

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2012-0419; FRL-9390-2]

### Imazosulfuron; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of imazosulfuron in or on the melon subgroup 9A and the tuberous and corm subgroup 1C. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective July 24, 2013. Objections and requests for hearings must be received on or before September 23, 2013, 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:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0419, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: [RDfRNNotices@epa.gov](mailto:RDfRNNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather

provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

###### 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.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

###### 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-2012-0419 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 September 23, 2013. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0419, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 22, 2012 (77 FR 50661) (FRL-9358-9), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8025) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W., Princeton, NJ 08540. The petition requested that 40 CFR 180.651 be amended by establishing tolerances for residues of the herbicide imazosulfuron, (2-chloro-N-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]imidazo-[1,2-a]pyridine-3-sulfonamide), in or on tuberous and corm vegetables, crop subgroup 1C at 0.02 parts per million (ppm); and in melon, crop subgroup 9A at 0.02 ppm. That document referenced a summary of the petition prepared by Valent USA Corporation, 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 modified the commodity definitions to be consistent with Agency policy. The reason for these changes 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 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 imazosulfuron including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with imazosulfuron 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.

The toxicology data for imazosulfuron suggest that this herbicide possesses relatively low toxicity. Many of the effects of single or repeated dosing were observed near or beyond the respective limit doses.

The primary target organ of imazosulfuron in repeated-dose studies was the liver in all species tested. Mild to moderate thyroid effects were apparent only in the chronic toxicity study in dogs. Dramatic eye effects (retinal degeneration, lens vascularization, cataracts and corneal scarring) were observed in rats fed >1,000 mg/kg/day beginning at 3 months in the chronic toxicity/carcinogenicity study. Ocular effects (increased incidence of eye opacity, corneal edema, inflammation and neovascularization) were also observed in the high-dose males (4,577 mg/kg/day) in the 90-day feeding toxicity study in rats. Decreased body weight and body weight gain compared to control were frequent findings throughout the toxicology database for imazosulfuron.

Clinical signs (decreased motor activity, abnormal gait, upward curvature of the spine and piloerection) were observed in males at the limit dose of the acute neurotoxicity study; however, these effects can be attributed to generalized toxicity and were resolved by day 2 of the study. No neurotoxic effects were observed during the subchronic screening battery or noted as clinical signs in any other repeated-dose study.

No developmental effects were observed at the highest dose tested (HDT) (125 mg/kg/day) in the rabbit developmental toxicity study. No developmental or reproductive toxicity was observed in the 1-generation rat study. Decreased pup viability was observed in the rat 2-generation reproduction study at a dose approaching the limit dose (LOAEL = 892 mg/kg/day) in both the F1 and F2 offspring generations. Mortality was also observed in the parental generation at this dose. No increased qualitative or quantitative offspring susceptibility was apparent in any of the submitted studies for imazosulfuron.

There was no evidence of carcinogenicity in rats and mice up to the limit dose at 24 and 18 months, respectively. Imazosulfuron was determined to be non-mutagenic in bacteria and negative in an *in vivo* mammalian cytogenetics assay. Overall, there was no evidence that imazosulfuron was either mutagenic or clastogenic in either *in vivo* or *in vitro* assays. The cancer classification is "not likely to be carcinogenic to humans," based on the absence of significant tumor increases in the carcinogenicity studies.

Specific information on the studies received and the nature of the adverse effects caused by imazosulfuron 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 titled "Imazosulfuron: Human Health Risk Assessment for Proposed Uses on Melon (Crop Subgroup 9A) and Tuberous and Corm Vegetables (Crop Subgroup 1C)," pp. 29–33 in docket ID number EPA-HQ-OPP-2012-0419.

#### B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as

a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for imazosulfuron used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of December 29, 2010 (75 FR 81878) (FRL-8857-4).

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to imazosulfuron, EPA considered exposure under the petitioned-for tolerances as well as all existing imazosulfuron tolerances in 40 CFR 180.651. EPA assessed dietary exposures from imazosulfuron 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.

Such effects were identified for imazosulfuron. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues for all registered and proposed uses.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 NHANES/WWEIA. As to residue levels in food, EPA assumed 100 PCT and tolerance-level residues for all registered and proposed uses.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that imazosulfuron does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT

information in the dietary assessment for imazosulfuron. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for imazosulfuron in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of imazosulfuron. 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 Tier 1 Rice Model and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of imazosulfuron for acute exposures are estimated to be 278.9 parts per billion (ppb) for surface water and 4.8 ppb for ground water and for chronic exposures are estimated to be 278.9 ppb for surface water and 4.8 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 278.9 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 278.9 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).

Imazosulfuron is currently registered for the following uses that could result in residential exposures: Residential turfgrass and recreational areas. EPA assessed residential exposure using the following assumptions:

Residential handlers may receive short-term dermal and inhalation exposure to imazosulfuron when mixing, loading, and applying the pesticide on home lawns. Since a dermal endpoint of concern was not identified for imazosulfuron, only short-term inhalation exposure of residential handlers was assessed.

Post-application inhalation exposure is not expected due to the nature of pesticide applications to residential lawns. Based on climate effects (such as rain) and post-application activities (such as lawn mowing), inhalation exposure to imazosulfuron is expected to be negligible. Furthermore, imazosulfuron has low acute inhalation

toxicity, low vapor pressure ( $<3.5 \times 10^{-6}$  Pa) and a low proposed use rate (0.3 lb ai/A). Therefore, EPA assessed only short-term post-application incidental oral exposure of children (toddlers) based on the following scenarios: Incidental oral exposure from treated turf via hand-to-mouth activities; incidental oral exposure from treated turf via object-to-mouth activities; and incidental oral exposure from treated turf via soil ingestion.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/science/residential-exposure-sop.html>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found imazosulfuron to share a common mechanism of toxicity with any other substances, and imazosulfuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that imazosulfuron does not have 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 Web site at <http://www.epa.gov/pesticides/cumulative>.

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility following *in utero* and/or

postnatal exposure in the developmental toxicity studies in rats or rabbits, or in the 2-generation rat reproduction study. Neither the rat nor rabbit developmental studies identified developmental effects. The parental NOAEL is clearly defined, less than or equal to the offspring NOAEL and based on general systemic toxicity. At near-limit dose, 20%–30% decreases in numbers of implants/dam, total pups/dam and live pups/dam on post-natal day (PND) 0, and viability index were observed in F<sub>1</sub> pups of the 2-generation reproductive study in rats. Similarly, decreased live pups/dam and live births and viability and lactation indices were noted for F<sub>2</sub> pups at doses that induced parental mortality. The points of departure are protective of these effects.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for imazosulfuron is complete.
- ii. There is no indication that imazosulfuron is a neurotoxic chemical based on clinical observations of neurotoxicity during the conduct of developmental or chronic studies. No adverse neurobehavioral signs were observed at doses approaching the limit dose in any of the short-term studies (subchronic oral, 21-day dermal). No neurotoxic effects were observed during the subchronic neurotoxicity screen in which adverse effects of decreased body weight, body weight gain and food efficiency were observed at 575 mg/kg/day (LOAEL). The acute neurotoxicity screen (ACN) yielded a LOAEL at the limit dose for clinical signs, abnormal gait, decreased activity, piloerection and upward curvature of the spine and decreased motor activity in males, all of which were resolved by day 2. No treatment-related effects were observed in Functional Observational Battery (FOB) parameters, gross and neurohistopathology, motor activity or brain morphometrics of the ACN. The weight of evidence demonstrates that imazosulfuron is not a neurotoxic compound because the clinical findings in the ACN study occurred only at the limit dose and may be attributed to generalized toxicity. A developmental neurotoxicity study is not required at this time.

iii. As discussed in Unit III.D.2., there is no concern for increased susceptibility to offspring following pre- and postnatal exposure to rats or *in utero* exposure in rabbits.

iv. There are no residual uncertainties identified in the exposure databases.

The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to imazosulfuron in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by imazosulfuron.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to imazosulfuron will occupy 1.2% of the aPAD for all infants less than one year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to imazosulfuron from food and water will utilize 2% of the cPAD for all infants less than one year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of imazosulfuron is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Imazosulfuron 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 exposure through food and water with short-term residential exposures to imazosulfuron.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 33,000 for adults and 8,700 for

children. Because EPA's level of concern for imazosulfuron is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, imazosulfuron is not registered for any use patterns that would result in intermediate-term residential exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for imazosulfuron.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, imazosulfuron is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to imazosulfuron residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (high performance liquid chromatography method with tandem mass spectroscopy detection (LC/MS/MS)) 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; email 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

United Nations 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 any MRLs for imazosulfuron.

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

The proposed commodity definitions are being modified from "Melon crop subgroup 9A" to "Melon subgroup 9A" and "Tuberous and corm vegetables crop subgroup 1C" to "Vegetable, tuberous and corm, subgroup 1C" to be in line with Agency terminology.

#### **V. Conclusion**

Therefore, tolerances are established for residues of imazosulfuron, (2-chloro-N-[[[4,6-dimethoxy-2-pyrimidinyl]amino]carbonyl]imidazo-[1,2-a]pyridine-3-sulfonamide), in or on melon subgroup 9A at 0.02 ppm and vegetable, tuberous and corm, subgroup 1C at 0.02 ppm.

#### **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under FFDCA section 408(d) 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 FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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) (2 U.S.C. 1501 *et seq.*).

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) (15 U.S.C. 272 note).

## VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: July 17, 2013.

**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(g), 346a and 371.

■ 2. In § 180.651, in paragraph (a), add alphabetically the following commodities to the table to read as follows:

#### § 180.651 Imazosulfuron; tolerances for residues.

(a) \* \* \*

Commodity	Parts per million
Melon subgroup 9A .....	0.02
* * * * *	
Vegetable, tuberous and corm, subgroup 1C .....	0.02
* * * * *	

[FR Doc. 2013-17823 Filed 7-23-13; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2012-0628; FRL-9393-2]

### Mancozeb; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of mancozeb in or on walnuts and tangerines. United Phosphorus requested the tolerance for walnuts and Dow AgroSciences requested the tolerance for tangerines under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective July 24, 2013. Objections and requests for hearings must be received on or before September 23, 2013, 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:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0628, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs

Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: [RDPRNotices@epa.gov](mailto:RDPRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

##### 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 eCFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

##### 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-