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

Agricultural commodities, Pesticides, Food and feed commodities, Food and feed handling establishments.

ACTION:

AGENCY:

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[FR Doc. 2011–22981 Filed 9–8–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[http://www.regulations.gov]


2,4-D; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of 2,4-D in or on beef, bran; beef, forage; beef, grain; and beef, straw. 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–2010–0905. 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, 2000 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7390; e-mail address: 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 212).
• 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.

§ 180.598 Novaluron; tolerances for residues.

(a) ** *

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corn, sweet, forage</td>
<td>16</td>
</tr>
<tr>
<td>Corn, sweet, kernel plus cob with husks removed</td>
<td>0.05</td>
</tr>
<tr>
<td>Corn, sweet, stover</td>
<td>50</td>
</tr>
<tr>
<td>Food commodities and feed commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food and feed handling establishments</td>
<td>0.01</td>
</tr>
<tr>
<td>Goat, meat byproducts, except kidney and liver</td>
<td>11</td>
</tr>
<tr>
<td>Hog, meat byproducts, except kidney and liver</td>
<td>1.5</td>
</tr>
<tr>
<td>Horse, meat byproducts, except kidney and liver</td>
<td>11</td>
</tr>
<tr>
<td>Poultry, meat byproducts, except kidney and liver</td>
<td>7.0</td>
</tr>
<tr>
<td>Sheep, meat byproducts, except kidney and liver</td>
<td>11</td>
</tr>
</tbody>
</table>

[FR Doc. 2011–22981 Filed 9–8–11; 8:45 am]

BILLING CODE 6560–50–P
B. How can I get electronic access to other related information?


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–2010–0905 in the subject line on your non-CBI objection or hearing request with the Hearing Clerk of the EPA Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

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–2010–0905, by one of the following methods:

- 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 bound information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the Federal Register of February 4, 2011 (76 FR 6465) (FRL–8858–7), 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 0F7796) by IR–4, 500 College Road East, Suite 201W, Princeton, NJ 08540. PP 0F7796 was incorrectly reported and should have read PP 0E7796, the correct petition number. The petition requested that 40 CFR 180.142 be amended by establishing a tolerance for residues of the herbicide 2,4-D (2,4-dichlorophenoxyacetic acid), both free and conjugated, determined as the acid, in or on teff, bran at 4.0 parts per million (ppm); teff, forage at 25.0 ppm; teff, grain at 2.0 ppm; and teff, straw at 50.0 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. Comments were received on the notice of filing. EPA’s response to these comments is discussed in Unit IV.C.

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 these changes is explained in Unit IV.D.

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 2,4-D including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with 2,4-D follows.

In the Federal Register of July 27, 2005 (70 FR 43298) (FRL–7726–8), EPA published a final reestablishing tolerances for combined residues of the herbicide 2,4-D (2,4-dichlorophenoxyacetic acid), in or on hops, wild rice, and soybeans, based on upon EPA’s conclusion that aggregate exposure to 2,4-D is safe for the general population, including infants and children. Since 2005, there have been no additional tolerance actions for 2,4-D.

As noted in this unit, the current action concerns a tolerance for 2,4-D 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 2,4-D on teff. In that assessment, EPA determined that aggregate 2,4-D 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 2005 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 2,4-D; therefore, a significant increase in dietary exposure to residues of 2,4-D from consumption of teff-containing foods will not occur. Furthermore, residues of 2,4-D in teff livestock feeds will be similar to those in other forages, hays, and silages for which tolerances of 2,4-D 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–2010–0905. Except as supplemented by the information described in this unit, EPA
is relying on the safety finding in the 2005 rulemaking and the risk assessment underlining that action in establishing tolerances for 2,4-D on teff, bran; teff, forage; teff, grain; and teff, straw. Further information regarding the safety finding for the last rulemaking can be found in the Federal Register of July 27, 2005 (70 FR 43307) (FRL–7726–8), at http://www.epa.gov/fedrgstr/EPA-PEST/2005/July/Day-27/p14886.htm.

For the 2005 rulemaking, the 2,4-D toxicity database was considered complete except for the submission of a developmental neurotoxicity study (DNT) and a repeat 2-generation reproduction study. The absence of these studies led EPA to retain an additional safety factor for the protection of infants and children as provided by FFDCA section 408(b)(2)(C). Additionally, recent changes to 40 CFR part 158 imposed requirements for the neurotoxicity screening battery have been met. To address the other deficiencies, the registrant submitted an F1-extended 1-generation toxicity study in rats. This study has been reviewed and found acceptable, and fulfills the outstanding requirements for a DNT study, a repeat 2-generation reproduction study, and immunotoxicity testing. After review of these studies, EPA has concluded that they do not affect EPA’s derivation of 2,4-D’s acute reference dose (aRfD) or chronic reference dose (cRfD). It is likely, however, that in the future EPA will remove the additional safety factor for the protection of infants and children now that the 2,4-D database is complete. Thus, once a full reassessment of 2,4-D is completed, estimated risks are likely to decline substantially. However, because a full reassessment of 2,4-D risk taking into account the new studies has not been formally conducted, EPA is relying primarily on the 2005 rulemaking to support this action. Therefore, the safety finding for this action relies on the additional margin of safety provided by retaining the additional safety factor for protection of infants and children. For further information on EPA’s review of these studies, contact EPA is available at http://www.regulations.gov, in docket ID number EPA–HQ–OPP–2010–0905.

In the 2005 rulemaking, EPA relied upon data showing the percent of crops treated with 2,4-D in assessing chronic risk. In evaluating the proposed teff tolerances, EPA considered updated data on percent crop treated and has concluded that the updated data would increase the chronic risk estimates from the 2005 assessment for the general population and children 1–6 years old (the most sensitive subpopulation) by 2.2% and 3.1% of the cPAD, respectively. Because the chronic risk estimates for the 2005 assessment were well below the level of concern, these differences are considered insignificant. Therefore, based upon the 2005 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 2,4-D residues. Refer to the July 27, 2005 (70 FR 43298) (FRL–7726–8) 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 methodology, a gas chromatography with electron capture detection (GC/ECD) method, designated as EN–CAS Method No. ENC–2/93, is available to enforce the tolerance expression.

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.

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 2,4-D in or on any commodities associated with this action.

C. Response to Comments

EPA received one comment to the Notice of Filing that made a general objection to proposed new tolerances and new tolerance exemptions for several chemicals, including 2,4-D. The commenter additionally noted that, “prior to approval of these or other chemicals in the food system the EPA must be confident that these will not cause harm” and “only long term studies can provide data on the health impact of exposure to these chemicals.” The commenter stated that none of the mentioned chemicals, including 2,4-D, should be permitted in food.

The Agency understands the commenter’s concerns and recognizes that some individuals believe that certain pesticide chemicals should not be permitted in our food. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. When new or amended tolerances are requested for residues of a pesticide in food or feed, the Agency, as is required by section 408 of the FFDCA, estimates the risk of the potential exposure to these residues. The Agency has concluded after this assessment, which includes the consideration of long-term animal studies with 2,4-D, that there is a reasonable certainty that no harm will result from aggregate human exposure to 2,4-D and that, accordingly, the 2,4-D tolerances on teff are “safe.”

D. Revisions to Petitioned-For Tolerances

The EPA has revised the tolerance expression to clarify: 1. Tvided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of 2,4-D not specifically mentioned; and 2. Tcompliance 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 2,4-D (2,4-dichlorophenoxyacetic acid), including its metabolites and degradates, in or on teff, bran at 4.0 ppm; teff, forage at 25.0...
ppm; teff, grain at 2.0 ppm; and teff, straw at 50.0 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 and youth, and 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(a)(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 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, 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]

§ 180.142 2,4-D; tolerances for residues.

(a) General. Tolerances are established for residues of the herbicide, plant regulator, and fungicide 2,4-D, 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 residues of 2,4-D (2,4-dichlorophenoxyacetic acid), both free and conjugated, determined as the acid, in or on the following commodities:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teff, bran</td>
<td>4.0</td>
</tr>
<tr>
<td>Teff, forage</td>
<td>25.0</td>
</tr>
<tr>
<td>Teff, grain</td>
<td>2.0</td>
</tr>
<tr>
<td>Teff, straw</td>
<td>50.0</td>
</tr>
</tbody>
</table>

(c) Tolerances with regional registrations. Tolerances with regional registration, as defined in § 180.11(l), are established for residues of the herbicide, plant regulator, and fungicide 2,4-D, 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 residues of 2,4-D (2,4-dichlorophenoxyacetic acid), both free and conjugated, determined as the acid, in or on the following commodities:

(d) Indirect or inadvertent residues. Tolerances are established for indirect or inadvertent residues of the herbicide, plant regulator, and fungicide 2,4-D, 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 residues of 2,4-D (2,4-dichlorophenoxyacetic acid), both free and conjugated, determined as the acid, in or on the following commodities:

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 73 and 76

[DA 11–1432]

Broadcast Applications and Proceedings; Fairness Doctrine and Digital Broadcast Television Redistricting Control; Fairness Doctrine, Personal Attacks, Political Editorials and Complaints Regarding Cable Programming Service Rates

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission makes several nonsubstantive, editorial revisions to parts 1, 73 and 76 of the Commission’s rules. The Commission removes rules that are without current legal effect and are obsolete. The deleted rules include