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 § 180.629, in the table in paragraph (a), add alphabetically entries for ''Coffee, green, bean'' and ''Coffee, instant,'' and revise footnote 1 to read as follows:

§ 180.629 Flutriafol; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Coffee, green, bean [1]	0.15
Coffee, instant [1]	0.30
* * * * *	

[1] There are no U.S. registrations as of October 22, 2013.

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[FR Doc. 2013–29556 Filed 12–10–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0038; FRL–9902–07]

Flonicamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flonicamid in or on multiple commodities which are identified and discussed later in this document. In two separate petitions, Interregional Research Project No. 4 (IR–4) and ISK Biosciences Corporation (ISK) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 11, 2013. Objections and requests for hearings must be received on or before February 10, 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–2013–0038, 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–2013–0038 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 February 10, 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–2013–0038, 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 June 5, 2013 (78 FR 33785) (FRL–9386–2), 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 2E8137) by IR–4, 500 College Rd. East, Suite 201W., Princeton, NJ 08540. The petition requested that 40 CFR 180.613 be amended by establishing tolerances for residues of the insecticide flonicamid and its metabolites and degradates determined by measuring flonicamid (*N*-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide) and its metabolites TFNA (4-trifluoromethylnicotinic acid), TFNA–AM (4-trifluoromethylnicotinamide), and TFNG (*N*-(4-trifluoromethylnicotinoyl)glycine), calculated as the stoichiometric equivalent of flonicamid, in or on alfalfa, forage at 7.0 parts per million (ppm); alfalfa, hay at 0.20 ppm; alfalfa, seed at 1.5 ppm; clover, forage at 7.0 ppm; clover, hay at 4.0 ppm;

peppermint, tops at 7.0 ppm; spearmint, tops at 7.0 ppm; vegetable, fruiting, group 8–10 at 0.40 ppm; vegetable, cucurbit, group 9 at 1.5 ppm; fruit, pome, group 11–10 at 0.20 ppm; and fruit, stone, group 12–12 at 0.60 ppm. The petition also requested, upon the approval of the aforementioned tolerances, removal of the established tolerances for residues of the flonicamid in or on the following crop groups: Vegetable, fruiting, group 8; fruit, pome, group 11; fruit, stone, group 12; cucumber; and vegetable, cucurbit, group 9, except cucumber. That document referenced a summary of the petition prepared by ISK Biosciences Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

In addition, in the **Federal Register** of February 27, 2013 (78 FR 13295) (FRL–9380–2), 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 2F8088) by ISK Biosciences Corporation, 7470 Auburn Rd., Suite A, Concord, OH 44077. The petition requested that 40 CFR 180.613 be amended by establishing tolerances for residues of the insecticide, flonicamid (*N*-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide) and its metabolites, TFNA (4-trifluoromethyl nicotinic acid), TFNA–AM (4-trifluoromethylnicotinamide), and TFNG (*N*-(4-trifluoro methylnicotinoyl)glycine), calculated as the stoichiometric equivalent of flonicamid, in or on tree, nuts, crop group 14–12 at 0.09 ppm; almond at 0.09 ppm; pecan at 0.04 ppm; and almond, hulls at 10.0 ppm. That document referenced a summary of the petition prepared by ISK Biosciences Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the levels at which tolerances are being established for some commodities and has determined not to establish tolerances for some of the requested commodities. The reason for these changes is explained in Unit IV.C.

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 flonicamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with flonicamid 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 the 28-day dermal study with flonicamid technical, no dermal or systemic toxicity was seen at the limit dose. In oral studies using rats and dogs, the kidney and liver are the target organs for flonicamid toxicity. Increased kidney weight and hyaline droplet deposition were observed as well as liver centrilobular hypertrophy in the rat 28-day oral range-finding, 90-day oral, developmental, and reproductive studies. The 90-day dog study showed kidney tubular vacuolation as well as increased adrenal weights, increased reticulocytes and decreased thymus weights. Increased reticulocyte count was noted in both the subchronic and chronic dog studies.

In rats, developmental effects including increased incidence of cervical ribs were observed at maternally toxic (liver and kidney gross and histopathological effects) dose levels. In rabbits, developmental effects were not observed at any dose level including maternally toxic doses. Offspring effects (decreased body weight and delayed sexual maturation) in the multi-generation study were seen only in the presence of parental toxicity (kidney effects in males, blood effects in females). Thus, there is no evidence that flonicamid results in increased susceptibility (qualitative or quantitative) in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

There are no concerns for flonicamid neurotoxicity. Although clinical signs suggesting potential neurotoxic effects (e.g., decreased motor activity, tremors) were seen in the acute and subchronic neurotoxicity studies; other effects in these studies (e.g., increased mortality, and significant decreases in food consumption and body weight) indicated that the clinical signs were a result of the animals being in an extreme condition or otherwise compromised and in a state of general malaise. Also, these types of effects were not observed in the other subchronic or chronic studies in mice, rats or dogs. Thus, there is not clear evidence of neurotoxicity. Lastly, clear no-observed-adverse-effect-levels (NOAELs) and lowest-observed-adverse effect-levels (LOAELs) were defined for the clinical signs, which are above the levels currently used for risk assessment purposes.

A 28-day oral (dietary) immunotoxicity study of technical flonicamid in female CD–1 mice demonstrated that flonicamid is not an immuno-suppressant, either structurally or functionally up to and including dose levels exceeding the limit dose.

Although there is some limited evidence suggesting that flonicamid has a potential for carcinogenic effects, EPA determined that quantification of risk using a non-linear approach (i.e., using a chronic reference dose (cRfD)) adequately accounts for all chronic toxicity, including carcinogenicity that could result from exposure to flonicamid. The following considerations support that determination. First, mutagenicity studies were negative for the parent chemical, flonicamid, and its metabolites, TFNA, TFNA–AM, TFNG, TFNG–AM, and TFNA–OH. Second, although flonicamid is carcinogenic in CD–1 mice, based on increased incidences of lung tumors associated with Clara cell activation, this tumor type is associated with species and strain sensitivity and is not directly correlated with cancer risks in humans. Third, nasal cavity tumors seen in male

Wistar rats were linked to incisor inflammation and not considered to be treatment related. These tumor findings were confounded by the lack of a dose response and the biological significance is questionable.

Specific information on the studies received and the nature of the adverse effects caused by flonicamid as well as the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in the document entitled ''Flonicamid—Human Health Risk Assessment for a Section 3 Registration of New Uses on Alfalfa and Clover Grown for Seed, Mint, Greenhouse Grown Tomatoes, and Tree Nuts,'' pp. 33–39 in docket ID number EPA–HQ–OPP–2013–0038.

B. Toxicological Points of Departure/Levels of Concern

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

A summary of the toxicological endpoints for flonicamid used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of November 14, 2012 (77 FR 67771) (FRL–9368–7).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to flonicamid, EPA considered exposure under the petitioned-for tolerances as well as all existing flonicamid tolerances in 40 CFR 180.613. EPA assessed dietary exposures from flonicamid 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 flonicamid; 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 U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, the chronic dietary exposure assessment was a conservative assessment, conducted using tolerance-level residues and 100 percent crop treated (PCT).

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to flonicamid. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/;or PCT information in the dietary assessment for flonicamid. Tolerance level residues and 100 PCT were assumed for all food commodities.

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

The drinking water assessment was conducted using a parent only and total toxic residues of flonicamid (TTR) approach. Total toxic residues include TFNA, TFNA–AM, TFNA–OH, TFNG, and TFNG–AM.

Based on the Pesticide Root Zone Model/;Exposure Analysis Modeling System (PRZM/;EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of total toxic residues of flonicamid for chronic exposures for non-cancer assessments are estimated to be 0.94 parts per billion (ppb) for surface water and 9.92 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 9.92 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). Flonicamid is not registered for any specific use patterns that would result in residential exposure.

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

EPA has not found flonicamid to share a common mechanism of toxicity with any other substances, and flonicamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that flonicamid 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.* The prenatal and postnatal toxicity database for flonicamid includes prenatal developmental toxicity studies in rats and rabbits and a multi-generation reproduction toxicity study in rats. There is no evidence that flonicamid results in increased susceptibility (qualitative or quantitative) in rats or rabbits exposed *in utero* in the prenatal developmental studies or in young rats in the multi-generation reproduction study. No developmental effects were seen in rabbits. In the multi-generation reproduction study, developmental delays in the offspring (decreased body weights, delayed sexual maturation) were seen only in the presence of parental toxicity (kidney and blood effects). Also, there are clear NOAELs and LOAELs for all effects. The degree of concern for prenatal and/;or post-natal susceptibility is, therefore, low due to the lack of evidence of qualitative and quantitative susceptibility.

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 for chronic dietary and other exposures, except as noted below. That decision is based on the following findings:

i. The toxicity database for flonicamid is complete except for a subchronic inhalation study. In the absence of a route specific inhalation study, EPA has retained a 10X FQPA SF to assess risks for inhalation exposure scenarios. However, residential inhalation exposures are not expected.

ii. The available data base includes acute and subchronic neurotoxicity studies. As discussed in Unit III.A., EPA has concluded that the clinical signs observed in those studies were not the result of a neurotoxic mechanism and that therefore a developmental neurotoxicity study is not required.

iii. There was no evidence for quantitative or qualitative susceptibility following oral exposures to rats *in utero* or oral exposure to rabbits *in utero.*

iv. There are no residual uncertainties identified in the exposure databases. An unrefined conservative chronic dietary exposure assessment for food and drinking water was conducted, assuming tolerance level residues for all existing and proposed commodities and 100 PCT of registered and proposed crops. The drinking water assessment utilized water concentration values generated by models and associated modeling parameters which are designed to produce conservative, health protective, high-end estimates of water concentrations which are not likely to be exceeded. The dietary (food and drinking water) exposure assessment does not underestimate the potential exposure for infants, children, or women of child bearing age.

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-term, intermediate-term, 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, flonicamid 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 flonicamid from food and water will utilize 30% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for flonicamid.

3. *Short-term and intermediate-term risk.* Short- term and intermediate-term aggregate exposure takes into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Short-term and intermediate-term adverse effects were identified; however, flonicamid is not registered for any use patterns that would result in short-term or intermediate-term residential exposure. Short-term and intermediate-term risk is assessed based on short-term and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short-term or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term or intermediate-term risk), no further assessment of short-term or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term and intermediate-term risk for flonicamid.

4. *Aggregate cancer risk for U.S. population.* Based on the discussion in Unit III.A., EPA has concluded that the cPAD is protective of possible cancer effects from flonicamid, and as evidenced in Unit III.E.2, aggregate exposure to flonicamid is below the cPAD.

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 flonicamid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available to enforce the tolerances for flonicamid and the major metabolites in plants and livestock. The proposed method for plants uses liquid chromatography with tandem mass spectrometry (LC/MS/MS) (FMC No. P–3561M) to determine the residues of flonicamid and its major metabolites, TFNA–AM, TFNA, and TFNG. Three enforcement methods are used for livestock commodities:

1. An LC/MS/MS method RCC No. 844743 for determination of residues in eggs, poultry tissues, and fat of cattle, goat, hog, horse, and sheep;

2. LC/MS method RCC No. 842993 for determination of residues in milk; and

3. LC/MS/MS method FMC No. P–3580, which includes an acid hydrolysis step, for determination of residues in meat and meat products (kidney and liver) of cattle, goat, hog, horse, and sheep. All three methods determine flonicamid and the metabolites OH–TFNA–AM, TFNA–AM, TFNG, and TFNA

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

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint

United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established any MRLs for flonicamid.

C. Revisions to Petitioned-For Tolerances

Based on the review of the residue data, EPA is modifying the proposed tolerance on alfalfa forage from 7.0 ppm to 10.0 ppm; alfalfa hay from 0.20 ppm to 1.0 ppm; almond hulls from 10.0 ppm to 9.0 ppm; and the tree nut group 14–12 from 0.09 ppm to 0.15 ppm. For alfalfa forage, the tolerance was calculated using 5x the mean of the field trial data instead of using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures because there are only two field trials reflecting the proposed application rate and pre-harvest interval. For alfalfa hay, the level of quantitation (LOQ) was used since all residues were <LOQ. The tolerances for the almond hulls and tree nuts were calculated using the OECD tolerance calculation procedures including using average field trial residues.

Second, due to the need for additional field trials, the Agency is not establishing the tolerances requested for clover forage and clover hay at this time.

Additionally, because ''almond'' and ''pecan'' are part of the tree nut group 14–12, the Agency is not establishing separate tolerances on these commodities.

And lastly, EPA is increasing the established tolerance on milk and establishing new tolerances for hog commodities based on the maximum reasonably balanced diets (MRBD), calculated using ''Table 1 Feedstuffs'' (June 2008), and additional livestock feed items associated with the proposed uses in both PPs 2E8137 and 2F8088.

V. Conclusion

Therefore, tolerances are established for residues of flonicamid and its metabolites and degradates determined by measuring flonicamid (*N*-(cyanomethyl)-4-(trifluoromethyl)- 3-pyridinecarboxamide) and its metabolites TFNA (4-trifluoromethylnicotinic acid), TFNA–AM (4-trifluoromethyl-nicotinamide), and TFNG (*N*-(4-trifluoromethylnicotinoyl) glycine), calculated as the stoichiometric equivalent of flonicamid, in or on alfalfa, forage at 10.0 ppm; alfalfa, hay at 1.0 ppm; alfalfa, seed at 1.5 ppm; peppermint, tops at 7.0 ppm; spearmint, tops at 7.0 ppm; vegetable, fruiting, group 8–10 at 0.40 ppm; vegetable, cucurbit, group 9 at 1.5 ppm; fruit, pome, group 11–10 at 0.20 ppm; fruit, stone, group 12–12 at 0.60 ppm; almond, hulls at 9.0 ppm; nut, tree, group 14–12 at 0.15; hog, fat at 0.03 ppm; hog, meat at 0.03 ppm; and hog, meat byproducts at 0.03 ppm. The existing tolerance for milk is revised from 0.03 ppm to 0.05 ppm. Lastly, as a result of the establishment of the above tolerances, the following existing tolerances are removed as unnecessary: Fruit, pome, group 11; fruit, stone, group 12; vegetable, fruiting, group 8; cucumber; vegetable, cucurbit, group 9, except cucumber.

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: November 12, 2013.

G. Jeffrey Herndon,

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 § 180.613:

■ a. Remove from the table in paragraph (a)(1) the entries for ''Fruit, pome, group 11,'' ''Fruit, stone, group 12,'' ''Vegetable, cucurbit, group 9, except cucumber'' and ''Vegetable, fruiting, group 8''.

■ b. Add alphabetically to the table in paragraph (a)(1) the following entries.

■ c. Add alphabetically to the table in paragraph (a)(2) the entries for ''Hog, fat,'' ''Hog, meat,'' and ''Hog, meat byproducts.''

■ d. Revise the entry for ''Milk'' in the table in paragraph (a)(2).

The amendments read as follows:

§ 180.613 Flonicamid; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Alfalfa, forage	10.0
Alfalfa, hay	1.0
Alfalfa, seed	1.5
Almond, hulls	9.0
* * * * *	
Fruit, pome, group 11–10	0.20
Fruit, stone, group 12–12	0.60
* * * * *	
Nut, tree, group 14–12	0.15
* * * * *	
Peppermint, tops	7.0
* * * * *	
Spearmint, tops	7.0
* * * * *	
Vegetable, cucurbit, group 9	1.5
Vegetable, fruiting, group 8–10	0.40
* * * * *	

(2) * * *

Commodity	Parts per million
* * * * *	
Hog, fat	0.03
Hog, meat	0.03
Hog, meat byproducts	0.03
* * * * *	
Milk	0.05
* * * * *	

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[FR Doc. 2013–29576 Filed 12–10–13; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 111220786–1781–01]

RIN 0648–XD012

Fisheries of the Northeastern United States; Summer Flounder Fishery; Commercial Quota Available for the State of New Jersey

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule.

SUMMARY: NMFS announces that the 2013 summer flounder commercial fishery in the State of New Jersey will be reopened to provide the opportunity for the fishery to fully harvest the available quota. Vessels issued a commercial Federal fisheries permit for the summer flounder fishery may land summer flounder in New Jersey until the quota is fully harvested. Regulations governing the summer flounder fishery require publication of this notification to advise New Jersey that quota remains available, and the summer flounder fishery is open to vessel permit holders for landing summer flounder in New Jersey, and to inform dealer permit holders in New Jersey that they may purchase summer flounder.

DATES: Effective December 6, 2013, through December 31, 2013.

FOR FURTHER INFORMATION CONTACT: Carly Bari, (978) 281–9224, or *Carly.Bari@noaa.gov*.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found at 50 CFR part 648. The regulations require annual specification of a commercial quota that is apportioned on a percentage basis among the coastal states from North Carolina through Maine. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.102.

The initial total commercial quota for summer flounder for the 2013 fishing year is 11,793,596 lb (5,349,575 kg) (77 FR 76942, December 31, 2012). The percent allocated to vessels landing summer flounder in New Jersey is 16.72499 percent, resulting in a commercial quota of 1,972,478 lb (894,716 kg). The 2013 allocation was adjusted to 1,972,066 lb (894,514 kg) after deduction of research set-aside, adjustment for 2012 quota overages, and adjustments for quota transfers between states. On November 27, 2013, NMFS closed the 2013 commercial summer flounder fishery in New Jersey prematurely, quota remains available for harvest.

The Administrator, Northeast Region, NMFS (Regional Administrator), monitors the state commercial landings and has determined that, due to an error, there is still commercial summer flounder quota available for harvest in New Jersey. NMFS is required to publish notification in the **Federal Register** advising and notifying commercial vessels and dealer permit holders that, effective upon a specific date, there is commercial quota available for landing summer flounder in that state.

Therefore, effective December 6, 2013, vessels holding summer flounder commercial Federal fisheries permits can land summer flounder in New Jersey until the commercial state quota is fully harvested. Effective December 6, 2013, federally permitted dealers can also purchase summer flounder from federally permitted vessels that land in New Jersey until the commercial state quota is fully harvested.

Classification

This action is required by 50 CFR part 648 and is exempt from review under Executive Order 12866.

The Assistant Administrator for Fisheries, NOAA (AA), finds good cause pursuant to 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment because it would be contrary to the public interest. This action reopens the summer flounder fishery for New Jersey until the state commercial summer flounder quota is fully harvested, under current regulations. If implementation of this reopening was delayed to solicit prior public comment, the quota for this fishing year would not be fully harvested, thereby undermining the conservation objectives of the Summer Flounder Fishery Management Plan. The AA further finds, pursuant to 5 U.S.C. 553(d)(3), good cause to waive the 30-day delayed effectiveness period for the reason stated above.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 6, 2013.

Sean F. Corson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–29525 Filed 12–6–13; 4:15 pm]

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