



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2024-0308; 13314-01-OCSPP]

***Bacillus amyloliquefaciens* strain AT-332; Exemption from the Requirement of a Pesticide 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 amyloliquefaciens* strain AT-332 in or on all food and feed commodities when used in accordance with label directions and good agricultural practices. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), Gowan Company, in cooperation with SDS Biotech K.K., c/o Landis International, Inc., submitted a petition to EPA requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of this pesticide when used in accordance with the terms of the exemption.

DATES: This rule is effective on [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 this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2024-0308, is available online at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket center in person, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Shannon Borges, Biopesticides and Pollution

Prevention Division (7511M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460-0001; telephone number: (202) 566-1400; email address: BPPDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

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 might apply to them:

- 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 action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is EPA's authority for taking this action?

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. 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 exemption 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. 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, among other things, “available information concerning the cumulative effects of a particular pesticide's residues” and “other substances that have a common mechanism of toxicity.”

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 the docket ID number EPA-HQ-OPP-2024-0308 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), 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* “Order Urging Electronic Filing and Service,” dated December 3, 2025, which can be found at <https://www.epa.gov/system/files/documents/2025-12/2025-12-03-order-urging-electronic-filing-and-service.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.

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 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. If you wish to include CBI in your request, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Petitioned for Exemption

In the *Federal Register* of May 20, 2022 (87 FR 30855) (FRL-9410-13-OCSP), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 1F8915) by Gowan Company in cooperation with SDS Biotech K.K., c/o Landis International, Inc. (P.O. Box 5126, 3185 Madison Highway, Valdosta, GA 31603). The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the fungicide *Bacillus amyloliquifaciens* strain AT-332 in or on all food commodities. That document referenced a summary of the petition prepared by the petitioner and included in the docket.

There were no comments received in response to the notice of filing. EPA modified the tolerance exemption by removing “fungicide.” The reason for this change is explained in Unit III.C.

III. Final Tolerance Actions

A. EPA’s Safety Determination

EPA has assessed the individual risks from exposure to the pesticide active ingredients identified and discussed in this rule, taking into consideration all reliable data on toxicity and exposure, including for infants and children, and has included a safety finding under FFDCA section 408(b) for the tolerance actions in this rule. The data upon which EPA relied and its risk assessment based on those data can be found within the document entitled “Human Health Risk Assessment of *Bacillus amyloliquefaciens* strain AT-332, a New Active Ingredient, in SB-950 (Manufacturing-use Product) and SB-9503 (End-use Product) Proposed for Registration and an Associated Petition Requesting a Tolerance Exemption.” (*Bacillus amyloliquefaciens* strain AT-332 Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action, docket ID number EPA-HQ-OPP-2024-0308.

The toxicological profile of *Bacillus amyloliquefaciens* strain AT-332 is described in the *Bacillus amyloliquefaciens* strain AT-332 Human Health Risk Assessment. Based upon its evaluation, EPA concludes that, with regards to humans, *Bacillus amyloliquefaciens* strain AT-332 is not anticipated to be toxic, pathogenic, or infective. *Bacillus amyloliquefaciens* strain AT-332 is ubiquitous in soil and the rhizosphere. Dietary and drinking water and residential exposure is expected. However, *Bacillus amyloliquefaciens* is present in soil, on fresh produce, and in water. Further, food crops undergo postharvest washing and municipal water treatment practices would reduce any residues further. Even if dietary or residential exposure to residues of *Bacillus amyloliquefaciens* strain AT-332 were to occur, there are no risks of concern due to the lack of adverse effects from toxicity, pathogenicity, or infectivity of *Bacillus amyloliquefaciens* strain AT-332. EPA determined that no additional margin of safety is necessary to protect infants and children as part of the qualitative assessment conducted, as data and rationale demonstrated that *Bacillus amyloliquefaciens* strain AT-332 is not toxic, pathogenic, or infective.

Based on the supporting assessments and registration review documents, which demonstrate that the aggregate exposure for each individual chemical is below the Agency’s level of concern, EPA concludes there is a reasonable certainty that no harm will result to the

general population, or specifically to infants and children, from aggregate exposure to residues of the pesticide active ingredients identified and discussed in this action.

B. Analytical Enforcement Methodology

An analytical method is not required for *Bacillus amyloliquefaciens* strain AT-332 because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Revisions to the Requested Tolerance Exemption

The Agency removed the descriptor “fungicide” from the tolerance exemption to reduce any unnecessary future regulatory burden and conform with current standard practices.

D. Conclusion

Therefore, EPA is finalizing the tolerance exemption that was petitioned for by Gowan Company in cooperation with SDS Biotech K.K., c/o Landis International, Inc. (PP 1F8915) for residues of *Bacillus amyloliquefaciens* strain AT-332 in or on all food commodities when used in accordance with label directions and good agricultural practices.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 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.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq.*, because it does not contain any information collection activities.

D. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to the APA but is subject to FFDCA section 408(d), which does not require notice and comment rulemaking to take this action in response to a petition.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on

the distribution of power and responsibilities between the Federal Government and Indian Tribes.

H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

However, EPA's 2026 *Policy on Children's Health* applies to this action. This rule finalizes tolerance actions under the FFDCA, which 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 408(b)(2)(C)). The Agency's consideration is documented in the pesticide-specific review documents, located in the applicable docket at <https://www.regulations.gov>.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. 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: September 9, 2026.

Edward Messina,

Director, Office of Pesticide Programs.

For the reasons set forth 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 § 180.1425 to Subpart D to read as follows:

§ 180.1425 *Bacillus amyloliquefaciens* strain AT-332; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Bacillus amyloliquefaciens* strain AT-332 in or on all food commodities when used in accordance with label directions and good agricultural practices.

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