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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-0325; FRL-8356-6]

Dicamba; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of dicamba and its 5-hydroxy metabolite in or on corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; and corn, sweet, stover. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

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-2007-0325. 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; 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-2007-0325 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-2007-0325, 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 May 9, 2007 (72 FR 26375) (FRL-8128-1), 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) 0E6209) 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 180.227 be amended by establishing tolerances for combined residues of the herbicide 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 parts per million (ppm); corn, sweet, kernel plus cob with husks removed at 0.04 ppm; and corn, sweet, stover at 0.50 ppm. That notice referenced a summary of the petition prepared by BASF 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.

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 tolerances for combined residues of dicamba on corn, sweet, forage at 0.50 ppm; corn, sweet, kernel plus cob with husks removed at 0.04 ppm; and corn, sweet, stover at 0.50 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.

Dicamba has low acute toxicity via the oral, dermal and inhalation routes. It is an eye and dermal irritant but it is not a skin sensitizer. Following oral administration, dicamba is rapidly absorbed and excreted in urine and feces. Consistent neurotoxic signs (e.g., ataxia, decreased motor activity, impaired righting reflex and gait) were observed in many studies in rats and rabbits at high doses. Prenatal developmental toxicity studies in rats and rabbits showed no evidence (qualitative or quantitative) of increased susceptibility following *in utero* or post-natal exposure to dicamba. There was an increased incidence of abortion in the rabbit developmental toxicity study at doses that also showed maternal toxicity. In a 2-generation reproduction study, offspring toxicity was manifested as decreased pup body weight gain in all generations at a dose lower than the parental systemic toxicity NOAEL. Dicamba is classified as "Not Likely to be Carcinogenic to Humans" by the oral route. Mutagenicity studies did not demonstrate evidence of mutagenic potential for dicamba although some positive results were reported in published literature.

Specific information on the studies received and the nature of the adverse effects caused by dicamba 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 *Dicamba: Human-Health Risk Assessment for Proposed Section 3 New Uses on Sweet Corn*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA-HQ-OPP-2007-0325-0004 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-term, intermediate-term, 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>. A summary of the toxicological endpoints for dicamba used for human risk assessment can be found at <http://www.regulations.gov> in the document *Dicamba: Human-Health Risk Assessment for Proposed Section 3 New Uses on Sweet Corn*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA-HQ-OPP-2007-0325-0004 in that docket.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to dicamba, EPA considered exposure under the petitioned-for tolerances as well as all existing dicamba tolerances in 40 CFR 180.227. EPA assessed dietary exposures from dicamba 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. In estimating acute dietary exposure to dicamba, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed all foods for which there are tolerances were treated and contain tolerance-level residues. No anticipated residues or percent crop

treated (PCT) data were used in the acute dietary exposure assessment.

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. No anticipated residues or percent crop treated (PCT) data were used in the chronic dietary exposure assessment.

iii. *Cancer.* Based on the results of carcinogenicity studies in rats and mice, EPA has concluded that dicamba is “not likely to be carcinogenic to humans.” Consequently, a quantitative cancer exposure and risk assessment is not appropriate for dicamba.

2. *Dietary exposure from drinking water.* The residues of concern in drinking water include dicamba and its major degradate, DCSA. The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for dicamba and DCSA 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 dicamba and DCSA. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the combined estimated environmental concentrations (EECs) of dicamba and DCSA for acute exposures are estimated to be 367 parts per billion (ppb) for surface water and 0.016 ppb for ground water. The combined EECs for chronic exposures are estimated to be 13.8 ppb for surface water and 0.016 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 367 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 13.8 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).

Dicamba is currently registered for use on residential sites, including home lawns and golf courses. EPA assessed residential exposure using the following assumptions: Residential handlers are likely to be exposed to dicamba residues via dermal and inhalation routes during handling, mixing, loading and applying activities. Based on the current use patterns, EPA expects duration of handler exposure to be short-term (1–30 days). EPA assessed several residential handler scenarios and found that handlers who mix/load and apply dicamba using a hose-end sprayer have the highest estimated exposures.

There is also potential for short-term (1–30 days) post-application exposure of adults and children/toddlers on lawns and other turf areas previously treated with dicamba, as well as the potential for acute, episodic exposure of toddlers from ingestion of granules containing dicamba. EPA assessed short-term dermal exposure of adults doing yardwork; short-term dermal and incidental oral exposure of toddlers playing on treated turf; and acute toddler exposure from episodic granule ingestion. Post-application inhalation exposures are expected to be negligible and were, therefore, not assessed.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCFA 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 dicamba and any other substances and dicamba 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 dicamba 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(b)(2)(C) of FFDCFA 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 prenatal and postnatal toxicology database for dicamba includes rat and rabbit developmental toxicity studies and a 2-generation reproduction toxicity study in rats. There was no evidence (qualitative or quantitative) of increased susceptibility following *in utero* exposure in the developmental toxicity studies in rats and rabbits. There was evidence of increased sensitivity of the offspring following pre-/postnatal exposure in the 2-generation reproduction study in rats. In that study, offspring toxicity was manifested as decreased pup body weight in all generations at a dose lower than the parental systemic toxicity NOAEL. However, there is low concern and there are no residual uncertainties for the increased susceptibility for the following reasons. The NOAEL of 45 milligrams/kilogram/day (mg/kg) identified in this study was chosen for risk assessments for all routes and exposure durations other than acute oral exposures. Since this NOAEL is the lowest (most sensitive endpoint) in the dicamba toxicity database, and the dose response observed in the study is well defined, assuring that this dose is a clear NOAEL, use of the NOAEL and endpoint for risk assessment is protective for all observed toxic effects of the chemical. The endpoint (decreased pup body weight) is not expected to occur as a result of a single (acute) exposure and was, therefore, not deemed appropriate for assessing acute oral exposures.

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 3X for acute oral exposures and to 1X for all other routes and durations of exposure. That decision is based on the following findings:

- i. The toxicity database for Dicamba is complete.
- ii. A developmental neurotoxicity study is not required. Consistent

neurotoxic signs (e.g., ataxia, decreased motor activity, impaired righting reflex and gait) were observed in many studies in rats and rabbits at high doses. After considering the available toxicity data, however, EPA determined that there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity for the following reasons:

a. Although clinical signs of neurotoxicity were seen in pregnant animals, no evidence of developmental anomalies of the fetal nervous system were observed in the prenatal developmental toxicity studies, in either rats or rabbits, at maternally toxic doses up to 300 or 400 mg/kg/day, respectively;

b. There was no evidence of behavioral or neurological effects on the offspring in the 2-generation reproduction study in rats; and

c. The ventricular dilation of the brain in the combined chronic toxicity and carcinogenicity study in rats was only observed in females at the high dose after two years' exposure. The significance of this observation is questionable, since no similar histopathological finding was seen in the subchronic neurotoxicity study.

iii. There is no evidence that dicamba results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental toxicity studies.

Although there is quantitative evidence of increased susceptibility in the 2-generation reproduction study in rats, the degree of concern is low, because there is a well established offspring toxicity NOAEL in the study and the risk assessment team did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of dicamba for all routes and durations of exposure, except acute oral exposures.

iv. EPA selected an endpoint from the acute neurotoxicity study in rats for use in assessing acute oral exposures. In this study, neurotoxicity was seen in both sexes at the lowest dose tested, 300 mg/kg/day. Since a NOAEL was not established in the study, EPA has determined that an FQPA safety factor of 3X should be used in acute oral risk assessments for dicamba to account for uncertainty arising from the use of the LOAEL instead of a NOAEL. EPA has reduced the factor from 10X to 3X based on the following considerations. A comparison of the acute neurotoxicity (ACN) study with the rat developmental toxicity study that showed similar clinical signs and a NOAEL of 160 mg/kg/day after 10 days of treatment indicates that the NOAEL for the acute

neurotoxicity study is unlikely to be more than 3-fold lower than the LOAEL (ACN LOAEL/3 = 100 mg/kg; rat developmental study NOAEL = 160 mg/kg). Therefore, it was determined that an uncertainty factor of 3X for extrapolation of LOAEL to NOAEL was adequate.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100%CT and tolerance-level residues. Conservative ground water and surface water modeling estimates were used. Similarly, conservative assumptions were used to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by dicamba.

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-term, intermediate-term, 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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to dicamba will occupy 11% of the aPAD for infants less than 1 year old, the population with the greatest estimated exposure. Dicamba is currently registered for uses that could result in acute residential exposure of toddlers from episodic granule ingestion; however, the Agency has determined that it is not appropriate to aggregate acute dietary (food and water) and acute residential exposures for dicamba, since it is unlikely that high end dietary exposure would occur in the same day as high end oral residential exposure. High end oral residential exposure is aggregated with background dietary exposure in evaluating short-term risk (see Unit III.E.3.).

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to dicamba from food and water will utilize 6.7% of the cPAD for children, 1 to 2 years old, the population group with the greatest estimated exposure. Based the use

pattern, chronic residential exposure to residues of dicamba 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). Dicamba is currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for dicamba.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of 1,600 for adults and 1,000 for children. The MOE for adults takes into consideration combined residential handler and postapplication exposures from doing yardwork on treated turf. The MOE for children includes combined postapplication dermal and incidental oral exposures of toddlers playing on treated turf.

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). Dicamba 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.* Dicamba has been classified as "not likely" to be a human carcinogen and is, therefore, not expected to pose a cancer risk.

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 dicamba residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. Methods I and II (Gas Chromatography with Electron Capture Detection) in the Pesticide Analytical Manual (PAM) Volume II, are adequate for the enforcement of tolerances for residues of dicamba and its metabolite 5-OH dicamba in/on plant commodities and milk.

B. International Residue Limits

There are no CODEX, Canadian or Mexican maximum residues limits

(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 |
| * * * * * | * * |

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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