



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2019-0572; FRL-12526-01-OCSP]

### ***Bacillus Thuringiensis* Strain EX 297512 in Pesticide Formulations; 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 *Bacillus thuringiensis* strain EX 297512, when used as an inert ingredient (diluent and/or carrier) in pesticide formulations applied for seed treatment purposes. BASF Corporation, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *B. thuringiensis* strain EX 297512, when used in accordance with the terms of this exemption.

**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-2019-0572, is available online at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Charles Smith, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania

Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@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).

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *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. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. 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-2019-0572, 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*]**.

EPA's Office of Administrative Law Judges (OALJ), where the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. See "Revised Order Urging Electronic Service and Filing", dated June 22, 2023, which can be found at <https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf>. Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at [https://yosemite.epa.gov/OA/EAB/EAB-ALJ\\_Upload.nsf/HomePage?ReadForm](https://yosemite.epa.gov/OA/EAB/EAB-ALJ_Upload.nsf/HomePage?ReadForm).

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-2019-0572, online at <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. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

## II. Petition for Exemption

In the *Federal Register* of February 4, 2020 (86 FR 6129, FRL-10003-17), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11282) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* strain EX 297512, whole broth when used as an inert ingredient (diluent and/or carrier) in pesticide formulations for seed treatments only. That document referenced a summary of the petition prepared by BASF Corporation, the petitioner, which is available in the docket, <https://www.regulations.gov>.

The Agency received one comment opposing the exemption because of a perception that it is deregulatory and allowing more pollution. Although the Agency recognizes that some individuals believe that no residue of pesticide products should be allowed in or on food, the existing legal framework provided by FFDCA section 408 authorizes the establishment of pesticide tolerances or exemptions where the Agency determines that tolerance or exemption meets the safety standard imposed by the statute. EPA has sufficient data to support a safety determination for the exemption from the requirement of a tolerance for *B. thuringiensis* strain EX 297512. The commenter provided no information to indicate that the exemption is not safe.

## III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the

low toxicity of the individual inert ingredients.

#### **IV. Aggregate Risk Assessment and Determination of Safety**

FFDCA section 408(c)(2)(A)(i) 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 tolerance is “safe.” FFDCA section 408(c)(2)(A)(ii) 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. When making a safety determination for an exemption for the requirement of a tolerance, FFDCA section 408(c)(2)(B) directs EPA to consider the considerations in FFDCA section 408(b)(2)(C) and (D). FFDCA section 408(b)(2)(C) requires 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....” FFDCA section 408(b)(2)(D) lists other factors for EPA consideration making safety determinations, e.g., the validity, completeness, and reliability of available data, nature of toxic effects, available information concerning the cumulative effects of the pesticide chemical and other substances with a common mechanism of toxicity, and available information concerning aggregate exposure levels to the pesticide chemical and other related substances, among others.

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. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of

pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, 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 safety determination regarding the aggregate exposure for *B. thuringiensis* strain EX 297512, including exposure from uses related to the exemption established by this action. EPA's assessment of aggregate exposure associated with *B. thuringiensis* strain EX 297512, follows.

#### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies 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. Specific information on the studies received and the nature of the adverse effects caused by *B. thuringiensis* strain EX 297512, are discussed in this unit.

All *Bacillus thuringiensis* strains will generally have some level of broth residue left in the end-use product. The broth is the food that the microbes use for growth and is needed to make (i.e., ferment) the bacteria. *B. thuringiensis* strain EX 297512 consists of the microbial strain *B. thuringiensis* EX 297512, as well as the spent fermentation broth and nutrients.

“*Bacillus thuringiensis* fermentation solids and/or solubles” are exempt under 40 CFR 180.910, when used as a “diluent, carrier”; therefore, this exemption is for the *B. thuringiensis* strain EX 297512.

*B. thuringiensis* strain EX 297512 is an engineered microbial strain derived from another *B. thuringiensis* strain, which was transformed with a plasmid to produce the enzyme beta-1,4-

endoglucanase, which breaks down organic matter in the soil increase the available nutrient pool when it is expressed on the spore surface of this microbial strain.

The toxicological database of *B. thuringiensis* strain EX 297512 is supported by data regarding *B. thuringiensis* strain EX 297512, and data on *B. thuringiensis* (Bt), as described in the *Bacillus thuringiensis* Reregistration Decision (Bt RED, 1998) for the active ingredient. Unlike the *B. thuringiensis* strains registered as active ingredients, *B. thuringiensis* strain EX 297512, lacks the plasmids carrying insecticidal toxins and thus it is an inert ingredient. However, EPA finds that the data can be bridged, since *B. thuringiensis* strain EX 297512 satisfies the requirements at 40 CFR 180.1011, such as being considered an authentic Bt strain and lacking exotoxins.

The available data demonstrates that *B. thuringiensis* strain EX 297512 exhibits low levels of acute toxicity via the oral, dermal, and inhalation routes of exposure. It is slightly irritating to the skin and eyes. Subchronic and chronic is not expected since no toxicological endpoints were identified for *B. thuringiensis* strain EX297512 in Tier I toxicity studies, and no virus contamination is suspected. Moreover, EPA conducted an allergenicity analysis of the enzyme, which is a protein, and has determined that the enzyme is not expected to pose any concern for allergenicity.

#### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a

population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program>.

The hazard profile of *B. thuringiensis* strain EX 297512 is adequately defined. Overall, *B. thuringiensis* strain EX 297512 is of low toxicity. Since signs of toxicity or pathogenicity were not observed, no toxicological endpoints of concern or PODs were identified. Therefore, a qualitative risk assessment for *B. thuringiensis* strain EX 297512 was performed.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to *B. thuringiensis* strain EX 297512, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from *B. thuringiensis* strain EX 297512 in food as follows:

Dietary exposure (food and drinking water) to *B. thuringiensis* strain EX 297512 may occur following ingestion of foods with residues from their use in accordance with this exemption. However, a quantitative dietary exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

2. *From 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).

*B. thuringiensis* strain EX 297512 may be present in pesticide and non-pesticide products that may be used in and around the home. However, a quantitative residential exposure assessment was not conducted since a toxicological endpoint for risk assessment was not

identified.

3. *Cumulative effects from substances with a common mechanism of toxicity.* FFDC section 408(b)(2)(D)(v) 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.”

Based on the lack of toxicity in the available database, EPA has not found *B. thuringiensis* strain EX 297512 to share a common mechanism of toxicity with any other substances, and *B. thuringiensis* strain EX 297512 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance exemption, therefore, EPA has assumed that *B. thuringiensis* strain EX 297512 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 the Protection of Infants and Children*

FFDC section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines 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 (SF). In applying this provision, EPA Protection Act 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.

Based on an assessment of *B. thuringiensis* strain EX 297512 EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children. Because there are no threshold effects associated with *B. thuringiensis* strain EX

297512, EPA conducted a qualitative assessment. As part of that assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

#### *E. Aggregate Risks and Determination of Safety*

Because no toxicological endpoints of concern were identified, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to *B. thuringiensis* strain EX 297512 residues.

### **V. Other Considerations**

#### *A. 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.

#### *B. Revisions to Petitioned-For Tolerances*

BASF Corporation requested that an exemption from the requirement of a tolerance be established for residues of “*Bacillus thuringiensis* strain EX 297512 whole broth”. *B. thuringiensis* strain EX 297512 whole broth consists of the microbial strain *B. thuringiensis* EX 297512 as well as the spent fermentation broth and nutrients. “*Bacillus thuringiensis* fermentation solids and/or solubles” is exempt under 40 CFR 180.910 when used as a “diluent, carrier”; therefore, “whole broth” has been removed from the name because an exemption from the requirement of a tolerance already exists for this component.

### **VI. Conclusions**

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for residues of *B. thuringiensis* strain EX 297512 when used as an inert ingredient (diluent and/or carrier) in pesticide formulations applied for seed treatment.

### **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.*).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemptions 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 (CRA)**

This action is subject to the CRA (5 U.S.C. 801 *et seq.*), and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

### **List of Subjects in 40 CFR Part 180**

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

Dated: February 13, 2025.

**Charles Smith,**

*Director, Registration Division, 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. In § 180.920, amend Table 1 to 180.920 by adding, in alphabetical order, an entry for “*Bacillus thuringiensis* strain EX 297512” to read as follows:

**§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

**Table 1 to § 180.920**

<b>Inert ingredients</b>	<b>Limits</b>	<b>Uses</b>
* * * * *		
<i>Bacillus thuringiensis</i> strain EX 297512	For seed treatment use only. This inert ingredient must meet the specifications contained in 40 CFR 180.1011(a)(1)-(4).	Diluent and/or carrier
* * * * *		