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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA-HQ-OPP-2017-0115; FRL-9969-94]

Pseudomonas fluorescens 4-hydroxyphenylpyruvate dioxygenase (HPPD-4); 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 the HPPD-4 protein derived from the 4-hydroxyphenylpyruvate dioxygenase enzyme of *Pseudomonas fluorescens* in or on all food commodities, when used as a plant-incorporated protectant inert ingredient. Bayer CropScience LP submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting this exemption from the requirement of a tolerance. This regulation eliminates the need under FFDCA to establish a maximum permissible level for such residues.

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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-2017-0115, 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. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION, CONTACT: Robert McNally, 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 174 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*.

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-2017-0115 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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-2017-0115, 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 June 8, 2017 (82 FR 26639 (FRL-9961-90) and 82 FR 26641 (FRL-9961-14)), EPA issued notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (IN-11022) by Bayer CropScience LP 2 T.W. Alexander Dr. Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for plant-pesticide inert HPPD-4 in or on all food commodities. A summary of the petition prepared by the petitioner Bayer CropScience LP, is available in the docket via *http://www.regulations.gov.* There were no comments received in response to either notice.

Two modifications have been made to the original request for a tolerance exemption. EPA changed "plant-pesticide inert" to "plant-incorporated protectant inert" to align with the Agency's vocabulary, which is published in 40 CFR part 174.3. Also, because EPA publishes all tolerances or exemptions for plant-incorporated protectants in part 174, EPA's rule is being issued in part 174, rather than part 180 as requested.

III. Final Rule

A. EPA's Safety Determination

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 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), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption 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 . . . ." Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity."

EPA evaluated the available toxicity and exposure data on HPPD-4 and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which EPA relied and its risk assessment based on that data can be found within the October 02, 2017, document entitled "Federal Food, Drug, and Cosmetic Act (FFDCA) Assessment of the plant-incorporated protectant inert *Pseudomonas fluorescens* 4-hydroxyphenylpyruvate dioxygenase (HPPD-4)." This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

The HPPD-4 protein is derived from the 4-hydroxyphenylpyruvate dioxygenase (HPPD) enzyme of the bacterium *Pseudomonas fluorescens*. Four amino acid changes were made to the original bacterial protein sequence in order to decrease the binding efficacy of the HPPD-inhibitor herbicide. The resulting modified protein (the HPPD-4 protein) is the PIP inert ingredient. As a PIP inert, the HPPD-4 protein functions as a selectable marker in a PIP.

Based upon available data, EPA concludes that the HPPD-4 protein derived from the *Pseudomonas fluorescens* HPPD enzyme does not show evidence of toxicity. Moreover, the source is not allergenic, nor is there any significant similarity between the HPPD-4 protein and known toxins and allergens. In addition, the HPPD-4 protein readily digests in gastric fluids and therefore cumulative, chronic, and acute effects are unlikely.

Given the lack of toxicity or allergenicity of the HPPD-4 protein, the Agency has not identified any toxicological endpoints for assessing risk. Consequently, the Agency's assessment of exposure is qualitative. In addition, due to the lack of any threshold effects, EPA has determined that the provision to retain a 10X safety factor for the protection of infants and children does not apply. Similarly, the lack of any toxic mode of action or toxic metabolites means that the provision requiring an assessment of cumulative effects does not apply.

Oral exposure may occur from ingestion of the raw crops containing HPPD-4, as well as their processed derivatives. Currently, HPPD-4 is only proposed to be used as a PIP inert ingredient in soybean, although it could be used in other crops in the future. The current proposed use results in the presence of HPPD-4 protein at low levels within the plant, although future uses could be higher. Based on the lack of adverse effects and the rapid digestibility of the protein, however, the Agency does not anticipate any risk from reasonably foreseeable levels of exposure. Residues in drinking water may theoretically be present because plant stubble may release modified HPPD-4 protein into ground water upon decay. However, the protein would not be expected to survive in the soil due to microbial degradation, adherence to soil components, and removal upon drinking water treatment procedures. In addition, oral toxicity testing showed no adverse effects. Moreover, because the PIP inert ingredient is currently only proposed to be used only in plants grown for commercial use, the Agency does not anticipate residential exposures. In the event that future uses are sold for residential use,

the Agency does not expect there to be residential, non-occupational dermal or inhalation exposures, due to containment of the HPPD-4 protein within the plant.

Based on the lack of any evidence of adverse effects in the toxicological database, dietary exposure to the HPPD-4 protein is not anticipated to pose any harm to the U.S. population. 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 the HPPD-4 protein derived from the *Pseudomonas fluorescens* HPPD enzyme. Therefore, an exemption from the requirement of a tolerance is established for residues of the plant-incorporated protectant inert ingredient *Pseudomonas fluorescens* HPPD-4 protein in or on all food commodities.

B. Analytical Enforcement Methodology

An analytical method is not required because the lack of adverse effects makes enforcement and monitoring of residues unnecessary to ensure food safety.

IV. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to EPA. 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). 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 action, 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. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA 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, EPA 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 EPA's 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).

V. 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 174

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 13, 2017.

Richard P. Keigwin, Jr.,
Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 174--[AMENDED]

1. The authority citation for part 174 continues to read as follows:

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

2. Add § 174.537 to subpart W to read as follows:

§174.537 HPPD-4 protein; exemption from the requirement of a tolerance.

Residues of the HPPD-4 protein, which is a modified protein derived from the 4-hydroxyphenylpyruvate dioxygenase enzyme of *Pseudomonas fluorescens*, in or on all food commodities are exempt from the requirement of a tolerance, when the HPPD-4 protein is used as a plant-incorporated protectant inert ingredient.

[FR Doc. 2017-26086 Filed: 12/1/2017 8:45 am; Publication Date: 12/4/2017]