

amino-4-[(carboxyimino-methyl)amino]-2,3,4,6-tetradeoxy- $\alpha$ -D-arabino-hexopyranosyl]-D-chiro-inositol), in or on tea, dried at 3 ppm.

**VI. Statutory and Executive Order Reviews**

This action establishes tolerances 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 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).

**VII. 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 5, 2024.

**Charles Smith,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended 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 § 180.614, in paragraph (a), add a heading to the table and an entry in alphabetical order for “Tea, dried” to read as follows:

**§ 180.614 Kasugamycin; tolerances for residues.**

(a) \* \* \*

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * *	*
Tea, dried <sup>2</sup> .....	3
* * * * *	*

<sup>2</sup> There is no U.S. registration as of August 12, 2024.

\* \* \* \* \*  
[FR Doc. 2024-17805 Filed 8-9-24; 8:45 am]  
BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2022-0323; FRL-10389-01-OCSPP]

**Bacillus Paralicheniformis Strain CH0273; 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 paralicheniformis* strain CH0273 in or on all food commodities when used in accordance with label directions and good agricultural practices. Chr. Hansen, Inc., submitted a petition to the 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 *Bacillus paralicheniformis* strain CH0273 under FFDCA when used in accordance with this exemption.

**DATES:** This regulation is effective August 12, 2024. Objections and requests for hearings must be received on or before October 11, 2024 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-2022-0323, 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 20004. 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 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:** Madison H. 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) 566-1400; email address: [BPPDFRNotices@epa.gov](mailto: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 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 the EPA, you must identify docket ID number EPA-HQ-OPP-2022-0323, 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 11, 2024.

The EPA's Office of Administrative Law Judges (OALJ), in which 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 Filing and Service," dated June 22, 2023, which can be found at <https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf>. Although the EPA's

regulations require submission via U.S. Mail or hand delivery, the EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, the 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](https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf).

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 the EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2022-0323, 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 April 28, 2022 (87 FR 25178) (FRL-9410-12), the EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance exemption petition (PP 1F8943) by Chr. Hansen, Inc., 9015 W Maple St., Milwaukee, WI 53214. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of fungicide and nematocide *Bacillus paralicheniformis* strain CH0273. That notice referenced a summary of the petition prepared by the petitioner Chr. Hansen, Inc., and available in the docket via <https://www.regulations.gov>. The EPA received a comment on the notice of filing. The

EPA's response to this comment is discussed in Unit III.C.

### III. Final Rule

#### A. The EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows the EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if the 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, the EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require the 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 the EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity."

The EPA evaluated the available toxicological and exposure data on *Bacillus paralicheniformis* strain CH0273 and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which the EPA relied and its risk assessment based on those data can be found within the document entitled "Human Health Risk Assessment of *Bacillus paralicheniformis* strain CH0273 and *Bacillus subtilis* strain CH4000, two New Active Ingredients, in the Manufacturing-use Products (MUPs) CH0273 (2375-U) and CH4000 (2375-A), and End-use Products (EPs) Kansas 3 SC (2375-L) and Kansas 3 WP (2375-T) Proposed for Registration and two Associated Petitions Requesting Tolerance Exemptions." This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

The available data demonstrated that, with regard to humans, *Bacillus paralicheniformis* strain CH0273, is not toxic, pathogenic, irritating, or infective. According to the toxicity/infectivity and acute studies, *Bacillus paralicheniformis* strain CH0273 has a low toxicity profile, and no toxicological endpoints were identified. This active ingredient is a biological fungicide and nematicide and the proposed mode of action is mediated by the mechanisms of antagonism of pest and pathogens, promotion of host nutrition and growth, and stimulation of plant host defenses. Application of products containing *Bacillus paralicheniformis* strain CH0273 will briefly result in adding to the bacterial population already present in the environment. However, population levels for this active ingredient are expected to decrease to environmental background levels relatively rapidly following application. This active ingredient present in the environment and humans are naturally exposed to it. Dietary and drinking water exposure is expected to be negligible since significant residues are not expected because the EPs containing this active ingredient are meant for indirect application to food crops through seed and soil treatment. The EPA does not expect dietary (food and drinking water) or other non-occupational risks from use of *Bacillus paralicheniformis* strain CH40273 as a microbial active ingredient in the proposed pesticide products.

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/effects from *Bacillus paralicheniformis* strain CH0273 has been identified as no toxicity has been shown for *Bacillus paralicheniformis* strain CH0273 in the submitted studies. Therefore, the EPA has not assumed that *Bacillus paralicheniformis* strain CH0273 has a common mechanism of toxicity with other substances.

Additionally, 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, the EPA has determined that there are no such effects due to the lack of toxicity of *Bacillus paralicheniformis* strain CH0273. Because there are no threshold levels of concern with the toxicity,

pathogenicity, or infectivity of *Bacillus paralicheniformis* strain CH0273, the EPA determined that no additional margin of safety is necessary to protect infants and children as part of the qualitative assessment conducted.

Based upon its evaluation in the human health risk assessment of *Bacillus paralicheniformis* strain CH0273, and *Bacillus subtilis* strain CH4000, which concludes that there are no risks of concern from aggregate exposure to *Bacillus paralicheniformis* strain CH0273, the 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 *Bacillus paralicheniformis* strain CH0273.

#### B. Analytical Enforcement Methodology

An analytical method is not required for *Bacillus paralicheniformis* strain CH0273 because the EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

#### C. Response to Comments

One comment was received in response to the notice of filing. The EPA reviewed the comment and determined that it was irrelevant to the tolerance exemption in this action.

#### IV. Statutory and Executive Order Reviews

This action establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to the EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act, 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 (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, the 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, the 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 (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require the EPA’s consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (15 U.S.C. 272 note).

#### V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the 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 6, 2024.

**Edward Messina,**

*Director, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, the 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 § 180.1410, to subpart D to read as follows:

### **§ 180.1410 *Bacillus paralicheniformis* strain CH0273; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of *Bacillus paralicheniformis* strain CH0273 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2024–17860 Filed 8–9–24; 8:45 am]

**BILLING CODE 6560–50–P**

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA–HQ–OPP–2022–0318; FRL–10390–01–OCSPP]**

### ***Bacillus Subtilis* Strain CH4000; 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 subtilis* strain CH4000 in or on all food commodities when used in accordance with label directions and good agricultural practices. Chr. Hansen Inc., submitted a petition to the 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 *Bacillus subtilis* strain CH4000 under FFDCA when used in accordance with this exemption.

**DATES:** This regulation is effective August 12, 2024. Objections and requests for hearings must be received on or before October 11, 2024 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–2022–0318, 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 20004. 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 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:** Madison H. 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) 566–1400; email address: [BPPDFR.Notices@epa.gov](mailto:BPPDFR.Notices@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 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 the EPA, you must identify docket ID number EPA–HQ–OPP–2022–0318 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 11, 2024.

The EPA’s Office of Administrative Law Judges (OALJ), in which 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 Filing and Service,” 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 the EPA’s regulations require submission via U.S. Mail or hand delivery, the EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, the 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](https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf).

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 the EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2022–0318, 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>.