this cite-all option must submit to the Agency:

* * * * *

(b) * * *

(2) * * *

(v) The applicant's name, address, and contact information, including a telephone number and email address.

* * * * *

■ 13. Revise § 152.96 to read as follows:

§ 152.96 Claim of data gap.

(a) *When a data gap may be claimed.* Except as provided in paragraph (b) of this section, an applicant may defer his obligation to satisfy an applicable data requirement until the Agency requires the data if no other person has previously submitted to the Agency a valid study that would satisfy the data requirement in question.

(b) *When a data gap may not be claimed*—(1) *Product containing a new active ingredient.* An applicant for registration of a product containing a new active ingredient may not defer his obligation by claiming a data gap unless he can demonstrate to the Agency's satisfaction that the data requirement was imposed so recently that insufficient time has elapsed for the study to have been completed and that, in the public interest, the product should be registered during the limited period of time required to complete the study. Refer to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(7)(C).

(2) *Product not containing a new active ingredient.* An applicant for registration of a product under FIFRA sections 3(c)(7)(A) or (B) (a product not containing a new active ingredient) may not defer his obligation by claiming a data gap if the data are:

(i) Data needed to determine whether the product is identical or substantially similar to another currently registered product or differs only in ways that would substantially increase the risk of unreasonable adverse effects on the environment.

(ii) Efficacy data specific to the product, if required to be submitted to the Agency.

(iii) If a new use is proposed for a product that is identical or substantially similar to an existing product, data to demonstrate whether the new use would substantially increase the risk of unreasonable adverse effects on the environment.

(c) *Approval of application with a data gap claim*—(1) In accordance with § 152.115(a), any registration that is approved based upon a data gap claim shall be conditioned on the submission of the data no later than the time that the data are required to be submitted for similar products already registered.

(2) Notwithstanding paragraph (c)(1) of this section, the Agency will not approve an application if it determines that the data for which a data gap claim has been made are needed to determine if the product meets the requirements of FIFRA sections 3(c)(5) or (7).

■ 14. Revise § 152.97 to read as follows:

§ 152.97 Rights and obligations regarding the Data Submitters List.

(a) Each original data submitter shall have the right to be included on the Agency's Data Submitters List.

(b) Each original data submitter who wishes to have his name added to the current Data Submitters List must submit to the Agency the following information:

(1) Name and current address.

(2) Chemical name, common name (if any) and Chemical Abstracts Service (CAS) number (if any) of the active ingredients(s), with respect to which he is an original data submitter.

(3) For each such active ingredient, the type(s) of study he has previously submitted (identified by reference to data/information requirements listed in part 158 of this chapter), the date of submission, and the EPA registration number, file symbol, or other identifying reference for which it was submitted.

(c) Each applicant not already included on the Data Submitters List for a particular active ingredient must inform the Agency at the time of the submission of a relevant study whether he wishes to be included on the Data Submitters List for that pesticide.

■ 15. In § 152.99:

■ a. Remove paragraph (a)(2)(iv).

■ b. Redesignate paragraphs (a)(2)(v) and (a)(2)(vi) as paragraphs (a)(2)(iv) and (a)(2)(v).

■ c. Revise newly redesignated paragraph (a)(2)(iv) and paragraph (b)(2).

The amendments read as follows:

§ 152.99 Petitions to cancel registration.

* * * * *

(a) * * *

(2) * * *

(iv) The applicant has falsely or improperly claimed that a data gap existed at the time of his application.

(b) * * *

(2) *Notice to affected registrant.* At the same time that the petitioner files his petition with the Agency, the petitioner shall send a copy to the affected applicant or registrant by certified mail or by any other method that provides evidence of delivery. The affected applicant or registrant shall have 60 days from the date of receipt of the petition to submit written comments to the Agency.

* * * * *

[FR Doc. 2014–02294 Filed 2–4–14; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0668; FRL–9388–7]

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 that are identified and discussed later in this document. E.I. du Pont de Nemours & Company (DuPont) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 5, 2014. Objections and requests for hearings must be received on or before April 7, 2014, 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–2011–0668, 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), EPA West 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: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; 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 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–2011–0668 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 April 7, 2014. 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–2011–0668, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 23, 2012 (77 FR 30481) (FRL–9347–8), 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 1F7894) by E.I. du Pont de Nemours & Company (DuPont), 1007 Market St., Wilmington, DE 19898. The petition requested that 40 CFR part 180 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]-1*H*-pyrazole-5-carboxamide, including its metabolites and degradates, in or on almond hulls at 30 parts per million (ppm); berries and small fruits, bushberries (subgroup 13–07B) at 4 ppm; *Brassica* (cole) leafy vegetables, head and stem *Brassica* (subgroup 5A) at 2 ppm; *Brassica* (cole) leafy vegetables, leafy *Brassica* greens (subgroup 5B) at 30 ppm; bulb vegetables, onion, bulb (subgroup 3–07A) at 0.04 ppm; bulb vegetables, onion, green (subgroup 3–07B) at 8 ppm; cattle, fat at 0.01 ppm; cattle, liver at 0.04 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts, except liver at 0.01 ppm; cherries at 6 ppm; citrus fruits (group 10–10) at 0.7 ppm; cotton gin byproduct at 10 ppm; cucurbit vegetables (group 9) at 0.3 ppm; fruiting vegetables (group 8–10) at 2 ppm; goat, fat at 0.01 ppm; goat, liver at 0.04 ppm; goat, meat at 0.01 ppm; goat, meat byproducts, except liver at 0.01 ppm; hog, fat at 0.01 ppm; hog, liver at 0.04 ppm; hog, meat at 0.01 ppm; hog, meat byproducts, except liver at 0.01 ppm; horse, fat at 0.01 ppm; horse, liver at 0.04 ppm; horse, meat at 0.01 ppm; horse, meat byproducts, except liver at 0.01 ppm; leafy vegetables (except *Brassica* vegetables) (group 4) at 15 ppm; milk at 0.01 ppm; milk, fat at 0.04 ppm; oilseeds, except cotton gin byproduct (group 20) at 1 ppm; pome fruits (group 11–10) at 0.8 ppm; root and tuber vegetables, tuberous and corm vegetables (subgroup 1C) at 0.15 ppm; sheep, fat at 0.01 ppm; sheep, liver at 0.04 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts, except liver at 0.01 ppm; stone fruits, except cherries (group 12) at 1.5 ppm; tree nuts, except almond hulls (group 14) at 0.06 ppm; citrus, oil at 6 ppm; citrus, raw peel at 2 ppm; and potato, wet peel at 0.3 ppm.

In addition, DuPont requested to amend 40 CFR part 180 to establish indirect or inadvertent tolerances 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 the following commodities: Foliage of legume vegetables (group 7), forage at 0.15 ppm; foliage of legume vegetables (group 7), hay at 0.6 ppm; forage, fodder and straw of cereal grains (group 16), forage at 0.06 ppm; forage, fodder and straw of cereal grains (group 16), hay and straw at 0.15 ppm; grass forage, fodder, and hay (group 17), forage at 0.06 ppm; grass forage, fodder, and hay (group 17), hay at 0.15 ppm; leaves of root and tuber vegetables (human food or animal feed) (group 2) at 0.04 ppm; nongrass animal feeds (forage, fodder, straw, and hay) (group 18), forage at 0.06 ppm; nongrass animal feeds (forage, fodder, straw, and hay) (group 18), hay at 0.15 ppm; peanut hay at 0.03 ppm; root and tuber vegetables, root vegetables (subgroup 1A) at 0.03 ppm.

That document referenced a summary of the petition prepared by DuPont, the registrant, which is available in the docket, *http://www.regulations.gov.*

Based upon review of the data supporting the petition, EPA is establishing several tolerances that vary from levels requested in the original petition. 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. Cyantraniliprole is a 2-generation ryanodine receptor (RyR) insecticide belonging to the diamide class of chemistry whose pesticidal mode of action (MOA) is through unregulated activation of insect RyR channels. This leads to internal calcium store depletion and impaired regulation of muscle contraction, causing paralysis and eventual death of the insect. Mammalian RyR are shown to be 350 to >2,500 times less sensitive than those of insects. 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 only as a result of the adverse effects on the liver. 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. In addition, there are no genotoxicity, mutagenicity, neurotoxicity, or immunotoxicity concerns. There are also no developmental or reproductive toxicity concerns. 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 ''Cyantraniliprole. Aggregate Human Health Risk Assessment for the Proposed New Uses of the New Active Insecticide (March 7, 2013)'' at p.16 in docket ID number EPA–HQ–OPP–2011–0668.

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 (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints and points of departure for cyantraniliprole used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CYANTRANILIPROLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	POD and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (general population, including infants and children and females 13–49 years of age).	An effect attributed to a single dose was not identified in the toxicology database.		
Chronic dietary (All populations)	NOAEL = 1 mg/kg/day. UF_A = 10x. UF_H = 10x. FQPA SF = 1x.	Chronic RfD = 0.01 mg/kg/day. cPAD = 0.01 mg/kg/day.	Based on 1-year oral study in dogs. LOAEL = 6 mg/kg/day based on effects indicative of liver toxicity (increased liver weights and alkaline phosphatase activity), and significant decreases in albumin level.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CYANTRANILIPROLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	POD and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Incidental oral short-term (1 to 30 days) and incidental oral intermediate-term (1 to 6 months).	NOAEL = 3 mg/kg/day. UF_A = 10x. UF_H = 10x. FQPA SF = 1x.	LOC for MOE = 100	Based on both 28-day and 90-day oral study in dogs. 28-Day LOAEL = 35 mg/kg/day (lowest dose tested) based on decreases in body weight, food consumption, food efficiency, and changes in clinical chemistry (increased alkaline phosphatase, decreased cholesterol and decreased albumin). 90-Day LOAEL = 32 mg/kg/day based on a collection of treatment-related effects indicative of liver toxicity. The effects included decreases in total protein, albumin, and cholesterol in males and females; increases in alkaline phosphatase in males and females; increases in alanine aminotransferase in females; and increases in liver weights in males and females.
Dermal short-term (1 to 30 days).	A toxicity endpoint was not identified. Systemic toxicity was not seen in 28-day dermal toxicity in rats at the limit dose (1,000 mg/kg/day). There are no concerns for developmental or reproductive toxicity or neurotoxicity.		
Inhalation short-term (1 to 30 days).	Inhalation study NOAEL = 0.1 mg/kg/day. UF_A = 3x.[a] UF_H = 10x. FQPA SF = 1x. HEC = 0.05 mg/L. HED = 7.2 mg/kg/day.	LOC for MOE = 30 ..	Based on 28-day inhalation toxicity study in rats. A LOAEL was not established because the highest concentration tested (0.1 mg/L) did not demonstrate any adverse portal of entry or systemic effects.
Cancer (oral, dermal, inhalation).	Classification: ''Not likely to be Carcinogenic to Humans'' based on data showing lack of treatment-related increase in tumor incidence in the rat and mouse carcinogenicity studies. Mutagenic concern was not reported in the mutagenicity studies.		

FQPA SF = Food Quality Protection Act Safety Factor. HEC = human equivalent concentration. HED = human equivalent dose. LOAEL = lowest observed adverse effect level. LOC = level of concern. mg/kg/day = milligram/kilogram/day.

mg/L = milligram/Liter. MOE = margin of exposure. NOAEL = no observed adverse effect level. PAD = population-adjusted dose. POD = point of departure. RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

[a] The magnitude of the UFs applied is dependent on the methodology used to calculate risk. The reference concentration (RfC) methodology takes into consideration the pharmacokinetic (PK) differences, but not the pharmacodynamic (PD) differences. Consequently, the UF for interspecies extrapolation may be reduced to 3x (to account for the PD differences).

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. 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 food consumption data from the U.S. 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, EPA conducted a somewhat refined chronic (food and drinking water) dietary assessment assuming average field trial residues for all crops (except crop subgroup 1A which used tolerance levels). Tolerance-level residues were used to cover residues in all livestock commodities except liver and meat byproducts for which higher anticipated residue calculations were used. For processed commodities, input values included combined average residues of parent and the metabolite with relevant processing factors. It was assumed that 100% crop treated (PCT) for all crops.

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

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for 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://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of cyantraniliprole for acute exposures are estimated to be 43.14 parts per billion (ppb) for surface water and 6.33 ppb for ground water. For chronic exposures for non-cancer assessments EDWCs are also estimated to be 24.45 ppb for surface water and 6.33 for ground water.

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 chronic dietary risk assessment, the water concentration of value 24.45 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 proposed for use on the following sites that could result in residential exposures: indoor crack/crevice application, turfgrass, golf courses, and ornamentals including both outdoors and in interior plantscapes. EPA assessed residential exposure using the following assumptions: Residential exposure 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 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 *http://www.epa.gov/opp00001/science/residential-exposure-sop.html.*

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 Web site at *http://www.epa.gov/pesticides/cumulative.*

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 Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10x, or uses a different additional SF 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 decrease in fetal body weight is 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 (offspring of P_0 generation) at 14 mg/kg/day which is lower than that for the parental (P_0) generation (110 mg/kg/day). 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.

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 1. 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. As discussed in Unit III.D.2., there is no evidence that cyantraniliprole results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and average field trial residues. The field trial data were validated against the appropriate guideline criteria and found acceptable. The field trial data reflect the maximum residues that are likely to occur on food commodities when cyantraniliprole is used according to label directions at the maximum allowed application rate and minimum allowed interval from treatment to harvest. These are farm gate residues and do not reflect decreases in residues that may occur during transport and storage prior to consumption. No corrections were made for the percentage of crops treated, that is, it was assumed that 100% of all crops for which there is a cyantraniliprole tolerance will be treated. Therefore, the data are considered unlikely to underestimate actual dietary exposure to cyantraniliprole. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cyantraniliprole in drinking water. In addition, the residential exposure assessment is based on the updated 2012 Residential Standard Operating Procedures (SOPs) employing surrogate study data, including conservative exposure assumptions based on day 0 dermal/oral contact to turf and surfaces treated at the maximum application rate. These data are reliable and are not expected to underestimate risks to adults or children. The Residential SOPs are based upon reasonable ''worst-case'' assumptions are not expected to underestimate risk.

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 50% of the cPAD for children 1–2 years old (the population group receiving the greatest exposure) and 22% of the general U.S. population.

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 proposed 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. Residential exposure estimates of all possible scenarios are not of concern. Short-term inhalation MOEs range from 22,000 to 220,000,000. Furthermore, these calculated risk estimates are highly conservative because the inhalation exposure POD is based on an exposure duration of 24 hours per day.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 290 for children 1–2 years old (the population group receiving the greatest exposure) and 22,000 for adults. Because EPA's LOC for cyantraniliprole is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). For adults, intermediate-term exposure is not expected for the residential exposure pathway. Therefore, the intermediate-term aggregate risk would be equivalent to the chronic dietary exposure estimate. For children 1 to <2 years old, the short-term aggregate risk is protective of the intermediate-term duration.

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 residue analytical method data have been submitted. Validation data have been provided for the proposed enforcement methods. Methods for measuring cyantraniliprole include the European Union (EU) multi-residue method DFG S19 (LC/MS/MS module, Dupont-21328) and the North American Free Trade Association (NAFTA) LC/MS/MS 1187 and 1552 methods. These methods utilize two mass ion transitions so confirmatory methods are not required. EU Method DFG S19 has been independently validated with a limit of quantification (LOQ) of 0.01 ppm for parent cyantraniliprole in cereals and dry products, matrices with high water content, acidic matrices, and fatty products. NAFTA method 1187 has been independently validated with an LOQ of 0.01 ppm for parent cyantraniliprole in almonds, onions, tomato paste, and sun dried tomatoes. NAFTA method 1552 has been independently validated with an LOQ of 0.01 ppm for parent cyantraniliprole in milk, muscle, and kidney. Note that cyantraniliprole is not recovered using the Food and Drug Administration (FDA) multi-residue methods.

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. Currently there are no Codex MRLs for cyantraniliprole.

C. Response to Comments

The Agency did not receive any public comments on the May 23, 2012 **Federal Register** Notice of Filing.

D. Revisions to Petitioned-For Tolerances

Based on the residue data provided and using the Organization of Economic Cooperation and Development (OECD) statistical calculation procedures, EPA is revising the tolerance levels for the following plant commodities: Almond hulls; *Brassica* head and stem vegetables (subgroup 5A); fruit, pome (group 11–10); fruit, stone; nut, tree (group 14–12); oilseed (group 20); vegetable, cucurbit (group 9); and vegetable, leafy (except *Brassica*) (group 4).

The proposed tolerance for citrus oil was lowered from 4 ppm to 2.4 ppm, consistent with the results from application of the median processing factor to the highest average field trials (HAFT) for oranges. EPA is not establishing tolerances for the processed commodities citrus raw peel and potato wet peel. The processing studies do not show a concentration of residue in these commodities relative to the raw agricultural commodities (RAC); therefore, the tolerances on RAC are sufficient to cover residues in these processed commodities.

EPA is not establishing separate tolerances for liver of cattle, goat, horse, and sheep; hog fat, liver, meat, and meat byproducts; and milk fat. The livestock commodity tolerances are derived from consideration of the maximum reasonably balanced livestock diets and the livestock feeding studies. A tolerance value of 0.01 ppm is appropriate for liver (of cattle, goat, horse, and sheep), which is covered by the meat byproducts tolerance. The dietary exposures of hogs and poultry do not indicate a need for tolerances (residues are not anticipated), and there is no indication of significant

concentration of cyantraniliprole in milk fat relative to milk.

With the exception of the proposed tolerance for leaves of root and tuber vegetables, EPA is revising all of the proposed tolerances for inadvertent residues (with a plantback interval (PBI) of 30 days) based on available residue data and use of the OECD statistical calculation procedures. For some crop groups, more than one tolerance was proposed for various components of the group (e.g., crop group 16 which includes forage, fodder, and straw of cereal grains); however, only one tolerance is possible per group, and the tolerance is based on the member commodity with the highest residue levels.

EPA issued a final rule in the **Federal Register** of August 22, 2012 (77 FR 50617) (FRL–9354–3) that revised some crop grouping regulations. As part of that action, EPA expanded and revised the previously existing tree nut crop group 14. Changes to crop group 14 included adding pistachios plus a number of other nuts, revising the taxonomic names for several commodities, and naming the new crop group tree nut group 14–12. The representative commodities remain the same as previous almond and pecan. That final rule became effective on October 22, 2012. EPA indicated in the August 22, 2012 final rule as well as the earlier proposed rule published in the **Federal Register** of November 9, 2011 (76 FR 69693) (FRL–8887–8) that, for existing petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA has assessed and is establishing a tolerance for cyantraniliprole on tree nuts crop group 14–12.

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 almond, hulls at 8.0 ppm; *Brassica* head and stem (subgroup 5A) at 3.0 ppm; *Brassica* leafy vegetables (subgroup 5B) at 30 ppm; bushberry (subgroup 13–07B) at 4.0 ppm; cattle, fat at 0.01 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.01 ppm; cherry (subgroup 12–12A) at 6.0 ppm; citrus, oil at 2.4 ppm; cotton, gin byproducts at 10 ppm; fruit, citrus (group 10–10) at 0.70 ppm; fruit, pome (group 11–10) at 1.5 ppm; goat, fat at 0.01 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.01 ppm; horse, fat at 0.01 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.01 ppm; milk at 0.01 ppm; nut, tree (group 14–12) at 0.04 ppm; oilseed (group 20) at 1.5 ppm; onion, bulb (subgroup 3–07A) at 0.04 ppm; onion, green (subgroup 3–07B) at 8.0 ppm; peach (subgroup 12–12B) at 1.5 ppm; plum (subgroup 12–12C) at 0.50 ppm; sheep, fat at 0.01 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts at 0.01 ppm; vegetable, cucurbit (group 9) at 0.40 ppm; vegetable, fruiting (group 8–10) at 2.0 ppm; vegetable, leafy (except *Brassica*) (group 4) at 20 ppm; vegetable, tuberous and corm (subgroup 1C) at 0.15 ppm. In addition, indirect or inadvertent tolerances for 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 the following commodities: Animal feed, nongrass (group 18) at 0.20 ppm; grain, cereal, forage, fodder and straw (group 16) at 0.50 ppm; grass forage, fodder and hay (group 17) at 0.50 ppm; peanut, hay at 0.01 ppm; vegetable, foliage of legume (group 7) at 0.70 ppm; vegetable, leaves of root and tuber vegetables (group 2) at 0.04 ppm; vegetable, root (subgroup 1A) at 0.02 ppm.

VI. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: January 24, 2014.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Add new § 180.672 to subpart C 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]-1*H*-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
Brassica head and stem (subgroup 5A)	3.0
Brassica leafy vegetables (subgroup 5B)	30
Bushberry (subgroup 13–07B)	4.0
Cattle, fat	0.01
Cattle, meat	0.01
Cattle, meat byproducts	0.01
Cherry (subgroup 12–12A)	6.0
Citrus, oil	2.4
Cotton, gin byproducts	10
Fruit, citrus (group 10–10)	0.70
Fruit, pome (group 11–10)	1.5
Goat, fat	0.01
Goat, meat	0.01
Goat, meat byproducts	0.01
Horse, fat	0.01
Horse, meat	0.01
Horse, meat byproducts	0.01
Milk	0.01
Nut, tree (group 14–12)	0.04
Oilseed (group 20)	1.5
Onion, bulb (subgroup 3–07A)	0.04
Onion, green (subgroup 3–07B)	8.0
Peach (subgroup 12–12B)	1.5
Plum (subgroup 12–12C)	0.50
Sheep, fat	0.01
Sheep, meat	0.01
Sheep, meat byproducts	0.01
Vegetable, cucurbit (group 9)	0.40
Vegetable, fruiting (group 8–10)	2.0
Vegetable, leafy (except *Brassica*) (group 4)	20
Vegetable, tuberous and corm (subgroup 1C)	0.15

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent tolerances 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 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
Animal feed, nongrass (group 18)	0.20
Grain, cereal, forage, fodder and straw (group 16)	0.50
Grass forage, fodder and hay (group 17)	0.50
Peanut, hay	0.01
Vegetable, foliage of legume (group 7)	0.70
Vegetable, leaves of root and tuber vegetables (group 2)	0.04
Vegetable, root (subgroup 1A)	0.02

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2013–0002; Internal Agency Docket No. FEMA–8321]

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 *http://www.fema.gov/fema/csb.shtm.*

DATES: *Effective 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 David Stearrett, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2953.

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