in table 1: zinc, 3-methyl-4-chlorophenol.

(iv) *Freshwater and saltwater aquatic life criteria.* Freshwater and saltwater aquatic life criteria apply as specified in paragraph (c)(3) of this section.

* * * * *

(c) * * *

(3) * * *

(ii) For waters in which the salinity is equal to or greater than 10 parts per thousand 95% or more of the time, the applicable criteria are the saltwater criteria in column C, except for selenium in waters of the San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta where the applicable criteria are the freshwater criteria in column B of the National Toxic Rule (''NTR'') at § 131.36.

(iii) For waters in which the salinity is between 1 and 10 parts per thousand as defined in paragraphs (c)(3)(i) and (ii) of this section, the applicable criteria are the more stringent of the freshwater or saltwater criteria, except for selenium in waters of the San Francisco Bay upstream to and including Suisun Bay and the Sacramento-San Joaquin Delta where the applicable criteria are the freshwater criteria in column B of the NTR. However, the Regional Administrator may approve the use of the alternative freshwater or saltwater criteria if scientifically defensible information and data demonstrate that on a site-specific basis the biology of the water body is dominated by freshwater aquatic life and that freshwater criteria are more appropriate; or conversely, the biology of the water body is dominated by saltwater aquatic life and that saltwater criteria are more appropriate. Before approving any change, the EPA will publish for public comment a document proposing the change.

* * * * *

[FR Doc. 2024–29483 Filed 12–16–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2022–0231; FRL–12399–01–OCSPP]

Brevibacillus Laterosporus Mpp75Aa1.1 and Bacillus Thuringiensis Vpb4Da2 Proteins; Exemptions From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of the *Brevibacillus laterosporus* Mpp75Aa1.1 and *Bacillus thuringiensis* Vpb4Da2 proteins (hereafter Mpp75Aa1.1 and Vpb4Da2 proteins) in or on the food and feed commodities of corn: corn, field; corn, sweet, and corn, pop when used as plant-incorporated protectants (PIP) in corn. Bayer CropScience LP., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting these exemptions. These regulations eliminate the need to establish maximum permissible levels for residues of Mpp75Aa1.1 and Vpb4Da2 proteins.

DATES: This regulation is effective December 17, 2024. Objections and requests for hearings must be received on or before February 18, 2025, 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–2022–0231, is available at *https://www.regulations.gov*. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Madison Le, Biopesticides and Pollution Prevention Division (7511M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 564–5754; 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 Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-174.*

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–2022–0231, 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 February 18, 2025. 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–2022–0231, by one of the following methods:

Federal eRulemaking Portal: https://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 *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

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

II. Background and Statutory Findings

In the **Federal Register** of December 19, 2023 (88 FR 87733) (FRL–10579–11–OCSPP), 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 3F9076) by Bayer CropScience LP, 800 N. Lindbergh Blvd., St. Louis, Missouri 63167. The petition requested that 40 CFR part 174 be amended by establishing an exemption from the requirement of a tolerance for residues of the plant-incorporated protectants (PIPs) *Brevibacillus laterosporus* Mpp75Aa1.1 and *Bacillus thuringienisis* Vpb4Da2 in or on corn. That document referenced a summary of the petition prepared by the petitioner Bayer Crop Science LP, which is available in the docket at *https://www.regulations.gov.* There was one comment received in response to the notice of filing.

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 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 it 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 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 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 evaluated the available toxicity and exposure data on Mpp75Aa1.1 and Vpb4Da2 proteins and considered their validity, completeness, and reliability, as well as 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. A summary of the data upon which EPA relied and its risk assessment based on those data can be found within the document entitled ''Review of the Application for an Experimental Use Permit to Test MON 95275 Corn (OECD Unique Identifier MON–95275–7) Expressing Transgenic Plant-Incorporated Protectants Mpp75Aa1.1, Vpb4Da2, and Double Stranded RNA DvSnf7.1 and the Genetic Material Necessary for their Production (Vector PV–ZMIR525664)'' (hereafter Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action EPA–HQ–OPP–2022–0231.

Mpp75Aa1.1 is a modified protein derived from the bacterium *Brevibacillus laterosporus* and is active against certain coleopteran pests of corn. Available data demonstrated that, with regard to humans, the Mpp75Aa1.1 protein does not pose a toxic or allergenic risk. An acute oral toxicity study using purified Mpp75Aa1.1 protein shows that the protein is not toxic to mammals via the oral route of exposure at levels well above those that are reasonably anticipated through normal dietary consumption of the crop. In addition, a bioinformatics analysis of the primary protein sequence did not identify any significant homologies of the Mpp75Aa1.1 protein to known mammalian toxins. Likewise, the potential for allergenicity is low because: (1) the bacterial source of the Mpp75Aa1.1 protein, *Brevibacillus laterosporus,* is ubiquitous in the environment, which implies widespread human and animal exposure, and a scientific literature search of the bacterium did not indicate any allergenic history; (2) bioinformatic analyses indicate no biologically relevant similarity between the Mpp75Aa1.1 protein and any known allergens; (3) the Mpp75Aa1.1 protein degrades rapidly when exposed to digestive enzymes (gastric proteases) present in the human gastrointestinal tract; (4) the Mpp75Aa1.1 protein shows loss of function under high temperatures (≥75 °C), indicating that it is heat labile and will likely denature in the course of normal thermal treatment during food preparation; and (5) the Mpp75Aa1.1 protein is not glycosylated, which further reduces its allergenicity potential. Glycosylation is an enzymatic post-translational process in which carbohydrates (glycans) link to proteins, creating structures which could lead to an immune response in humans.

The most likely route of exposure to this plant-incorporated protectant is dietary, via products produced from corn expressing the Mpp75Aa1.1 protein. Oral exposure from ingestion of drinking water is unlikely because the Mpp75Aa1.1 protein is present at very low levels within the plant cells, and the amounts likely to enter the water column from leaves, pollen or plant detritus are low. Further, if Mpp75Aa1.1 protein were to enter the water column, it is expected to break down rapidly through natural processes (*e.g.,* microbial or UV degradation) or normal communal water-treatment procedures. Even if there may be dietary exposure to residues of the Mpp75Aa1.1 protein, such exposure presents no concern for adverse effects based on the available toxicity and allergenicity analysis mentioned above.

Non-dietary non-occupational exposure via dermal or ocular routes is not likely since the Mpp75Aa1.1 protein is contained within plant cells. The most likely non-dietary route of exposure to the Mpp75Aa1.1 protein may be through inhalation of corn pollen. However, exposure to the Mpp75Aa1.1 protein through this route of exposure is expected to be negligible for several reasons: (1) its presence in pollen was demonstrated to be very low (below the limit of quantification), and (2) corn pollen is not respirable, as it consists of spherical particles ranging in size from 80 to 125 µm, in contrast with respirable particles that are less than 10 µm. Even if inhalation of dust-like particles were to occur, the Mpp75Aa1.1 protein is contained within plant cells, which essentially eliminates pulmonary exposure to the proteins. Further, as described above, such exposure would not be expected to present any risk due to the lack of toxicity or allergenicity observed for the Mpp75Aa1.1 protein. These findings are discussed in more detail in the Human Health Risk Assessment.

Vpb4Da2 is derived from the bacterium *Bacillus thuringiensis* (*Bt*) and is active against certain coleopteran pests of corn. Available data demonstrated that, with regard to humans, the Vpb4Da2 protein does not pose a toxic or allergenic risk. An acute oral toxicity study using purified Vpb4Da2 protein shows that the protein is not toxic to mammals via the oral route of exposure at levels well above those that are reasonably anticipated through normal dietary consumption of the crop. In addition, a bioinformatics analysis of the primary protein sequence

did not identify any significant homologies of the Vpb4Da2 protein to known mammalian toxins. Likewise, the potential for allergenicity is low because: (1) the bacterial source of the Vpb4Da2 protein, *Bacillus thuringiensis,* has a long history of safe use, including use as a pesticide, and is not considered to be a source of allergenic proteins; (2) bioinformatic analyses indicate no biologically relevant similarity between the Vpb4Da2 protein and any known allergens; (3) the Vpb4Da2 protein degrades rapidly when exposed to digestive enzymes (gastric proteases) present in the human gastrointestinal tract; (4) the Vpb4Da2 protein shows loss of function under high temperatures (≥55 °C), indicating that it is heat labile and will likely denature in the course of normal thermal treatment during food preparation; and (5) the Vpb4Da2 protein is not glycosylated, which further reduces its allergenicity potential. Glycosylation is an enzymatic post-translational process in which carbohydrates (glycans) link to proteins, creating structures which could lead to an immune response in humans.

The most likely route of exposure to this plant-incorporated protectant is dietary, via products produced from corn expressing the protein. Oral exposure from ingestion of drinking water is unlikely because the Vpb4Da2 protein is present at very low levels within the plant cells and the amounts likely to enter the water column from leaves, pollen or plant detritus are low. Further, if protein were to enter the water column, it is expected to break down rapidly through natural processes (*e.g.,* microbial or UV degradation) or normal communal water-treatment procedures. Even if there may be dietary exposure to residues of the Vpb4Da2 protein, such exposure presents no concern for adverse effects based on the toxicity and allergenicity discussion above.

Non-dietary non-occupational exposure via dermal or ocular routes is not likely since the Vpb4Da2 protein is contained within plant cells. The most likely non-dietary route of exposure to the Vpb4Da2 protein may be through inhalation of corn pollen. However, exposure to the Vpb4Da2 protein through this route of exposure is expected to be negligible for several reasons: (1) its presence in pollen was demonstrated to be very low (below the limit of quantification), and (2) corn pollen is not respirable, as it consists of spherical particles ranging in size from 80 to 125 µm, in contrast with respirable particles that are less than 10 µm. Even if inhalation of dust-like particles were to occur, the Vpb4Da2 protein is contained within plant cells, which essentially eliminates pulmonary exposure to the proteins. Further, as described above, such exposure would not be expected to present any risk due to the lack of toxicity or allergenicity observed for the Vpb4Da2 protein These findings are discussed in more detail in the Human Health Risk Assessment.

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.'' No risk of cumulative toxicity or effects from the Mpp75Aa1.1 protein has been identified as no toxicity or allergenicity has been shown for this protein in the submitted studies. Therefore, EPA has concluded that the Mpp75Aa1.1 protein does not have a common mechanism of toxicity with other substances. Similarly, no risk of cumulative toxicity or effects from the Vpb4Da2 protein has been identified as no toxicity or allergenicity has been shown for this protein in the submitted studies. Therefore, EPA has concluded that the Vpb4Da2 protein does not have a common mechanism of toxicity with other substances.

Although FFDCA section 408(b)(2)(C) provides for an additional tenfold margin of safety for infants and children in the case of threshold effects, EPA has determined that there are no such effects due to the lack of toxicity of the Mpp75Aa1.1 protein. As a result, an additional margin of safety for the protection of infants and children is unnecessary. Similarly, EPA has determined that there are no such effects due to the lack of toxicity of the Vpb4Da2 protein. As a result, an additional margin of safety for the protection of infants and children is unnecessary.

Based upon its evaluation described above and in the Human Health Risk Assessment, 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 Mpp75Aa1.1 protein derived from the bacterium *Brevibacillus laterosporus.* Therefore, an exemption from the requirement of a tolerance is established for residues of the Mpp75Aa1.1 protein in or on the food and feed commodities of corn: corn, field; corn, sweet; and corn, pop when used as a plant-incorporated protectant in corn.

Similarly, based upon its evaluation described above and in the Human Health Risk Assessment, 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 Vpb4Da2 protein derived from the bacterium *Bacillus thuringiensis* (*Bt*). Therefore, an exemption from the requirement of a tolerance is established for residues of the Vpb4Da2 protein in or on the food and feed commodities of corn: corn, field; corn, sweet; and corn, pop when used as a plant-incorporated protectant in corn.

B. Analytical Enforcement Methodology

EPA has determined that validated Enzyme-Linked Immunosorbent Assays (ELISA) are available for the detection of Mpp75Aa1.1 and Vpb4Da2 proteins. These assays have been demonstrated to reliably detect the levels of the Mpp75Aa1.1 and Vpb4Da2 proteins in the tissues of corn.

C. Response to Comment

One comment was received during the public comment period for the notice of filing. The commentor provided general objections to EPA establishing exemptions from tolerances for pesticides but did not provide any specific or substantive objections to the petition to exempt the Mpp75Aa1.1 and Vpb4Da2 proteins when used as plant-incorporated protectants. Based on its review of the data and other information submitted in support of the tolerance exemption petition (as described above in Unit III.A), EPA has determined that a tolerance exemption for Mpp75Aa1.1 and Vpb4Da2 proteins, when used as plant-incorporated protectants, is safe under the FFDCA. Therefore, EPA is establishing an exemption from the requirement of a tolerance for residues of Mpp75Aa1.1 and Vpb4Da2 proteins in or on the food and feed commodities of corn.

IV. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of 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 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 exemptions from the requirement of a 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 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).

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: December 4, 2024.

Edward Messina,

Director, Office of Pesticide Programs.

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

PART 174—PROCEDURES AND REQUIREMENTS FOR PLANT-INCORPORATED PROTECTANTS

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

Authority: 7 U.S.C. 136–136y; 21 U.S.C. 321(q), 346a and 371.

■ 2. Add §§ 174.551 and 174.552 to subpart W to read as follows:

Subpart W—Tolerances and Tolerance Exemptions

* * * * *

§ 174.551 *Brevibacillus laterosporus* Mpp75Aa1.1 protein; exemption from the requirement of a tolerance.

Residues of *Brevibacillus laterosporus* Mpp75Aa1.1 protein in or on the food and feed commodities of corn: corn, field; corn, sweet; and corn, pop are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in corn.

§ 174.552 *Bacillus thuringiensis* Vpb4Da2 protein; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Vpb4Da2 protein in or on the food and feed commodities of corn: corn, field; corn, sweet; and corn, pop are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in corn.

[FR Doc. 2024–29133 Filed 12–16–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

[Docket No. CDC–2020–0024]

RIN 0920–AA71

Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This rule finalizes updates to the HHS list of select agents and toxins that could pose a severe threat to public health and safety. These updates were proposed along with other changes to the select agent and toxin regulations, which will be addressed in a separate regulatory action. In a companion document published in this issue of the **Federal Register**, the U.S. Department of Agriculture (USDA) is making parallel regulatory changes.

DATES: This final rule is effective January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Daniel A. Singer, MD, Acting Director, Division of Regulatory Science and Compliance, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–4, Atlanta, Georgia 30329. Telephone: (404) 553–8266.

SUPPLEMENTARY INFORMATION: The final rule is organized as follows: