ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0146; FRL–10018–54]

Complex Polymeric Polyhydroxy Acids (CPPA); Amendment to the Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the existing tolerance exemption for residues of Complex Polymeric Polyhydroxy Acids (CPPA) in or on all food commodities as a plant growth regulator to add use as a nematicide in pesticide formulations. FBSciences, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) requesting this amendment. This regulation adds use as a nematicide to the existing tolerance exemption of CPPA under FFDCA.

DATES: This regulation is effective February 19, 2021. Objections and requests for hearings must be received on or before April 20, 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–2020–0146, 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: Charles Smith, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@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.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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–2020–0146 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 20, 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–2020–0146, 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

In the **Federal Register** of May 05, 2020 (85 FR 26684) (FRL–10008–46), 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 0F8822) by FBSciences, Inc., 153 N. Main Street, Ste. 100, Collierville, TN 38017–2691. The petition requested that 40 CFR 180.1321 be amended by the addition of use as a nematicide to the already established exemption from the requirement of a tolerance for residues of Complex Polymeric Polyhydroxy Acids (CPPA). That document referenced a summary of the petition prepared by the petitioner FBSciences, Inc., which is available in the docket for this action at *http://www.regulations.gov.* Although comments were received on the notice of filing, none were relevant to this tolerance rulemaking.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of 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 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 making a determination to establish or maintain 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), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance 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. . . .'' Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider ''available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity. . . .''

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 through other exposures that occur as a result of pesticide use in residential settings.

II. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A. Overview of Complex Polymeric Polyhydroxy Acids

Complex Polymeric Polyhydroxy Acids (CPPA) is a complex mixture of naturally occurring organic substances found in dead plant materials. The components of CPPA are widespread in nature, being found in soils and fresh and saltwater environments as a result of decaying plant materials and are used to condition agricultural soils. Its major components are humic acid, fulvic acid, and tannins, and their relative concentrations in soil and water systems are influenced by environmental conditions, such as climate, soil types, vegetation, and hydrology. CPPA is made by concentrating the organic substances from water leached through forest soil using a proprietary manufacturing process.

B. Biochemical Pesticide Toxicology Data Requirements

All applicable mammalian toxicology data requirements supporting the existing tolerance exemption for residues of CPPA in or on all food commodities as a plant growth regulator have been fulfilled. The mammalian toxicology data requirements supporting the addition of nematicide use to the existing tolerance exemption have also been fulfilled as EPA has relied upon the same mammalian toxicology data that supported the existing tolerance exemption for CPPA. No acute, subchronic, or chronic toxicity endpoints were identified in guideline studies or in data obtained from open technical literature. Moreover, CPPA is not a mutagen, and is not a developmental toxicant. There are no known effects on endocrine systems via oral, dermal, or inhalation exposure. A more in-depth synopsis of the data upon which EPA relied and its human health risk assessment based on that data can be found in the document ''Biopesticides Registration Action Document, Complex Polymeric Polyhydroxy Acids (CPPA),'' which is available in Docket Number EPA–HQ–OPP–2009–0917–0011, as well as the docket for this action, via *www.regulations.gov* as described under **ADDRESSES**.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA 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).

A. Dietary Exposure

The proposed use pattern may result in dietary exposure with possible residues in or on agricultural commodities. No significant exposure via drinking water is expected beyond what is already present, when CPPA is used according to the product label directions, because the active ingredient biodegrades rapidly (half-life = 25.7 days) in the environment, is applied at low application rates, and is not directly applied to water. Should exposure occur, however, minimal to no risk is expected for the general population, including infants and children, due to low toxicity of CPPA and its components as demonstrated in the data submitted and evaluated by the Agency. In addition, the lack of reported incidents in spite of the exposure from use in commercial agriculture for years to condition soils and its abundance in nature support a conclusion that minimal to no risk is expected.

B. Other Non-Occupational Exposure

Non-occupational exposure is not expected because CPPA will be applied as a plant growth regulator and nematicide for agricultural purposes only and there are no residential uses.

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

Section 408(b)(2)(D)(v) of FFDCA requires that, in establishing a tolerance or tolerance exemption for a pesticide chemical residue, the Agency consider ''available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity. . . .'' EPA has determined CPPA to have a non-toxic mode of action; therefore, 408(b)(2)(D)(v) does not apply.

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

FFDCA section 408(b)(2)(C) provides that, in establishing a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) 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 that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data are available to support the choice of a different safety factor. As part of its qualitative assessment, EPA evaluated the available toxicity and exposure data on CPPA and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA considers the toxicity database to be complete and has identified no residual uncertainty with regard to prenatal and postnatal toxicity or exposure. No hazard was identified based on the available studies. Based upon its evaluation, EPA concludes that there are no threshold effects of concern to infants, children, or adults when CPPA

is applied as a plant growth regulator or nematicide and used in accordance with label directions and good agricultural practices. As a result, EPA concludes that no additional margin of exposure (safety) is necessary.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for Complex Polymeric Polyhydroxy Acids (CPPA) because EPA is amending an exemption from the requirement of a tolerance without any numerical limitation.

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). Codex 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 an MRL for CPPA.

VIII. Conclusion

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of CPPA. Therefore, EPA is establishing an exemption from the requirement of a tolerance for residues of CPPA in or on all food commodities when applied as a nematicide and used in accordance with good agricultural practices.

IX. Statutory and Executive Order Reviews

This action establishes a tolerance exemption 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 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 FFDCA section 408(d), such as the tolerance 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 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 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: February 16, 2021.

Charles Smith,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended 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. Revise § 180.1321 to read as follows:

§ 180.1321 Complex Polymeric Polyhydroxy Acids; exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for the residues of complex polymeric polyhydroxy acids in or on all food commodities when applied as a plant growth regulator and used in accordance with good agricultural practices.

(b) An exemption from the requirement of a tolerance is established for the residues of complex polymeric polyhydroxy acids in or on all food commodities when applied as a nematicide and used in accordance with good agricultural practices.

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