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, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the State Plan is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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 May 15, 2023. 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. 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 62

Environmental protection, Air pollution control, Administrative practice and procedure, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur oxides, Waste treatment and disposal.

Dated: March 6, 2023.

David Cash,

Regional Administrator, EPA Region 1.

Part 62 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 62—APPROVAL AND PROMULGATION OF STATE PLAN FOR DESIGNATED FACILITIES AND POLLUTANTS

■ 1. The authority citation for part 62 continues to read as follows:

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

Subpart U—Maine

■ 2. Amend Section 62.4845 by revising paragraph (b)(4) and adding paragraphs (b)(7) and (8) and (d) to read as follows:

§ 62.4845

* * * * *

(b)

* * * * *

(4) Control of metals, acid gases, organic compounds and nitrogen oxide emissions from existing large municipal waste combustors with the capacity to combust greater than 250 tons per day of municipal solid waste, submitted on April 15, 1998.

* * * * *

(7) A revision to the plan controlling metals, acid gases, organic compounds and nitrogen oxide emissions from large municipal waste combustors with the capacity to combust greater than 250 tons per day of municipal solid waste, submitted on December 24, 2019 (incorporated by reference, see paragraph (d)(1) of this section).

(8) Control of metals, acid gases, organic compounds and nitrogen oxide emissions from existing small municipal waste combustors with the capacity to combust less than or equal to 250 tons per day of municipal solid waste, submitted on December 24, 2019 (incorporated by reference, see paragraph (d)(1) of this section).

* * * * *

(d) *Incorporation by reference.* The material listed in this paragraph (d) is incorporated by reference in this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the EPA and at the National Archives and Records Administration (NARA). Contact EPA at: EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square-Suite 100, Boston, MA, 617–918–1111. For information on the availability of this material at NARA, visit: *www.archives.gov/federal-register/cfr/ibr-locations.html* or email *fr.inspection@nara.gov.* The material may be obtained from: State of Maine, Maine Department of Environmental Protection. 17 State House Station, 28 Tyson Drive, Augusta, Maine 04333, 207–287–7688, *www.maine.gov/dep/:*

(1) 06–096 Code of Maine Regulations: Department of Environmental Protection, Chapter 121, ''Emission Limitations and Emission Testing of Resource Recovery Facilities,'' excluding Section 6 ''Large Municipal Waste Combustor Units Subject to 40 CFR part 60, subpart Eb,'' amended September 14, 2019.

(2) [Reserved]

■ 3. Section 62.4975 is revised to read as follows:

§ 62.4975 Identification of sources.

(a) Penobscot Energy Recovery Company, Orrington, Maine

(b) [Reserved]

(c) ecomaine, Portland, Maine

■ 4. Add an undesignated center heading and § 62.5000 to subpart U to read as follows:

Metals, Acid Gases, Organic Compounds and Nitrogen Oxide Emissions From Existing Municipal Waste Combustors With the Capacity To Combust Less Than or Equal to 250 Tons per Day of Municipal Solid Waste

§ 62.5000 Identification of sources.

(a) Mid-Maine Waste Action Corporation, Auburn, Maine

(b) [Reserved]

[FR Doc. 2023–05020 Filed 3–13–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2020–0234; FRL–10776–01–OCSPP]

BLB2 and AMR3 Proteins in Potato; Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the BLB2 and AMR3 proteins in potato, when used as a plant-incorporated protectant (PIP) in accordance with the terms of Experimental Use Permit (EUP) No. 8971–EUP–3. J.R. Simplot Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act

(FFDCA), requesting the temporary tolerance exemption. This regulation eliminates the need under FFDCA to establish a maximum permissible level for residues of BLB2 and AMR3 proteins. The temporary tolerance exemption expires on March 31, 2024.

DATES: This regulation is effective March 14, 2023. Objections and requests for hearings must be received on or before May 15, 2023, 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–2020–0234, is available at *https://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 and the OPP Docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, 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) 566–1400; 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 Publishing Office's e-CFR site at *https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-174?toc=1.*

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–2020–0234 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 May 15, 2023. 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–2020–0234, 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

In the **Federal Register** of June 24, 2020 (85 FR 37806) (FRL–10010–82), 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 0G8830) by J.R. Simplot Company, 5369 W Irving Street, Boise, ID 83706. The petitioner requested that 40 CFR part 174 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of the plant-incorporated protectants BLB2 and AMR3 proteins in potato. That document referenced a summary of the petition prepared by the petitioner J.R. Simplot Company, which is available in the docket via *https://www.regulations.gov.* There were no comments received in response to the Notice of Filing.

III. Final Rule

A. EPA's Safety Determination

Section 408(r) of FFDCA authorizes EPA to establish a temporary exemption from the requirement of a tolerance for residues covered by an experimental use permit issued under the Federal Insecticide, Fungicide, and Rodenticide Act. That section states that the provisions of section 408(c)(2) of FFDCA apply to exemptions issued under FFDCA section 408(r). 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), 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 BLB2 and AMR3 proteins and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. In summary, the available data does not indicate any adverse effects due to toxicity or allergenicity of the BLB2 and AMR3 proteins. A full summary of the data upon which EPA relied and its risk assessments based on that data can be found within the document entitled ''Review of the Application for an Experimental Use Permit for Gen 3 Potatoes expressing transgenic R-proteins BLB2, AMR3 and VNT1, PVY Coat Protein Hairpin RNA and inert ingredient StmALS and associated FFDCA Petitions for the Temporary Exemption from a Tolerance for AMR3 and BLB2, as well as FFDCA Petition for the Exemption from a Tolerance for StmALS'' (Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

Available data have demonstrated that, with regard to humans, BLB2 and AMR3 proteins are not anticipated to be toxic or allergenic via any reasonably foreseeable route of exposure. The plant-incorporated protectant (PIP) active ingredients are resistance (''R'') proteins that confer protection against potato pathogens by directly or indirectly recognizing pathogen-secreted effector proteins. This recognition leads to the activation of the hypersensitive response, which is a form of programmed cell death characterized by cytoplasmic shrinkage, chromatin condensation, mitochondrial swelling, vacuolization and chloroplast disruption. This hypersensitive response pathway involves immune signaling triggered by R proteins that is specific to plants; activated R-proteins cannot trigger cell death in mammals. Thus, BLB2 and AMR3 proteins do not have a toxic mechanism of action, but instead activate signaling cascades within the plant which invoke the plant cell death pathway to prevent growth and spread of the pathogen.

There is likely to be dietary exposure to BLB2 and AMR3 through consumption of potato-derived foods containing the proteins. However, the Agency has concluded that any potential dietary risk from the use of BLB2 and AMR3 proteins to human health is considered negligible for the following reasons. (1) As described above, the mode-of-action of BLB2 and AMR3 is specific to plants and does not affect mammalian cells. (2) Both the BLB2 and AMR3 proteins are expressed at extremely low levels in potato, which indicates very low human exposure to the proteins through the consumption of BLB2- and AMR3-expressing potatoes. (3) Bioinformatics analyses of BLB2 and AMR3 proteins revealed no homology with known toxins or allergens. (4) The source organisms for the active ingredients, *Solanum bulbocastanum* (BLB2) and *Solanum americanum* (AMR3), are not known as allergens. (5) Both proteins have a history of safe use. BLB2 originates from *S. bulbocastanum* (ornamental nightshade), a close potato relative that has 82% sequency similarity with the tomato gene Mi–1, which has a history of safe use since tomatoes have been consumed by humans for hundreds of years. Furthermore, the BLB2 protein is present in two *Solanum tuberosum* potato varieties (Toluca and Bionica) that have been conventionally bred and cultivated for food use in Europe. AMR3 originates from *S. americanum* (American black nightshade) which is cultivated for medicinal and food use, and as part of breeding programs for improved nutrition. Although some members of the *Solanum* genus have toxicity, these effects are caused by glycoalkaloids, which can cause toxicity even in the common potato, *Solanum tuberosum.* Neither BLB2 nor AMR3 are glycoalkaloids; instead, they belong to a large family of R-proteins found throughout the plant kingdom. There are hundreds to thousands of R-proteins in *S. tuberosum* and other crops which have a long history of safe consumption.

Oral exposure from ingestion of drinking water is unlikely because BLB2 and AMR3 proteins are present at very low levels within the plant cells. If AMR3 and BLB2 do enter the water column, they are expected to degrade rapidly in the presence of soil microbes, or upon normal communal water-treatment procedures. In addition, there is unlikely to be residential or non-occupational exposure given that the active ingredients are plant-incorporated protectants in potato. Therefore, the only possible route of non-occupational exposure, other than dietary, is via handling of the plants and plant products. However, BLB2 and AMR3 proteins are present in the transformed potato tissues at levels below the level of detection, resulting in minimal to negligible exposure. Furthermore, there are no risks associated with these exposure routes because bioinformatics analysis and the history of safe use have shown that the proteins are not toxic or allergenic.

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 and allergenicity for these PIP active ingredients. As a result, an additional margin of safety for the protection of infants and children is unnecessary.

Based upon its evaluation, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of the BLB2 and AMR3 proteins in potatoes. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the mode-of-action, history of safe use, and lack of toxicity and allergenicity for the BLB2 and AMR3 proteins in potato.

B. Analytical Enforcement Methodology

EPA has determined that an analytical method is not required for enforcement purposes since the Agency is establishing a temporary exemption from the requirement of a tolerance without any numerical limitation. Nonetheless, the petitioner submitted a reverse transcription-quantitative polymerase chain reaction (RT-qPCR) method for detection of BLB2 and AMR3 in transformed leaves and tubers.

C. Conclusion

Based upon its evaluation 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 BLB2 and ARM3 proteins in potatoes. Therefore, an exemption from the requirement of a tolerance is established for residues of BLB2 and AMR3 proteins in potato when used in accordance with label directions and good agricultural practices.

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); Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997); or 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 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: March 6, 2023.

Charles Smith,

Director, Biopesticides and Pollution Prevention Division.

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 § 174.545 to subpart W to read as follows:

§ 174.545 BLB2 and AMR3 proteins in potato; temporary exemption from the requirement of a tolerance.

Residues of BLB2 and AMR3 proteins in potato are temporarily exempt from the requirement of a tolerance when used as a plant-incorporated protectant in potato in accordance with the terms of Experimental Use Permit No. 8917–EUP–3. This temporary exemption from the requirement of a tolerance expires on March 31, 2024.

[FR Doc. 2023–05246 Filed 3–13–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0519; FRL–10544–01–OCSPP]

Bacteriophage Active Against Pseudomonas syringae pv. syringae; Bacteriophage Active Against Xanthomonas arboricola pv. corylina; Bacteriophage Active Against Xanthomonas arboricola pv. juglandis; and Bacteriophage Active Against Xanthomonas arboricola pv. pruni; Exemptions From the Requirement of Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of Bacteriophage active against *Pseudomonas syringae* pv. *syringae,* Bacteriophage active against *Xanthomonas arboricola* pv. *corylina,* Bacteriophage active against *Xanthomonas arboricola* pv. *juglandis,* and Bacteriophage active against *Xanthomonas arboricola* pv. *pruni,* in or on all food commodities when used in accordance with label directions and good agricultural practices. OmniLytics, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of Bacteriophage active against *Pseudomonas syringae* pv. *syringae,* Bacteriophage active against *Xanthomonas arboricola* pv. *corylina,* Bacteriophage active against *Xanthomonas arboricola* pv. *juglandis,* and Bacteriophage active against *Xanthomonas arboricola* pv. *pruni* under FFDCA when used in accordance with this exemption.

DATES: This regulation is effective March 14, 2023. Objections and requests for hearings must be received on or before May 15, 2023, 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–2021–0519, is available at *https://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