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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0551; FRL-10019-19]

Fluindapyr; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0551, 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.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, 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-2018-0551 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or

before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2018-0551, 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 9, 2019 (84 FR 20320) (FRL-9992-36), 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 8F8685) by FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide, fluindapyr, 3-(difluoromethyl)-N-(7-fluoro-2,3-dihydro-1,1,3-trimethyl-1H-inden-4-yl)-1-methyl-1H-pyrazole-4-carboxamide, in or on almond, hulls at 15 parts per million (ppm); aspirated grain fractions at 60 ppm; cattle, fat at 0.15 ppm; cattle, meat byproducts at

0.6 ppm; field corn, grain at 0.01 ppm; field corn, oil at 0.03 ppm; fruit, small vine-climbing except fuzzy kiwifruit, crop subgroup 13-07F at 3 ppm; grain, cereal, crop group 15, except rice and corn at 0.9 ppm; grain, cereal, forage, crop group 16, except rice, forage at 15 ppm; grain, cereal, hay, crop group 16 except rice, hay at 8 ppm; grain, cereal, stover, crop group 16 except rice, stover, and sweet corn stover at 4 ppm; grain, cereal, straw, crop group 16, except rice, straw at 20 ppm; poultry, meat byproducts at 0.03 ppm; soybean, forage at 15 ppm; soybean, hay at 30 ppm; soybean, hulls at 0.6 ppm; soybean, seed at 0.2 ppm; sweet corn, K+CWHR at 0.01 ppm; sweet corn, stover at 20 ppm; swine, meat byproducts at 0.02 ppm; and tree nuts, crop group 14-12 at 0.04 ppm. That document referenced a summary of the petition prepared by FMC Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i) to establish tolerances that vary from what was requested, EPA is establishing several tolerances at different levels than were requested, including additional livestock commodities as necessary. In addition, tolerances for fruit, small vine-climbing except fuzzy kiwifruit crop group 13-07F and soybeans were removed. The reasons 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 fluindapyr including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluindapyr 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 target organs of fluindapyr are the liver and thyroid. Liver effects include hepatocellular hypertrophy, increased liver weights, and bile duct hyperplasia with correlated increases in alkaline phosphatase (ALP), alanine aminotransferase (ALT), and gamma glutamyl transferase (GGT) at the highest dose tested. Liver effects progress with time in treated dogs, while similar effects are not seen in rats and mice at high dose levels. Liver effects are seen in the mouse carcinogenicity study at a higher dose level than the liver effects observed in dogs; the effects consisted of increased incidence of hepatocellular alterations (basophilic, eosinophilic, vacuolated), necrosis, and pigmented macrophages. Thyroid effects include increased instances of follicular hypertrophy/hyperplasia.

In the acute neurotoxicity study, potential evidence of neurotoxicity in the form of decreases in total and ambulatory motor activities and in rearing were seen in the rat. However, no additional functional observation (FOB) parameters were affected, and no neuropathological findings of both central and peripheral nerves were observed.

There is no evidence of increased quantitative or qualitative susceptibility in the developmental toxicity studies in rabbits or rats; or the reproductive toxicity study in rats. With *in-utero* exposure in the developmental toxicity studies, fluindapyr did not produce any adverse effects in either rat or rabbit parental animals or fetuses at or approaching the limit dose. In the reproduction study, in parental animals (P and F1 males and females), fluindapyr induced an increase in thyroid follicular hypertrophy/hyperplasia. It also induced adverse effects on a host of reproductive parameters. It also produced adverse offspring effects as indicated by decreases in F1 and F2 pup body weights in both sexes; thymus and spleen weights were also decreased. The parental, reproductive, and offspring effects all occurred at the same dose levels. The increased incidence of thyroid follicular hypertrophy/hyperplasia raised concerns for the potential of thyroid effects on the developing animals. EPA applied a 10X safety factor to the appropriate exposure scenarios to account for the uncertainties associated with the life stage susceptibility.

In the chronic toxicity/carcinogenicity studies in rats and mice, there was no evidence of carcinogenicity. The mutagenicity battery was negative. Fluindapyr is classified as "Not Likely to be Carcinogenic to Humans".

Specific information on the studies received and the nature of the adverse effects caused by fluindapyr as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document "Fluindapyr: Human Health Risk Assessment for Section 3 Registration and Tolerance Requests for a New Active Ingredient Proposed for Use on Cereal Grains Crop Group 15 except Rice; Forage, Fodder and Straw of Cereal Grains Crop Group 16; and Soybean" (hereinafter "Fluindapyr Human Health Risk Assessment") on pages 14-20 in docket ID number EPA-HQ-OPP-2018-0551.

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-pesticide.*

A summary of the toxicological endpoints for fluindapyr used for human risk assessment can be found in the Fluindapyr Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to fluindapyr, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from fluindapyr 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 fluindapyr. In estimating acute dietary exposure, EPA used 2003-2008 food consumption information from the United States Department of Agriculture (USDA) Nationwide Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, the acute analysis assumed 100% crop treated (PCT) for all commodities, highest average field trial (HAFT) residue values, empirical and default processing factors, and

anticipated livestock residues based on calculated livestock dietary burden and tissue transfer rates from the livestock feeding studies.

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, chronic analysis assumed 100 PCT for all commodities, field trial mean residue values, empirical and default processing factors, and anticipated livestock residues based on calculated livestock dietary burden and tissue transfer rates from the livestock feeding studies and metabolite ratios from the metabolism studies.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that fluindapyr 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*. 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.

EPA did not use information on the percent of food actually treated in the dietary assessment for fluindapyr; 100 PCT was assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluindapyr in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluindapyr. 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.*

Using the Pesticide Water Calculator (PWC, version 1.52), the estimated drinking water concentrations (EDWCs) of fluindapyr were determined to be higher in groundwater than in surface water for both acute and chronic exposure durations. The following groundwater EDWCs were used directly in the dietary exposure model to account for the contribution of fluindapyr and relevant transformation products (3-OH-F9990 and 1-COOH-F9990) residues in drinking water as follows: 254.1 ppb was used in the acute assessment and 217.8 ppb was used in the chronic assessment.

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).

Fluindapyr is currently registered for the following use that could result in residential exposures: golf course turf. The currently registered use on golf courses will result in short-term (1 to 30 days) residential post-application dermal exposures to adult, youth 11 to less than 16 years old, and children 6 to less than 11 years old. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

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 fluindapyr and any other substances and fluindapyr does not appear to produce a toxic

metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that fluindapyr 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*. In the developmental toxicity studies (rat and rabbit), fluindapyr did not produce any adverse effects in parental animals or fetuses at or approaching the limit dose (1,000 mg/kg/day). In the reproduction study, in parental animals (P and F1 males and females), fluindapyr induced an increase in thyroid follicular hypertrophy/hyperplasia. It also induced adverse effects on a host of reproductive parameters. There is no evidence of increased quantitative or qualitative susceptibility in the developmental toxicity studies in rabbits or rats or the reproductive toxicity study in rats. In the 2-generation reproduction study in rats, reproductive effects were observed, and offspring toxicity (decreased pup weights in F1 and F2 generation; thymus and spleen weights were decreased) was observed in the presence (same dosage) of parental toxicity (increase in thyroid follicular hypertrophy/hyperplasia and reproductive effects).

3. *Conclusion*. Due to the uncertainties concerning the potential life stage susceptibility related to adverse thyroid effects seen in parental animals of the reproductive study, EPA is retaining the FQPA 10X SF for exposure scenarios that rely on the reproductive study in which such effects were seen. For purposes of this safety assessment, those scenarios are the post-application short-term dermal exposures and the short-term aggregate risk assessment. For the

acute and chronic dietary assessments, 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 fluindapyr is complete. Fluindapyr caused an increased in the thyroid follicular hypertrophy/hyperplasia in the 2-generation reproduction study. The results of these findings raised concerns about the potential impact to the developing brain in response to changing thyroid levels brought on by thyroid effect in the parents. A database uncertainty factor of 10X is placed on fluindapyr to address this concern.

ii. In the acute neurotoxicity study (ACN), decreases in total and ambulatory motor activities and in rearing were seen and could be considered as potential evidence for neurotoxicity. However, concern with fluindapyr is low because (1) no other effects were observed in database including in the subchronic neurotoxicity study (SCN); (2) no neurohistopathology was found in the ACN, SCN or any toxicity study in the fluindapyr database; and (3) the toxicity endpoints and PoD selected for risk assessment are protective of the effects seen in the ACN.

iii. There is no evidence that fluindapyr results in increased quantitative or qualitative susceptibility in the developmental toxicity studies in rabbits or rats or the reproductive toxicity study in rats. In the 2-generation reproduction study in rats, reproductive effects were observed, and offspring toxicity (decreased pup weights in F1 and F2 generation; thymus and spleen weights were decreased) was observed in the presence (same dosage) of parental toxicity. Based on the effects in the 2-generation reproduction study, there is some uncertainty about the potential thyroid-related effects on the developing fetus or child. While EPA is retaining the 10X FQPA SF for short-term aggregate risk assessment, there is no concern for this uncertainty for the acute dietary exposure assessment because perturbation of thyroid after a single dose is not anticipated to impact the developing fetus or offspring. Nor is there a concern for this uncertainty in the chronic dietary assessment because the chronic dietary endpoint,

based on effects in dogs, is protective of potential thyroid-related effects observed in developing rats or offspring.

iv. There are no residual uncertainties identified in the exposure databases. The dietary risk assessments are based on high-end assumptions such as 100 PCT assumptions, HAFT and field trial mean residue values, empirical and default processing factors, anticipated livestock residues based on calculated livestock dietary burden and tissue transfer rates from the livestock feeding studies and modeled, high-end estimates of residues in drinking water. All of the exposure estimates are based on high-end assumptions and are not likely to underestimate risk. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluindapyr in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children. These assessments will not underestimate the exposure and risks posed by fluindapyr.

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 fluindapyr will occupy 8.9% of the aPAD for all infants (<1 year 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 fluindapyr from food and water will utilize 33% of the cPAD for infants <1 year 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 fluindapyr is not expected.

3. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account short- term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short-term and intermediate-term endpoints and residential exposure estimates are identical, and so short-term aggregate exposure is considered protective of intermediate-term aggregate exposures. The three population subgroups assessed for residential post-application exposures are: adults, youth 11 to < 16 years old, and children 6 to < 11 years old. Of the three population subgroups, the children 6 to < 11 years old represent the highest dermal exposure from post-application exposures and the highest background dietary exposure. Therefore, this population subgroup is considered protective of the other two population subgroups.

For adults, intermediate-term exposure is not expected for the residential exposure pathway. Therefore, the intermediate-term aggregate risk would be equivalent to the chronic dietary exposure estimate. For children, all intermediate-term aggregate risks are equivalent to short-term aggregate risks.

Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded the combined short- and intermediate term food, water, and residential exposures result in aggregate MOEs of 720 for youth (6 to < 11 yrs. old) with dermal exposure from post-application exposure to residue from treated golf course. Because EPA's level of concern for fluindapyr is a MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fluindapyr is not expected to pose a cancer risk to humans.

5. *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 fluindapyr residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner has proposed a liquid chromatography with tandem mass spectrometer (LC/MS/MS) for determination of fluindapyr and metabolites 3-OH-F9990, F9990-DM-glucoside, 1-OH-Me-F9990, 1-OH-Me-DM-F9990, and 1-COOH-F9990 in plant commodities. For livestock commodities, adequate enforcement methodology using LC/MS/MS is available for determination of residues of fluindapyr and its metabolites.

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 an MRL for fluindapyr.

C. Response to Comments

One comment was received in response to the notice of filing that argued against the use fluindapyr on several commodities and the overall toxicity of pesticides. In addition, the commenter raised three additional concerns: the lack of tests involving the combination of fluindapyr and other chemicals; fluindapyr a potential cancer-causing agent; and fluindapyr is a fluoride compound. Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by

section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) authorized EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that these fluindapyr tolerances are safe. The commenter has provided no information supporting a contrary conclusion.

In its assessment of safety under the FFDCA, EPA considers combinations of pesticides by evaluating the cumulative effects of pesticides that have a common mechanism of toxicity. At this time, EPA has not identified a common mechanism of toxicity between fluindapyr and other pesticides and thus there are no combinations of pesticides to consider at this time.

EPA has evaluated available data concerning carcinogenicity and determined that fluindapyr is not likely to be carcinogenic to humans. This conclusion is based on a lack of treatment-related tumors seen in male or female rats or mice and no concern for mutagenicity. The commenter has provided no additional information about potential carcinogenicity.

Fluindapyr contains a difluoromethyl group and a fluorine-substituted phenyl group. The difluoromethyl group remains intact on the compounds identified in crop (primary and rotational), livestock, and environmental fate studies, including the compounds identified as the residues of concern for tolerance enforcement and risk assessment purposes for crop and livestock commodities. While the metabolism studies show the phenyl group does degrade, it is extremely unlikely for the fluorine to form a free fluorine because the stability of the bond between the fluorine and carbon atom. Therefore, applications of fluindapyr are not expected to result in dietary exposure to fluoride.

D. Revisions to Petitioned-For Tolerances

Based on EPA's review of the data supporting the petition, EPA is establishing tolerances that vary from what the petitioner requested under its authority in FFDCA section 408(d)(4)(A)(i). Some commodity terms are altered to be consistent with Agency nomenclature. EPA is not establishing tolerances for corn oil since EPA determined that residues on this commodity will be adequately covered under corn, field, grain due to the lack of concentration

during processing. EPA is also not establishing tolerances for fruit, small vine-climbing except fuzzy kiwifruit, crop subgroup 13-07F and the soybean commodities as initially requested since they are not necessary at this time, due to the withdrawal of the proposed uses by the petitioner.

EPA is establishing tolerance levels lower than what the petitioner requested for grain, aspirated fractions; grain, cereal, group 15, except rice and corn from 0.9 ppm; and cattle, fat based on the submitted field trial data for those commodities using the OEDC MRL (Maximum Residue Limit) calculator.

Because of potential increase of fluindapyr (including metabolites and degradates) in livestock diet, largely due to cereal grain crop group 15 and 16 use, and based on updated maximum reasonably balanced diet (MRBD) calculations for livestock, the Agency has determined that finite residues will be incurred in poultry (egg, fat, meat, and meat byproducts), ruminants (fat, milk, meat, and meat byproducts), hog (fat, meat, and meat byproducts), and horse (fat, meat, and meat byproducts); therefore, under 40 CFR 180.6, EPA is establishing tolerances for those commodities.

V. Conclusion

Therefore, tolerances are established for residues of fluindapyr, 3-(difluoromethyl)-N-(7-fluoro-2,3-dihydro-1,1,3-trimethyl-1H-inden-4-yl)-1-methyl-1H-pyrazole-4-carboxamide, in or on almond, hulls at 15 ppm ; corn, field, grain at 0.01 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, stover at 20 ppm; grain, aspirated fractions at 20 ppm; grain, cereal, forage, fodder, and straw, group 16 forage, except rice at 15 ppm; grain, cereal, forage, fodder, and straw, group 16, hay, except rice at 8 ppm; grain, cereal, forage, fodder, and straw, group 16, stover, except rice at 4 ppm; grain, cereal, forage, fodder, and straw, group 16, straw, except rice at 20 ppm; grain, cereal, group 15, except rice and corn at 0.8 ppm; nut, tree, group 14-12 at 0.04 ppm; egg at 0.01 ppm; milk at 0.01 ppm; cattle, fat at 0.03 ppm; cattle, meat at 0.01; goat, fat at 0.03 ppm; goat, meat at 0.01 ppm; hog, fat at 0.01 ppm; hog, meat at 0.01 ppm; horse, fat at 0.03 ppm; horse, meat at 0.01 ppm; poultry, fat at 0.01 ppm; poultry, meat at

0.01 ppm; sheep, fat at 0.03 ppm; and sheep, meat at 0.01 ppm. In addition, tolerances are established for residues of fluindapyr, 3-(difluoromethyl)-*N*-(7-fluoro-1,1,3-trimethyl-2,3-dihydro-1*H*-inden-4-yl)-1-methyl-1*H*-pyrazole-4-carboxamide, and 3-(difluoromethyl)-*N*-(7-fluoro-1-hydroxymethyl-1,3-dimethyl-2,3-dihydro-l*H*-inden-4-yl)-1-methyl-l*H*-pyrazole-4-carboxamide, in or on cattle, meat byproducts at 0.3 ppm; goat, meat byproducts at 0.3 ppm; horse, meat byproducts at 0.3 ppm; hog, meat byproducts at 0.01 ppm; poultry, meat byproducts at 0.01 ppm; and sheep, meat byproducts 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). 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.

Edward Messina,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

2. Add § 180.716 to subpart C to read as follows:

§ 180.716 Fluindapyr; tolerances for residues.

(a) *General*. (1) Tolerances are established for residues of the fungicide fluindapyr, including its metabolites and degradates, in or on the commodities in Table 1 of this section. Compliance with the tolerance levels specified in Table 1 is to be determined by measuring only fluindapyr, 3-(difluoromethyl)-*N*-(7-fluoro-1,1,3-trimethyl-2,3-dihydro-1*H*-inden-4-yl)-1-methyl-1*H*-pyrazole-4-carboxamide, in or on the commodity.

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
Almond, hulls	15
Cattle, fat	0.03
Cattle, meat	0.01
Corn, field, grain	0.01
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	20
Egg	0.01
Goat, fat	0.03
Goat, meat	0.01
Grain, aspirated fractions	20
Grain, cereal, forage, fodder, and straw, group 16, forage, except rice	15
Grain, cereal, forage, fodder, and straw, group 16, hay, except rice	8
Grain, cereal, forage, fodder, and straw, group 16, stover, except rice	4
Grain, cereal forage, fodder, and straw, group 16, straw, except rice	20
Grain, cereal group 15, except rice and corn	0.8
Hog, fat	0.01
Hog, meat	0.01
Horse, fat	0.03
Horse, meat	0.01
Milk	0.01
Nut, tree, group 14-12	0.04

Poultry, fat	0.01
Poultry, meat	0.01
Sheep, fat	0.03
Sheep, meat	0.01

(2) Tolerances are established for residues of the fungicide fluindapyr, including its metabolites and degradates, in or on the commodities in Table 2 of this section. Compliance with the tolerance levels specified in Table 2 is to be determined by measuring the sum of fluindapyr, 3-(difluoromethyl)-*N*-(7-fluoro-1,1,3-trimethyl-2,3-dihydro-1*H*-inden-4-yl)-1-methyl-1*H*-pyrazole-4-carboxamide, and 3-(difluoromethyl)-*N*-(7-fluoro-1-hydroxymethyl-1,3-dimethyl-2,3-dihydro-l*H*-inden-4-yl)-1-methyl-l*H*-pyrazole-4-carboxamide, calculated as the stoichiometric equivalent of fluindapyr, in or on the commodity.

Table 2 to Paragraph (a)(2)

Commodity	Parts per million
Cattle, meat byproducts	0.3
Goat, meat byproducts	0.3
Horse, meat byproducts	0.3
Hog, meat byproducts	0.01
Poultry, meat byproducts	0.01
Sheep, meat byproducts	0.3

(b) - (d) [Reserved]

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