Section 8.30: Severability (Effective 3/9/2018)

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2017–0694; FRL–9985–32]**

### Cyantraniliprole; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of cyantraniliprole in or on multiple commodities which are identified and discussed later in this document. The Interregional Research Project No. 4 (IR–4) and DuPont Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective November 13, 2018. Objections and requests for hearings must be received on or before January 14, 2019, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2017–0694, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg. Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

**FOR FURTHER INFORMATION CONTACT:** Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. General Information

*A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp* and select ''Test Methods and Guidelines.''

*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–2017–0694 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 January 14, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2017–0694, 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 *https://www.epa.gov/dockets/where-send-comments-epa-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 March 21, 2018 (83 FR 12311) (FRL–9974–76), 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 7E8631) by The Interregional Research Project No. 4 (IR–4), Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.672 be amended by establishing tolerances for residues of the insecticide, cyantraniliprole, 3-bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide, in or on Berry, low growing, except strawberry, subgroup 13–07H, except blueberry, lowbush and lingonberry at 0.08 parts per million (ppm) (proposal to replace an existing tolerance at the same level that is only for imported Berry, low growing, except strawberry, subgroup 13–07H, with a tolerance supporting both domestic production and imported low growing berries, except strawberries); *Brassica,* leafy greens, subgroup 4–16B at 30 ppm; Caneberry subgroup 13–07A at 4.0 ppm; Celtuce at 20 ppm; Coffee, green bean at 0.05 ppm (proposal to replace an existing tolerance at the same level that is only for imported Coffee, green bean with a tolerance supporting both domestic production and imported coffee); Florence fennel at 20 ppm; Kohlrabi at 3.0 ppm; Leafy greens subgroup 4–16A at 20 ppm; Leaf petiole vegetable subgroup 22B at 20 ppm; and Vegetable,

*Brassica,* head and stem, group 5–16 at 3.0 ppm. Upon the establishment of the above tolerances, IR–4 proposed to remove existing tolerances in 40 CFR part 180.672 in or on the following commodities: *Brassica* head and stem, subgroup 5A at 3.0 ppm; *Brassica* leafy vegetables, subgroup 5B at 30 ppm; and Vegetable, leafy, except *Brassica,* group 4 at 20 ppm.

In the **Federal Register** of April 11, 2018 (83 FR 15528) (FRL–9975–57), 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 7F8622) by DuPont Crop Protection, Stine-Haskell Research Center, P.O. Box 30, Newark, DE 19714–0030. The petition requested that 40 CFR 180.672 be amended by establishing tolerances for residues of the insecticide cyantraniliprole, 3-bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide, in or on Rice, hulls at 0.05 ppm; Rice, straw at 0.015 ppm; Soybean, forage at 15 ppm; Soybean, hay at 50 ppm; Soybean, hulls at 1 ppm; Soybean, seed at 0.4 ppm; and Aspirated grain fractions at 200 ppm. Upon the approval of the proposed tolerances in soybean forage and hay, it is proposed that the existing tolerances for indirect or inadvertent residues in soybean forage and hay be cancelled. In addition, DuPont Crop Protection requests to amend the tolerances in 40 CFR 180.672, in or on rice, grain at 0.02 ppm by replacing an existing tolerance at the same level that is only for imported grain with a tolerance supporting both domestic production and imported grain.

These documents referenced summaries of the petitions prepared by DuPont Crop Protection, the registrant, which are available in the docket, *http://www.regulations.gov.* Three comments were received on the notices of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA modified some of the tolerance levels to conform to EPA's rounding classes and revised the commodity terminology for two tolerances. 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 cyantraniliprole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyantraniliprole 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.

In general, cyantraniliprole administration in mammalian test species produces both adverse and adaptive changes in the liver, thyroid gland, and adrenal cortex. With repeated dosing, consistent findings of mild to moderate increases in liver weights across multiple species (rats, mice and dogs) are observed. Dogs appear to be more sensitive than rats and mice; cyantraniliprole produces adverse liver effects (increases in alkaline phosphatase, decreases in cholesterol, and decreases in albumin) in dogs at lower dose levels than in rats. In addition, the liver effects in the dog show progressive severity with increased duration of exposure. The available data also show thyroid hormone homeostasis is altered in rats following exposure to cyantraniliprole after 28 or 90 days; however, cyantraniliprole is not a direct thyroid toxicant.

Cyantraniliprole is classified as ''not likely to be carcinogenic to humans'' based on the absence of increased tumor incidence in acceptable/guideline carcinogenicity studies in rats and mice, and there are no mutagenicity concerns. There are also no developmental or reproductive toxicity concerns and no offspring susceptibility concerns. Cyantraniliprole does not produce developmental toxicity in either rats or rabbits. The 2-generation reproduction study in rats shows that cyantraniliprole has no adverse effect on any reproductive parameters.

Acute and subchronic neurotoxicity studies reveal no evidence of neurotoxicity. Similarly, cyantraniliprole does not adversely impact the immune system in rats and mice. Based on the results of a 28-day dermal study in rats (as well as the dermal $LD_{50}$ study), cyantraniliprole does not demonstrate any appreciable toxicity via dermal exposure. The 28-day inhalation toxicity study in rats does not show any adverse systemic or portal of entry effect at the highest concentration tested (100 $mg/m^3$, equivalent to 18 mg/kg/day).

Cyantraniliprole has no significant acute toxicity via the oral, dermal, and inhalation routes of exposure. Cyantraniliprole is not an eye or skin irritant and does not cause skin sensitization.

Specific information on the studies received and the nature of the adverse effects caused by cyantraniliprole 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 ''Cyantraniliprole. Human Health Risk Assessment for Proposed Uses and Tolerance Requests on Coffee; Caneberry Subgroup 13–07A; Low Growing Berry Subgroup 13–07H, Except Strawberry, Lowbush Blueberry and Lingonberry; *Brassica* Leafy Greens Subgroup 4–16A; Leafy Greens Subgroup 4–16B; *Brassica* Head and Stem Vegetable Group 5–16; Leaf Petiole Vegetable Subgroup 22B; Celtuce; Florence Fennel; Kohlrabi; Rice; Soybean; and Aspirated Grain Fractions'' on pages 36–45 in docket ID number EPA–HQ–OPP–2017–0694.

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

A summary of the toxicological endpoints for cyantraniliprole used for human risk assessment is discussed in Unit III.B of the final rule published in the **Federal Register** of February 5, 2014 (79 FR 6826) (FRL–9388–7).

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyantraniliprole, EPA considered exposure under the petitioned-for tolerances as well as all existing cyantraniliprole tolerances in 40 CFR 180.672. EPA assessed dietary exposures from cyantraniliprole 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 cyantraniliprole; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the 2003–2008 United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, a refined chronic (food and drinking water) dietary assessment was conducted assuming average field trial residues for all crops (except crop subgroup 1A, for which tolerance level residues were assumed); percent crop treated (PCT) data; empirical processing factors; and default processing factors were used as appropriate.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that cyantraniliprole 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)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition c:* If data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such areas.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the average PCT for existing uses as follows: Citrus: oranges 62%, grapefruit 87%, and lemons 46%; pome fruit: apples 61% and pears 76%; stone fruits: apricots 53%, cherries 48%, peaches 41%, and plums/prunes 59%; tree nuts: almonds 72%, hazelnuts 65%, pecans 22%, pistachios 49%, and walnuts 53%; bushberries (subgroup 13–07B): blueberries 45%; fruiting vegetables: peppers 45% and tomatoes 54%; cucurbits: cantaloupes 50%, cucumbers 23%, pumpkins 18%, squash 24%, and watermelons 29%; leafy vegetables: celery 70%, lettuce 78%, and spinach 53%; *Brassica* (cole) leafy vegetables: broccoli 81%, cabbage 50%, and cauliflower 83%; onion 58%; potato 50%; oilseeds: canola 15% and sunflower 35%; corn 56%, cotton 41%; peanuts 41%; carrots 23%; soybeans 21%; strawberries 59%; vegetable crop group 7: dry beans/peas 6%, soybeans 21%, beans (snap, bush, etc.) 49%, and peas fresh/green/sweet) 38%; vegetable crop group 2: sugar beets 40%; vegetable crop group 6A: soybeans 21%, beans (snap, bush, etc., string) 49%; peas fresh/green/sweet) 38%; and vegetable crop group 6C: dried bean and peas 6%. 100 PCT was assumed for all other crops, including all proposed new use crops. For imported grapes (wine grapes), a 50% import estimate was used in the chronic dietary risk assessment.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figures for each existing use are derived by combining available public and private market survey data for that use, averaging across all observations, and rounding up to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to

which cyantraniliprole may be applied in a particular area.

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

Based on the Pesticides in Water Calculator (PWC; version 1.52) and Pesticide Root Zone Model Ground Water (PRZM GW) for ground water and FQPA Index Reservoir Screening Tool (FIRST) for surface water, the estimated drinking water concentrations (EDWCs) of cyantraniliprole for chronic exposures for non-cancer assessments are estimated to be 24 ppb for surface water and 64 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration value of 64 ppb was used to assess the contribution to drinking water.

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

Cyantraniliprole is currently registered for the following uses that could result in residential exposures: Turf grass (including residential, recreational, and golf course turf), ornamentals, and structural buildings (including indoor crack/crevice and outdoor broadcast). EPA assessed residential exposure using the following assumptions: EPA determined that residential exposures may occur by the dermal, oral, and inhalation routes of exposures. However, since dermal hazard has not been identified for cyantraniliprole, the only exposures of concern are handler inhalation (for adults), and post-application incidental oral (for children). Residential handler exposure is expected to be short-term in duration. The turf and ornamental labels indicate that a maximum of two applications are allowed per season. Thus, intermediate-term handler exposures are not likely because of the intermittent nature of applications by homeowners. Post-application incidental oral exposures for children may occur for short- and intermediate-term durations due to the persistence of cyantraniliprole. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' EPA has not found cyantraniliprole to share a common mechanism of toxicity with any other substances, and cyantraniliprole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cyantraniliprole does not have 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.* There is no evidence of susceptibility in developmental toxicity studies in rats and rabbits. The developmental toxicity study in rats is tested up to the limit dose (1,000 mg/kg/day). In the rabbit developmental toxicity study, decreases in fetal body weight are seen at a dose higher than that resulting in maternal effects. In the reproductive toxicity study, increased incidence of thyroid follicular epithelium hypertrophy/hyperplasia occurs in $F_1$ parental animals at a dose lower than that for the parental (P) generation. A clear NOAEL (1.4 mg/kg/day) is established for $F_1$ parental animals, and the PODs selected for risk assessment from the dog studies (1 or 3 mg/kg/day) are protective of the effect (thyroid effect) seen in the $F_1$ parental animals. In addition, the submitted data support the conclusion that the effects on the thyroid are secondary to effects on the liver. As such, a comparative thyroid study is not required at this time.

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 cyantraniliprole is complete.

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

iii. There is no evidence that cyantraniliprole results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The exposure databases are complete or are estimated based on data that reasonably account for potential exposures. The chronic dietary food exposure assessment was a refined assessment which assumed average field trial residues for all crops (except crop subgroup 1A); PCT when available; empirical processing factors, if available, or default processing factors, as appropriate. The 2012 Residential standard operating procedures (SOPs) were previously used to assess post-application exposure to children including incidental oral exposure, and the residential post-application assessment assumed that maximum application rates are applied and that hand-to-mouth activities occur on the day of application. All of the exposure estimates are based on conservative, health-protective 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 cyantraniliprole in drinking water. EPA used similarly conservative assumptions to assess post application exposure of children as well as

incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by cyantraniliprole.

*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, cyantraniliprole 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 cyantraniliprole from food and water will utilize 99% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of cyantraniliprole is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Cyantraniliprole is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to cyantraniliprole.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 149 for children 1 to 2 years old. For adults, the oral and inhalation routes of exposure are not appropriate to be aggregated since the endpoints of concern are not common. Because EPA's level of concern for cyantraniliprole is a MOE of 100 or below, this MOE is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Cyantraniliprole is currently registered for uses that could result in intermediate-term residential exposure, however, the short-term aggregate risk estimate described above is protective of potential intermediate-term exposures and risks in children.

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

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

## IV. Other Considerations

*A. Analytical Enforcement Methodology*

Adequate enforcement methodology (liquid chromatography with tandem mass spectroscopy (LC/MS/MS)) is available to enforce the tolerance expression.

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

*B. International Residue Limits*

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

There are no established Codex MRLs on the caneberry subgroup 13–07A, soybean, aspirated grain fractions, celtuce, Florence fennel and rice. The U.S. tolerances being established for coffee and *Brassica,* leafy greens subgroup 4–16A are harmonized with Codex. The U.S. tolerances being established for the low growing berry subgroup 13–07H; leaf petiole vegetable subgroup 22B; *Brassica* head and stem vegetable group 5–16; leafy greens subgroup 4–16B; and kohlrabi are not harmonized with Codex MRLs. The Codex MRLs established for residues of cyantraniliprole on these commodities are lower than the recommended U.S. tolerances. The U.S. tolerances cannot be harmonized because following the label use directions could result in residues above the established Codex MRLs.

*C. Response to Comments*

EPA received three comments in response to the Notices of Filing. The first comment indicated IR–4 and Rutgers University are profiteering by registering pesticides. The content of this comment is not material to the safety of the tolerances that are the subject of this action; pesticide registration occurs under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act. The FFDCA allows any person to file a petition proposing the establishment of a tolerance, and financial benefit from associated registration of pesticides is not a factor EPA considers when determining whether a tolerance is safe.

The second comment stated, in part, that no residues should be allowed. The Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

The last comment expressed concern about pollutant loadings and relatively high costs of regulations. The commenter also mentioned the Shelby Amendment, the Freedom of Information Act and the Intergovernmental Panel on Climate Change. The comment did not raise any issue related to the Agency's safety determination for cyantraniliprole tolerances. The receipt of this comment

is acknowledged; however, this comment is not relevant to this action.

*D. Revisions to Petitioned-For Tolerances*

EPA modified the proposed tolerance levels for soybean, hulls and soybean, seed to conform to the Agency's rounding classes. The Agency also revised the commodity terminology to use the correct commodity definitions for Florence fennel (Fennel, Florence, fresh leaves and stalk) and Aspirated grain fractions (Grain, aspirated grain fractions).

## V. Conclusion

Therefore, tolerances are established for residues of cyantraniliprole, 3-bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-[((methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide, in or on Berry, low growing, except strawberry, subgroup 13–07H, except blueberry, lowbush and lingonberry at 0.08 parts per million (ppm); *Brassica,* leafy greens, subgroup 4–16B at 30 ppm; Caneberry subgroup 13–07A at 4.0 ppm; Celtuce at 20 ppm; Fennel, Florence, fresh leaves and stalk at 20 ppm; Grain, aspirated grain fractions at 200 ppm; Kohlrabi at 3.0 ppm; Leaf petiole vegetable subgroup 22B at 20 ppm; Leafy greens subgroup 4–16A at 20 ppm; Rice hulls at 0.05 ppm; Rice, straw at 0.015 ppm; Soybean, forage at 15 ppm; Soybean, hay at 50 ppm; Soybean, hulls at 1.0 ppm; Soybean, seed at 0.40 ppm; and Vegetable, *Brassica,* head and stem, group 5–16 at 3.0 ppm. In addition, EPA is removing the following tolerances as they are superseded by the new tolerances being established in this rulemaking: from paragraph (a) (Berry, low growing, except strawberry, subgroup 13–07H at 0.08 ppm; *Brassica* head and stem, subgroup 5A at 3.0 ppm; *Brassica* leafy vegetables, subgroup 5B at 30 ppm; and Vegetable, leafy, except *Brassica,* group 4 at 20 ppm) and from paragraph (d) (soybean, forage at 0.70 ppm and soybean, hay at 0.70 ppm). Finally, EPA is removing the footnote noting the lack of US registrations for the tolerances for coffee, green bean and rice, grain.

## VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the 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: October 24, 2018.

**Michael Goodis,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

## PART 180—[AMENDED]

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

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

■ 2. In § 180.672:

■ a. In the table to paragraph (a):

■ i. Remove the entry ''Berry, low growing, except strawberry, subgroup 13–07H[1]''.

■ ii. Add alphabetically the entry ''Berry, low growing, except strawberry, subgroup 13–07H, except blueberry, lowbush and lingonberry''.

■ iii. Remove the entry ''*Brassica* head and stem, subgroup 5A''.

■ iv. Add alphabetically the entry ''*Brassica,* leafy greens, subgroup 4–16B.

■ v. Remove the entry ''*Brassica* leafy vegetables, subgroup 5B''.

■ vi. Add alphabetically the entries: ''Caneberry subgroup 13–07A'' and ''Celtuce''.

■ vii. Revise the entry ''Coffee, green bean''.

■ viii. Add alphabetically the entries: ''Fennel, Florence, fresh leaves and stalk''; ''Grain, aspirated grain fractions''; ''Kohlrabi''; ''Leaf petiole vegetable subgroup 22B''; ''Leafy greens subgroup 4–16A'';

■ ix. Revise the entry ''Rice, grain''.

■ x. Add alphabetically the entries: ''Rice hulls''; ''Rice, straw''; ''Soybean, forage''; ''Soybean, hay''; ''Soybean, hulls''; ''Soybean, seed''; and ''Vegetable, *Brassica,* head and stem, group 5–16''.

■ xi. Remove the entry ''Vegetable, leafy, except *Brassica,* group 4''.

■ b. Remove from the table in paragraph (d) the entries: ''Soybean, forage''; and ''Soybean, hay''.

The additions and revisions read as follows:

**§ 180.672 Cyantraniliprole; tolerances for residues.**

(a) * * *

| Commodity | Parts per million |
|---|---|
| * * * * * * * | |
| Berry, low growing, except strawberry, subgroup 13–07H, except blueberry, lowbush and lingonberry | 0.08 |
| * * * * * * * | |
| *Brassica,* leafy greens, subgroup 4–16B | 30 |
| * * * * * * * | |
| Caneberry subgroup 13–07A | 4.0 |
| * * * * * * * | |
| Celtuce | 20 |
| * * * * * * * | |
| Coffee, green bean | 0.05 |
| * * * * * * * | |
| Fennel, Florence, fresh leaves and stalk | 20 |
| * * * * * * * | |
| Grain, aspirated grain fractions | 200 |
| * * * * * * * | |
| Kohlrabi | 3.0 |
| Leaf petiole vegetable subgroup 22B | 20 |
| Leafy greens subgroup 4–16A | 20 |
| * * * * * * * | |
| Rice, grain | 0.02 |
| Rice, hulls | 0.05 |
| Rice, straw | 0.015 |
| * * * * * * * | |
| Soybean, forage | 15 |
| Soybean, hay | 50 |
| Soybean, hulls | 1.0 |
| Soybean, seed | 0.40 |
| * * * * * * * | |
| Vegetable, *Brassica,* head and stem, group 5–16 | 3.0 |
| * * * * * * * | |

* * * * *

[FR Doc. 2018–24379 Filed 11–9–18; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

### 44 CFR Part 64

**[Docket ID FEMA–2018–0002; Internal Agency Docket No. FEMA–8555]**

### Suspension of Community Eligibility

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Final rule.

**SUMMARY:** This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *https://www.fema.gov/national-flood-insurance-program-community-status-book.*

**DATES:** The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

**FOR FURTHER INFORMATION CONTACT:** If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Adrienne L. Sheldon, PE, CFM, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW, Washington, DC 20472, (202) 212–3966.

**SUPPLEMENTARY INFORMATION:** The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

*National Environmental Policy Act.* FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) does not apply.

*Regulatory Flexibility Act.* The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

*Regulatory Classification.* This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

*Executive Order 13132, Federalism.* This rule involves no policies that have federalism implications under Executive Order 13132.

*Executive Order 12988, Civil Justice Reform.* This rule meets the applicable standards of Executive Order 12988.

*Paperwork Reduction Act.* This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

**List of Subjects in 44 CFR Part 64**

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

## PART 64—[AMENDED]

■ 1. The authority citation for part 64 continues to read as follows:

**Authority:** 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

**§ 64.6 [Amended]**

■ 2. The tables published under the authority of § 64.6 are amended as follows: