water concentrations (EDWCs) of mefentrifluconazole for acute exposures are estimated to be 42.3 parts per billion (ppb) for surface water and 30.3 ppb for ground water, and for chronic exposures are estimated to be 18.4 ppb for surface water and 5.1 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 42.3 ppb was used to assess the contribution to drinking water and for the chronic dietary risk assessment, the water concentration of value 18.4 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).

Mefentrifluconazole is proposed to be registered for the following uses that could result in residential exposures: non-residential turf (*i.e.,* golf courses). EPA assessed residential exposure using the following assumptions: Residential handler exposures are not anticipated based on the proposed use sites and therefore have not been quantitatively assessed. 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 mefentrifluconazole. Short-term dermal exposures were assessed for adults, youth 11 to less than 16 years old, and children 6 to less than 11 years old.

The residential exposure scenario used in both the adult aggregate assessment and the children 6 to <11 years old aggregate assessment is from post-application dermal exposure after applications to golf courses from golfing activities. These scenarios for aggregation, adults and children (6 to <11 years old), represent the worst-case risk estimates and are protective of all other lifestages and exposure scenarios.

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 mefentrifluconazole and any other substances; the Agency's previous statements regarding the potential for a common mechanism among the conazoles noted that the underlying data available at the time were inconclusive. 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 supporting risk assessment concludes that aggregate risks are below the Agency's level of concern and can be found at *http://www.regulations.gov* in the document titled ''*Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address New Section 3 Registrations For Use of Difenoconazole and Mefentrifluconazole*'' in docket ID number EPA–HQ–OPP–2018–0002. Mefentrifluconazole 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 mefentrifluconazole 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 was no evidence of increased quantitative or qualitative fetal susceptibility in the developmental toxicity studies in rats and rabbits or offspring susceptibility in the two-generation reproduction toxicity studies in rats.

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 existing toxicological database for mefentrifluconazole is adequate for FQPA evaluation. Developmental toxicity studies in rats and rabbits as well as a two-generation reproduction study in rats are available for FQPA consideration. The Agency has determined, using a weight-of-evidence approach, that the subchronic neurotoxicity, subchronic inhalation toxicity, and immunotoxicity studies are not required at this time.

ii. In the acute neurotoxicity study in rats, unsteady gait, increased foot splay, and decreased motor activity were considered adverse at 2,000 mg/kg (NOAEL = 600 mg/kg). However, concern is low since the effects are characterized by clear NOAEL and LOAEL values, there is no other evidence of neurotoxicity in the database, there were no corroborating histopathological findings in the central or peripheral nervous system, and the effects were seen at a dose that is not considered relevant for human health risk assessment.

iii. There is no evidence that mefentrifluconazole results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the two-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary assessment is based on high-end assumptions, assuming 100 PCT, and average field trial residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to mefentrifluconazole in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children. These assessments will not underestimate the exposure and risks posed by mefentrifluconazole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to mefentrifluconazole will occupy 2.2% of the aPAD for females 13 to 49 years old, the only population group of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to mefentrifluconazole from food and water will utilize 19% of the cPAD for

children 1 to 2 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 mefentrifluconazole 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).

Mefentrifluconazole 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 mefentrifluconazole.

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 2,600 for adults and 1,900 for children 6 to less than 11 years old. Because EPA's level of concern for mefentrifluconazole is a 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, mefentrifluconazole 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 mefentrifluconazole.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, mefentrifluconazole 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 mefentrifluconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The registrant, BASF, has proposed a Quick Easy Cheap Effective Rugged and Safe (QuEChERS) multi-residue method (BASF method L0295/01) for the determination of mefentrifluconazole residues in plant matrices. BASF Analytical Method No. L0272/01 is proposed as the enforcement method for the determination of residues of mefentrifluconazole in livestock commodities by liquid chromatography coupled with tandem mass spectrometry (LC–MS/MS).

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

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

The Codex has not established any MRLs for mefentrifluconazole.

C. Revisions to Petitioned-For Tolerances

Under FFDCA section 408(d)(4)(A)(i), EPA may establish tolerances that vary from those sought by the petition. For consistency in nomenclature, EPA has used the Agency's preferred commodity terms for the commodities for which tolerances were requested. In addition, the levels at which several tolerances are being established vary from the original petition due to differences in how tolerance values were calculated. Finally, EPA is establishing tolerances for processed commodities where residues concentrate in commodities for which tolerances are being established. A summary and rationale behind these modifications can be found at *http://www.regulations.gov* in the document titled ''*Mefentrifluconazole. Human Health Risk Assessment for the Section 3 Registration Action of the New Active Ingredient on Non-Residential Turf, Sod Farms, Ornamentals, Commercial and On-Farm Seed Treatment; and Pome Fruit, Crop Group 11–10; Stone Fruit, Crop Group 12–12; Tree Nuts, Crop Group 14–12; Cereal Grains, Crop Group 15; Legume Vegetables, Crop Group 6; Foliage of Legume Vegetables, Crop Group 7; Citrus Fruit, Crop Group 10–10; Small Fruit Vine Climbing, Except Fuzzy Kiwifruit Subgroup 13–07F; Soybeans; Peanuts; Sugar Beet; Rapeseed Subgroup 20A; and Tuberous and Corm Vegetables Subgroup 1C*'' on pages 10–13 in docket ID number EPA–HQ–OPP–2018–0002.

V. Conclusion

Therefore, tolerances are established for residues of mefentrifluconazole, including its metabolites and degradates, in or on Almond, hulls at 4 ppm; Beet, sugar, dried pulp at 2 ppm; Beet, sugar, leaves at 9 ppm; Beet, sugar, roots at 0.6 ppm; Cattle, fat at 0.2 ppm; Cattle, meat at 0.03 ppm; Cattle, meat byproducts at 0.3 ppm; Cherry subgroup 12–12A at 4 ppm; Corn, field, grain at 0.01 ppm; Corn, milled byproducts at 0.03 ppm; Corn, pop, grain at 0.01 ppm; Corn, sweet, kernel plus cob with husks removed at 0.03 ppm; Egg at 0.01 ppm; Fruit, citrus, group 10–10, dried pulp at 2 ppm; Fruit, citrus, group 10–10, oil at 15 ppm; Fruit, pome, group 11–10 at 1.5 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 1.5 ppm; Goat, fat at 0.2 ppm; Goat, meat at 0.03 ppm; Goat, meat byproducts at 0.3 ppm; Grain, aspirated grain fractions at 6 ppm; Grain, cereal, forage, fodder, and straw, group 16, forage at 6 ppm; Grain, cereal, forage, fodder, and straw, group 16, hay at 15 ppm; Grain, cereal, forage, fodder, and straw, group 16, stover at 9 ppm; Grain, cereal, forage, fodder, and straw, group 16, straw at 30 ppm; Grain, cereal, group 15, except wheat and corn at 4 ppm; Grape, raisin at 4 ppm; Grapefruit subgroup 10–10C at 0.5 ppm; Hog, fat at 0.015 ppm; Hog, meat at 0.01 ppm; Hog, meat byproducts at 0.03 ppm; Horse, fat at 0.2 ppm; Horse, meat at 0.03 ppm; Horse, meat byproducts at 0.3 ppm; Lemon/lime subgroup 10–10B at 1 ppm; Lentil, dry, seed at 2 ppm; Milk at 0.03 ppm; Milk, fat at 0.8 ppm; Nut, tree, group 14–12 at 0.06 ppm; Orange subgroup 10–10A at 0.6 ppm; Peach subgroup 12–12B at 1.5 ppm; Peanut at 0.01 ppm; Peanut, hay at 30 ppm; Plum prune, dried at 4 ppm; Plum subgroup 12–12C at 2 ppm; Poultry, fat at 0.015 ppm; Poultry, meat at 0.01

ppm; Poultry, meat byproducts at 0.01 ppm; Rapeseed subgroup 20A at 1 ppm; Sheep, fat at 0.2 ppm; Sheep, meat at 0.03 ppm; Sheep, meat byproducts at 0.3 ppm; Soybean, seed at 0.4 ppm; Vegetable, foliage of legume, group 7 at 20 ppm; Vegetable, legume, group 6, except lentil and soybean seed at 0.15 ppm; Vegetable, tuberous and corm, subgroup 1C at 0.04 ppm; and Wheat, grain at 0.3 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this 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 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 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: June 19, 2019.

Richard Keigwin,

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. Add § 180.705 to subpart C to read as follows:

§ 180.705 Mefentrifluconazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of mefentrifluconazole, 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 mefentrifluconazole, α-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-α-methyl-1*H*-1,2,4-triazole-1-ethanol, in or on the commodity.

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Almond, hulls	4
Beet, sugar, dried pulp	2
Beet, sugar, leaves	9
Beet, sugar, roots	0.6
Cattle, fat	0.2
Cattle, meat	0.03
Cattle, meat byproducts	0.3
Cherry subgroup 12–12A	4
Corn, field, grain	0.01
Corn, milled byproducts	0.03
Corn, pop, grain	0.01
Corn, sweet, kernel plus cob with husks removed	0.03
Egg	0.01
Fruit, citrus, group 10–10, dried pulp	2
Fruit, citrus, group 10–10, oil	15
Fruit, pome, group 11–10	1.5
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F	1.5
Goat, fat	0.2
Goat, meat	0.03
Goat, meat byproducts	0.3
Grain, aspirated grain fractions	6
Grain, cereal, forage, fodder, and straw, group 16, forage	6
Grain, cereal, forage, fodder, and straw, group 16, hay	15
Grain, cereal, forage, fodder, and straw, group 16, stover	9
Grain, cereal, forage, fodder, and straw, group 16, straw	30
Grain, cereal, group 15, except wheat and corn	4
Grape, raisin	4
Grapefruit subgroup 10–10C	0.5
Hog, fat	0.015
Hog, meat	0.01
Hog, meat byproducts	0.03
Horse, fat	0.2
Horse, meat	0.03
Horse, meat byproducts	0.3
Lemon/lime subgroup 10–10B	1
Lentil, dry, seed	2
Milk	0.03
Milk, fat	0.8
Nut, tree, group 14–12	0.06
Orange subgroup 10–10A	0.6
Peach subgroup 12–12B	1.5
Peanut	0.01
Peanut, hay	30
Plum prune, dried	4
Plum subgroup 12–12C	2
Poultry, fat	0.015
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Rapeseed subgroup 20A	1
Sheep, fat	0.2
Sheep, meat	0.03
Sheep, meat byproducts	0.3
Soybean, seed	0.4
Vegetable, foliage of legume, group 7	20
Vegetable, legume, group 6, except lentil and soybean seed	0.15

TABLE 1 TO PARAGRAPH (a)—Continued

Commodity	Parts per million
Vegetable, tuberous and corm, subgroup 1C	0.04
Wheat, grain	0.3

(b) [Reserved]
(c) [Reserved]
(d) [Reserved]

[FR Doc. 2019–13520 Filed 6–27–19; 8:45 am]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 204 and 252

[Docket DARS–2019–0027]

RIN 0750–AK69

Defense Federal Acquisition Regulation Supplement: Annual Representations and Certifications—Alternate A (DFARS Case 2019–D030)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to correct paragraph references in the DFARS provision on annual representations and certifications and also correct the structure of the prescription for that provision.

DATES: Effective June 28, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Amy G. Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

This final rule amends the provision at DFARS 252.204–7007, Annual Representations and Certifications—Alternate A, and the prescription for this provision at DFARS 204.1202. DFARS 252.204–7007 provides alternate paragraphs (d) and (e), to replace paragraph (d) of the provision at Federal Acquisition Regulation (FAR) 52.204–8, Annual Representations and Certifications, in order to include DoD-unique representations and certifications.

II. Discussion and Analysis

Paragraph (b) of FAR provision 52.204–8 includes a reference to paragraph (d) of the FAR provision. When the DFARS alternate is used, this reference to paragraph (d) creates an inconsistency. To correct the inconsistency, this final rule amends DFARS 252.204–7007 to include an alternate to paragraph (b) of FAR 52.204–8 that references paragraph (e) of the DFARS alternate, instead of paragraph (d) of FAR 52.204–8.

In addition, the prescription at DFARS 204.1202(1) is restructured so that the lead-in tying the prescription to the use of FAR 52.204–8 applies to both paragraphs (1) and (2), as originally intended. DFARS 204.1202(1) previously stated that the DFARS provision 252.204–7007 is only used when using FAR 52.204–8, Annual Representations and Certification. FAR 52.204–8 is not used in solicitations for the acquisition of commercial items, so DFARS 252.204–7007 is also not used in solicitations for the acquisition of commercial items. Paragraph (2) of the prescription states that the following provisions listed in 204.1202 do not need to be separately listed in the solicitation, because they are included in the provision at DFARS 252.204–7007. Although this prescription is in part 204, not part 212, and has probably been correctly interpreted to apply only to acquisition of noncommercial items, paragraph (2) could technically be misinterpreted in a way that could lead to an inconsistency. Since DFARS 252.204–7007 only applies to noncommercial acquisitions, the provisions listed in 204.1202 would only be included in the solicitation through inclusion of the provision at DFARS 252.204–7007 when acquiring noncommercial items. By restructuring the prescription, the limitation of paragraph (2) to noncommercial acquisitions is unambiguous.

II. Publication of This Final Rule for Public Comment Is Not Required by Statute

The statute that applies to the publication of the FAR is 41 U.S.C. 1707 entitled ''Publication of Proposed Regulations.'' Paragraph (a)(1) of the statute requires that a procurement policy, regulation, procedure or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because it only makes minor administrative corrections. These requirements affect only the internal operating procedures of the Government.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule makes a minor correction to an existing provision at DFARS 252.204–7007, Alternate A, Annual Representations and Certifications, and clarifies the prescription for use of the provision, which applies below the simplified acquisition threshold but does not apply to the acquisition of commercial items.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

This final rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

VI. Regulatory Flexibility Act

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 41 U.S.C. 1707(a)(1) (see section III. of this preamble), the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

VII. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).