(1) EPA—APPROVED PENNSYLVANIA REGULATIONS AND STATUTES—Continued

State citation	Title/subject	State effective date	EPA approval date	Additional explanation/ § 52.2063 citation
Section 127.710	Fees for the use of general plan approvals and general operating permits under Subchapter H..	1/16/2021	*8/9/2023,* [*INSERT* ***FEDERAL REGISTER*** *CITATION*].	Added section 127.710 to establish application fees for the use of general plan approvals and general operating permits for stationary or portable sources
*	*	*	*	*	*	*

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PART 70—STATE OPERATING PERMIT PROGRAMS

■ 3. The authority citation for part 70 continues to read as follows:

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

■ 4. Appendix A to part 70 is amended by adding paragraph (e) to the entry for Pennsylvania to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permit Programs

* * * * *

Pennsylvania

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(e) The Pennsylvania Department of Environmental Protection submitted a program revision to amends Chapter 127 sections 127.704 and 127.705 on July 20, 2021; approval effective on August 9, 2023.

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[FR Doc. 2023–16734 Filed 8–8–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0226; FRL–11264–01–OCSPP]

Flg22-Bt Peptide; 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 Flg22-Bt Peptide in or on all food commodities when used as a plant regulator and inducer of local and systemic resistance in accordance with label directions and good agricultural practices. Elemental Enzymes Ag & Turf, LLC submitted a petition, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), requesting an exemption from the requirement of a tolerance for the biochemical pesticide Flg22-Bt Peptide. This regulation eliminates the need to establish a maximum permissible level for residues of Flg22-Bt Peptide under FFDCA when used in accordance with this exemption.

DATES: This regulation is effective August 9, 2023. Objections and requests for hearings must be received on or before October 10, 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–2021–0226, 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: Chris Pfeifer, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1599; 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, greenhouse owner, 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 Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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–2021–0226 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 October 10, 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–2021–0226 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 April 22, 2021 (86 FR 21317) (FRL–10022–59), 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 0F8889) by Elemental Enzymes Ag & Turf, LLC, 1685 Galt Industrial Blvd. Saint Louis, MO 63132. The petition requested that 40 CFR part 180 be amended to establish an exemption from the requirement of a tolerance for residues of Flg22-Bt Peptide, when used as a plant regulator and an inducer of local and systemic resistance in accordance with label directions and good agricultural practices. That document referenced a summary of the petition prepared by Elemental Enzymes Ag & Turf, LLC, which is available in the docket at *https://www.regulations.gov.* No comments were received on the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

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 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 establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm to human health. If EPA is able to determine that a tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure to Flg22-Bt Peptide, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with Flg22-Bt Peptide follows.

A. Toxicological Profile

Flg22-Bt Peptide is a synthetically produced and purified peptide containing 22 amino acids. The amino acid sequence is naturally occurring and is derived from the *Bacillus thuringiensis* flagellin protein. *Bacillus thuringiensis* is a ubiquitous soil-dwelling bacterium and is a common active ingredient in microbial pesticide products. Mode-of-action claims for the active ingredient include activation of multiple plant defense mechanisms, promotion of plant growth and increased vigor. With regard to activation of plant defenses, it is proposed that the active ingredient activates plant cell-surface receptor Flagellin-Sensing 2, which results in the initiation of various intra- and extra-cellular responses that ultimately inhibit pathogen growth.

As an active ingredient in pesticidal end-use products (EPs), Flg22-Bt Peptide is intended to be applied as part of a solution, primarily as a spray applied to crops, but also as a commercial seed treatment and an injection for trees. Potential exposures to the biochemical active ingredient Flg22-Bt Peptide are not expected to result in any risks of toxicological concern. The active ingredient is naturally occurring and is derived from the *Bacillus thuringiensis* flagellin Deleprotein to which humans are already exposed. (Flagellin is the major structural protein of the flagella of Gram-negative bacteria, including *Bacillus thuringiensis,* and these microbes are ubiquitous in the environment.) Flg22-Bt Peptide is not expected to pose a risk through any pathways for the following reasons. (1) Flg22-Bt Peptide degrades in the gastrointestinal tract as it is digested by the common digestive enzyme Pepsin. (2) This peptide sequence is dissimilar to any allergenic peptide sequences. As such, the potential for any allergenicity is negligible. (3) Negligible potential for allergenicity notwithstanding, Flg22-Bt Peptide is rapidly degraded under simulated mammalian gastric conditions and will not persist long enough under these conditions to induce an allergic response. (4) Flg22-Bt Peptide degrades rapidly in the environment and is not anticipated to be present in any concentration outside potential naturally occurring background levels. (5) No toxicological endpoints have been identified for Flg22-Bt Peptide. All the data submitted in support of the registration of this peptide confirm its low toxicity profile.

With regard to the overall toxicological profile, Flg22-Bt Peptide is of low toxicity. Acute toxicity data indicate that Flg22-Bt Peptide is Toxicity Category IV for acute oral toxicity, acute dermal toxicity, dermal irritation, and eye irritation, and Toxicity Category III for acute inhalation toxicity. The available data also suggest it is not a skin sensitizer. Guideline

studies were submitted for all the acute toxicity data requirements.

All subchronic data requirements for the active ingredient Flg22-Bt Peptide (90-day oral toxicity, 90-day dermal toxicity and 90-day inhalation toxicity) were satisfied with acceptable waiver rationales, based on low toxicity and low exposure. The 90-day oral toxicity rationale provided the following points of support: (1) Flg22-Bt Peptide is of low acute oral toxicity (Toxicity Category IV); (2) based on an acceptable *in vitro* digestion study using simulated gastric fluid, Flg22-Bt Peptide is anticipated to be rapidly and completely degraded in the gastrointestinal tract; (3) a search of *in silico* databases revealed no similarity in sequence between the Flg22-Bt Peptide and any known protein toxins, indicating low toxicity through its structural relationships; (4) Flg22-Bt Peptide is naturally occurring and is derived from the *Bacillus thuringiensis* flagellin protein to which humans are regularly exposed.; and (5) dietary exposure is expected to be negligible based on low application rates (*e.g.,* maximum rate of 0.00052 lb AI/acre for foliar applications) and rapid degradation in the environment. The 90-day dermal toxicity data requirement was also addressed with an acceptable rationale that contained the same information provided to address the 90-day oral toxicity requirement combined with the following additional information: (1) the active ingredient is of low acute dermal toxicity (Toxicity Category IV), is only slightly irritating to the skin (Toxicity Category IV), and is not a skin sensitizer; and (2) significant repeat dermal exposure is not anticipated as the proposed end-use products containing this peptide will not be directly applied to the skin and will be applied in low concentrations (0.002–0.012%, by weight) at low application rates. As a final limitation to dermal exposure, personal protective equipment (PPE) required for pesticides using Flg22-Bt Peptide (*i.e.,* long-sleeved shirt and long pants, shoes plus socks, and waterproof gloves) will mitigate dermal exposure to pesticide applicators and other handlers. The 90-day inhalation toxicity data requirement was also addressed with an acceptable rationale that contained the same information used to address the 90-day oral toxicity requirement combined with the following additional information: (1) Flg22-Bt Peptide is of low acute inhalation toxicity; (2) because Flg22-Bt Peptide is of low acute toxicity for all paths of exposure, there is minimal concern for localized or portal-of-entry inhalation effects; (3) significant repeat inhalation exposure is not anticipated as the proposed end-use products will be applied at low concentrations of active ingredient (0.002–0.012%, by weight) and at low application rates; and (4) based on its physical and chemical properties, such as low vapor pressure and high water solubility, inhalation exposure due to volatilization is not expected for Flg22-Bt Peptide.

The data requirements for developmental toxicity were also satisfied with the submission of an acceptable rationale, which was nearly identical to that submitted to satisfy the subchronic toxicity data requirements. For details of that rationale, refer to the points of support in the preceding paragraph. In short, Flg-22 Bt Peptide is of low toxicity and significant exposure from use as a pesticide is not anticipated and, as such, is not expected to pose any risks with regard to developmental toxicity.

As for the mutagenicity data requirements, those were satisfied through the submission of guideline studies. There were no indications of genotoxicity or mutagenicity in the submitted guideline *in vitro* studies. Specifically, there was no evidence of induced mutant colonies over background with or without metabolic activation in the reverse gene mutation assay in bacteria; and there was no evidence of inducted mutant colonies over background with or without metabolic activation in the mammalian forward gene mutation assay in Chinese hamster ovary cells. All submitted data indicate that Flg22-Bt Peptide is non-genotoxic and non-mutagenic.

B. Toxicological Points of Departure/ Levels of Concern

No toxicological endpoints have been identified for Flg22-Bt Peptide. The active ingredient is of low toxicity, and significant exposure is not expected based on the low application rates and rapid degradation in the environment.

C. Exposure Assessment

1. *Dietary exposure from food, feed uses, and drinking water.* As part of its qualitative risk assessment for Flg22-Bt Peptide, the Agency considered the potential for dietary exposure to residues of the chemical. EPA concludes that dietary (food and drinking water) exposures are possible, but they are expected to be negligible based on low application rates and rapid degradation in the environment and are not anticipated in any concentration outside potential naturally occurring background levels. Moreover, no toxicological endpoint of concern was identified for Flg22-Bt Peptide; and therefore, a quantitative assessment of dietary exposure is not necessary. Dietary risk is not of a concern.

2. *Non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). There are currently no proposed residential uses for this active ingredient, although there is a potential for residential post-application exposure from pesticide applications to turf. However, no risks of concern have been identified for this turf application due to the low toxicity of the Flg22-Bt Peptide and negligible exposure based on low application rates and rapid degradation in the environment. Therefore, a quantitative assessment of residential exposure is not necessary.

3. *Cumulative effects from substances with a common mechanism of toxicity.* 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.'' EPA has not found that Flg22-Bt Peptide shares a common mechanism of toxicity with any other substances, and it does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed Flg22-Bt Peptide 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.*

D. Safety Factor for Infants and Children

FFDCA Section 408(b)(2)(C) provides that EPA shall retain 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 based on reliable data 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 (FQPA) safety factor. In applying this provision, EPA

either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor. An FQPA safety factor is not required at this time for Flg22–Bt Peptide because no toxicological endpoints have been established and the qualitative risk assessment has concluded that Flg22–BT Peptide is of low toxicity and that no significant exposures are expected.

E. Aggregate Risk

In accordance with the FFDCA, OPP must consider and aggregate (add) pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources that have the same toxicological endpoints are added together and compared to quantitative estimates of hazard, or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, EPA considers both the route and duration of exposure. A qualitative aggregate risk assessment has been conducted for the proposed use of Flg22–Bt Peptide based on the lack of identified endpoints in the toxicological database and minimal exposure to the active ingredient. No risks of concern have been identified.

A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the April 7, 2023, document entitled ''Product Chemistry Review and Human Health Assessment for a FIFRA Section 3 Registration of Flg22–BtPeptide Technical, Containing 70% Flg22–Bt Peptide as the Active Ingredient.'' This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

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

Based on the Agency's assessment, 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 Flg22–Bt Peptide.

V. 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.

VI. Conclusion

Therefore, EPA is establishing an exemption from the requirement of a tolerance for residues of Flg22–BtPeptide in or on all food commodities when used as a plant regulator and inducer of local and systemic resistance in accordance with label directions and good agricultural practices.

VII. 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 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 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).

VIII. 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: August 3, 2023.

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 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 § 180.1405 to subpart D to read as follows:

§ 180.1405 Flg22–Bt Peptide; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of Flg22–Bt Peptide in or on all food commodities when used as a plant regulator and inducer of local and systemic resistance in accordance with label directions and good agricultural practices.

[FR Doc. 2023–17019 Filed 8–8–23; 8:45 am]

BILLING CODE 6560–50–P