State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because it merely approves a State rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

F. Executive Order 13175, Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This final rule does not have tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045, because it approves a State rule implementing a Federal standard.

H. Executive Order 13211, Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Population

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA lacks the discretionary authority to address environmental justice in this rulemaking.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. section 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804, however, exempts from section 801 the following types of rules: rules of particular applicability; rules relating to agency management or personnel; and rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). Because this is a rule of particular applicability, EPA is not required to submit a rule report regarding this action under section 801.

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 14, 2013. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: November 1, 2012.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2012–27564 Filed 11–13–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0985; FRL–9368–7]

Flonicamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flonicamid in or on Berry, low growing, subgroup 13–07G; Rapeseed subgroup 20A, and cucumber. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 14, 2012. Objections and requests for hearings must be received on or before January 14, 2013, 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–2011–0985, 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: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; email address: *jackson.sidney@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://ecfr.gpoaccess.gov/cgi/t/text/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–2011–0985 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 14, 2013. 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–2011–0985, 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 Confidential Business Information (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.htm.* 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 Wednesday, March 14, 2012 (77 FR 15012) (FRL–9335–9), 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 1E7842) by IR–4, IR–4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.613 be amended by establishing tolerances for combined residues of the insecticide, flonicamid, *N*-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide and its metabolites TFNA, 4-trifluoromethylnicotinic acid, TFNA-AM, 4-trifluoromethylnicotinamide, TFNG, *N*-(4-trifluoromethylnicotinoyl)glycine, in or on cucumber at 1.3 parts per million (ppm), Berry, low growing subgroup 13–07G at 1.4 and Rapeseed subgroup 20A at 1.5 ppm. That document referenced a summary of the petition prepared by ISK Biosciences, 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 and/or current Agency policies, EPA has revised/modified the petitioned-for flonicamid residue tolerance level in certain commodities and revised the tolerance expression for flonicamid residues. EPA is also revising the existing crop group tolerance on ''Vegetable, cucurbit, group 9'' to exclude cucumbers. The reasons for these changes are 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 their 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.

Flonicamid has low acute toxicity via the oral, inhalation and dermal routes of exposure. Flonicamid is nonirritating to the eye and skin and is not a dermal sensitizer. Its metabolites, TFNA, TFNA–AM, TFNG, TFNG–AM, and TFNA–OH, also demonstrated low toxicity in acute oral toxicity studies. 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. Preliminary results of a 28-day oral (dietary) immunotoxicity study of technical flonicamid in female CD–1 mice suggest 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 document, ''Flonicamid: Human Health Risk Assessment for the Proposed Use on Low Growing Berry, Rapeseed, and Greenhouse Grown Cucumbers'' at page 29 in docket ID number EPA–HQ–OPP–2011–0985.

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 shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLONICAMID 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).	None/NA	None/NA	No toxicological effects seen in a single dose study.
Chronic dietary (All populations).	NOAEL= 3.7 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	cRfD = 0.04 mg/kg/day. cPAD = 0.04 mg/kg/day	2-Generation reproduction rat study. Parental LOAEL = 22 mg/kg/day based on increased kidney weights, kidney hyaline deposition, increased blood serum LH (F_1 females).

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLONICAMID 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
Cancer	A nonlinear RfD approach was used to assess cancer risk.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. POD = Point of Departure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). 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).

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 (USDA) 1994–1996 and 1998 Continuing Service of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used an unrefined chronic dietary assessment conducted assuming 100 percent crop treated (PCT) estimates, tolerance-level residues for all commodities, and empirical or Dietary Exposure Evaluation Model–Food Commodity Intake Database (DEEM–FCID™) default processing factors.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determine mutagenic mode of action, a default linear cancer slope factor approach is utilized. 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., *chronic exposure.*

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 (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) 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 1.9 parts per billion (ppb) for surface water and 0.00132 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 1.9 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 currently registered for the following uses that could result in non-occupational exposures: Commercial ornamentals, interiorscapes, and nurseries. However, these product labels do not allow use in home gardens and greenhouses or in any residential settings. Therefore, residential handler scenarios are not expected and need not be assessed. Additionally, because no dermal toxicity endpoint was identified for flonicamid, a post-application residential exposure/risk assessment is not necessary. Post-application inhalation exposures are expected to be negligible. Therefore, no residential exposure is expected.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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 FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* 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 *in utero* rats or rabbits 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 an immunotoxicity study and a subchronic inhalation study. Existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA. Except for decreased thymus weights in the subchronic dog study, there are no other indications in the available studies that organs associated with immune function are affected by flonicamid, and preliminary results of the above-mentioned immunotoxicity study suggested that flonicamid is not an immunosuppressant. EPA does not believe that the final results of the immunotoxicity study will result in a dose less than the point of departure already used in this risk assessment and an additional database uncertainty factor for potential immunotoxicity does not need to be applied.

A subchronic 28-day inhalation study is required and is outstanding at this time. 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 treated. 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-, 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. An endpoint attributable to a single oral dose was not identified in the toxicity database; 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 11% of the cPAD for the general U.S. population and 28% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. There are no expected long-term residential exposures. Because drinking water estimates have been combined with dietary exposures, the dietary assessment discussed in Unit III.C.3., serves as the aggregate exposure and risk assessment for flonicamid.

3. *Short-term and Intermediate-term risk.* Short- and intermediate-term aggregate exposures take into account short- and intermediate-term residential exposures plus chronic exposure to food and water (considered to be a background exposure level). Short- and intermediate-term aggregate risk assessments were not conducted because residential exposure is not expected from the use pattern proposed in this registration request, or from any registered uses.

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.

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

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

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever

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

There are no Codex MRLs established on the proposed crops.

C. Revisions to Petitioned-For Tolerances

Based on results from the Organization for Economic Cooperation and Development (OECD) spreadsheet tolerance calculation procedures, EPA modified certain IR–4 proposed tolerances for flonicamid residues. EPA increased the proposed tolerance from 1.4 to 1.5 ppm for Berry, low growing, subgroup 13–07G and from 1.3 to 1.5 ppm for cucumber. Because there is an existing crop group tolerance for ''Vegetable, cucurbit, group 9'' that applies to cucumbers, EPA, for the sake of clarity, is revising that existing crop group tolerance to exclude cucumbers.

Finally, EPA has revised the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of flonicamid not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for the residues of flonicamid, *N*-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide, and its metabolites TFNA (4-trifluoromethylnicotinic acid, TFNA–AM (4-trifluoromethylnicotinamide) and TFNG, *N*-(4-trifluoromethylnicotinoyl)glycine, in or on cucumber at 1.5 ppm; Berry, low growing, subgroup 13–07G at 1.5 ppm; and Rapeseed subgroup 20A at 1.5 ppm. Additionally, the tolerance entry for Vegetable, cucurbit group 9, is revised to exclude 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 tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This 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 1, 2012.

Lois Rossi,

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. Amend § 180.613 as follows:
■ i. Revise the introductory text of paragraph (a)(1).
■ ii. Remove the entry ''Vegetable, cucurbit, group 9'' from the table in paragraph (a)(1), and add alphabetically four new entries.
■ iii. Revise the introductory text of paragraph (a)(2).

The added and revised text read as follows:

§ 180.613 Flonicamid; tolerances for residues.

(a) * * * (1) Tolerances are established for the residues of the insecticide flonicamid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of 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 the following commodities.

Commodity	Parts per million
Berry, low growing, subgroup 13–07G	1.5
* * * * *	
Cucumber	1.5
* * * * *	
Rapeseed subgroup 20A	1.5
* * * * *	
Vegetable, cucurbit, group 9, except cucumber	0.4
* * * * *	

(2) Tolerances are established for the residues of the insecticide flonicamid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of flonicamid, *N*-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide, and its metabolites, TFNA (4-trifluoromethylnicotinic acid), and TFNA–AM (4-trifluoromethylnicotinamide), calculated as the Stoichiometric equivalent of flonicamid, in or on the following commodities.

* * * * *

[FR Doc. 2012–27702 Filed 11–13–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1986–0005; FRL 9751–2]

National Oil and Hazardous Substance Pollution Contingency Plan; National Priorities List Deletion of the Waste Management of Michigan-Holland Lagoons Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Direct Final Rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) Region 5 is publishing a direct final Notice of Deletion of the Waste Management of Michigan-Holland Lagoons Superfund Site (Site), located in Ottawa County, Michigan from the National Priorities List (NPL). The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the State of Michigan, through the Michigan Department of Environmental Quality (MDEQ), because EPA has determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: This direct final rule is effective January 14, 2013 unless EPA receives adverse comments by December 14, 2012. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public that the deletion will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–1986–0005, by one of the following methods:

- *http://www.regulations.gov:* Follow on-line instructions for submitting comments.
- *Email:* Gladys Beard, NPL Deletion Process Manager, at *beard.gladys@epa.gov* or Dave Novak, Community Involvement Coordinator, at *novak.dave@epa.gov.*
- *Fax:* Gladys Beard, NPL Deletion Process Manager, at (312) 697–2077.
- *Mail:* Gladys Beard, NPL Deletion Process Manager, U.S. Environmental Protection Agency (SR–6J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–7253; or Dave Novak, Community Involvement Coordinator, U.S. Environmental Protection Agency (SI–7J), 77 West Jackson Boulevard, Chicago, IL 60604, (312) 886–7478 or (800) 621–8431.
- *Hand delivery:* Dave Novak, Community Involvement Coordinator, U.S. Environmental Protection Agency (SI–7J), 77 West Jackson Boulevard, Chicago, IL 60604. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. The normal business hours are Monday through Friday, 8:30 a.m. to 4:30 p.m. CST, excluding federal holidays.

Instructions: Direct your comments to Docket ID no. EPA–HQ–SFUND–1986–0005. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information may not be publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in the hard copy. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at:

- U.S. Environmental Protection Agency-Region 5, 77 West Jackson Boulevard, Chicago, IL 60604, Phone: (312) 353–1063. Hours: Monday through Friday, 8:30 a.m. to 4:30 p.m. CST, excluding Federal holidays.
- Herrick District Library, 303 South River Avenue, Holland, MI 49423, Phone: (616) 355–3100. Hours: Monday through Tuesday, 9:00 a.m. to 9:00 p.m. EST; Wednesday through Friday, 9:00 a.m. to 6:00 p.m. EST.

FOR FURTHER INFORMATION CONTACT: Gladys Beard, NPL Deletion Process Manager, U.S. Environmental Protection Agency (SR–6J), 77 West Jackson