

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: August 31, 2011.

**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. Section 180.637 is amended by revising paragraph (b) to read as follows:

**§ 180.637 Mandipropamid; tolerances for residues.**

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the mandipropamid, 4-chloro-N-[2-[3-methoxy-4-(2-propynyloxy)phenyl]ethyl]-α-(2-propynyloxy)-benzeneacetamide in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FFIFRA section 18 emergency exemptions. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration date
Basil, dried .....	240	12/31/12
Basil, fresh .....	20	12/31/12

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2010-0496; FRL-8881-6]

**Dicamba; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of dicamba in or on teff, forage; teff, grain; teff, straw; and teff, hay. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 9, 2011. Objections and requests for hearings must be received on or before November 8, 2011, 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-2010-0496. All documents in the docket are listed in the docket index available at <http://www.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:** Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; *telephone number:* (703) 305-7390; *e-mail address:* [nollen.laura@epa.gov](mailto:nollen.laura@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).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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 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](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the harmonized test guidelines referenced in this document electronically, please go <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

*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-2010-0496 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 November 8, 2011. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0496, 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 Facility'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. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 22, 2010 (75 FR 65321) (FRL-8851-1), 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 0E7779) by IR-4, 500 College Rd. East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.227 be amended by establishing a tolerance for residues of the herbicide dicamba, 3,6-dichloro-o-anisic acid, and its metabolite 3,6-dichloro-5-hydroxy-o-anisic acid (5-OH dicamba), in or on teff, forage at 90.0 parts per million (ppm); teff, grain at 6.0 ppm; teff, straw at 30.0 ppm; and teff, hay at 40.0 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by Helena Chemical Company, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the tolerance expression for all established commodities to be consistent with current Agency policy. The reason for this change is explained in Unit IV.C.

## III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA

determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 dicamba including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with dicamba follows.

In the **Federal Register** of April 2, 2008 (73 FR 17914) (FRL-8356-6), EPA published a final rule 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 ppm; corn, sweet, kernel plus cob with husks removed 0.04 ppm; and corn, sweet, stover at 0.50 ppm, based on EPA's conclusion that aggregate exposure to dicamba is safe for the general population, including infants and children. Since 2008, there have been no additional tolerance actions for dicamba.

As noted in this unit, the current action concerns a tolerance for dicamba on teff. Teff is an intermediate grass that is morphologically and taxonomically similar to other cereal grains, including wheat. It is used to make flour in a manner similar to wheat and other cereal grains. EPA recently assessed the proposed use of dicamba on teff. In that assessment, EPA determined that aggregate dicamba exposures and risks will not increase as a result of the addition of the proposed teff uses to the uses assessed as part of the 2008 rulemaking. Teff is not included in the Continuing Survey of Food Intakes by Individuals (CSFII). However, because it is used to make flour in a manner similar to wheat and other cereal grains,

it will likely substitute in the diet for cereal grain foods which will contain similar residues of dicamba; therefore, a significant increase in dietary exposure to residues of dicamba from consumption of teff-containing foods will not occur. Furthermore, residues of dicamba in teff livestock feeds will be similar to those in other forages, hays, and silages for which tolerances of dicamba are currently established. As such, there would be no increase in the livestock dietary burden should teff be substituted in the livestock diet for other hays and silages; residues in meat, milk, poultry and eggs will remain the same.

Further information about EPA's risk assessment and determination of safety for this action can be found at <http://www.regulations.gov> in document "2,4-D and Dicamba: Petition for the Establishment of Tolerances on Teff; Request for Registration of Latigo (EPA Reg. No. 5905-564) on Teff." in docket ID number EPA-HQ-OPP-2010-0496. Except as supplemented by the information described in this unit, EPA is relying on the safety finding in the 2008 rulemaking and the risk assessment underlying that action in establishing the tolerances for dicamba on teff, forage; teff, grain; teff, straw; and teff, hay. Further information regarding the safety finding for the last rulemaking can be found in the **Federal Register** of April 2, 2008 (73 FR 17917) (FRL-8356-6), at <http://www.epa.gov/fedrgstr/EPA-PEST/2008/April/Day-02/p6674.htm>.

For the 2008 rulemaking, the toxicity database was considered complete. However, recent changes to 40 CFR part 158 imposed new data requirements for immunotoxicity testing (OPPTS Guideline 870.7800) and acute and subchronic neurotoxicity testing (OPPTS Guideline 870.6200) for pesticide registration. The toxicity database for dicamba includes acceptable acute and subchronic neurotoxicity studies; therefore, the requirements for the neurotoxicity screening battery have been met. Additionally, an immunotoxicity study was recently submitted and is currently under review. A screening level review of this study indicates that no effects, including immunotoxic effects, were observed at the highest dose tested of approximately 307 milligrams/kilograms (mg/kg/day). This value is higher than the doses currently used for risk assessment; therefore, risk assessment endpoints will not change and the toxicity database is considered complete.

Based upon the 2008 rulemaking and the other information discussed in this unit, EPA concludes that there is a

reasonable certainty that no harm will result to the general population, and to infants and children, from aggregate exposure to dicamba residues. Refer to the April 2, 2008 (73 FR 17914) (FRL-8356-6) **Federal Register** document, available at <http://www.regulations.gov>, for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies upon those risk assessments and the findings made in the **Federal Register** document in support of this action.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodologies, Methods I and II—gas chromatography with electron capture detection (GC/ECD), are available to enforce the tolerance expression. The methods are published in the Pesticide Analytical Manual (PAM) Volume II. 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; e-mail address: [residuemethods@epa.gov](mailto: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 U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for dicamba in or on commodities associated with this action.

##### C. Revisions to Petitioned-For Tolerances

The 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 dicamba 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 residues of dicamba, 3,6-dichloro-o-anisic acid, including its metabolites and degradates, in or on teff, forage at 90.0 ppm; teff, grain at 6.0 ppm; teff, straw at 30.0 ppm; and teff, hay at 40.0 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 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 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 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) (Pub. L. 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: August 31, 2011.

**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. Section 180.227 is amended by revising the introductory text in paragraphs (a)(1), (2), and (3); and 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) Tolerances are established for the residues of the herbicide dicamba (3,6-dichloro-o-anisic

acid), including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels is to be determined by measuring only the sum of the residues of dicamba (3,6-dichloro-*o*-anisic acid) and its metabolite, 3,6-dichloro-5-hydroxy-*o*-anisic acid, calculated as the stoichiometric equivalent of dicamba, in or on the following commodities:

Commodity	Parts per million
* * * *	*
Teff, forage .....	90.0
Teff, grain .....	6.0
Teff, hay .....	40.0
Teff, straw .....	30.0
* * * *	*

(2) Tolerances are established for residues of the herbicide dicamba, 3,6-dichloro-*o*-anisic acid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels is to be determined by measuring only the residues of dicamba (3,6-dichloro-*o*-anisic acid) and its metabolite, 3,6-dichloro-2-hydroxybenzoic acid, calculated as the stoichiometric equivalent of dicamba, in or on the following commodities:

\* \* \* \*

(3) Tolerances are established for residues of the herbicide dicamba, 3,6-dichloro-*o*-anisic acid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels is to be determined by measuring only the residues of dicamba, 3,6-dichloro-*o*-anisic acid, and its metabolites, 3,6-dichloro-5-hydroxy-*o*-anisic acid, and 3,6-dichloro-2-hydroxybenzoic acid, calculated as the stoichiometric equivalent of dicamba, in or on the following commodities:

\* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2010-0466; FRL-8882-1]

**Novaluron; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances under the Federal Food,

Drug, and Cosmetic Act (FFDCA) for residues of novaluron in or on multiple commodities which are identified and discussed later in this document. Additionally, the Agency is amending existing tolerances for meat byproducts and revising commodity terms for hog and poultry byproducts. Interregional Research Project Number 4 (IR-4) requested the sweet corn tolerances; Makhteshim-Agan of North America, Inc. requested the food and feed handling establishment tolerances.

**DATES:** This regulation is effective September 9, 2011. Objections and requests for hearings must be received on or before November 8, 2011, 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-2010-0466. All documents in the docket are listed in the docket index available at <http://www.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:** Jennifer Gaines, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; *telephone number:* (703) 305-5967; *e-mail address:* [gaines.jennifer@epa.gov](mailto:gaines.jennifer@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:

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*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-2010-0466 in the subject line on the first page of your. All requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before November 8, 2011. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number