64300). That final rule was published under Regulatory Identification Number (RIN) 0651–AD55. As part of that final rule, the USPTO set a period of three months for responses to post-registration office actions and provided the option to request a single three-month extension of the deadline, subject to the payment of a fee. The final rule stated that the post-registration changes would go into effect on December 1, 2022.

On October 13, 2022, the USPTO published in the **Federal Register** a final rule delaying the effective date for responses and extensions in the examination of post-registration filings from December 1, 2022, until October 7, 2023. *See* Changes To Implement Provisions of the Trademark Modernization Act of 2020; Delay of Effective Date and Correction (87 FR 62032).

Under this final rule, the USPTO is further delaying the provisions that address post-registration responses and extensions. The USPTO anticipates that these provisions will go into effect sometime in the spring or early summer of 2024.

The USPTO is currently upgrading its internal and public databases, search system, and internal examination systems. These major updates will provide far-reaching efficiencies for both customers and staff. The implementation of the regulatory changes to post-registration responses and extensions cannot be completed until the migration to the new systems is complete. The USPTO anticipates that this will occur in the spring or early summer of 2024. The delay will also provide the public with additional time to prepare for the new response periods. The USPTO will publish a final rule in the **Federal Register** providing the new effective date of the provisions addressing post-registration responses and extensions once it has been determined.

In the final rule published at 86 FR 64300, the cross-reference in 37 CFR 7.40(b) to ''§ 7.39(b) and (c)'' is incorrect. The reference should have been to ''§ 7.39(a) and (b).'' When the USPTO publishes a final rule providing the new effective date of the provisions addressing post-registration responses and extensions, that section will also be corrected.

Rulemaking Requirements

A. Administrative Procedure Act: The changes in this rulemaking involve rules of agency practice and procedure, and/or interpretive rules. *See Perez* v. *Mortg. Bankers Ass'n,* 135 S. Ct. 1199, 1204 (2015) (Interpretive rules ''advise the public of the agency's construction of the statutes and rules which it administers.'' (citation and internal quotation marks omitted)); *Nat'l Org. of Veterans' Advocates* v. *Sec'y of Veterans Affairs,* 260 F.3d 1365, 1375 (Fed. Cir. 2001) (Rule that clarifies interpretation of a statute is interpretive.); *Bachow Commc'ns Inc.* v. *FCC,* 237 F.3d 683, 690 (D.C. Cir. 2001) (Rules governing an application process are procedural under the Administrative Procedure Act.); *Inova Alexandria Hosp.* v. *Shalala,* 244 F.3d 342, 350 (4th Cir. 2001) (Rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims.).

Accordingly, prior notice and an opportunity for public comment for the changes in this rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. *See Perez,* 135 S. Ct. at 1206 (Notice-and-comment procedures are required neither when an agency ''issue[s] an initial interpretive rule'' nor ''when it amends or repeals that interpretive rule.''); *Cooper Techs. Co.* v. *Dudas,* 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), does not require notice-and-comment rulemaking for ''interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice'' (quoting 5 U.S.C. 553(b)(A))).

Moreover, the Under Secretary of Commerce for Intellectual Property and Director of the USPTO, pursuant to the authority at 5 U.S.C. 553(b)(B), finds good cause to adopt the change to the effective date without prior notice and an opportunity for public comment, as such procedures would be impracticable and contrary to the public interest. The USPTO is currently upgrading its internal and public databases, search system, and internal examination systems. These major updates will provide far-reaching efficiencies for both customers and staff. The implementation of the regulatory changes to post-registration responses and extensions cannot be completed until the migration to the new systems is complete. The USPTO anticipates that this will occur in the spring or early summer of 2024. The delay will also provide the public with additional time to prepare for the new response periods. Delay of this provision to provide prior notice and comment procedures is also impracticable because it would allow the provisions to go into effect before the agency is ready to implement the regulatory changes regarding post-registration responses and extensions.

The Director also finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effectiveness of this rule. Immediate implementation of the delay in the effective date is in the public interest because it will provide the agency the ability to effectively manage and utilize the resources needed to complete all these initiatives. The delay will also provide the public with additional time to prepare for the new response periods. Delay of this rule to provide for the 30-day delay in effectiveness is impracticable because it would allow the provisions to go into effect before the agency is ready to implement the regulatory changes regarding post-registration responses and extensions.

B. Regulatory Flexibility Act: As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 or any other law, neither a Regulatory Flexibility Act analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is required. *See* 5 U.S.C. 603.

C. Executive Order 12866 (Regulatory Planning and Review): This rule has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2023–19669 Filed 9–11–23; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0065; FRL–8786–01–OCSPP]

Fluazaindolizine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluazaindolizine in or on multiple commodities that are identified and discussed later in this document. E.I. du Pont de Nemours & Company (''DuPont'', now Corteva) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 12, 2023. Objections and requests for hearings must be received on or before November 13, 2023, 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–2020–0065, is available online at *http://www.regulations.gov* or in-person 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 and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; 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 Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title40.*

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–2020–0065 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 November 13, 2023. 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–2020–0065, 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.*

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 April 15, 2020 (85 FR 20910) (FRL–10006–54), 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 9F8795) by E.I. du Pont de Nemours & Company (''DuPont''), Chestnut Run Plaza, 974 Centre Road, Wilmington, DE 19805. The petition requested to establish tolerances in the 40 CFR part 180 for residues of the nematicide, fluazaindolizine, by measuring the sum of post-hydrolysis residues IN–A5760, IN–F4106, IN–QEK31, IN–QZY47, IN–TMQ01, IN–UJV12, and IN–UNS90 (expressed in parent equivalents) in or on Carrots at 15 parts per million (ppm); Cucurbit Vegetables (Crop Group 9) at 3 ppm; Fruiting Vegetables (Crop Group 8–10) at 3 ppm; Sun dried tomatoes at 30 ppm; Tomato paste at 15 ppm; Tomato puree at 6 ppm; Tomato wet pomace at 6 ppm; Tuberous and Corm Vegetables (Crop Subgroup 1C) at 9 ppm; Dried potato at 30 ppm; Potato process waste at 40 ppm; and establishing tolerances for residues of fluazaindolizine plus its metabolites IN–QEK and IN–F4106 (expressed in parent equivalents), in the animal commodities: Cattle, whole milk at 0.5 ppm; Cattle, fat at 0.09 ppm; Cattle, muscle at 0.02 ppm; Cattle, liver at 0.2 ppm; Cattle, kidney at 0.5 ppm; Goat, whole milk at 0.5 ppm; Goat, fat at 0.09 ppm; Goat, muscle at 0.02 ppm; Goat, liver at 0.2 ppm; Goat, kidney at 0.5 ppm; Hog, whole milk at 0.5 ppm; Hog, fat at 0.09 ppm; Hog, muscle at 0.02 ppm; Hog, liver at 0.2 ppm; Hog, kidney at 0.5 ppm; Horse, whole milk at 0.5 ppm; Horse, fat at 0.09 ppm; Horse, muscle at 0.02 ppm; Horse, liver at 0.2 ppm; Horse, kidney at 0.5 ppm; Sheep, whole milk at 0.5 ppm; Sheep, fat at 0.09 ppm; Sheep, muscle at 0.02 ppm; Sheep, liver at 0.2 ppm; Sheep, kidney at 0.5 ppm. In addition, DuPont proposed pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish indirect or inadvertent tolerances for residues of fluazaindolizine, by measuring the sum of post-hydrolysis residues IN–A5760, IN–F4106, IN–QEK31, IN–QZY47, IN–TMQ01, IN–UJV12, and IN–UNS90 (expressed in parent equivalents) in or on the following commodities: Brassica Head and Stem Vegetables (Crop Group 5–16) at 0.5 ppm; Bulb Vegetables (Crop Group 3–07) at 3 ppm; Cereal Grains (Crop Group 15) at 3 ppm; Corn milled by-products at 6 ppm; Foliage of Legume Vegetables (Crop Group 7), Vines at 8 ppm; Foliage of Legume Vegetables (Crop Group 7), Forage and Straw at 5 ppm; Foliage of Legume Vegetables (Crop Group 7), Hay at 40 ppm; Forage, Fodder and Straw of Cereal Grains (Crop Group 16), Fodder at 4 ppm; Forage, Fodder and Straw of Cereal Grains (Crop Group 16), Forage at 8 ppm; Forage, Fodder and Straw of Cereal Grains (Crop Group 16), Hay at 15 ppm; Forage, Fodder and Straw of Cereal Grains (Crop Group 16), Straw at 10 ppm; Fruiting Vegetables (Crop Group 8–10) at 1 ppm; Grain, Aspirated Fractions at 0.5 ppm; Grass, Forage, Fodder and Hay (Crop Group 17), Forage at 8 ppm; Grass, Forage, Fodder and Hay (Crop Group 17), Hay at 15

ppm; Leafy Vegetables (Crop Group 4–16) at 9 ppm; Leaves of Root and Tuber (Crop Group 2) at 15 ppm; Legume Vegetables (Crop Group 6), Mature Seed at 9 ppm; Legume Vegetables (Crop Group 6), Immature Seed and Pod at 3 ppm; Low Growing Berry (Crop Subgroup 13–07G) at 0.6 ppm; Nongrass Animal Feeds (Forage, Fodder, Straw and Hay) (Crop Group 18), Fodder at 5 ppm; Nongrass Animal Feeds (Forage, Fodder, Straw and Hay) (Crop Group 18), Forage at 8 ppm; Nongrass Animal Feeds (Forage, Fodder, Straw and Hay) (Crop Group 18), Hay at 15 ppm; Nongrass Animal Feeds (Forage, Fodder, Straw and Hay) (Crop Group 18), Straw at 10 ppm; Oilseed (Crop Group 20) at 9 ppm; Oilseed Crop Group 20), Forage and Straw at 5 ppm; Root Vegetables (Crop Subgroup 1A) at 7 ppm; Root Vegetables Except Sugar Beet (Crop Subgroup 1B) at 7 ppm; Soybean Hulls at 20 ppm; Soybean Meal at 20 ppm; Stalk, Stem and Leaf Petiole Vegetables (Crop Group 22) at 3 ppm; Strawberry, Dehydrated at 3 ppm; and Wheat Milled By-Products at 6 ppm. That document referenced a summary of the petition prepared by DuPont (now Corteva), the registrant, which is available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

In the **Federal Register** of June 28, 2021 (86 FR 33922) (FRL–10025–08), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), amending the previous NOF dated April 15, 2020 by announcing commodities that were not included in the previous NOF. E.I. du Pont de Nemours & Company (''DuPont''), Chestnut Run Plaza, 974 Centre Road, Wilmington, DE 19805, requests to establish a tolerance in 40 CFR part 180 for residues of the nematicide, fluazaindolizine in or on Poultry, fat at 0.01 ppm; Poultry, meat at 0.01 ppm; Poultry, meat byproducts at 0.01 ppm; and Eggs at 0.01 ppm. In addition, DuPont is proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish indirect or inadvertent tolerances for residues of fluazaindolizine, including its metabolites and their conjugates, expressed as the stoichiometric equivalent of fluazaindolizine, in or on the following commodity: Grass, forage, fodder and hay, group 17, straw at 0.15 ppm.

Based upon review of the data supporting the petition, EPA is establishing tolerances at different levels than petitioned-for and has determined that tolerances for certain petitioned-for commodities are not necessary. The Agency has also modified all of the commodity definitions used and updated certain crop groups. 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 fluazaindolizine including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluazaindolizine 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 main target organs of fluazaindolizine are the urinary tract (rat and mouse), liver and/or gallbladder (mouse and dog), and hematopoietic system (dog). In the mouse carcinogenicity study, the incidence and severity of amyloidosis in specific tissues was increased in both sexes. There was no evidence of increased *in utero* susceptibility in the rat or rabbit developmental studies; however, increased quantitative susceptibility was observed in the rat reproductive toxicity study, based on urinary tract histopathological lesions in F_2 generation weanlings at a lower dose than doses resulting in toxicity in parental animals. Fluazaindolizine is classified as ''Not likely to be carcinogenic to humans'' based on lack of evidence of treatment-related increases in tumors in adequately conducted carcinogenicity studies in rats and mice.

Specific information on the studies received and the nature of the adverse effects caused by fluazaindolizine 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 the document titled ''Fluazaindolizine: Human Health Risk Assessment for the New Active Ingredient'' (hereinafter ''Fluazaindolizine Human Health Risk Assessment'') on pages 54–82 in docket ID number EPA–HQ–OPP–2020–0065.

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://www.epa.gov/pesticide-science-and-assessing-pesticide-risks.*

A summary of the toxicological endpoints for fluazaindolizine used for

human risk assessment can be found in the Fluazaindolizine Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluazaindolizine, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from fluazaindolizine 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 fluazaindolizine; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the 2003–2008 food consumption data 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 used field-trial based anticipated residue calculations for all crops and assumed 100 percent crop treated (PCT) for all crops.

iii. *Cancer.* Based on the data summarized in the Fluazaindolizine Human Health Risk Assessment, EPA has concluded that fluazaindolizine does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (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 fluazaindolizine in drinking water. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment.*

Separate estimated drinking water concentrations (EDWCs) were calculated for the metabolite IN–VM862 and a combination of fluazaindolizine and the other metabolites IN–QEK31, IN–REG72, IN–F4106, and IN–A5760, due to greater toxicological potency of IN–VM862. This combination is referred to as the Fluazaindolizine Drinking Water Total Residue Fraction (FDWTRF). Based on the Pesticide Water Calculator (PWC), EPA used an EDWC of 990 ppb for FDWTRF and 1,300 ppb for IN–VM862 in the chronic dietary risk 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). Fluazaindolizine is not registered for any specific use patterns that would result in residential exposure.

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

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 fluazaindolizine and any other substances and fluazaindolizine does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fluazaindolizine has a common mechanism of toxicity with other substances.

For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

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.* Increased quantitative susceptibility was observed for fluazaindolizine in the rat 2-generation reproductive study. An increased incidence and severity of urinary tract histopathology was observed in male and female F_2 weanlings at a lower dose than in P and F_1 adult animals. No susceptibility was observed in the rat or rabbit developmental toxicity studies. The metabolite IN–F4106 showed increased prenatal susceptibility (decreased fetal body weight) in the rat developmental toxicity study. However, concern for prenatal susceptibility is low for both parent and metabolite because clear NOAELs and LOAELs were identified for fetal toxicity and endpoints selected for risk assessment are protective of these findings.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for fluazaindolizine is complete.

ii. There is no indication that fluazaindolizine is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors to account for neurotoxicity.

iii. Increased quantitative susceptibility was observed for fluazaindolizine in the rat two-generation reproductive study. However, as noted above, concern for prenatal susceptibility is low for both parent and metabolite because clear NOAELs and LOAELs were identified for fetal toxicity and endpoints selected for risk assessment are protective of these findings.

iv. There are no residual uncertainties with regard to the exposure assessment

for fluazaindolizine. An acute dietary endpoint was not identified for any population and therefore an assessment of acute dietary risk was not performed. For chronic dietary exposure, risk estimates were partially refined by using average field trial residues and empirical processing factors. Conservative, upper bound estimates were used to assess exposure to fluazaindolizine and its residues of concern through drinking water. Based on these considerations, exposure from food and drinking water will not be underestimated. No residential use patterns are proposed at this time.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, fluazaindolizine is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluazaindolizine from food and water will utilize 82% of the cPAD for all infants less than one year old, the population group receiving the greatest exposure. There are no residential uses for fluazaindolizine.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate risk takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, fluazaindolizine is not registered for any use patterns that would result in either short- or intermediate-term residential exposure. Because there is no short- or 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 short- or intermediate-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for fluazaindolizine.

4. *Aggregate cancer risk for U.S. population.* Fluazaindolizine 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 fluazaindolizine residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Crops: The petitioner submitted method validation, supplemental method validation, and radiovalidation data for Method No. DuPont-33861 (Rev. 3). This method successfully quantitates two ion transitions for fluazaindolizine via liquid chromatography with tandem mass spectrometry (LC–MS/MS). Method No. DuPont-33861 (Rev. 3) meets HED's criteria for enforcement analytical methods.

Livestock: The petitioner submitted method validation and an independent laboratory validation (ILV) for Method No. DuPont-39226 (Rev. 1). This method successfully quantitates two ion transitions for fluazaindolizine via LC–MS/MS. Method No. DuPont-39226 (Rev. 1) meets HED's criteria for enforcement analytical methods.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; 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 has not established any MRLs for fluazaindolizine.

C. Response to Comments

One comment was received on the April 15, 2020, notice of filing that stated in part ''this application should be denied. stop using this chemical.'' 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 FFDCA authorizes 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 the fluazaindolizine tolerances are safe. The commenter has provided no information indicating that a safety determination cannot be supported.

D. Revisions to Petitioned-For Tolerances

All tolerance values being established in this rulemaking vary slightly from what the petitioner requested. This is primarily because the petitioner proposed various metabolites as residues of concern for crop and livestock commodities, whereas EPA has concluded that the only residue needed to measure compliance with the tolerance is fluazaindolizine. All raw agricultural commodity (RAC) crop tolerances were calculated according to the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedure. Tolerances in/on processed commodities were calculated by multiplying average processing factors by the mean or highest average field trial (HAFT) value for blended and non-blended commodities, respectively. Commodity definitions are used in accordance with EPA's correct commodity definition guideline.

EPA is not establishing the requested primary crop tolerances for dried potato, potato process waste, tomato paste, and tomato puree, or the requested rotational crop tolerances for aspirated grain fractions (AGF), corn milled byproducts, soybean hulls, soybean meal, dehydrated strawberries, and wheat milled byproducts. Residues of parent fluazaindolizine in these processed commodities are not expected to concentrate to levels above the associated tolerances for the raw agricultural commodities, so processed commodity tolerances are not necessary. The Agency is not establishing the requested primary crop tolerance on tomato wet pomace, as this processed fraction is not considered a significant feed item and a tolerance is not necessary.

The Agency is not establishing the requested rotational crop tolerance for fruiting vegetable crop group 8–10, as residues of parent fluazaindolizine are

expected to be below the limit of quantitation (LOQ) in fruiting vegetables planted as rotational crops and therefore the primary crop tolerance is adequate.

The Agency is not establishing the requested rotational crop tolerances for the straw of commodities in crop groups 7 and 20, as these are not identified as significant feed items and tolerances are not needed. Similarly, EPA is not establishing the requested rotational crop tolerance for the fodder of crop group 18, as this is not a recognized commodity for the crop group.

Finally, EPA is establishing rotational crop tolerances for crop groups 6–22, 7–22, 15–22 and 16–22 rather than the requested rotational crop tolerances on crop groups 6, 7, 15 and 16. EPA proposed changes to these four crop groups on January 10, 2022 (87 FR 1091) (FRL–5031–12–OCSPP) and finalized the revised crop groups as 6–22, 7–22, 15–22 and 16–22 on September 21, 2022 (87 FR 57627) (FRL–5031–13–OCSPP). EPA regulations state ''Once a revised crop group is established, EPA will no longer establish tolerances under the pre-existing crop group.'' 40 CFR 180.40(j)(4). EPA has determined that the residue data support rotational crop tolerances for crop groups 6–22, 7–22, 15–22 and 16–22 based on EPA's practice for evaluating residue data for rotational crop tolerances and because there were no changes to major crops in groups 6–22, 7–22, 15–22 and 16–22. No food commodities are included in the revised crop groups that were not already accounted for in the initial dietary exposure assessment. Therefore, an updated dietary assessment is not needed, and the exposure and risk assessments do not change as a result of the crop group updates.

V. Conclusion

Therefore, tolerances are established for residues of fluazaindolizine, including its metabolites and degradates in or on carrot at 0.05 ppm; cattle, fat at 0.01 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.01 ppm; egg at 0.01 ppm; goat, fat at 0.01 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.01 ppm; hog, fat at 0.01 ppm; hog, meat at 0.01 ppm; hog, meat byproducts at 0.01 ppm; horse, fat at 0.01 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.01 ppm; milk at 0.01 ppm; poultry, fat at 0.01 ppm; poultry meat at 0.01 ppm; poultry, meat byproducts at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts at 0.01 ppm; tomato, dried at 0.4 ppm; vegetable, cucurbit, group 9 at 0.15 ppm; vegetable, fruiting, group 8–10 at 0.07 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.2 ppm.

Additionally, tolerances are established for inadvertent residues of fluazaindolizine, including its metabolites and degradates in or on animal feed, nongrass, group 18, forage at 0.01 ppm; animal feed, nongrass, group 18, hay at 0.015 ppm; animal feed, nongrass, group 18, straw at 0.15 ppm; berry, low growing, subgroup 13–07G at 0.01 ppm; grain, cereal, forage, hay, stover, and straw group 16–22, forage at 0.01 ppm; grain, cereal, forage, hay, stover, and straw group 16–22, hay at 0.015 ppm; grain, cereal, forage, hay, stover, and straw group 16–22, stover at 0.15 ppm; grain, cereal, forage, hay, stover, and straw group 16–22, straw at 0.15 ppm; grain, cereal, group 15–22 at 0.01 ppm; grass, forage, fodder and hay, group 17, forage at 0.01 ppm; grass, forage, fodder, and hay, group 17, hay at 0.015 ppm; grass, forage, fodder and hay, group 17, straw at 0.15 ppm; oilseed group 20 at 0.8 ppm; rapeseed, forage at 0.09 ppm; stalk, stem, and leaf petiole vegetable group 22 at 0.03 ppm; vegetable, *Brassica,* head and stem, group 5–16 at 0.015 ppm; vegetable, bulb, group 3–07 at 0.03 ppm; vegetable, legume, forage and hay, group 7–22, forage at 0.09 ppm; vegetable, legume, forage and hay, group 7–22, hay at 0.4 ppm; vegetable, leafy, group 4–16 at 0.015 ppm; vegetable, leaves of root and tuber, group 2 at 0.015 ppm; vegetable, legume, group 6–22 at 0.8 ppm; and vegetable, root, subgroup 1B at 0.02 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 tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: September 5, 2023.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I 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 § 180.720 to subpart C to read as follows:

§ 180.720 Fluazaindolizine; tolerances for residues.

(a) *General.* Tolerances are established for residues of the nematicide fluazaindolizine, including its metabolites and degradates, in or on the commodities to Table 1 of this section. Compliance with the tolerance levels specified in Table 1 is to be determined by measuring only fluazaindolizine, 8-chloro-*N*-[(2-chloro-5-methoxyphenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2-*a*]pyridine-2-carboxamide, in or on the commodity.

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Carrot	0.05
Cattle, fat	0.01
Cattle, meat	0.01
Cattle, meat byproducts	0.01
Egg	0.01
Goat, fat	0.01
Goat, meat	0.01
Goat, meat byproducts	0.01
Hog, fat	0.01
Hog, meat	0.01
Hog, meat byproducts	0.01
Horse, fat	0.01
Horse, meat	0.01
Horse, meat byproducts	0.01
Milk	0.01
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Sheep, fat	0.01
Sheep, meat	0.01
Sheep, meat byproducts	0.01
Tomato, dried	0.4
Vegetable, cucurbit, group 9	0.15
Vegetable, fruiting, group 8–10	0.07
Vegetable, tuberous and corm, subgroup 1C	0.2

(b)–(c) [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of the nematicide fluazaindolizine, including its metabolites and degradates, in or on the commodities to Table 2 of this section. Compliance with the tolerance levels specified in Table 2 is to be determined by measuring only fluazaindolizine, 8-chloro-*N*-[(2-chloro-5-methoxyphenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2-*a*]pyridine-2-carboxamide, in or on the commodity.

TABLE 2 TO PARAGRAPH (d)

Commodity	Parts per million
Animal feed, nongrass, group 18, forage	0.01
Animal feed, nongrass, group 18, hay	0.015
Animal feed, nongrass, group 18, straw	0.15
Berry, low growing, subgroup 13–07G	0.01
Grain, cereal, forage, hay, stover, and straw group 16–22, forage	0.01
Grain, cereal, forage, hay, stover, and straw group 16–22, hay	0.015
Grain, cereal, forage, hay, stover, and straw group 16–22, stover	0.15
Grain, cereal, forage, hay, stover, and straw group 16–22, straw	0.15
Grain, cereal, group 15–22	0.01
Grass, forage, fodder and hay, group 17, forage	0.01
Grass, forage, fodder and hay, group 17, hay	0.015
Grass, forage, fodder and hay, group 17, straw	0.15
Oilseed group 20	0.8
Rapeseed, forage	0.09
Stalk, stem and leaf petiole vegetable group 22	0.03

TABLE 2 TO PARAGRAPH (d)—Continued

Commodity	Parts per million
Vegetable, Brassica, head and stem, group 5–16	0.015
Vegetable, bulb, group 3–07	0.03
Vegetable, legume, forage and hay, group 7–22, forage	0.09
Vegetable, legume, forage and hay, group 7–22, hay	0.4
Vegetable, leafy, group 4–16	0.015
Vegetable, leaves of root and tuber, group 2	0.015
Vegetable, legume, group 6–22	0.8
Vegetable, root, subgroup 1B	0.02

[FR Doc. 2023–19607 Filed 9–11–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MB Docket No. 22–239; DA 23–740; FR ID 169282]

Update to Publication for Television Broadcast Station DMA Determinations for Cable and Satellite Carriage

AGENCY: Federal Communications Commission.

ACTION: Technical amendment.

SUMMARY: In this document, the Federal Communications Commission (Commission) conforms a section of its rules to the requirements of the Communications Act, correcting errors that were inadvertently introduced in the prior Report and Order, which revised Commission rules to use the Nielsen Company's Local TV Station Information Report as the successor publication to the annual Station Index Directory and United States Television Household Estimates in determining a television station's designated market area for satellite and cable carriage under the Commission's regulations. This action makes no substantive changes to this regulation.

DATES: This rule is effective October 12, 2023.

FOR FURTHER INFORMATION CONTACT: Contact Kenneth Lewis, *Kenneth.lewis@fcc.gov,* of the Media Bureau, Policy Division, (202) 418–2622.

SUPPLEMENTARY INFORMATION: This is a summary of the Media Bureau's Order, in MB Docket No. 22–239; DA 23–740, adopted and released on August 21, 2023. The full text of this document is available for download at *https://docs.fcc.gov/public/attachments/DA-23-740A1.pdf.* To request materials in accessible formats (braille, large print, computer diskettes, or audio recordings), please send an email to *FCC504@fcc.gov* (*mailto:FCC504@fccc.gov*) or call the Consumer and Government Affairs Bureau at (202) 418–0530 (VOICE), (202) 418–0432 (TTY).

Synopsis

On November 17, 2022, the Commission adopted the *Nielsen Update Report and Order,* MB Docket No. 22–239, FCC 22–89, which revised Commission rules to use the Nielsen Company's Local TV Station Information Report as the successor publication to the annual Station Index Directory and United States Television Household Estimates in determining a television station's designated market area for satellite and cable carriage under the Commission's regulations.[1] Pursuant to that change, § 76.66(e)(3) of the Commission's rules was revised, and the time periods mentioned in that rule were brought up to date.[2] These updates were intended to reflect the upcoming statutorily-established carriage election cycle periods,[3] but contained errors.

Technical Correction

Section 47 U.S.C. 325(b)(3)(B) requires that television stations, within one year after October 5, 1992, and every three years thereafter, make an election between the right to grant retransmission consent under this subsection and the right to signal carriage under section 534 of this title.''[4] In this Order, we revise § 76.66(e)(3) of the Commission's rules in order to conform to the requirements of the Communications Act. Specifically, we correct the references to the upcoming carriage election cycles in the first and second sentences to confirm that the next cycle runs from 2024–2026 (not 2024–2027), and the following cycle runs from 2027–2029 (not 2028–2030).

Regulatory Analyses

Administrative Procedure Act

We find that notice and comment procedures are unnecessary under the ''good cause'' exception of the Administrative Procedure Act (APA) because correcting the references in § 76.66(e)(3) entails no exercise of our administrative discretion.[5] The dates of each carriage cycle are long-established as a matter of law, and the reference to these dates in § 76.66 is merely as an aid to understanding. The rule change does not establish additional regulatory obligations or burdens on regulated entities. Consequently, we find notice and comment procedures are unnecessary for this action.

Paperwork Reduction Act Analysis

This document does not contain any new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA).[6] In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002.[7]

Congressional Review Act

Because this is a technical correction, there is no impact under the Congressional Review Act, 5 U.S.C. 804(2). Thus, the Bureau will not send

[1] *Update to Publication for Television Broadcast Station DMA Determinations for Cable and Satellite Carriage,* Report and Order, FCC 22–89, MB Docket No. 22–239 (rel. Nov. 18, 2022).

[2] *Id.* at Appendix B, Final Rules, para. 3.

[3] 47 U.S.C. 325(b)(3)(B) (''The regulations required by subparagraph (A) shall require that television stations, within one year after October 5, 1992, and every three years thereafter, make an election between the right to grant retransmission consent under this subsection and the right to signal carriage under section 534 of this title.'').

[4] *Id.*

[5] 5 U.S.C. 553(b)(3)(B) (notice and comment is not necessary ''when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest'').

[6] The Paperwork Reduction Act of 1995, Public Law 104–13, 109 Stat. 163 (1995) (codified in Chapter 35 of title 44 U.S.C.).

[7] The Small Business Paperwork Relief Act of 2002 (SBPRA), Public Law 107–198, 116 Stat. 729 (2002) (codified in Chapter 35 of title 44 U.S.C.); *see* 44 U.S.C. 3506(c)(4).