(MRLs) for residues of dicamba on sweet corn.

V. Conclusion

Therefore, tolerances are established for combined residues of dicamba, 3,6-dichloro-o-anisic acid, and its metabolite, 3,6-dichloro-5-hydroxy-o-anisic acid, in or on corn, sweet, forage at 0.50 ppm; corn, sweet, kernel plus cob with husks removed at 0.04 pm; and corn, sweet, stover at 0.50 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 rule has been exempted from review under Executive Order 12866, 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) 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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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 6, 2000) do not apply to this rule. In addition, This 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) (Public Law 104–4).

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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: March 24, 2008.

Daniel C. Kenny,

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. Section 180.227 is amended by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

180.227 Dicamba; tolerances for residues.

(a) *General.*

(1) * * *

Commodity	Parts per million
* * *	* *
Corn, sweet, forage	0.50
Corn, sweet, kernel plus cob with husks removed	0.04
Corn, sweet, stover	0.50
* * *	* *

* * * * *

[FR Doc. E8–6674 Filed 4–1–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0338; FRL–8356–7]

Flonicamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of flonicamid and its metabolites TFNA, TFNA-AM, and TFNG in or on Brassica, leafy greens, subgroup 5B; hop, dried cones; okra; radish, tops; turnip, greens; vegetable, root, except sugar beet, subgroup 1B; and vegetable, tuberous and corm, subgroup 1C. It also increases established tolerances for combined residues of flonicamid and its metabolites TFNA and TFNA-AM in or on cattle, fat; cattle, meat; egg; goat, fat; goat, meat; horse, fat; horse, meat; milk; poultry, fat; poultry, meat; poultry, meat byproducts; sheep, fat; and sheep, meat. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also removes existing tolerances for flonicamid and its metabolites on mustard greens and potatoes which are superseded by the new tolerances on ''Brassica, leafy greens, subgroup 5B'' and ''vegetable, tuberous and corm, subgroup 1C,'' respectively.

DATES: This regulation is effective April 2, 2008. Objections and requests for hearings must be received on or before June 2, 2008, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0338. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert

the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2007–0338 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before June 2, 2008.

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 that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–0338, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of June 27, 2007 (72 FR 35237) (FRL–8133–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E7081) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540–6635. 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 vegetables, root, except sugar beet, subgroup 1B at 0.45 parts per million (ppm); radish, tops at 16 ppm; vegetables, tuberous and corm, subgroup 1C at 0.2 ppm; Brassica, leafy greens, subgroup 5B at 16 ppm; turnip, greens at 16 ppm; hop, dried cone at 7.0 ppm; and okra at 0.4 ppm. That notice referenced a summary of the petition prepared by ISK Biosciences Corporation, the registrant, which is available to the public 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 determined that the proposed tolerance on ''vegetables, root, except sugar beet, subgroup 1B'' should be increased to 0.60 ppm and that existing tolerances for several livestock commodities should be increased. 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....'' These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

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 the petitioned-for tolerance for combined residues of flonicamid and its metabolites TFNA, TFNA-AM, and TFNG on Brassica, leafy greens, subgroup 5B at 16 parts per million (ppm); hop, dried cones at 7.0 ppm; okra at 0.40 ppm; radish, tops at 16 ppm; turnip, greens at 16 ppm; vegetable, root, except sugar beet, subgroup 1B at 0.60 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.20 ppm; and for combined residues of flonicamid and its metabolites TFNA and TFNA-AM in or on cattle, fat at 0.03 ppm; cattle, meat at 0.08 ppm; egg at 0.04 ppm; goat, fat at 0.03 ppm; goat, meat at 0.08 ppm; horse, fat at 0.03 ppm; horse, meat at 0.08 ppm; milk at 0.03 ppm; poultry, fat at 0.03 ppm; poultry, meat at 0.03 ppm; poultry, meat byproducts at 0.03 ppm; sheep, fat at 0.03 ppm; and sheep, meat at 0.08 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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.

Flonicamid has low acute toxicity via the oral, dermal, and inhalation routes of exposure. Its metabolites TFNA, TFNA-AM, and TFNG also demonstrated low toxicity in acute oral toxicity studies. Flonicamid is non-irritating to the eye and skin and is not a dermal sensitizer. In the 28–day dermal study no dermal or systemic toxicity was seen at the limit dose for flonicamid technical.

The oral studies in rats and dogs indicate the kidney and liver are the target organs for flonicamid toxicity. Kidney weight increases, kidney hyaline deposition and liver centrilobular hypertrophy effects were seen in the rat 28–day oral range-finding study, 90–day oral study, developmental toxicity study, and reproduction study. These effects were not observed in the rabbit developmental study. The 90–day dog study showed kidney tubular vacuolation, as well as increased adrenal weights, increased reticulocytes and decreased thymus weights. Increased reticulocyte was noted in both the subchronic and chronic dog studies.

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. Developmental effects (increased incidence of cervical rib) were observed only in the rat at high doses, and the developmental and reproductive effects (decreased uterus weights and delayed sexual maturation) that were seen in these studies occurred only at doses that were also maternally toxic. Further, although neurotoxic signs (decreased motor activity, tremors, impaired respiration, and impaired gait) were noted in the acute and subchronic neurotoxicity studies, they occurred only at high doses and were not seen in other flonicamid toxicity studies.

Mutagenicity studies were negative for the parent chemical, flonicamid, and its metabolites TFNA, TFNA-AM, TFNG, TFNG-AM, and TFNA-OH. Flonicamid was carcinogenic in CD-1 mice, based on increased incidences of lung tumors associated with Clara cell activation; the effects, however, were associated with species and strain sensitivity and thus not deemed highly relevant to human cancer risk. Nasal cavity tumors in male Wistar rats were linked to incisor inflammation; data were not sufficient to make a similar determination in female rats. Based on these findings and analysis of the cancer and mutagenicity studies, EPA classified flonicamid as having suggestive evidence of carcinogenicity but concluded that the carcinogenic potential of flonicamid is very low and has determined that quantification of human cancer risk is not appropriate.

Specific information on the studies received and the nature of the adverse effects caused by flonicamid 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 Flonicamid: Human Health Risk Assessment for Proposed Uses on Root Vegetables (Except Sugar beet; Subgroup 1B), Tuberous and Corm Vegetables (Subgroup 1C), Leafy Brassica Green Vegetables (Subgroup 5B), Turnip Greens, Hops, and Okra. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as docket ID number EPA–HQ–OPP–2007–0338–0003 in that docket.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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 can be found at *http://www.regulations.gov* in the document Flonicamid: Human Health Risk Assessment for Proposed Uses on Root Vegetables (Except Sugar beet; Subgroup 1B), Tuberous and Corm Vegetables (Subgroup 1C), Leafy Brassica Green Vegetables (Subgroup 5B), Turnip Greens, Hops, and Okra at pages 22–23. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as docket ID number EPA–HQ–OPP–2007–0338–0003 in that docket.

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 USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed all foods for which there are tolerances were treated and contain tolerance-level residues. EPA did not rely on any anticipated residues or percent crop treated (PCT) estimates in the chronic dietary exposure assessment.

iii. *Cancer*. As noted in Unit III.A., EPA has concluded that flonicamid has low carcinogenic potential and that, accordingly, quantitative assessment of cancer risk is not appropriate. Therefore, a cancer exposure assessment was not conducted.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for flonicamid in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate 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 residues of concern in drinking water include flonicamid and its degradates TFNA, TFNG-AM, TFNG, TFNA-OH, and TFNA-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 environmental concentrations (EECs) of flonicamid and its degradates for acute exposures are estimated to be 9.8 parts per billion (ppb) for surface water and 0.00132 ppb for ground water. The EECs for chronic exposures are estimated to be 1.5 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. As explained in Unit III.C.1.i., an acute dietary risk assessment was not conducted for flonicamid. For chronic dietary risk assessment, the water concentration value of 1.5 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 use on landscape ornamentals, which could include landscape ornamentals in residential areas. Since applications to landscape ornamentals are limited to professional pest control operators, residential handler exposures are not expected and were not assessed. There may be potential for post-application dermal exposure of adults or children entering areas previously treated with flonicamid; however, since a dermal endpoint of concern was not identified in the toxicity studies for flonicamid, a dermal assessment is unnecessary and was not conducted. Post-application inhalation exposures are expected to be negligible.

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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to flonicamid and 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 not assumed that flonicamid has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. The pre- and postnatal toxicity database for flonicamid includes prenatal developmental toxicity studies in rats and rabbits and a 2-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 2–generation reproduction study. Developmental effects (increased incidence of cervical rib) were observed only in the rat at high doses, and the developmental and reproductive effects (decreased uterus weights and delayed sexual maturation) seen in these studies occurred only in the presence of maternal effects (including increased liver weights, liver and kidney pathological changes, increased relative kidney weight and increased blood serum LH levels in F1 females).

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That

decision is based on the following findings:

i. The toxicity database for flonicamid is complete.

ii. Neurotoxic signs were seen in the acute and subchronic neurotoxicity studies, but only at the high doses and in the presence of other effects indicating general overt toxicity (mortality in the acute neurotoxicity study and decreases in body weight and body weight gain, along with reduced food consumption in the subchronic neurotoxicity study). Neurotoxic signs were not observed in other studies, and systemic toxicity was observed at considerably lower doses than those that produced neurotoxic effects in the acute and subchronic neurotoxicity studies. Further, there were no signs of neurotoxicity and no indications of increased susceptibility of *in utero* rats or rabbits or offspring in the developmental and reproduction studies for flonicamid. Based on these considerations, EPA has determined that there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

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

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated and tolerance-level residues. Conservative ground and surface water modeling estimates were used. There may be potential for residential dermal exposure of children entering areas previously treated with flonicamid; however, since a dermal endpoint of concern was not identified in the toxicity studies for flonicamid, such exposures are not expected to pose a health risk to children. These assessments will not underestimate the exposure and risks posed by flonicamid.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. None of the toxicology studies available for flonicamid has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure; 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 exposure to flonicamid from food and water will utilize 23 % of the cPAD for children 1 to 2 years old, the population group with the greatest estimated exposure. Based on the use pattern, chronic residential exposure to residues of flonicamid is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Although short-term, post-application dermal exposures could occur from residential use of flonicamid on landscape ornamentals, no toxicological effects from dermal exposure have been identified for flonicamid. Therefore, the aggregate risk is the sum of the risk from food and water.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Flonicamid is not registered for use on any sites that would result in intermediate-term residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. As discussed in Unit III.A., EPA regards the carcinogenic potential of flonicamid as very low and concludes that it poses no greater than a negligible 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 flonicamid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods (FMC No. P–3561M, a Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS) method and FMC No. P–3822, a modification of FMC No. P–3561M) are available to enforce the tolerances for flonicamid and its metabolites, TFNA, TFNA-AG, and TFNG in plants. For enforcement of tolerances for livestock commodities, three methods are available: LC/MS/MS method (RCC No. 844743) for residues in eggs and livestock tissues; LC/MS method (RCC No. 842993) for residues in milk; and LC/MS/MS method (FMC P3580) which includes an acid hydrolysis step for residues in cattle muscle, kidney, and liver. The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican maximum residue levels (MRLs) for flonicamid.

C. Changes to Proposed Tolerances

Based upon review of the data supporting the petition, EPA determined that the proposed tolerance on ''vegetables, root, except sugar beet, subgroup 1B'' should be increased from 0.45 ppm to 0.60 ppm. EPA revised the tolerance level based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data Standard Operating Procedure (SOP). EPA also determined that existing tolerances for residues of flonicamid, TFNA and TFNA-AM in or on cattle, fat; cattle, meat; egg; goat, fat; goat, meat; horse, fat; horse, meat; milk; poultry, fat; poultry, meat; poultry, meat byproducts; sheep, fat; and sheep, meat should be increased to the following levels: cattle, fat at 0.03 ppm; cattle, meat at 0.08 ppm; egg at 0.04 ppm; goat, fat at 0.03 ppm; goat, meat at 0.08 ppm; horse, fat at 0.03 ppm; horse, meat at 0.08 ppm; milk at 0.03 ppm; poultry, fat at 0.03 ppm; poultry, meat at 0.03 ppm; poultry, meat byproducts at 0.03 ppm; sheep, fat at 0.03 ppm; and sheep, meat at 0.08 ppm. EPA revised these levels based on recalculated livestock dietary burdens for poultry and ruminants, taking into account potential flonicamid residues under the proposed tolerances.

V. Conclusion

Therefore, tolerances are established for combined residues of 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 Brassica, leafy greens, subgroup 5B at 16 ppm; hop, dried cones at 7.0 ppm; okra at 0.40 ppm; radish, tops at 16

ppm; turnip, greens at 16 ppm; vegetable, root, except sugar beet, subgroup 1B at 0.60 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.20 ppm. Revised tolerances are established for combined residues of flonicamid its metabolites TFNA and TFNA-AM in or on cattle, fat at 0.03 ppm; cattle, meat at 0.08 ppm; egg at 0.04 ppm; goat, fat at 0.03 ppm; goat, meat at 0.08 ppm; horse, fat at 0.03 ppm; horse, meat at 0.08 ppm; milk at 0.03 ppm; poultry, fat at 0.03 ppm; poultry, meat at 0.03 ppm; poultry, meat byproducts at 0.03 ppm; sheep, fat at 0.03 ppm; and sheep, meat at 0.08 ppm.

Tolerances currently exist for combined residues of flonicamid and its metabolites TFNA, TFNA-AM, and TFNG in or on mustard greens at 11 ppm and potato at 0.20 ppm. These tolerances are no longer needed, since residues on these commodities will be covered by the new tolerances being established on ''Brassica, leafy greens, subgroup 5B'' at 16 ppm and ''vegetable, tuberous and corm, subgroup 1C'' at 0.20 ppm. Therefore, EPA is revoking these existing, redundant tolerances.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA 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, *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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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 6, 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) (Public Law 104–4).

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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this rule in the **Federal Register**. This rule 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: March 21, 2008.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 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. Section 180.613 is amended as follows:

■ a. By removing the commodities ''Mustard greens'' and ''Potato'' from the table in paragraph (a)(1).

■ b. By alphabetically adding commodities to the table in paragraph (a)(1).

■ c. By revising the table in paragraph (a)(2).

§ 180.613 Flonicamid; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
* * *	* *
Brassica, leafy greens, subgroup 5B	16
* * *	* *
Hop, dried cones	7.0
Okra	0.40
* * *	* *
Radish, tops	16
* * *	* *
Turnip, greens	16
* * *	* *
Vegetable, root, except sugar beet, subgroup 1B	0.60
Vegetable, tuberous and corm, subgroup 1C	0.20

(2) * * *

Commodity	Parts per million
Cattle, fat	0.03
Cattle, meat	0.08
Cattle, meat byproducts	0.08
Egg	0.04
Goat, fat	0.03
Goat, meat	0.08
Goat, meat byproducts	0.08
Horse, fat	0.03
Horse, meat	0.08
Horse, meat byproducts	0.08
Milk	0.03
Poultry, fat	0.03
Poultry, meat	0.03
Poultry, meat byproducts	0.03
Sheep, fat	0.03
Sheep, meat	0.08
Sheep, meat byproducts	0.08

* * * * *

[FR Doc. E8–6668 Filed 4–1–08; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[EPA–R04–RCRA–2007–0992; FRL–8550–3]

Alabama: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate Final Rule.

SUMMARY: Alabama has applied to EPA for Final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA proposes to grant final authorization to Alabama. In the ''Rules and Regulations'' section of this **Federal Register**, EPA is authorizing the changes by an immediate final rule. EPA did not make a proposal prior to the immediate final rule because we believe this action is not controversial and do not expect comments that oppose it. We have explained the reasons for this authorization in the preamble of the immediate final rule. Unless we get written comments which oppose this authorization during the comment period, the immediate final rule will become effective on the date it establishes, and we will not take further action on this proposal. If we receive comments that oppose this action, we will withdraw the immediate final rule and it will not take effect. We will respond to public comments in a later final rule based on this proposal. You may not have another opportunity for comment.

DATES: Final authorization will become effective on June 2, 2008 unless EPA receives adverse written comment on or before May 2, 2008. If EPA receives such comment, it will publish a timely withdrawal of this immediate final rule in the **Federal Register** and inform the public that this authorization will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–RCRA–2007–0992 by one of the following methods:

- *http://http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: johnson.otis@epa.gov.*
- *Fax:* (404) 562–9964 (prior to faxing, please notify the EPA contact listed below)
- *Mail:* Send written comments to Otis Johnson, Permits and State Programs Section, RCRA Programs and Materials Management Branch, RCRA Division, U.S. Environmental Protection Agency, The Sam Nunn Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960.
- *Hand Delivery:* Otis Johnson, Permits and State Programs Section, RCRA Programs and Materials Management Branch, RCRA Division, U.S. Environmental Protection Agency, The Sam Nunn Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R04–RCRA–2007–0992. EPA's policy is that all comments received will be included in the public docket without change and may be made available online 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 e-mail. The *http://www.regulations.gov* website 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 e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail 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. (For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*).

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not 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 hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy. You may view and copy Alabama's application from 8 a.m. to 4:30 p.m. at the EPA Region 4, RCRA Division, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960.

You may also view and copy Alabama's application from 8 a.m. to 4:30 p.m. at The Alabama Department of Environmental Management, 1400 Coliseum Blvd, Montgomery, Alabama 36110–2059.

FOR FURTHER INFORMATION CONTACT: Otis Johnson, Permits and State Programs Section, RCRA Programs and Materials Management Branch, RCRA Division, U.S. Environmental Protection Agency, The Sam Nunn Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960; (404) 562–8481; *fax number:* (404) 562–9964; *e-mail address:johnson.otis@epa.gov*.

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273, and 279.

B. What Decisions Have We Made in This Rule?

We conclude that Alabama's application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we grant Alabama Final authorization to operate its hazardous waste program with the changes described in the authorization application. Alabama has responsibility for permitting Treatment, Storage, and Disposal Facilities (TSDF) within its borders and for carrying out the aspects of the RCRA program described in its revised program application, subject to