PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

Subpart MM—Oregon

2. Section 52.1970 is amended by adding paragraphs (c)(116)(i)(D) and (c)(156) to read as follows:

§ 52.1970 Identification of plan.

* * * * *

(c) * * * *

(116) * * *

(i) Additional Material:

(A) The following revised sections of Oregon Administrative Rules Chapter 340 effective March 13, 2005: Division 12 Enforcement Procedures and Civil Penalties: Rule 0026 Policy, Rule 0028 Scope of Applicability, Rule 0030 Definitions, Rule 0038 Warning Letters, Pre-Enforcement Notices and Notices of Permit Violation, Rule 0041 Formal Enforcement Action, Rule 0042 Determination of Base Penalty, Rule 0045 Civil Penalty Determination Procedure, Rule 0145 Determination of Aggravating or Mitigating Factors, Rule 0150 Determination of Economic Benefit, Rule 0160 Department Discretion Regarding Penalty Assessment, Rule 0162 Inability to Pay the Penalty, Rule 0165 Stipulated Penalties, Rule 0170 Compromise or Settlement of Civil Penalty by Department.

(B) The following revised sections of Oregon Administrative Rules Chapter 340 effective March 29, 2006: Division 12 Enforcement Procedures and Civil Penalties: Rule 0027 Rule Effective Date, Rule 0053 Violations that Apply to all Programs, Rule 0054 Air Quality Classification of Violations, Rule 0073 Environmental Cleanup Classification of Violation, Rule 0082 Contingency Planning Classification of Violations, Rule 0130 Determination of Violation Magnitude, Rule 0135 Selected Magnitude Categories, Rule 0140 Determination of Base Penalty, Rule 0155 Additional or Alternate Civil Penalties.

(D) Based on a SIP revision submitted by Oregon on February 16, 2001, Oregon Administrative Rules Chapter 340, Division 23 “Rules for Open Burning,” as effective March 10, 1993, is removed from the SIP.

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(i) Incorporation by reference.

(A) The following sections of the OAR Chapter 340, Division 264, effective December 15, 2000: Division 264, Rules For Open Burning: Rule 0010 How to Use These Open Burning Rules; Rule 0020 Policy; Rule 0030 Definitions; Rule 0040 Exemptions, Statewide; Rule 0050 General Requirements Statewide; Rule 0060 General Prohibitions Statewide; Rule 0070 Open Burning Conditions; Rule 0075 Delegation of Authority; Rule 0078 Open Burning Control Areas; Rule 0080 County Listing of Specific Open Burning Rules; Rule 0100 Open Burning Requirements, Baker, Clatsop, Crook, Curry, Deschutes, Gilliam, Grant, Harney, Hood River, Jefferson, Klamath, Lake, Lincoln, Malheur, Morrow, Sherman, Tillamook, Umatilla, Union, Wallowa, Wasco and Wheeler Counties; Rule 0110 Open Burning Requirements, Benton, Linn, Marion, Polk, and Yamhill Counties; Rule 0120, Open Burning Requirements, Clackamas County; Rule 0130, Open Burning Requirements, Multnomah County; Rule 0140 Open Burning Requirements, Washington County; Rule 0150 Open Burning Requirements, Columbia County; Rule 0160 Open Burning Requirements, Lane County; Rule 0170 Open Burning Requirements, Coos, Douglas, Jackson and Josephine Counties; Rule 0180 Open Burning Requirements, Letter Permits, Rule 0190 Open Burning Requirements, Forced-Air Pit Incinerators.

(B) [Reserved.]

(ii) Additional Material:

(A) The following revised sections of Oregon Administrative Rules Chapter 340 effective May 13, 2005: Division 12 Enforcement Procedures and Civil Penalties: Rule 0026 Policy, Rule 0028 Scope of Applicability, Rule 0030 Definitions, Rule 0038 Warning Letters, Pre-Enforcement Notices and Notices of Permit Violation, Rule 0041 Formal Enforcement Action, Rule 0042 Determination of Base Penalty, Rule 0045 Civil Penalty Determination Procedure, Rule 0145 Determination of Aggravating or Mitigating Factors, Rule 0150 Determination of Economic Benefit, Rule 0160 Department Discretion Regarding Penalty Assessment, Rule 0162 Inability to Pay the Penalty, Rule 0165 Stipulated Penalties, Rule 0170 Compromise or Settlement of Civil Penalty by Department.

(B) The following revised sections of Oregon Administrative Rules Chapter 340 effective March 29, 2006: Division 12 Enforcement Procedures and Civil Penalties: Rule 0027 Rule Effective Date, Rule 0053 Violations that Apply to all Programs, Rule 0054 Air Quality Classification of Violations, Rule 0073 Environmental Cleanup Classification of Violation, Rule 0082 Contingency Planning Classification of Violations, Rule 0130 Determination of Violation Magnitude, Rule 0135 Selected Magnitude Categories, Rule 0140 Determination of Base Penalty, Rule 0155 Additional or Alternate Civil Penalties.


[FR Doc. 2013–09695 Filed 4–24–13; 8:45 am]
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 related information?


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 or 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, 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 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(l)(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” as the determination 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 registration of *Bacillus mycoides* isolate J by a State for special local needs under FIFRA section 24(c).

**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 × 10⁶ 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, foliar 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 pseudomyco*ides, *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 × 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

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

49 CFR Part 1572

[Docket No. TSA–2004–19605; Amendment No. 1572–10]

Provisions for Fees Related to Hazardous Materials Endorsements and Transportation Worker Identification Credentials

AGENCY: Transportation Security Administration, DHS.

ACTION: Final rule.

SUMMARY: The Transportation Security Administration (TSA) is removing specific fee amounts from regulations regarding security threat assessments (STAs) and credentialing for Hazardous Materials Endorsements (HMEs) and Transportation Worker IdentificationCredentials (TWICs). These provisions include State collection of the HME fee, TSA collection of the HME fee, and collection of the TWIC fee. Removing specific fee references will enable TSA to have the necessary flexibility to lower or increase fees as necessary to meet the statutory obligation to recover its costs. Current fee amounts as identified in these sections will remain unchanged until any future revisions to fee schedules are published in the Federal Register.


FOR FURTHER INFORMATION CONTACT: Carolyn Mitchell, Office of Intelligence and Analysis (OIA), TSA–10, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6010; telephone (571) 227–2372; email carolyn.mitchell@dhs.gov. For legal questions: Traci.Klemm@dhs.gov.

SUPPLEMENTARY INFORMATION:

Availability of Rulemaking Document

You can get an electronic copy using the Internet by—


(2) Accessing the Government Printing Office’s Web page at http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR to view the daily published Federal Register edition; or accessing the “Search the Federal Register by...