This regulation establishes an exemption from the requirement of a tolerance for residues of 
\textit{Bacillus amyloliquefaciens} subspecies \textit{plantarum} strain FZB42 in or on all 
food commodities when used in accordance with label directions and 
good agricultural practices. Andermatt Biocontrol AG (c/o SciReg, Inc.) 
submitted a petition to 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 
provide 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 
113). 
- Food manufacturing (NAICS code 
311). 
- Pesticide manufacturing (NAICS 
code 32532).

**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 
113). 
- 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 Government Printing 
Office’s e-CFR site at 
http://www.ecfr.gov/cgi-bin/text- 
idx?&c=ecfr&tpl=/ecfrbrowse/Title40/
40tab_02.tpl.

**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–2014–0560 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 
August 19, 2019. 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–2014–0560, by one of the following methods:

- Federal eRulemaking Portal: http://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.
- Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http://www.epa.gov/dockets/contacts.html. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.

II. Background

In the Federal Register of May 18, 2018 (83 FR 23247) (FRL–9976–87), 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 petition (PF 7F8620) by Andermatt Biocontrol AG, Stahlematten 6, CH–6146 Grossdietwil, Switzerland (c/o SciReg, Inc., 12733 Director’s Loop, Woodbridge, VA 22192). 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 amyloliquefaciens subspecies plantarum strain FZB42 in or on all food commodities. That Notice referenced a summary of the petition prepared by the petitioner Andermatt Biocontrol AG and available in the docket via http://www.regulations.gov. Comments were received on the notice of filing. EPA’s response to these comments is discussed in Unit III.C.

III. Final Rule

A. EPA’s Safety Determination

Section 408(c)(2)(A)(i) 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 children and infants 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 evaluated the available toxicity and exposure data on Bacillus amyloliquefaciens subspecies plantarum strain FZB42 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 EPA relied and its risk assessment based on those data can be found within the document entitled “Federal Food, Drug, and Cosmetic Act (FFDCA) Safety Determination for Bacillus amyloliquefaciens subspecies plantarum strain FZB42” (Safety Determination). 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 amyloliquefaciens subspecies plantarum strain FZB42 is not toxic, pathogenic, or infective via any route of exposure. Although there may be some exposure to residues when Bacillus amyloliquefaciens subspecies plantarum strain FZB42 is used on food commodities in accordance with label directions and good agricultural practices, dietary exposure to such residues presents no concern for adverse effects. EPA also determined that a Food Quality Protection Act (FQPA) safety factor is not necessary as part of the qualitative assessment conducted for Bacillus amyloliquefaciens subspecies plantarum strain FZB42. These findings are discussed in more detail in the Safety Determination.

Based upon its evaluation in the Safety Determination, 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 amyloliquefaciens subspecies plantarum strain FZB42. Therefore, an exemption from the requirement of a tolerance is established for residues of Bacillus amyloliquefaciens subspecies plantarum strain FZB42 in or on all food commodities when used in accordance with label directions and good agricultural practices.

B. Analytical Enforcement Methodology

An analytical method is not required because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Response to Comments

Three comments were received in response to the notice of filing. EPA reviewed the comments and determined that they are 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 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), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). 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
List of Subjects in 40 CFR Part 180

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

Dated: June 10, 2019.

Richard Keigwin,
Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:


2. Add § 180.1367 to subpart D to read as follows:

§ 180.1367 Bacillus amyloliquefaciens subspecies plantarum strain FZB42; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of Bacillus amyloliquefaciens subspecies plantarum strain FZB42 in or on all food commodities when used in accordance with label directions and good agricultural practices.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), June 13, 2019, until 2400 hrs, A.l.t., December 31, 2019.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council (Council) under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

In the Aleutian Islands subarea, the portion of the 2019 pollock total allowable catch (TAC) allocated to the Aleut Corporation’s directed fishing allowance (DFA) is 14,700 metric tons (mt) as established by the final 2019 and 2020 harvest specifications for groundfish in the BSAI (84 FR 9000, March 13, 2019).

As of June 12, 2019, the Administrator, Alaska Region, NMFS, (Regional Administrator) has determined that 14,600 mt of Aleut Corporation’s DFA in the Aleutian Islands subarea will not be harvested. Therefore, in accordance with § 679.20(a)(5)(iii)(B)(4), NMFS reallocates 14,600 mt of Aleut Corporation’s DFA from the Aleutian Islands subarea to the 2019 Bering Sea subarea allocations. The 14,600 mt of pollock in the Bering Sea subarea is apportioned to the AFA Inshore sector (50 percent), AFA catcher/processor sector (40 percent), and the AFA mothership sector (10 percent). The 2019 Bering Sea subarea pollock incidental catch allowance remains at 46,520 mt. As a result, the 2019 harvest specifications for pollock in the Aleutian Islands subarea included in the final 2019 and 2020 harvest specifications for groundfish in the BSAI (84 FR 9000, March 13, 2019 and 84 FR 9976, March 19, 2019) are revised as follows: 100 mt to Aleut Corporation’s DFA. Furthermore, pursuant to § 679.20(a)(5), Table 4 of the final 2019 and 2020 harvest specifications for groundfish in the BSAI (84 FR 9000, March 13, 2019 and 84 FR 9976, March 19, 2019) is revised to make 2019 pollock allocations consistent with this reallocation.