

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCFA 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, 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 FFDCFA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (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 FFDCFA. 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 (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, 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: May 2, 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. Amend § 180.434 as follows:

■ i. In the table to paragraph (a), remove the entries for “berry group 13,” “onion, bulb,” “onion, green,” and “strawberry”; revise the entries for “peppermint, tops” and “spearmint, tops”, and add alphabetically entries for “bushberry, subgroup 13-07B,” “caneberry, subgroup 13-07A,” “low growing berry subgroup 13-07G, except cranberry,” “onion, bulb subgroup 3-07A,” and “onion, green, subgroup 3-07B.”

■ ii. In the table to paragraph (b) add alphabetically and entry for “avocado.”

The added and revised text reads as follows:

§ 180.434 Propiconazole; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	*
Bushberry, subgroup 13-07B ...	1.0
Caneberry, subgroup 13-07A ..	1.0
* * * * *	*
Low growing berry subgroup 13-07G, except cranberry	1.3
* * * * *	*
Onion, bulb subgroup 3-07A ...	0.2
Onion, green, subgroup 3-07B	9.0
* * * * *	*
Peppermint, tops	10.0
* * * * *	*
Spearmint, tops	10.0
* * * * *	*

(b) * * *

Commodity	Parts per million	Expiration/revocation date
Avocado	10	12/31/13
* * * * *	*	*

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0938; FRL-8872-6]

Glyphosate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation increases the established tolerance for residues of glyphosate in or on corn, field, forage. Monsanto Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 11, 2011. Objections and requests for hearings must be received on or before July 11, 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-2010-0938. 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:

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).
- 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://www.gpoaccess.gov/ecfr>.

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-2010-0938 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 July 11, 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-2010-0938, 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 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 OF7741) by Monsanto Company, 1300 I St., NW., Suite 450 East, Washington, DC 20052. The petition requested that 40 CFR 180.364 be amended by establishing a tolerance for residues of the herbicide glyphosate, *N*-(phosphonomethyl) glycine, in or on corn, field, forage at 13 parts per million (ppm). That notice referenced a summary of the petition prepared by Monsanto 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.

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 glyphosate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with glyphosate follows.

In the **Federal Register** of April 8, 2011 (76 FR 19701) (FRL-8866-8), EPA issued a final rule establishing a tolerance for residues of glyphosate in or on sweet corn and reducing the established tolerance for residues of glyphosate and *N*-acetyl-glyphosate in or on poultry meat. When the Agency conducted the risk assessment in

support of the April 8, 2011 tolerance action, it considered secondary residues of glyphosate in livestock commodities from consumption of glyphosate-treated feed items, including corn forage. The Agency has determined that increasing the tolerance on corn forage from 6 ppm to 13 ppm will not increase residues of glyphosate in livestock commodities above those assumed in the previous risk assessment. The livestock dietary burdens for glyphosate were calculated assuming the roughage portion of the diet for beef and dairy cattle consisted of nongrass animal feed and grass forage, which have much higher tolerances (400 and 300 ppm, respectively) than corn forage. Therefore, increasing the tolerance for corn forage from 6 to 13 ppm will not affect the estimated livestock dietary burden or expected residues of glyphosate in livestock commodities and will not change the estimated aggregate risks resulting from use of glyphosate, as discussed in the April 8, 2011 (76 FR 19701; FRL-8866-8) **Federal Register** document. Refer to the **Federal Register** document, available at <http://www.regulations.gov>, for a detailed discussion of the aggregate risk assessment and determination of safety.

Therefore, based on the risk assessment discussed in the final rule published in the **Federal Register** of April 8, 2011 (76 FR 19701; FRL-8866-8) 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 glyphosate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography (HPLC) equipped with a fluorescence detector method; LOQ = 0.05 ppm) 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 FFDC 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established an MRL for residues of glyphosate in or on maize at 5 ppm. The MRL for maize would cover residues of glyphosate on corn (maize) forage. This MRL is different than the tolerance being established for glyphosate on field corn forage in the United States due to differences in Codex and U.S. residue definitions. The U.S. tolerance of 13 ppm for corn, field, forage is necessarily higher than the Codex MRL to account for residues of both glyphosate and its metabolite N-acetyl glyphosate. N-acetyl glyphosate is found in genetically modified (GMO) glyphosate-resistant commodities, including corn, grown in the U.S. Therefore, it is included in the U.S. tolerance but not the Codex expression, accounting for the difference in the established MRLs.

C. Response to Comments

EPA received comments from two individuals expressing concerns about pesticides generally and objecting to the presence of any pesticide residues in food. The Agency understands the commenters' concerns and recognizes that some individuals believe that pesticides should be banned completely. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDC) contemplates that tolerances greater than zero may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. The submitted comments appear to be directed at the underlying statute and not EPA's implementation of it; the commenters made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-For Tolerances

Monsanto Company proposed a tolerance for residues of glyphosate on corn, field, forage at 13 ppm. The current tolerance is expressed in terms of glyphosate, including its metabolites and degradates; and compliance with the tolerance level is determined by measuring glyphosate and its N-acetyl-glyphosate metabolite. EPA is increasing

the tolerance level from 6 ppm to 13 ppm, as proposed, but is retaining the current tolerance expression to clarify the chemical moieties that are covered by the tolerance and specify how compliance with the tolerance is to be measured.

V. Conclusion

Therefore, the previously established tolerance for residues of glyphosate, including its metabolites and degradates, in or on corn, field, forage is amended as set forth in the regulatory text.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDC 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 FFDC, 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 FFDC. 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: May 2, 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 180.364 is amended by revising the following entry in the table in paragraph (a)(2) to read as follows:

§ 180.364 Glyphosate; tolerances for residues.

(a)	*	*	*		
*	*	*	*	*	*
(2)	*	*	*		
				Commodity	Parts per million
*	*	*	*	*	*
				Corn, field, forage	13
*	*	*	*	*	*

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[EPA-HQ-OPPT-2009-0187; FRL-8874-2]

RIN 2070-AJ43

TSCA Inventory Update Reporting Modifications; Submission Period Suspension

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending the Toxic Substances Control Act (TSCA) section 8(a) Inventory Update Reporting (IUR) regulations by suspending the next IUR submission period. The IUR requires manufacturers (including importers) of certain chemical substances included on the TSCA Chemical Substance Inventory (TSCA Inventory) to report current data on the manufacturing, processing, and use of the chemical substances. In the **Federal Register** of August 13, 2010, EPA published proposed modifications to the IUR regulations. EPA is suspending the next submission period to allow additional time to finalize the proposed modifications to the IUR regulations, and to avoid finalizing changes to the reporting requirements in the midst of the 2011 submission period. EPA expects to finalize, in the near future, changes to the IUR reporting requirements which will supersede this action.

DATES: This final rule is effective May 11, 2011.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2009-0187. 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 OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Chenise Farquharson, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-7768; e-mail address: farquharson.chenise@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including manufacture as a byproduct) or import chemical substances listed on the TSCA Inventory. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers and importers (NAICS codes 325 and 324110; *e.g.*, chemical manufacturing and processing and petroleum refineries).
- Chemical users and processors who may manufacture a byproduct chemical substance (NAICS codes 22, 322, 331, and 3344; *e.g.*, utilities, paper manufacturing, primary metal