

remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

### III. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

- Does not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249,

November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 15, 2013. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 26, 2013.

**Jared Blumenfeld**,  
Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

### PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

- 1. The authority citation for Part 52 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq.*

#### Subpart F—California

- 2. Section 52.220, is amended by adding paragraphs (c)(70)(i)(B)(1), (c)(164)(i)(C)(5) and (c)(270)(i)(A)(2) to read as follows:

#### § 52.220 Identification of plan.

\* \* \* \* \*

(c) \* \* \*  
(70) \* \* \*  
(i) \* \* \*  
(B) \* \* \*

(1) Previously approved on September 2, 1981 in paragraph (c)(70)(i)(B) of this section and now deleted without replacement, for the Antelope Valley area only, Antelope Valley Rule 1101, previously South Coast Rule 1101. South Coast Rule 1101 remains in effect for the South Coast area.

\* \* \* \* \*

(164) \* \* \*  
(i) \* \* \*  
(C) \* \* \*

(5) Previously approved on April 17, 1987 in paragraph (c)(164)(i)(C)(1) of this section and now deleted without replacement, Ventura County Rule 67.

\* \* \* \* \*

(270) \* \* \*  
(i) \* \* \*  
(A) \* \* \*

(2) Previously approved on December 13, 1999 in paragraph (c)(270)(i)(A)(1) of this section and now deleted without replacement, Ventura County Rule 37.

\* \* \* \* \*

[FR Doc. 2013-19872 Filed 8-15-13; 8:45 am]

**BILLING CODE 6560-50-P**

### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA-HQ-OPP-2012-0384; FRL-9394-8]

#### Imazapic; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of imazapic in or on sugarcane, cane. BASF Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective August 16, 2013. Objections and

requests for hearings must be received on or before October 15, 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-2012-0384, 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/textidx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/textidx?&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-2012-0384 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 October 15, 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-2012-0384, 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 July 25, 2012 (77 FR 43562) (FRL-9353-6), 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 2E8021) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.490 be

amended by establishing tolerances for residues of the herbicide imazapic 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid in or on sugarcane at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by BASF 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 revised the proposed tolerance level and the commodity definition. EPA is also revising the tolerance expression to clarify the chemical moieties that are covered by the tolerances and specify how compliance will be measured. The reasons for these changes are 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 imazapic including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with imazapic 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.

Imazapic is categorized as having low acute toxicity by the oral, inhalation, and dermal routes of exposure. It is minimally irritating to the eye, non-irritating to the skin, and not a skin sensitizer.

No evidence of subchronic toxicity was observed to rodents via the oral or dermal routes. In the chronic oral toxicity study in dogs, minimal degeneration and/or necrosis of the skeletal muscle of the thigh and/or abdomen was seen at the lowest dose tested. At higher doses, additional effects were seen in the liver (increased absolute weights and changes in clinical chemical parameters), kidney (decreased urinary pH in females), and erythropoietic system (changes in hematological parameters, and microscopic changes in the bone marrow and spleen). At the high dose, there was also inflammation in the esophagus similar to that in skeletal muscle as well as discoloration of the lung in both sexes.

In the developmental toxicity study with rats, no maternal or developmental toxicity was seen at the limit dose. In the developmental toxicity study in rabbits, maternal effects of decreased body-weight gain and food consumption were observed at the dose level that did not result in developmental effects. In the 2-generation reproduction study in rats, no parental or reproductive toxicity was seen at the limit dose. In the battery

of mutagenicity studies, no evidence of mutagenicity was observed.

Imazapic is classified as a "Group E" chemical (not likely to be a human carcinogen) by any relevant route of administration based on the absence of carcinogenicity seen in rodents.

Since the last risk assessment in 2001, acute neurotoxicity, subchronic neurotoxicity, and immunotoxicity studies were submitted in response to the 40 CFR part 158 data requirements. There was no evidence of immunotoxicity or neurotoxicity observed in the submitted studies.

In the 2001 risk assessment and in the **Federal Register** of December 26, 2001 (66 FR 66325) (FRL-6816-2), a 28-day inhalation toxicity study was required due to the potential for repeated handler inhalation exposure anticipated from use on pastures and rangeland. However, EPA concluded in the April 17, 2012 document "Imazapic: Summary of Hazard and Science Policy Council (HASPOC) Meeting of March 15, 2012: Recommendations on the Requirement of a 28-day Inhalation Study" that based on a weight-of-evidence approach, this study is not required at this time.

Specific information on the studies received and the nature of the adverse effects caused by imazapic 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 "Imazapic. Human-Health Risk Assessment. Petition for Tolerances for Use on Soybeans and Sugarcane Without U.S. Registration," pp. 14–17 in

docket ID number EPA-HQ-OPP-2012-0384.

#### *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 imazapic used for human risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR IMAZAPIC FOR USE IN HUMAN HEALTH RISK ASSESSMENT

| Exposure/scenario                                                                                  | Point of departure and uncertainty/safety factors                                                              | RfD, PAD, LOC for risk assessment                              | Study and toxicological effects                                                                                                              |
|----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| Acute dietary (General population including infants and children; and Females 13–50 years of age). | None .....                                                                                                     | None .....                                                     | No acute dietary endpoint selected based on the absence of an appropriate endpoint attributed to a single dose.                              |
| Chronic dietary (All populations) .....                                                            | LOAEL = 137 mg/kg/day .....<br>UF <sub>A</sub> = 10X<br>UF <sub>H</sub> = 10X<br>FQPA SF/UF <sub>L</sub> = 10X | Chronic RfD = 0.137 mg/kg/day.<br>cPAD = 0.137 mg/kg/day ..... | One-Year Dog Feeding Study<br>LOAEL = 137 mg/kg/day based on increased incidence of minimal degeneration and/or necrosis of skeletal muscle. |

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). UF<sub>L</sub> = use of a LOAEL to extrapolate a NOAEL.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to imazapic, EPA considered exposure under the petitioned-for tolerances as well as all existing imazapic tolerances in 40 CFR 180.490. EPA assessed dietary exposures from imazapic 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. No such effects were identified in the toxicological studies for imazapic; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA incorporated tolerance-level residues and 100 percent crop treated (PCT) for all commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that imazapic 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 imazapic. 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 imazapic in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of imazapic. 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 FQPA Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of imazapic for chronic exposures for non-cancer assessments are estimated to be 1.46 ppb for surface water and 13.73 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered

into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 13.73 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). Imazapic is not registered for any specific use patterns that would result in residential exposure.

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 imazapic to share a common mechanism of toxicity with any other substances, and imazapic does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that imazapic 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 pre- or postnatal susceptibility based on the results of the rat and rabbit prenatal developmental toxicity studies and the

2-generation reproductive toxicity study.

3. *Conclusion.* EPA is retaining the default 10X FQPA safety factor for all exposure scenarios due to the use of a LOAEL to extrapolate a NOAEL for the POD for the chronic dietary endpoint. That decision is based on the following findings:

i. Although all required toxicity studies have been submitted for imazapic, the chronic study used for chronic dietary risk assessment did not demonstrate a NOAEL, and a LOAEL was used as an endpoint. Therefore, EPA is retaining the 10X FQPA safety factor for use of a LOAEL to extrapolate a NOAEL.

ii. There is no indication that imazapic is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that imazapic results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The chronic 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 imazapic in drinking water. These assessments will not underestimate the exposure and risks posed by imazapic.

### 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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, imazapic is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to imazapic from

food and water will utilize 4% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for imazapic.

3. *Short- and intermediate-term risks.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there are no currently registered residential uses, no short- or intermediate-term aggregate risk assessments were conducted for imazapic.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, imazapic 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 imazapic residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method SOP–PA.0288, a liquid chromatography with tandem mass spectroscopy (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 a MRL for imazapic on sugarcane.

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

EPA revised the proposed commodity definition of “sugarcane” to reflect the correct terminology of “sugarcane, cane” and revised the proposed tolerance of 0.01 ppm to 0.03 ppm. All residues (parent plus metabolites) were below the limit of quantification (LOQ). The revised tolerance level is based upon the sum of the LOQs (0.01 + 0.01 + 0.01 = 0.03 ppm) for each of the three compounds in the tolerance expression. In accordance with Agency guidance on tolerance expressions, the tolerance expressions for imazapic are revised by clarifying that the tolerances cover “residues of imazapic, including its metabolites and degradates”.

#### V. Conclusion

Therefore, tolerances are established for residues of imazapic, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid and its metabolites in or on sugarcane, cane at 0.03 ppm.

#### VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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: August 7, 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(q), 346a and 371.
- 2. Amend § 180.490 as follows:
  - a. Revise the section heading;
  - b. Revise the introductory text in paragraph (a)(1) and add alphabetically the following commodity to the table;
  - c. Revise the introductory text in paragraph (a)(2); and
  - d. Revise the heading in paragraph (c).The amendments read as follows:

**§ 180.490 Imazapic; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of the herbicide imazapic, including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified is to be determined by measuring the sum of imazapic (2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid) and its metabolites (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-hydroxymethyl-3-pyridinecarboxylic acid and (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(β-D-glucopyranosyloxy)methyl-3-pyridinecarboxylic acid, calculated as the stoichiometric equivalent of imazapic.

| Commodity             | Parts per million |
|-----------------------|-------------------|
| * * * * *             | *                 |
| Sugarcane, cane ..... | 0.03              |

(2) Tolerances are established for residues of the herbicide imazapic, including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified is to be determined by measuring the sum of imazapic (2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid) and its metabolite (±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-hydroxymethyl-3-pyridinecarboxylic acid, calculated as the stoichiometric equivalent of imazapic.

\* \* \* \* \*

(c) *Tolerances with regional registrations.* [Reserved]

\* \* \* \* \*

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180  
[EPA-HQ-OPP-2012-0405; FRL-9395-6]

Enamectin; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).  
**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of enamectin benzoate in or on wine grapes. Syngenta Crop Protection, LLC, requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA). This document also makes a technical correction to the tolerance expression in the section.

**DATES:** This regulation is effective August 16, 2013. Objections and requests for hearings must be received on or before October 15, 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-2012-0405, 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/textidx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/textidx?&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-2012-0405 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 October 15, 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-2012-0405, 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.