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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2022-0273; FRL-9963-01-OCSPP]

***Streptomyces* sp. strain K61; Exemption from the Requirement of a Tolerance**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the existing exemption from the requirement of a tolerance for residues of *Streptomyces* sp. strain K61 in or on all raw agricultural commodities when used as a fungicide for the treatment of seeds, cuttings, transplants, and plants of agricultural crops in accordance with good agricultural practices by removing the fungicidal use stipulation and clarifying that the exemption covers use in or on all food commodities when used in accordance with label directions and good agricultural practices. Danstar Ferment Ag/LALLEMAND PLANT CARE, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting that EPA amend the existing tolerance exemption for *Streptomyces* sp. strain K61. This regulation eliminates the need to establish a maximum permissible level for residues of *Streptomyces* sp. strain K61 under FFDCA.

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-2022-0273, 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. For the latest status information on EPA/DC services, docket access, visit *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 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-2022-0273 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*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b), although EPA strongly encourages those interested in submitting objections or a hearing request to submit objections and hearing requests electronically. *See* Order Urging Electronic Service and Filing (April 10, 2020), *https://www.epa.gov/sites/production/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf*. At this time, because of the COVID-19 pandemic, the judges and staff of the Office of Administrative Law Judges are working remotely and not able to accept filings or correspondence by courier, personal delivery, or commercial delivery, and the ability to receive filings or correspondence by U.S. Mail is similarly limited. When submitting documents to the U.S. EPA Office of Administrative Law Judges (OALJ), a person should utilize the OALJ e-filing system at *https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf*.

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 during this time that the Agency continues to maximize telework due to the pandemic; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. If it is impossible for a person to submit documents electronically or receive

service electronically, e.g., the person does not have any access to a computer, the person shall so advise OALJ by contacting the Hearing Clerk at (202) 564-6281. If a person is without access to a computer and must file documents by U.S. Mail, the person shall notify the Hearing Clerk every time it files a document in such a manner. The address for mailing documents is U.S. Environmental Protection Agency, Office of Administrative Law Judges, Mail Code 1900R**,** 1200 Pennsylvania Ave., NW., Washington, DC 20460.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2022-0273, 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*.

In the *Federal Register* of April 28, 2022 (87 FR 25178) (FRL-9410-12-OCSPP), 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 1F8953) by Danstar

Ferment Ag/LALLEMAND PLANT CARE, Postsrasse 20, CH-6300 Zug, Switzerland (c/o Amy Plato Roberts, P.O. Box 990, Hailey, ID 83333). The petition requested that 40 CFR part 180.1120 be amended by establishing an exemption from the requirement of a tolerance for residues of *Streptomyces* sp. strain K61 in or on all food commodities. That notice referenced a summary of the petition prepared by the petitioner Danstar Ferment Ag/LALLEMAND PLANT CARE and is available in the docket via *https://www.regulations.gov*. Two comments were received on the notice of filing. EPA's response to these comments is discussed in Unit V.B.

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 of 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 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 for *Streptomyces* sp. strain K61 including exposure resulting from the exemption established by this action. A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found in the *Streptomyces* Strain K61 Registration Review Final Decision available in docket EPA-HQ-OPP-2009-0509, *Streptomyces* Strain K61 Biopesticides Registration Action Document available in docket EPA-HQ-OPP-2009-0509, Review of Petition to Amend an Existing Tolerance Exemption for *Streptomyces* sp. Strain K61 and in the document entitled "Risk Assessment for a FIFRA Section 3 Registration of *Streptomyces* sp. Strain K61 Technical, Containing 100% of the Currently Registered Active Ingredient *Streptomyces* sp. Strain K61" (a.k.a. *Streptomyces* sp. strain K61 Risk Assessment). *Streptomyces* sp. strain K61 Risk Assessment, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

A. Toxicological Profile

Streptomyces strain K61 is a naturally occurring microbe found in soils throughout the world, and there are no known reports of any deleterious effects associated with its consumption. Additionally, the acute toxicity data on file with the

Agency confirm its lack of acute toxicity. There is also no evidence of adverse effects from oral exposure to this microbial agent. Data on file with the Agency confirm the lack of oral toxicity/pathogenicity of *Streptomyces* strain K61. For the full discussion of the Toxicological Profile of *Streptomyces* sp. strain K61, see the *Streptomyces* Strain K61 Registration Review Final Decision and, the *Streptomyces* Strain K61 Biopesticides Registration Action Document, both available in docket EPA-HQ-OPP-2009-0509.

B. Exposure Assessment

1. *Dietary exposure from food, feed uses, and drinking water. Streptomyces* sp. strain K61 is found in soils throughout the world. Dietary exposure to *Streptomyces* strain K61 is expected to be minimal. As the mode of action of *Streptomyces* strain K61 is through root colonization, the majority of applications are to seeds and soil. Certain foliar applications are permitted for the purposes of suppressing *Botrytis* infection and promoting growth; however, direct applications to crops are highly diluted and residues are not expected to persist.

Exposure to *Streptomyces* strain K61 via drinking water when the pesticide is used is not likely to be greater than current/existing exposures. Although *Streptomyces* strain K61 is found naturally, it does not thrive in aquatic environments. There are no aquatic use sites for the pesticide, so exposure in drinking water is not expected.

2. *From non-dietary exposure*. There are no residential uses for *Streptomyces* strain K61. Non-occupational exposures are not expected; in the event of accidental exposure, no non-occupational risks are anticipated.

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 or exemption, 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

Streptomyces sp. strain K61 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 *Streptomyces* sp. strain K61 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/pesticides/cumulative*.

C. 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 FQPA safety factor (SF). 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. Based on the low toxicity of *Streptomyces* sp. strain K61 in the available studies, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children, and therefore conducted a qualitative assessment of *Streptomyces* sp. strain K61. As part of its qualitative 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.

D. Aggregate Risk

Based on the available data and information, the EPA has concluded that a qualitative aggregate risk assessment is appropriate to support the pesticidal use of *Streptomyces* sp. strain K61, and that risks of concern are not anticipated from aggregate

exposure to the substance. This conclusion is based on the low toxicity of the active ingredient.

A full explanation of why the Agency is relying on prior 2011 *Streptomyces* sp. strain K61 registration review risk assessments for addressing the amendment to the exemption of a tolerance can be found within the Review of Petition to Amend an Existing Tolerance Exemption for *Streptomyces* sp. Strain K61 document. This document, as well as other relevant information, are 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 *Streptomyces* sp. strain K61.

V. Other Considerations

A. Analytical enforcement methodology

An analytical method is not required for *Streptomyces* sp. strain K61 because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. Response to comments

One comment was received in response to the notice of filing. The comment discusses potential risk to humans and nontarget organisms from the use of products containing this active ingredient. Consistent with FFDCA section 408(b)(2)(D), EPA reviews the available scientific data and other relevant information and considers their validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA also considers available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. EPA relied on a variety of data and information to conclude 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 *Streptomyces* sp. strain K61.

VI. Conclusions

Therefore, the existing tolerance exemption for *Streptomyces* sp. strain K61 is amended by establishing an exemption from the requirement of a tolerance for residues of *Streptomyces* sp. strain K61 in or on all food commodities when used 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 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, 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 (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 (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 12, 2022.

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 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. Revise § 180.1120 to read as follows:

§ 180.1120 *Streptomyces* sp. strain K61; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Streptomyces* sp. strain K61 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2022-18012 Filed: 8/23/2022 8:45 am; Publication Date: 8/24/2022]