If the EPA receives adverse written comment, we will publish a final rule informing the public that this rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. The EPA does not intend to institute a second comment period on this action. Any parties interested in commenting on these actions must do so at this time.

VI. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Effect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 21, 2003. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: October 15, 2002.

David A. Ullrich,

Acting Regional Administrator, Region 5.

For the reasons stated in the preamble, part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart P—Indiana

2. Section 52.770 is amended by adding paragraph (c)(153) to read as follows:

§ 52.770 Identification of plan.

* * * * *

(c) * * *

(153) On April 30, 2002 and September 6, 2002, Indiana submitted revised particulate matter regulations for Union Tank Car's railcar manufacturing facility in Lake County, Indiana. The submittal amends 326 IAC 6–1–10.1. The revisions consist of relaxing the limits for the grit blaster. The new limits are 0.01 grains per dry standard cubic foot and 9.9 pounds per hour.

(i) Incorporation by reference.

Amendments to Indiana Administrative Code Title 326: Air Pollution Control Board, Article 6: Particulate Rules, Rule 1: Non-attainment Area Limitations, Section 10.1: Lake County PM_{10} emission requirements. Filed with the Secretary of State on July 26, 2002 and effective on August 25, 2002. Published in 25 *Indiana Register* 4076 on September 1, 2002.

[FR Doc. 02–29473 Filed 11–19–02; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0291; FRL–7277–3]

Bacillus Cereus Strain BPO1; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Bacillus cereus* strain BPO1 on raw and processed food when applied/used as a

foliar applied biological plant growth regulator intended to promote root mass growth, earlier fruit initiation, increased fruit retention, and increased nutrient utilization. Micro Flow Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus cereus* strain BPO1.

DATES: This regulation is effective November 20, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0291, must be received on or before January 21, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Robyn Rose, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9581; e-mail address: rose.robyn@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:

- Industry (NACIS 111, 112, 311, 32532), e.g., Crop Production, Animal Production, Food Manufacturing, Pesticide Manufacturing.

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 Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2002–0291. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of November 21, 2001 (66 FR 58481) (FRL–6802–1), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e), as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide tolerance petition (PP 1F6324) by Micro Flow Company, P.O. Box 5948 Lakeland, FL 33807–5948. This notice included a summary of the petition prepared by the petitioner Micro Flow Company. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1181 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus cereus* strain BPO1.

III. Risk Assessment

New section 408(c)(2)(A)(i) of the 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 tolerance is ''safe.'' Section 408(c)(2)(A)(ii) of the 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. Section of the FFDCA (b)(2)(C) 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. . . .'' Additionally, section 408(b)(2)(D) of the 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.

IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of the 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.

Acute mammalian toxicity/pathogenicity studies via oral, dermal, inhalation, eye, intratracheal, and

intravenous routes were conducted with *Bacillus cereus* strain BPO1. No pathogenicity was observed. BPO1 was also tested for entero toxin emetic-toxin production; no toxins were detected. *Bacillus cereus* has been implicated in nosocomial infections in rare instances and in food poisoning incidents. In the ELISA Analysis of Enterotoxin data submitted, there was no evidence of diarrhoeal type enterotoxin production in the culture filtrates of *Bacillus cereus* strain BOP1 or the end use product. In a blood agar hemolysis assay conducted with BPO1, weak alpha hemolysis was observed. Based on the results of the studies in this unit, subchronic, reproductive, teratology, chronic, and mutagenicity studies were not deemed necessary.

1. *Acute oral toxicity/pathogenicity* (OPPTS 870.1100; 152A–10 and 152B–10; MRIDs 4417737–05 and 441773–06). In the acute oral toxicity test, five male and five female rats were treated with a split dose, (10 milliliters/kilograms/dose) (mL/kg) for a total of 5,000 milligrams (mg)/kg of *Bacillus cereus* strain BP01; the second dose administered 1 hour after the first dose. Rats were weighed and observed for mortality or abnormalities for 14 days. No abnormalities were noted in body weight or weight gain throughout the study or upon necropsy. The oral lethal dose $(LD)_{50}$ *Bacillus cereus* strain BP01 was determined to be greater than 5,000 mg/kg body weight.

In the acute oral toxicity/pathogenicity test, 15 males and 15 females received a dose of 1.23×10^8 colony forming units (CFU) of the test substance by oral gavage; nine males and nine females were treated with 1.23×10^8 CFU killed test substance (by steam sterilization). Rats were weighed on days 0, 3, 7, 14, and 18 and signs of toxicity were observed daily. Randomly sampled rats from each sex and each test group were sacrificed on days 0, 3, 7, 14, and 18 and examined for any macroscopic abnormalities. Samples of the kidneys, liver, spleen, and stomach as well as feces were homogenized and plated to determine the number of typical *Bacillus cereus* colonies after incubation at 30 ^{0}C for at least 18 hours. No clinical sign were noted throughout the study and no abnormalities were noted in any animal at necropsy. Two males displayed a loss in body weight from day 0 to 3 and five females lost weight from day 7 to 14. No other abnormalities were noted in body weights or weight gain. *Bacillus cereus* strain BP01 is not toxic, pathogenic or infective when 1×10^8 CFU was administered orally. A distinct clearance pattern was observed throughout the study.

2. *Acute dermal toxicity* (OPPTS 870.1200; 152A–11; MRID 441773–07). Five male and five female rabbits were given a dose of 4.4×10^{10} CFU (2 grams (g)) dermally for 24 hours and observed after dosing for signs of toxicity and dermal irritation for 14 days. No clinical signs, except dermal irritation, were noted during the study and no abnormalities were noted upon necropsy. Two males and five females displayed a loss in body weight from day 0 to day 7. All animals displayed a weight gain through the end of the study. All males and females showed slight to well defined redness through day 4; very slight erythema was present in up to three males and three females through day 11. Dermal irritation was no longer apparent by day 12. Slight signs of edema were apparent in two males on day 3. Edema was no longer present by day 4. The LD_{50} of *Bacillus cereus* strain BP01 is greater than 2 grams per animal. Mild to moderate dermal irritation was noted and was no longer present by day 13.

3. *Acute intratracheal toxicity/pathogenicity* (OPPTS 885.3150; 152A–12; MRID 441773–08). Fifty female and fifty male rats received a single dose of 7×10^7 (males), or 9.33×10^7 CFU (females) of the test substance in a volume of 0.5 mL by intratracheal administration; fifty females and fifty males were treated with the same concentration of killed test substance (by steam sterilization); an additional fifty males and fifty females served as controls. Rats were weighed weekly and observed for signs of toxicity daily. Ten rats of each sex from each group were sacrificed on days 0, 7, 14, 21, and 36. Animals were examined for macroscopic abnormalities by necropsy. Lungs were evaluated by histopathological examination. Samples of the kidneys, liver, spleen, brain, mesenteric lymph nodes, blood, lungs, and caecum were homogenized, plated, and incubated for at least 18 hours then examined for typical *Bacillus cereus* colonies. Body weight losses were noted in females from the test substance group, one during the first, second and third weeks. No other abnormalities were noted in body weight or weight gain throughout the study. In the group treated with the test substance, three females displayed a rough hair coat, two females showed signs of labored respiration, and one female had hunched posture on day 0. Clinical signs were no longer apparent by day 2. Each treatment group had three males and females displaying mottled, dark red lungs on day 0. Red to tan lesions remained on the majority of animals through day 21. *Bacillus cereus* strain BP01 is not toxic, pathogenic or infective to rats at an intratracheal dose of either 7×10^8 or 9.33×10^8 CFU. A slow but typical clearance pattern was observed; slow clearance in the lung with distinct clearance pattern noted in the liver and spleen. The lesions present in the histopathology sections in both the killed and live test substance animals indicate an inflammatory response to the treatment due to the presence of particulate material.

4. *Acute intravenous toxicity* (OPPTS 885.3200; 152A–13; MRID 441773–09). Five male and five female rates were intravenously injected with either 0.5 mL of *Bacillus cereus*, 0.5 mL of the killed test substance, or kept as a naive control. The rats were weighed before initial dosing and weekly thereafter. Animals were observed for clinical signs twice daily for 14 days. All rats were examined by necropsy for any macroscopic abnormalities at the end of the study. One female displayed a loss in body weight from day 0 to day 17. No other abnormalities were noted in body weight or weight gain throughout the study. No clinical signs were reported by the testing facilty and no abnormalities were noted upon necropsy. Although *Bacillus cereus* strain BP01 is not toxic to rats at an intravenous dose of 2.0×10^7 CFU, the registrant failed to submit the clearance portion of the study. However, this study does not need to be repeated because the oral and intratracheal studies demonstrated distinct clearance patterns.

5. *Primary eye irritation* (OPPTS; 870.2400; 152A–14; MRID 441773–10). Three male and three female, young adult, New Zealnad White rabbits were given a single dose of 0.1g (equivalent to 2.2×10^9 CFU) of the microbial pest control agent (MPCA) in the everted lower right eyelid of each animal. The eye was gently held together for 2 seconds to prevent a loss of material. The left eye served as the control for each animal. The Draize Method was used to score ocular irritation and lesions at 1 hour, and 1, 2, 3, 4, and 7 days post dosing. A 2% fluorescein solution and ultraviolet light was used after 24 hours to evaluate corneal epithelial damage. Slight to moderate redness, chemosis, and occasional discharge was observed in all 6 animals within 1 hour post dosing. Clinical signs were no longer apparent by day 3. No abnormalities were observed in any control eye during the study. The primary irritation scores at 24 hours post dosing was 4.8 when a 0.1g (2×10^9 CFU) ocular dose was administered.

Ocular irritation was no longer present by day 3.

6. *Immunotoxicity* (OPPTS 880.3800). Immune response, teratogenicity, virulence enhancement, and mammalian mutagenicity (40 CFR 158.740(c)(2)(vi) through (xv), were not required since survival, replication, infectivity, toxicity, or persistence of the microbial agent was not observed in the test animals treated in the Tier I infectivity tests.

7. *Hypersensitivity* (OPPTS 870.2600; 152–15). Incidents of hypersensitivity must be reported to the Agency in a timely manner. There have been no reports of incidents of hypersensitivity to *Bacillus cereus* since it was registered.

V. Aggregate Exposures

In examining aggregate exposure, section 408 of the 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

1. *Food.* While the suggested use pattern may result in dietary exposure with possible residues on food and feed, negligible risk is expected for both the general population, infants and children. Submitted acute toxicology tests confirm that based upon the use sites, use patterns, application method, use rates, low exposure, and lack of significant toxicology concerns, the potential risks, if any, to humans are considered negligible, therefore an exemption from the requirement of a tolerance is warranted. Acute exposure could occur from the proposed outdoor use sites but would be very low because of the low application rates of less than 48 fluid ounces of BP01/acre/year in cotton and less than 32 fluid ounces of BP01/acre/year in soybean. Considering the low application rates, lack of toxicity/pathogenicity, ubiquitous nature and natural occurrence of *Bacillius cereus*, no residue data were required.

2. *Drinking water exposure.* The microorganism *Bacillus cereus* is ubiquitous in many soils throughout the world. *Bacillus cereus* is not known as an aquatic bacterium and therefore is not expected to proliferate in aquatic habitats. The potential exists for *Bacillus cereus* strain BPO1 to enter ground water or other drinking water sources, after application. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to *Bacillus cereus* through drinking water. Moreover, *Bacillus cereus* strain BPO1 is not considered to be a risk to drinking water. The Agency has no drinking water exposure concerns, because exposure is minimal to non-existent and the demonstrated lack of toxicity or pathogenicity for the *Bacillus cereus* Strain BP01 microbe.

B. Other Non-Occupational Exposure

The potential of non-dietary exposures to *Bacillus cereus* strain BPO1 pesticide residues for the general population, including infants and children, is unlikely since this is only an agricultural use pesticide. The Agency believes that the potential aggregate exposure, derived from dermal and inhalation exposure via mixing, loading, and applying *Bacillus cereus* strain BPO1, should fall well below the currently tested microbial safety levels.

1. *Dermal exposure*. Dermal exposure via the skin would be the primary route of exposure for mixer/loader applications. Unbroken skin is a natural barrier to microbial invasion of the human body. Dermal absorption could occur only if the skin were cut, if the microbe were a pathogen equipped with mechanisms for entry through or infection of the skin, or if metabolites were produced that could be dermally absorbed. Submitted acute dermal toxicity data confirmed a lack of dermal toxicity and mild to moderate dermal irritation was only observed until day 13 of the study.

2. *Inhalation exposure*. Inhalation would be the primary route of exposure for mixer/loader applications. Because the pulmonary study showed no adverse effects, the risks anticipated for the route of exposure are considered minimal.

VI. Cumulative Effects

The Agency 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 mechanism of toxicity. Because there is no indication of mammalian toxicity to this, the Agency is confident that there will not be cumulative effects from the registration of this product

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

1. *U.S. population*. There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population from exposure to *Bacillus cereus*. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the very low levels of mammalian toxicity (no toxicity at the maximum doses tested, Toxicity Categories III and IV for irritation) associated with *Bacillus cereus* strain BP01 and the history of safe use of *Bacillus cereus*.

2. *Infants and children*. FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold margin of exposure (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 of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. A battery of acute toxicity/pathogenicity studies is considered sufficient by the Agency to perform a risk assessment for microbial pesticides. Other strains of *Bacillus cereus* have been implicated in nosocomial infections in rare instances and in food poisoning incidents. In the ELISA Analysis of Enterotoxin test data submitted there was no evidence of diarrhoeal type enterotoxin production in the culture filtration of *Bacillus cereus* strain BPO1 or the end use product. Data relating to the post application die off of *Bacillus cereus* species *vs.* background soil population counts demonstrated that this organism is very stable in the soil and rhizosphere. Also, for food use of microbial pesticides, the acute toxicity/pathogenicity studies have allowed for the conclusion that an exemption from the requirement of a tolerance is appropriate and adequate to protect human health, including that of infants and children.

VIII. Other Considerations

A. Endocrine Disruptors

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no

scientific basis for including, as part of the program, the androgen and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, *Bacillus cereus* may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Based on available data, no endocrine system-related effects have been identified with consumption of *Bacillus cereus* strain BP01. It is a naturally occurring bacteria. To date, there is no evidence to suggest that *Bacillus cereus* affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor.

B. Analytical Method(s)

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation based upon the lack of mammalian toxicity of *Bacillus cereus* and the lack of exposure with the plant growth regulator use pattern. For the same reasons, the Agency has concluded that an analytical method is not required for enforcement purpose for *Bacillus cereus.*

C. Codex Maximum Residue Level

There are no Codex harmonization consideration since there is currently no codex tolerance for *Bacillus cereus* residues.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, 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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0291 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 January 21, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by telephone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2002–0291, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of

the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.,* or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications '' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: October 31, 2002.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention 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), 346(a) and 374.

2. Section 180.1181 is revised to read as follows:

§ 180.1181 Bacillus cereus strain BPO1; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance for residues of the *Bacillus cereus* strain BPO1 in or on all raw agricultural commodities when applied/used in accordance with label directions.

[FR Doc. 02–29331 Filed 11–19–02; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 02–2231, MB Docket No. 02–223, RM–10520]

Digital Television Broadcast Service; Avalon, CA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Pappas Southern California License, LLC., and pursuant to Section 531 of the Public Health, Security and Bioterrorism Preparedness and Reponse Act of 2002, allots DTV channel 47c at Avalon, California. DTV channel 47c can be allotted to Avalon at the