

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[EPA-HQ-OPP-2020-0176; FRL-10017-66]

**Oxalic Acid; Exemption From the Requirement of a Tolerance****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of oxalic acid on honey and honeycomb. This regulation eliminates the need to establish a maximum permissible level on these commodities for residues of oxalic acid.

**DATES:** This regulation is effective February 23, 2021. Objections and requests for hearings must be received on or before April 26, 2021, 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-2020-0176, 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), West William Jefferson Clinton 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.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDFRNotices@epa.gov](mailto:RDFRNotices@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 40 CFR part 180 through the Government Publishing 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-2020-1076 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 April 26, 2021. 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-2020-0176, 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.html>.

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

**II. Background and Statutory Findings**

In the **Federal Register** of September 30, 2020 (85 FR 61682) (FRL-10014-74), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 0E8824) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W, Princeton, NJ 08540 as an agent for the U.S. Department of Agriculture, Agricultural Research Service (ARS), Bee Research Laboratory, 10300 Baltimore Ave. Bldg. 306, BARC-East, Beltsville, MD 20705. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance in or on honey and honeycomb for residues of oxalic acid dihydrate. That document referenced a summary of the petition prepared by the petitioner, ARS, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(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. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C) and (D), which 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 . . .”, as well as consider other factors.

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and other non-occupational exposures that occur as a result of use of the pesticide.

### III. Toxicological Profile

Consistent with FFDC section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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 nature of the toxic effects caused by oxalic acid are discussed in this unit.

Oxalic acid is ubiquitous in the environment being found naturally in many plants and vegetables, as well as in honey. Oxalic acid is commonly used as an analytical reagent in textile finishing, in metal, wood, or equipment cleaning, in bleaching straw and leather, in removing paint, varnish, rust, or ink stains, in dye manufacturing, in chemical synthesis, in the paper, ceramics, photographic, and rubber industries, as well as *in vitro* as a blood specimen anticoagulant in veterinary medicine. The available data indicate decreased body weight effects occurring only at high doses. Moreover, based on the literature and due to the lack of adverse effects associated with the long history of use in a number of manufacturing processes and goods, exposure to oxalic acid is unlikely to result in short-term, long-term, prenatal developmental, or mutagenic and/or genotoxic toxicological effects. A full discussion of the literature and background on the toxicological profile of oxalic acid can be found in docket number EPA-HQ-OPP-2020-0176 in the documents titled “Oxalic Acid. Label Amendment Regarding Use in Beehives with Honey Supers to Control Varroa Mites” and “Oxalic Acid. New Use in Beehives to control Varroa mites.”

### IV. Aggregate Exposures

In examining aggregate exposure, FFDC section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

Oxalic acid is ubiquitous in the environment being found naturally in many plants and vegetables, as well as in honey. Available studies and literature indicate that residues in or on honey from the proposed use will be insignificant and indistinguishable from background levels of oxalic acid, and due to the lack of toxicity, exposure is not expected to pose a risk. EPA had also considered the potential for aggregate exposure to oxalic acid residues in food and all other non-occupational exposures, including drinking water (ground and surface) and other pesticide uses in gardens, lawns, and/or buildings (residential and other indoor uses). The proposed use does not change the previous assessment’s conclusions about drinking water and residential exposure.

### V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDC 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 oxalic acid to share a common mechanism of toxicity with any other substances, and oxalic acid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that oxalic acid 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 website at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

### VI. Determination of Safety for U.S. Population, Infants and Children

Based on the lack of toxicity and the fact that residues will be below and

indistinguishable from naturally occurring oxalic acid, EPA concludes that there is a reasonable certainty that no harm to the general U.S. population or any population subgroup, including infants and children, will result from aggregate exposure when considering dietary exposure and all other non-occupational sources of pesticide exposure. Accordingly, EPA finds that exempting residues of oxalic acid from the requirement of a tolerance will be safe.

### VII. Other Considerations

#### *Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

### VIII. Conclusion

Therefore, an exemption is established for residues of oxalic acid in or on honey and honeycomb when applied to beehives.

### IX. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDC 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 action has been exempted from review under Executive Order 12866, this action 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), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action 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 FFDC section 408(d), such as the exemption 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 action 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 FFDC 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (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 (NTTAA) (15 U.S.C. 272 note).

#### X. 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: December 23, 2020.

**Marietta Echeverria,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

#### **PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

■ 1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.1381 to subpart D to read as follows:

##### **§ 180.1381 Oxalic Acid; exemption from the requirement of a tolerance.**

Residues of oxalic acid in or on honey and honeycomb are exempted from the requirement of a tolerance when oxalic acid is used as a miticide in honeybee hives.

[FR Doc. 2021–03256 Filed 2–22–21; 8:45 am]

**BILLING CODE 6560–50–P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **42 CFR Part 100**

**RIN 0906–AB24**

#### **National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table; Delay of Effective Date**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Final rule; delay of effective date.

**SUMMARY:** In accordance with the Presidential directive as expressed in the memorandum of January 20, 2021, from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” this action delays until April 23, 2021, the effective date of the rule entitled “National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table,” published in the **Federal Register** on January 21, 2021 (January 21, 2021 Final Rule).

**DATES:** As of February 22, 2021, the effective date of the January 21, 2021 Final Rule, published in the **Federal Register** at 86 FR 6249, is delayed for 60 days, from February 22, 2021 to April 23, 2021.

**FOR FURTHER INFORMATION CONTACT:** Please visit the National Vaccine Injury Compensation Program’s website, <https://www.hrsa.gov/>

*vaccinecompensation/*, or contact Tamara Overby, Acting Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, Room 08N146B, 5600 Fishers Lane, Rockville, MD 20857; by email at [vaccinecompensation@hrsa.gov](mailto:vaccinecompensation@hrsa.gov); or by telephone at (855) 266–2427.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

HHS published a notice of proposed rulemaking on July 20, 2020 (85 FR 43794), and a final rule on January 21, 2021 (86 FR 6249). The January 20, 2021 Final Rule amended the provisions of 42 CFR 100.3 by removing Shoulder Injury Related to Vaccine Administration (SIRVA), vasovagal syncope, and Item XVII from the Vaccine Injury Table. The January 20, 2021 memorandum from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” instructed Federal agencies to consider delaying the effective date of rules published in the **Federal Register**, but which have not yet taken effect, for a period of 60 days so that the new Administration may review recently published rules for “any questions of fact, law, and policy the rule may raise.” The memorandum notes certain exceptions that do not apply here. On January 20, 2021, the Office of Management and Budget (OMB) also published OMB Memorandum M–21–14, Implementation of Memorandum Concerning Regulatory Freeze Pending Review, which provides guidance regarding the Regulatory Freeze Memorandum. See OMB M–21–14, Implementation of Memorandum Concerning Regulatory Freeze Pending Review, <https://www.whitehouse.gov/wp-content/uploads/2021/01/M-21-14-Regulatory-Review.pdf>. OMB M–21–14 explains that pursuant to the Regulatory Freeze Memorandum, agencies “should consider postponing the effective dates for 60 days and reopening the rulemaking process” for “rules that have not yet taken effect and about which questions involving law, fact, or policy have been raised.” *Id.*

On February 12, 2021, HHS published a notice of proposed rulemaking, proposing, after a brief public comment period, to delay the effective date of the January 21, 2021 Final Rule for 60 days, from February 22, 2021, to April 23, 2021. HHS did so to determine whether the January 21, 2021 Final Rule’s promulgation raises any legal issues, including but not limited to (1) whether the Advisory Commission on Childhood Vaccines (ACCV) was properly notified of the proposed rule pursuant to 42