BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0397; FRL-9383-1]

Bacillus mycoides isolate J; Time-Limited Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited exemption from the requirement of a tolerance for residues of *Bacillus mycoides* isolate J in or on potato, when used in accordance with the terms of the section 18 emergency exemption. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on potato. The time-limited exemption from the requirement of a tolerance expires on December 31, 2015.

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** section.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0397, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West 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 is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Debra Rate, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 306-0309; email address: *rate.debra@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 Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, 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-2012-0397 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).

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-2012-0397, 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.

• *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 *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 and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing a time-limited exemption from the requirement of a tolerance for *Bacillus mycoides* isolate J, in or on potato. This time-limited exemption from the requirement of a tolerance expires on December 31, 2015.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement of a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances and exemptions from the requirement of a tolerance can be established without providing notice or period for public comment.

EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances or exemptions to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(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 tolerance is "safe." Section 408(b)(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 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...."

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Emergency Exemption for *Bacillus mycoides* isolate J on Potato and Exemption from the Requirement of a Tolerance

The Montana Department of Agriculture requested a specific emergency exemption, for the use of the unregistered active ingredient (ai), *Bacillus mycoides* isolate J (BmJ), to control tuber infections caused by potato virus Y (PVY), on generation 1 (G1) and generation 2 (G2) potatoes grown for certified seed potato stock. There are no registered alternatives to control PVY infections, only registered alternatives that inadequately control the aphids which vector the virus. The Montana Department of Agriculture, requested use for 2,675 acres of seed potato.

After having reviewed the submission, EPA determined that an emergency condition existed for this State, and that the criteria for approval of an emergency exemption were met. Accordingly, EPA authorized a specific exemption under FIFRA section 18 for the use of *Bacillus mycoides* isolate J on potato for control of PVY in Montana.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of *Bacillus mycoides* isolate J in or on potato. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary exemption from the requirement of a tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section

18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this exemption from the requirement of a tolerance without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). This time-limited exemption from the requirement of a tolerance expires on December 31, 2015. EPA will take action to revoke the time-limited exemption from the requirement of a tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicates that the residues are not safe.

Because this time-limited exemption from the requirement of a tolerance is being approved under emergency conditions, EPA has not made any decisions about whether *Bacillus mycoides* isolate J meets FIFRA's registration requirements for use on potato or whether permanent tolerances or exemption from the requirement of a tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited exemption from the requirement of a tolerance serves as a basis for registration of *Bacillus mycoides* isolate J by a State for special local needs under FIFRA section 24(c). Nor does this tolerance by itself serve as the authority for persons in any State other than Montana to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for *Bacillus mycoides* isolate J, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

IV. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information 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. The nature of the toxic effects caused by *Bacillus mycoides* isolate J, are discussed in this unit. Refer to risk assessments in docket number EPA-HQ-OPP-2005-0303 with the titles: (1) BPPD Review of Product Chemistry and Toxicity/Pathogenicity Data Submitted by Montana Microbial Products, for EUP of BmjJ WP, which contains *Bacillus mycoides* isolate J and (2) Ecological Risk Assessment for *Bacillus mycoides* Isolate J, for additional information.

The stomach is a hostile environment for most microbes, as most oral exposure to microbes, leads to inactivation by stomach acids, proteases, and subsequently bile salts (Ref. 1). In contrast, a pulmonary exposure study provides those microbes that are capable of infecting mammals with the greatest opportunity to express infectivity by directing them into the lungs, from where they may enter the bloodstream and other organs. Therefore, a microbe that does not show significant infectivity in a pulmonary exposure study, presents negligible risk via oral exposure.

An Acute Pulmonary Toxicity/Pathogenicity study (OPPTS 885.3150) in rats which were dosed intratracheally with *Bacillus mycoides* isolate J at 1.1×10^8 cfu/animal, did not show complete clearance from all organs during the study's 35-day length. The test substance, however, did show a pattern of clearance in most organs. This is similar to

what has been observed with other spore forming bacteria. Differential heat treatment of tissue samples showed that most of the recovered organisms were spores which are quiescent forms of this bacterium. Spores routinely take long periods to be cleared from pulmonary exposures (Ref. 2). Bacteria form spores when conditions do not support growth, so the predominance of spores among the *Bacillus mycoides* isolate J recovered from animal tissue, therefore indicates little infectivity. No treated animals died and there were no signs in the animals of toxicity or pathogenicity.

Associated with the manufacture of *Bacillus mycoides* isolate J, as well as all exposures during the previous experimental use permits, more than 20 people have worked with *Bacillus mycoides* isolate J for over 8 years, and no adverse effects or incidents of hypersensitivity reaction have been reported associated with *Bacillus mycoides* isolate J in the routine use of the experimental product.

Given the ubiquitous nature of this bacterium on plants, in soil, water, air, and decomposing plant tissue (Ref. 3), the lack of reported human pathogenicity, along with the lack of mortality of the test animals, and the absence of overt signs of toxicity or pathogenicity in the animals during the course of this pulmonary study, there is not expected to be an increase in dietary exposure or threshold effects of concern to infants and children when *Bacillus mycoides* isolate J is used as a foliar treatment on seed potatoes.

This finding is consistent with a previously granted food-use experimental use permit (82761-EUP-2), where the Agency granted requests for waivers for Acute Oral Toxicity and Pathogenicity (OPPTS 885.3050); Acute Injection Toxicity and Pathogenicity (OPPTS 885.3200); Acute Oral Toxicity (OPPTS 870.1100); Acute

Inhalation Toxicity (OPPTS 870.1300) mammalian studies for *Bacillus mycoides* isolate J, based on the following:

1. *Bacillus mycoides* is not reported as a human pathogen, or as a cause of foodborne illness, food spoilage, or plant diseases, and does not persist on plant surfaces. Due to the ubiquitous level of *Bacillus mycoides* present in agricultural soils, there has been long term human exposure to *Bacillus mycoides* in crops and to residual *Bacillus mycoides* cells or spores in food crops (Ref. 3). No toxicity, infectivity, or pathogenicity of *Bacillus mycoides* in humans was reported in numerous searched citations.

2. *Bacillus mycoides* is readily differentiable from other *Bacillus cereus* group organisms in production batches (including *Bacillus thuringiensis*, *Bacillus pseudomycoides*, *Bacillus anthracis*, *Bacillus cereus*, and *Bacillus weihenstephanensis*) and well defined quality control procedures are established to keep contaminants from fermentation batches during the production of *Bacillus mycoides* isolate J.

3. In connection with the manufacture of *Bacillus mycoides* isolate J, no adverse effects or incidents of hypersensitivity reaction have been reported associated with *Bacillus mycoides* isolate J in the routine use of the experimental product in a laboratory setting. Any such effects would be subject to the reporting requirements of 40 CFR 166.32(a) and guidelines for reporting Hypersensitivity Incidents (OPPTS 885.3400).

V. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or

surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

The authorized section 18 emergency exemption is not expected to result in increased dietary exposures of *Bacillus mycoides* isolate J to the general population based on the following:

1. *Food.* The section 18 emergency exemption is for foliar application on plants, grown from first and second generation seed potatoes grown for seed stock. Only a small fraction of seed potatoes collected from treated plants may enter the food chain as livestock feed. The quantity of *Bacillus mycoides* isolate J applied to plant foliage, 7.5 x 10^{11} spores/acre per application, is small compared to the natural background levels of *Bacillus mycoides*.

In agricultural soils, *Bacillus mycoides* typically occurs at about 10^5 spores per gram. In persistence studies, performed on a variety of crops (including peppers, potatoes, and sugar beets), the titer of *Bacillus mycoides* isolate J applied to the foliage typically declines from 10^6 spores/cm^2 to between 100 and 1,000 spores/cm^2 over a 2–week period. Specifically in potatoes, spores applied to foliage will not directly contact tubers. Tubers are exposed to natural soil concentrations of *Bacillus mycoides* that exceed the quantity of *Bacillus mycoides* isolate J spores applied to potato foliage (Ref. 3).

2. *Drinking water exposure*. According to the World Health Organization, *Bacillus* species are often detected in drinking water even after going through acceptable water treatment processes, largely because the spores are resistant to these disinfection processes (Ref. 4). Should this microbial pesticide be present, no adverse effects are

expected from exposure to *Bacillus mycoides* through drinking water, based on the results of toxicity studies described in Unit IV.

B. Other Non-Occupational Exposure

Natural background levels of *Bacillus mycoides* are reported to typically occur at about 10^5 spores per gram in agricultural soils. Use of *Bacillus mycoides* isolate J pursuant to the section 18 emergency exemption is not likely to result in increased exposure in the general population because the 2,675 treated acres are not accessible to the general population.

VI. Cumulative Effects

Pursuant to section 408(b)(2)(D)(v) of FFDCA, EPA has considered available information on the cumulative effects of such residues and other substances that have a common mechanism of toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common method of toxicity. Because there is no indication of mammalian toxicity or pathogenicity resulting from exposure to *Bacillus mycoides* isolate J, we conclude that there are no cumulative effects for this bacterium.

VII. Determination of Safety for U.S. Population, Infants, and Children

The Agency has determined that there is reasonable certainty that no harm will result to the U.S. population from exposure to residues of *Bacillus mycoides* isolate J in connection with the section 18 emergency exemption. This determination includes all anticipated dietary exposures and other non-occupational exposures for which there is reliable information. Oral ingestion of the *Bacillus mycoides* isolate J organism on potatoes treated under the section 18 emergency exemption is unlikely because the

portion of the potato plant that is treated is not intended for human or livestock consumption.

Data submitted in a pulmonary toxicity/pathogenicity study performed at doses several orders of magnitude above expected exposure revealed no signs of overt toxicity or pathogenicity in the test animals. The pulmonary exposure route is more sensitive than an oral exposure study which has the various inactivation processes discussed in Unit IV. The results of an extensive literature search, which included numerous citations of the test organism, yielded no reports of its pathogenicity for mammals (Ref. 5).

Section 408(b)(2)(C) of FFDCA provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, section 408(b)(2)(C) of FFDCA also provides that EPA shall apply an additional tenfold 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 unless EPA determines that a different margin will be safe for infants and children. In the absence of specific studies showing that infants and children are not at risk, the Agency has retained a 10X safety factor to account for gaps in the database for *Bacillus mycoides* isolate J. In this instance, however, based on all available information, the Agency concludes that *Bacillus mycoides* isolate J presents no oral toxicity effects of concern. Thus, there are no threshold effects of concern to infants and children when *Bacillus mycoides* isolate J is used in accordance with the authorized section 18 use directions.

VIII. Other Considerations

A. Endocrine Disruptors

The pesticidal active ingredient, *Bacillus mycoides* isolate J is not known to exert an influence on the endocrine system.

B. Analytical Method(s)

Analytical methods for *Bacillus mycoides* isolate J that are sufficient to justify the issuance of the section 18 emergency exemption have been submitted to the Agency. An enforcement analytical method is not required to support an exemption from the requirement of a tolerance.

C. Codex Maximum Residue Level

No codex maximum residue levels exist for the microbial *Bacillus mycoides* isolate J.

IX. Conclusion

Therefore, a time-limited exemption from the requirement of a tolerance is established for residues of *Bacillus mycoides* isolate J, in or on potatoes. This time-limited exemption from the requirement of a tolerance expires on December 31, 2015.

X. References

1. Martinsen, T.C., Bergh, K. & Waldrum, H.L., (2005) Gastric Juice: A Barrier Against Infectious Diseases, Basic and Clinical Pharmacology and Toxicology, vol. 96: 94-102.

2. USEPA. Prevention, Pesticides and Toxic Substances. Reregistration Eligibility Decision (RED) *Bacillus thuringiensis*. EPA738-R-98-004. March 1998.

3. Ludwig, W., Schleiffer, Whitman, W.H. (2009) Class I: Bacilli, class. nov., in "Bergey's Manual of Systematic Bacteriology", 2nd Edition, Volume 3, The Firmicutes, P. DeVos, G.M. Garrity, D. Jones, N.R.Krieg, W. Ludwig, K.H. Schleiffer, & W.B. Whitman (eds.) Springer Publishing.

4. World Health Organization, Guidelines for Drinking-Water Quality. (2011) Fourth Edition .

5. Logan, N.A. & Turnbull, P.C.B. (2003) Bacillus and other Endospore-forming Bacteria, Chap 32. in "Manual of Clinical Microbiology" 8th edition, P.R.Murray, E.J. Baron, J.H. Jorgensen, M.A. Pfaller & R.H. Yolken (eds), ASM Press.

XI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA sections 408(e) and 408(l)(6). 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerances 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (NTTAA(15 U.S.C. 272 note).

XII. 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: April 12, 2013

Daniel J. Rosenblatt,
Acting Director, Registration Division, 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:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Revise §180.1269 to read as follows:

§180.1269 *Bacillus mycoides* isolate J; exemption from the requirement of a tolerance.

Bacillus mycoides isolate J is temporarily exempt from the requirement of a tolerance when used as a fungicide on potatoes in accordance with a valid Federal

Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 18 emergency exemption. This temporary exemption from the requirement of a tolerance expires and is revoked on December 31, 2015.

[FR Doc. 2013-09706 Filed 04/24/2013 at 8:45 am; Publication Date: 04/25/2013]