existing petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA is establishing a tolerance on low growing berry, except strawberry, subgroup 13–07H. EPA concludes it is reasonable to establish the tolerance on the newly created subgroup, since the individual commodities for which tolerances were requested are identical to those which comprise low growing berry, except strawberry, subgroup 13–07H.

V. Conclusion

Therefore, a tolerance is established for residues of chlorimuron-ethyl, ethyl 2-[[[[(4-chloro-6-methoxypyrimidin-2yl) amino]carbonyl]sulfonyl]benzoate], in or on berry, low growing, except strawberry, subgroup 13–07H at 0.02 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 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 on the basis of a petition under section 408(d) of FFDCA, 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 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 section 408(n)(4) of FFDCA. 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) (Public Law 104–4).

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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: February 24, 2009.

Lois Rossi,

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. Section 180.429 is revised to read as follows:

§ 180.429 Chlorimuron ethyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide chlorimuron ethyl, ethyl 2-[[[[(4-chloro-6-methoxypyrimidin-2yl) amino]carbonyl]sulfonyl]benzoate], in or on the following raw agricultural commodities:

Commodity	Parts per million
Berry, low growing, except strawberry, subgroup 13–07H	0.02
Peanut	0.02
Soybean	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. E9–5192 Filed 3–10–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0303; FRL–8400–2]

Bacillus Mycoides Isolate J; Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the *Bacillus mycoides* isolate J in or on pecans, potatoes, sugar beets, tomatoes, and peppers when used in accordance with good agricultural practices. Montana Microbial Products, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting to amend the existing temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus mycoides* isolate J in or on pecans, potatoes, sugar beets, tomatoes, and peppers on a time-limited basis. The temporary tolerance exemption expires on March 31, 2011.

DATES: This regulation is effective March 11, 2009. Objections and requests for hearings must be received on or before May 11, 2009, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0303. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susanne Cerrelli, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8077; e-mail address: *cerrelli.susanne@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. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. 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. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guideline at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of 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. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2005–0303 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before May 11, 2009.

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 that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2005–0303, by one of the following methods.

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of June 18, 2008 (73 FR 34734-34736) (FRL–8366–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 8G7320) by Montana Microbial Products, 510 East Kent Ave., Missoula, MT 59801. The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of *Bacillus mycoides* isolate J. This notice included a summary of the petition prepared by the petitioner, Montana Microbial Products. There were no comments received in response to the notice of filing. The Agency has determined that the change sought by Montana Microbial products is actually a revision of § 180.1269, rather than an amendment of the exemption. The exemption for the commodities listed in § 180.1269 expired on December 31, 2007 and new exemptions for pecans, potatoes, tomatoes, and peppers based on the petition are being approved for a period that does not expire until March 31, 2011, based on the petition submitted by Montana Microbial Products. Therefore, the section is being revised to reflect these changes.

Section 408(c)(2)(A)(i) of FFDCA 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.'' 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 section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a

tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, 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, section 408(b)(2)(D) of FFDCA requires that 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 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. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, 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.

An Acute Pulmonary Toxicity/Pathogenicity study (OPPTS 885.3150) in rats which were dosed intratracheally with *Bacillus mycoides* isolate J at 1.1 x 10^8 cfu/animal, was reviewed and found to be supplemental because a clear pattern of clearance from all organs was not demonstrated during the study's 35–day length. The test substance, however, did show a pattern of clearance in some organs. Differential heat treatment of tissue samples had suggested that most of the recovered organisms were spores. No treated animals died nor were there signs in the animals of toxicity or pathogenicity. Given the ubiquitous nature of this spore forming bacterium which is found on plants, in soil, water, air and decomposing plant tissue, 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, issuance of the Experimental Use Permit (EUP) can be justified provided there are instructions for appropriate respiratory protection for the applicators specified on the product label.

The Agency has granted the 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 Dermal Toxicity (OPPTS 870.1200); Acute Inhalation Toxicity (OPPTS 870.1300) mammalian studies for *Bacillus mycoides* isolate ''J'' for this experimental–use permit (82761–EUP–2), based on the following submitted rationale:

1. Personnel who worked with BmJ, more than 20 people over 8 years, have not reported any exposure effects in routine use of the experimental product.

2. Exposure to BmJ will be limited by supervision and label mandated protective equipment.

3. *B. 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 *B. mycoides* present in agricultural soils, there has been long term human exposure to *B. mycoides* in crops and to residual *B. mycoides* cells or spores in food crops. No toxicity, infectivity or pathogenicity of *B. mycoides* in humans was reported in numerous searched citations.

4. *B. mycoides* is readily differentiable from other *B. cereus* group organisms in production batches (including *Bacillus thuringiensis*, *Bacillus pseudomycoides*, *Bacillus anthracis*, *Bacillus cereus*, and *Bacillus weihenstephanensis*) and well defined quality control procedures keep contaminants from fermentation batches. *B. mycoides* is a member of the closely related group of *Bacillus* species which includes *B. anthracis* and *B. cereus* strains known to cause food poisoning as well as the widely used microbial pesticide *B. thuringiensis*. As part of a well recognized screening procedure used for quality control of *B. thuringiensis* and *B. cereus*, similar procedures shall be required for *B. mycoides*.

The Agency has granted the requests for waivers for the studies Primary Eye Irritation (OPPTS 870.2400) and Primary Dermal Irritation (OPPTS 870.2500). The registrant had provided the following rationales for the requests with which the EPA agrees:

1. Personnel who worked with *Bacillus mycoides* isolate J for 2 to 7 years showed no eye or dermal exposure effects.

2. Eye or dermal exposure to *Bacillus mycoides* isolate J will be limited by supervision and protective equipment. If eye or dermal exposure did, however, occur, the spores will rinse out of the eye with water or wash off the skin with soap and water because spores are hydrophilic.

3. *Bacillus mycoides* isolate J is not recorded as a human pathogen. Due to the ubiquitous presence of *Bacillus mycoides* isolate J in agricultural soils, there has been long term human exposure to *Bacillus mycoides* isolate J in crops and to residual *Bacillus mycoides* isolate J cells or spores in food crops. No toxicity or pathogenicity of *Bacillus mycoides* isolate J in humans has been reported in numerous searched citations.

In connection with the requirement for reporting Hypersensitivity Incidents (OPPTS 885.3400), the Registrant has notified the Agency that no recorded or reported adverse hypersensitivity reaction to *Bacillus mycoides* isolate J has occurred during the period of 2 years in which the substance has been handled in a laboratory setting.

IV. 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 proposed EUP is not expected to result in increased dietary exposures of *Bacillus mycoides* isolate J to the general population.

1. *Food.* The experimental program will include five crops, pecans, potatoes, sugar beets, tomatoes and peppers. The quantity of BmJ applied to plant foliage, 7.5 x 10^{11} spores/acre per application in typical applications to a maximum of 3.75 x 10^{12} spores per acre in pecan trees, is small compared to the natural background levels of *Bacillus mycoides*. In agricultural soils *B. mycoides* typically occurs at about 10^5 spores per gram and 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. In pecans, spores applied as foliage spray will also contact nutshells, however spores would be removed when shells are removed prior to any human consumption. In potatoes, spores applied to foliage will not directly contact tubers. Tubers are exposed to natural soil concentrations of *Bacillus* that exceed the quantity of *Bacillus mycoides* isolate J spores

applied to potato foliage. Washing, peeling, and or cooking will remove or destroy any residual spores. Because the ordinary consumer encounters only the sugar produced from sugar beets, (in which the bacterium is not present), an increased dietary exposure is not foreseen from treated sugar beets. Residue of *Bacillus mycoides* isolate J applied to sugar beet foliage is not expected to carry through sugar beet processing to create a residue in refined sugar for human consumption. Application of *Bacillus mycoides* isolate J will create minimal residues on sugar beet foliage. Cattle fed sugar beet tops treated with *Bacillus mycoides* isolate J may have an exposure to a low level of *Bacillus mycoides* isolate J spores. Given the natural occurrence of *B. mycoides*, the exposure to applied *Bacillus mycoides* isolate J on sugar beet tops is not expected to represent a significant increase in natural exposure of cattle to *B. mycoides*. Nor is human exposure anticipated of *Bacillus mycoides* isolate J in meat or milk as a result of feeding sugar beet tops with *Bacillus mycoides* isolate J residue to cattle.

In tomatoes and peppers, spores applied as foliage sprays may leave a *Bacillus mycoides* isolate J spore residue on the tomatoes or peppers. From persistence studies, discussed in Unit III., residues of *Bacillus mycoides* isolate J are expected to decline by more than 1,000–fold over a 2–week period. Washing harvested fruit will also further reduce or eliminate any *Bacillus mycoides* isolate J residue.

2. *Drinking water exposure*. There is minimal to negligible risk that surface water and, thus, drinking water exposure would occur with the proposed EUP testing. The proposed test sites are at least one half mile from the nearest surface water. When spray drift or accidental application of *Bacillus mycoides* isolate J over surface water did occur, the concentration of *Bacillus mycoides* isolate J spores in the water had been found to be very low. For example an acre dose of *Bacillus mycoides* isolate J, 7.5 x 10^{11} spores to 100 square meters of surface water 1 meter deep, would result in a concentration of 750 spores per cc. of water as noted in the EPA ecological risk assessment for *Bacillus mycoides* isolate J which is based on data submitted by Montana Microbial Products.

B. Other Non-Occupational Exposure

Natural background levels of *Bacillus mycoides* isolate J are reported to typically occur at about 10^5 spores per gram in agricultural soils.

EPA concludes that dermal or inhalation exposure to *Bacillus mycoides* isolate J in the general population as a result of this EUP is not likely to occur, based on information submitted in pesticide tolerance petition 8G7320 indicating that the relevant EUP agricultural sites, which will not exceed 956 acres, are not accessible to individuals other than those conducting this EUP program.

V. 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 *Bacillus mycoides* isolate J, we conclude that there are no cumulative effects for this bacterium.

VI. 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 testing for the proposed EUP program. 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 crops treated under the proposed EUP is unlikely because: The portion of the pecans, potatoes, and sugar cane that is treated is not consumed by humans. The residues on peppers and tomatoes are readily removed by washing with water, and the U.S. population is already exposed to *B. mycoides* as a prevalent naturally occurring microbe in untreated soil. Data submitted in a pulmonary toxicity/pathogenicity study revealed no signs of overt toxicity or pathogenicity in the test animals. The results of an extensive literature search, which included numerous citations of the test organism, yielded no reports of its pathogenicity for mammals. There will be no access to persons other than participants in the program to the test sites for the EUP. The participants in the EUP program are required to wear appropriate respiratory protection. 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, also referred to as margins of exposure (MOEs), 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 MOE will be safe for infants and children. In this instance, based on all available information, the Agency concludes that there is a finding of no toxicity for *Bacillus mycoides* isolates J. Thus, there are no threshhold effects of concern to infants and children when the microbial is used as a fungicide. Accordingly, the Agency concludes that the additional MOE is not necessary to protect infants and children, and that not adding any additional MOE will be safe for infants and children.

VII. 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 an Experimental Use Permit (EUP) 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.

VIII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA 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 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 on the basis of a petition under section 408(d) of FFDCA, 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 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 section 408(n)(4) of FFDCA. 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) (Public Law 104–4).

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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: January 14, 2009.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is revised 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. Section 180.1269 is revised 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 pecans, potatoes, sugar beets, tomatoes, and peppers in accordance with the Experimental Use Permit 82761–EUP–2. This temporary exemption from the requirement of a tolerance expires and is revoked on March 31, 2011.

[FR Doc. E9–5266 Filed 3–10–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0617; FRL–8397–2]

2-Propenoic acid, polymer with α-[4-(ethenyloxy) butyl]-ω-hydroxypoly (oxy-1,2-ethanediyl) and 1,2-propanediol mono-2-propenoate, potassium sodium salt; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 2-Propenoic acid, polymer with α-[4-(ethenyloxy) butyl]-ω-hydroxypoly (oxy-1,2-ethanediyl) and 1,2-propanediol mono-2-propenoate, potassium sodium salt; (CAS Reg. No. 518026–64–7); when used as an inert ingredient in a pesticide chemical formulation. BASF Corporation 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 establish a maximum permissible level for residues of 2-propenoic acid, polymer with α-[4-(ethenyloxy) butyl]-ω-hydroxypoly (oxy-1,2-ethanediyl) and 1,2-propanediol mono-2-propenoate, potassium sodium salt on food or feed commodities.

DATES: This regulation is effective March 11, 2009. Objections and requests for hearings must be received on or before May 11, 2009, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0617. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Alganesh Debesai, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8353; e-mail address: *debesai.alganesh@epa.gov*.

SUPPLEMENTARY INFORMATION: