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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0357; FRL-9958-53]

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. E.I. DuPont de Nemours & Company and Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0357 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.

C. How Can I File an Objection or Hearing Request?

Under FFDCFA 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-2014-0357 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information

not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0357, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of January 28, 2015 (80 FR 4525) (FRL-9921-55), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 4F8258 and 4F8320) by E.I. du Pont de Nemours & Company, 1007 Market St., Wilmington, DE 19898 and Syngenta Crop Protection LLC, P.O. Box 18300, Greensboro, NC 27419, respectively. The petitions

requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide cyantraniliprole, in or on artichokes, globe (import tolerance) at 0.1 parts per million (ppm); berries, low growing, except strawberries (crop subgroup 13–07H) (import tolerance) at 0.08 ppm; coffee, bean, green (import tolerance) at 0.05 ppm; grapes (import tolerance) at 1.5 ppm; olives (import tolerance) at 1.5 ppm; peanuts at 0.01 ppm; peanut hay at 3 ppm; pomegranates (import tolerance) at 0.01 ppm; rice, grain (import tolerance) at 0.03 ppm; soybeans, seed at 0.4 ppm; strawberries at 1.0 ppm; vegetables, foliage of legume (crop group 7) at 50 ppm; vegetables, leaves of root and tuber (crop group 2) at 40 ppm; vegetables, legume, dried shelled, except soybean (crop subgroup 6C) at 0.9 ppm; vegetables, legume, edible podded (crop subgroup 6A) at 2 ppm; vegetables, legume, succulent shelled (crop subgroup 6B) at 0.2 ppm; vegetables, root, except sugar beet (crop subgroup 1B) at 0.4 ppm; and tea, dried (import tolerance) at 30 ppm (PP 4F8258) and corn, field and pop, forage at 0.04 ppm; corn, field and pop, grain at 0.01 ppm; corn, field and pop, stover at 0.015 ppm; corn, sweet, forage at 0.02 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; and corn, sweet, stover at 0.08 ppm (PP 4F8320). That document referenced a summary of the petitions prepared by E.I. du Pont de Nemours & Company and Syngenta Crop Protection LLC, the registrants, which is available in the dockets EPA-HQ-OPP-2014-0357 and EPA-HQ-OPP-2014-0890, respectively, at <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the levels at which and the commodities upon which tolerances are being established. 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 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 mammals 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 90 days due to enhanced metabolism of the thyroid hormones by the liver. However, cyantraniliprole does not act directly on the thyroid; the thyroid effects observed are secondary to the effects on the liver.

Cyantraniliprole is classified as “Not Likely to be Carcinogenic to Humans” based on the absence of increased tumor incidence in carcinogenicity studies in rats and mice. In addition, there are no genotoxicity, mutagenicity, neurotoxicity, or immunotoxicity concerns. There are also no developmental or reproductive toxicity concerns and there is no evidence of an adverse effect attributable to a single dose.

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 the document titled “*Cyantraniliprole. Human Health Risk Assessment for the Proposed Uses on Root Vegetables (except Sugar Beet) (Crop Subgroup 1B), Leaves of Root and Tuber Vegetables (Crop Group 2), Legume Vegetables (Crop Group 6 except soybean), Leaves of Legume Vegetables (Crop Group 7 except soybean), Peanuts, Strawberries, Tobacco and Seed Treatment Uses on Corn (Field, Pop, Seed, Sweet). Tolerance Requests without U.S. Registration for Artichokes, Coffee Green Bean, Wine Grapes, Low Growing Berries (except Strawberries) (Crop Subgroup 13-07H), Olives, Pomegranate, and Tea Dried. Amended Tolerance Requests for Cucurbit Vegetables (Crop Group 9) due to New Use Pattern and Amended Uses for Tomatoes and Peppers*” on page 40 in docket ID number EPA-HQ-OPP-2014-0357.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in

conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for 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 proposed crops (except sugar beet root), percent crop treated (PCT) where available, and percent crop treated for new uses (PCTn) for some crops. In addition, the estimated percentage of imported grapes was incorporated into the assessment. For processed commodities, input values included combined average residues of parent and the metabolite (IN-J9Z38) with relevant processing factors. The chronic assessment incorporated empirical processing factors, if available, or Dietary Exposure Evaluation Model (DEEM) Version 7.81 default processing factors as appropriate. Empirical processing factors were used for potato flakes and chips, tomatoes (paste, puree, dried, and juice), orange juice, apple juice, cottonseed oil, citrus oil, and dried plums. The processing factors for these commodities were set at 1 because the residue input values included combined residues of the parent and the metabolite with relevant processing factors. Crop field trial data depicting residues in/on citrus fruit peels (lemon and orange) were available and included into the assessment.

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 PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

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

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

The Agency estimated the 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%; and corn 56%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The

maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency estimated the PCT for new uses as follows:

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%; vegetable crop group 6C: dried bean and peas 6%. For the imported grapes (wine grapes) a 50% import estimate was used in the chronic dietary risk assessment.

EPA estimates of the PCT_n of cyantraniliprole represent the upper bound of use expected during the pesticide's initial five years of registration; that is, PCT_n for cyantraniliprole is a threshold of use that EPA is reasonably certain will not be exceeded for each registered use site. The PCT_n recommended for use in the chronic dietary assessment is calculated as the average PCT of the market leader or leaders (i.e., the currently registered pesticide(s) with the greatest PCT) on that site over the three most recent years of available data. Comparisons are only made among pesticides of the same pesticide type (e.g., the market leader for insecticides on the use site is selected for comparison with a new insecticide). The market leader included in the estimation may not be the same for each year since different pesticides may dominate at different times.

Typically, EPA uses USDA/NASS as the source of data because it is publicly available and directly reports values for PCT. When a specific use site is not reported by USDA/NASS, EPA uses market survey data and calculates the PCT given reported data on acres treated and acres grown. If no data are available, EPA may extrapolate PCTn from other crops, if the production area and pest spectrum are substantially similar.

A retrospective analysis to validate this approach shows few cases where the PCT for the overall market leaders were exceeded. Further review of these cases identified factors contributing to the exceptionally high use of a new pesticide. To evaluate whether the PCTn for cyantraniliprole could be exceeded, EPA considered whether there may be unusually high pest pressure, as indicated in emergency exemption requests for cyantraniliprole; how the pest spectrum of the new pesticide compares with the market leaders; and whether pest resistance issues with past market leaders provide cyantraniliprole with significant market potential. EPA also considered the potential for resistance to cyantraniliprole to develop as a limiting factor in its use. Given currently available information, EPA concludes that it is unlikely that actual PCT for cyantraniliprole will exceed the estimated PCT for new uses during the next five years.

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 <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the First Index Reservoir Screening Tool (FIRST) and Pesticide in Water Calculator (PWC), the estimated drinking water concentrations (EDWCs) of cyantraniliprole for chronic exposures are estimated to be 24 ppb for surface water and 64 ppb for ground water, respectively.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. An acute dietary risk assessment was not conducted since no acute toxicological effects were found. For the 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: turfgrass (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: Residential exposure may occur by the dermal, oral, and inhalation routes and is expected to be short-term in duration of exposures. However, since a 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). For adults, the oral and inhalation routes of exposure were not aggregated since the endpoints of concern are not common. The turf and ornamental labels indicate that a maximum of two applications are allowed per season. Thus, intermediate-term 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. Although intermediate-term incidental oral post-application exposures are possible (i.e., from soil ingestion, due to the persistence of cyantraniliprole), the short-term incidental oral exposures are protective of the possible intermediate-term incidental oral exposures because the POD for both durations is the same. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

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

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 <http://www2.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 Food Quality Protection Act (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 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 F₁ parental animals at a dose lower than that for the parental (P) generation. A clear NOAEL (1.4 mg/kg/day) is established for F₁ 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 at 14 mg/kg/day) seen in the F₁ parental animals. In addition, the submitted data support the conclusion that the effects on the thyroid are secondary to effects on the liver.

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 of susceptibility in developmental toxicity studies in rats and rabbits. In the reproductive toxicity study, increased incidence of thyroid follicular epithelium hypertrophy/hyperplasia occurs in F₁ parental animals at a dose lower than that for the parental (P) generation. However, for the reasons summarized in Unit III.D.2. these effects are not of concern.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessment was a refined assessment which assumed average field trial residues for all crops (except sugar beet root), PCT where available, and PCTn data. 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 98% of the cPAD for children 1-2 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 1-2 years old. For adults, the oral and inhalation routes of exposure were not 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.

For the commodities discussed in this action, there are only Codex MRLs established for residues of cyantraniliprole on coffee beans (0.03 ppm), cucurbit fruiting vegetables (0.3 ppm), legume animal feeds (in the U.S. identified as Foliage of legume vegetables) (0.8 ppm), and root and tuber vegetables (0.05 ppm). There are also Codex MRLs for residues of cyantraniliprole in/on ruminants at (0.01-0.05 ppm), milk (0.02 ppm), and poultry commodities at (0.01 ppm).

The EPA has not harmonized the tolerances for these commodities with the existing Codex MRLs. The petitioner requested a tolerance on coffee without a U.S. registration be established at 0.05 ppm to be line with the existing MRL for coffee in Canada. The Codex MRLs established for residues of cyantraniliprole on cucurbit fruiting vegetables at 0.3 ppm, root and tuber vegetables at 0.05 ppm, and legume animal feeds at 0.8 ppm are lower than the U.S. tolerances of 0.7 ppm, 0.15 ppm and 40 ppm, respectively. The U.S. tolerances cannot be harmonized because following the label use directions could result in residues above the established Codex MRLs. The Codex MRLs for residues of cyantraniliprole in/on ruminants at (0.01-0.05 ppm), milk (0.02 ppm), and poultry commodities at (0.01 ppm) are lower than the U.S. tolerances. The U.S. and Codex livestock MRLs are not harmonized due to different animal diets and tolerances (MRLs) established for different animal feed commodities. The U.S. tolerances cannot be harmonized (lowered) because following the label use directions could result in residues above the Codex MRLs.

C. Response to Comments

A comment was submitted on behalf of the Center for Biological Diversity and the Center for Food Safety and was primarily concerned about EPA's consideration of the impacts of cyantraniliprole on the environment, pollinators, and endangered species. This comment is not relevant to the Agency's evaluation of safety of the cyantraniliprole tolerances under section 408 of the FFDCA, which requires the Agency to evaluate the potential harms to human health, not effects on the environment.

EPA received two other comments to the Notices of Filing noting general concerns about the toxicity of this chemical and stating, in part, that “this product represents a clear and present danger” and “should not be approved to be sold.” The Agency understands the commenter’s concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the FFDCFA 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. EPA has assessed the effects of this chemical on human health and determined that aggregate exposure to it will be safe.

D. Revisions to Petitioned-For Tolerances

The Agency is not establishing the proposed tolerances for corn, field and pop, forage; corn, field and pop stover; corn, sweet, forage; and corn, sweet stover because the proposed uses are seed treatment only, not a foliar use, so no residues will be present on these feed commodities. Therefore, these tolerances are not necessary.

The proposed tolerance for residues of cyantraniliprole in/on rice, grain of 0.03 ppm is being modified to 0.02 ppm based on the OECD statistical calculation applied to the field trial residue data.

The proposed wine grape tolerance is being modified from 1.5 ppm to 2.0 ppm and a tolerance is being established on olive oil at 2.0 ppm due to concentration demonstrated in the processing studies.

The proposed tolerance for residues in/on legume vegetables, subgroup 6C of 0.9 ppm is being modified to 1.0 ppm based on the OECD statistical calculation applied to the field trial residue data.

The proposed tolerance for residues in/on soybean seed including the foliage (forage and hay) is not being established since processing studies were not submitted for soybean processed commodities (hulls, meal, oil). Therefore, the proposed tolerance for residues of cyantraniliprole in/on vegetables, foliage of legume (crop group 7) is being revised to “Vegetable, foliage of legume, except soybean, group 7A.”

Numerous ruminant commodity tolerances are already established. These ruminant (cattle, goats, horses, and sheep) commodity tolerances are being increased to reflect the new dietary burdens from the tolerances established by this document.

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]-1*H*-pyrazole-5-carboxamide, including its metabolites and degradates, in or on Artichoke, globe at 0.10 ppm; Berry, low growing, except strawberry, subgroup 13-07H at 0.08 ppm; Coffee, green bean at 0.05 ppm; Corn, field, grain at 0.01 ppm; Corn, pop, grain at 0.01 ppm; Corn, sweet, kernel plus cob with husks removed at 0.01 ppm; Grape, wine at 2.0 ppm; Olive at 1.5 ppm; Olive, oil at 2.0 ppm; Peanut at 0.01 ppm; Pomegranate at 0.01 ppm; Rice, grain at 0.02 ppm; Strawberry at 1.0 ppm; Tea at 30 ppm; Vegetable, foliage of legume, except soybean, group 7A at 40 ppm; Vegetable, leaves of root and

tuber, group 2 at 40 ppm; Vegetable, legume, dried shelled, except soybean, subgroup 6C at 1.0 ppm; Vegetable, legume, edible podded, subgroup 6A at 2.0 ppm; Vegetable, legume, succulent shelled, subgroup 6B at 0.20 ppm; and Vegetable, root, except sugar beet, subgroup 1B at 0.40 ppm.

In addition, the following tolerances are modified as follows: Peanut, hay from 0.01 ppm to 3.0 ppm and Vegetable, cucurbit, group 9 from 0.40 ppm to 0.70 ppm.

Also, due to the tolerances being established the following tolerances are modified as follows: Cattle, fat from 0.01 ppm to 0.10 ppm; Cattle, meat from 0.01 ppm to 0.10 ppm; Cattle, meat byproducts from 0.01 ppm to 0.40 ppm; Goat, fat from 0.01 ppm to 0.10 ppm; Goat, meat from 0.01 ppm to 0.10 ppm; Goat, meat byproducts from 0.01 ppm to 0.40 ppm; Horse, fat from 0.01 ppm to 0.10 ppm; Horse, meat from 0.01 to 0.10 ppm; Horse, meat byproducts from 0.01 ppm to 0.40 ppm; Milk from 0.01 ppm to 0.20 ppm; Sheep, fat from 0.01 ppm to 0.10 ppm; Sheep, meat from 0.01 ppm to 0.10 ppm; and Sheep, meat byproducts from 0.01 to 0.40 ppm.

Lastly, due to the tolerances being established above, the indirect or inadvertent tolerances under 40 CFR 180.672 (d) for Peanut, hay; Vegetable, foliage of legume (group 7); Vegetable, leaves of root and tuber vegetables (group 2); and Vegetable, root (subgroup 1A) are removed as unnecessary, and new tolerances are established under 180.672 (d) for Beet, sugar, roots at 0.02 ppm; Soybean, forage at 0.70 ppm; and Soybean, hay at 0.70 ppm.

VI. Statutory and Executive Order Reviews

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

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship

between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 17, 2017.

Daniel J. Rosenblatt,

Acting 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, revise paragraphs (a) and (d) to read as follows:

§ 180.672 Cyantraniliprole; tolerances for residues.

(a) *General.* Tolerances are established for the combined 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, including its metabolites and degradates, in or on commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only cyantraniliprole in or on the commodity.

Commodity	Parts per million
Almond, hulls	8.0
Artichoke, globe ¹	0.10
Berry, low growing, except strawberry, subgroup 13-07H ¹	0.08
Brassica head and stem, subgroup 5A	3.0
Brassica leafy vegetables, subgroup 5B	30

Bushberry, subgroup 13-07B	4.0
Cattle, fat	0.10
Cattle, meat	0.10
Cattle, meat byproducts	0.40
Cherry, subgroup 12-12A	6.0
Citrus, oil	2.4
Coffee, green bean ¹	0.05
Corn, field, grain	0.01
Corn, pop, grain	0.01
Corn, sweet, kernel plus cob with husks removed	0.01
Cotton, gin byproducts	10
Fruit, citrus, group 10-10	0.70
Fruit, pome, group 11-10	1.5
Goat, fat	0.10
Goat, meat	0.10
Goat, meat byproducts	0.40
Grape, wine ¹	2.0
Horse, fat	0.10
Horse, meat	0.10

Horse, meat byproducts	0.40
Milk	0.20
Nut, tree, group 14-12	0.04
Oilseed group 20	1.5
Olive ¹	1.5
Olive, oil ¹	2.0
Onion, bulb, subgroup 3-07A	0.04
Onion, green, subgroup 3-07B	8.0
Peach, subgroup 12-12B	1.5
Peanut	0.01
Peanut hay	3.0
Plum, subgroup 12-12C	0.50
Pomegranate ¹	0.01
Rice, grain ¹	0.02
Sheep, fat	0.10
Sheep, meat	0.10
Sheep, meat byproducts	0.40
Strawberry	1.0
Tea ¹	30

Vegetable, cucurbit, group 9	0.70
Vegetable, foliage of legume, except soybean, group 7A	40
Vegetable, fruiting, group 8-10	2.0
Vegetable, leafy, except <i>Brassica</i> , group 4	20
Vegetable, leaves of root and tuber, group 2	40
Vegetable, legume, dried shelled, except soybean, subgroup 6C	1.0
Vegetable, legume, edible podded, subgroup 6A	2.0
Vegetable, legume, succulent shelled, subgroup 6B	0.20
Vegetable, root, except sugar beet, subgroup 1B	0.40
Vegetable, tuberous and corm, subgroup 1C	0.15

¹ There are no U.S. registrations for these commodities

(d) *Indirect or inadvertant residues.* Tolerances are established for indirect or inadvertant tolerances for residues of cyantraniliprole, 3-bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-methyl-6-(((methylamino)carbonyl)phenyl)]-1H-pyrazole-5-carboxamide, including its metabolites and degradates, in or on commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only cyantraniliprole in or on the commodity.

Commodity	Parts per million
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Animal feed, nongrass, group 18	0.20
Beet, sugar, roots	0.02
Grain, cereal, forage, fodder and straw, group 16	0.50
Grass forage, fodder and hay, group 17	0.50
Soybean, forage	0.70
Soybean, hay	0.70

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