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[FR Doc. E8–9950 Filed 5–6–08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0159; FRL–8362–7]

Bacillus firmus isolate 1582; 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 firmus* isolate 1582 or *Bacillus firmus* I-1582 on all food/feed commodities when applied/used as soil applications and seed treatments. AgroGreen 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 firmus* I-1582.

DATES: This regulation is effective May 7, 2008. Objections and requests for hearings must be received on or before July 7, 2008, 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–2007–0159. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8097; e-mail address: *bacchus.shanaz@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. To determine whether you or your business may be affected by this action, you should carefully examine the applicable provisions. 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 an electronic copy of this **Federal Register** document through the electronic docket 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 pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, as amended by 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. 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–2007–0159 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 July 7, 2008.

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–2007–0159, 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'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 March 21, 2007 (72 FR 13277) (FRL–8117–4), 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 6F7111) by AgroGreen, Biological Division, Minrav Infrastructures (1993) Ltd., 3 Habossem Str, P.O. Box 153, Ashdod

77101, Israel. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus* firmus isolate I-1582 when used as a soil application or seed treatment. This notice included a summary of the petition prepared by the petitioner RegWest Company, LLC, 30856 Rocky Road, Greeley, CO 80631–9375, United States Department of Agriculture (USDA) and submitted on behalf of AgroGreen. The current representative for AgroGreen is SciReg, Inc. 12733 Director's Loop, Woodbridge, VA 22192, USA. There were no comments received in response to the notice of filing.

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.

Bacillus firmus isolate 1582 (called *B.* firmus I-1582) (U.S. Patent No. 6,406,690) is a Microbial Pesticide Control Agent (MPCA). It is intended to be used as a biological nematode suppressant on fruits, vegetables, field crops, and on such non-food crops as turf, and ornamentals. Further information regarding this MPCA can be found in the Biopesticide Registration Action Document (BRAD) on the Biopesticides and Pollution and Prevention Division website *http://www.epa.gov/pesticides/biopesticides*.

Studies submitted to the agency were issued Master Record Identification numbers (MRIDs) and then reviewed by the Biopesticides and Pollution Prevention Division (BPPD). The Agency also considered these submissions in light of the new microbial pesticides data requirements, which became final on December 26, 2007 (72 FR 61002). The following summaries of the toxicological profile of *Bacillus firmus* isolate I-1582 are based on Agency reviews or Data Evaluation Records (DERs) dated March 05, 2008. These reviews include the following acute toxicity/pathogenicity studies; oral, dermal, pulmonary and injection.

a. *Acute oral toxicity/pathogenicity - rats (OPPTS 885.3050; MRID #46933007; DER 03/05/2008).* Nineteen male and 19 female Sprague-Dawley rats were each treated by a single oral gavage dose of 0.1 mL per animal (>10^8 colony forming unit (cfu) animal) of *Bacillus firmus* I-1582 spores. The presented data showed no clinical signs and no weight loss related to test substance in rats. *Bacillus firmus* I-1582 was detected in brain, blood, cecum content, kidneys, lungs, lymph nodes, and spleen of the treated animals with clearance from the blood by day 7 and from all other organs by day 14. Necropsy was not conducted. Based on the presented/submitted data, *Bacillus firmus* I-1582 does not appear to be toxic, infective, and/or pathogenic in rats, when dosed orally at >10^8 cfu/animal. This study was classified as ''acceptable'' and the pesticide considered Toxicity Category IV for acute oral effects.

b. *Acute dermal toxicity/pathogenicity - rabbits (OPPTS 885.3100; MRID #46933008; DER 03/05/2008).* Five male and five female New Zealand White rabbits were each treated with 5,050 milligrams/kilogram/bodyweight (mg/kg/bwt) *Bacillus firmus* I-1582 spore suspension applied to the clipped dorsal trunk in an area of approximately 10% of the body surface in a dermal occlusion test according to standard laboratory procedures. Animals were observed for dermal irritation 60 minutes after patch removal. The test animals were observed for mortality and clinical signs of toxicity at least three times on the day of treatment and once daily thereafter for 14 days. The rabbits were euthanized on day 14 and necropsies were performed. With the exception of one female that lost weight during the first week, all animals had normal body weight gain. All rabbits appeared normal during the study and all survived the study. Very slight to well defined erythema was observed on day 1 with clearance by day 4. No observable abnormalities were noted at necropsy. The dermal LD_{50} for males, females, and combined was greater than 5,050 mg/kg. Thus, *Bacillus firmus* I-1582 is not toxic, infective, or pathogenic via the dermal route of exposure, and the active ingredient is placed in Toxicity Category IV for acute dermal effects.

c. *Acute pulmonary toxicity/pathogenicity - rats (OPPTS 885.3150; MRID #46933009; DER 03/05/2008).* Thirty male and 30 female Sprague-Dawley rats received 0.1 mL per animal (>10^8 cfu/animal) *Bacillus firmus* I-1582 by intratracheal instillation. The presented data show no adverse abnormal clinical signs in rats. No test organisms were detected in any sample from the control rats. All six animals sacrificed on day 3 had significant cfus (686 to 30,731 cfu/g) in their lungs. The test organism was detected in brain, blood, cecum content, kidneys, lungs, lymph nodes, and spleen of the treated animals. Clearance was observed from the blood, kidneys, and liver by day 7 and from all other organs by day 14. Necropsy studies were not conducted. Based on the presented/submitted data, the test organisms were not toxic, infective and/or pathogenic to rats and the active ingredient was placed in Toxicity Category IV for acute pulmonary effects.

d. *Acute inhalation toxicity (OPPTS 870.1300; MRID # 46933009; DER 03/05/2008).* An acute inhalation study was not required for this non-volatile active ingredient. The Agency also considered the acute pulmonary study in Unit III.c., the nature of the inert ingredients, the label requirements for Personal Protective Equipment for workers, and the potential low exposure associated

with the proposed application methods. Based on its non-volatile nature, if the pesticide is used as labeled, it will pose minimal to non-existent risk to non-occupationally-exposed populations via inhalation.

e. *Acute injection toxicity/ pathogenicity - rats (OPPTS 885.3200; MRID # 46933010; DER 03/05/2008).* Twenty six male and 26 female Sprague-Dawley rats each received a dose of 0.1 mL per animal (>10^7 cfu/animal), by injection into the tail vein. The presented data showed no observable clinical signs in treated rats. No test organisms were recovered in any samples from the control rats. The test organism was detected in the blood, kidneys, liver, lungs, lymph nodes, and spleen of the treated rats. Clearance from the brain, blood, kidneys, lymph nodes, and spleen was established by day 21 after dosing. Clearance from the cecum and liver was established by day 14 after dosing. Necropsy studies showed no abnormal findings. *Bacillus firmus* spores did not appear to be toxic, infective, and/or pathogenic in rats, when dosed at >107 cfu/animal. The submission is classified as acceptable.

f. *Cell culture (OPPTS 885.3500).* This data requirement is only required for active ingredients that are viruses and not for this type of bacterial pesticide.

g. *Waiver request: Hypersensitivity incidents technical-grade active ingredient (TGAI) (OPPTS 885.3400; DER 03/05/2008).* In addition to the rationales in Unit III.h., the applicant requested that hypersensitivity incidents be waived based on there being no adverse effects of *Bacillus firmus* or its metabolites to humans or mammals in literature searches. The request to waive this requirement is not granted. As required for all pesticides, the Agency requires that hypersensitivity incidents, should adverse effects occur, must be reported to comply with section 6(a)(2) 40CFR159.152.

h. *Waiver requests for Tiers II and Tier III (OPPTS 885.3550); MRID #s 46933011; 47024806; DER 03/05/2008).* The registrant requested that the Agency waive the requirement for submission of data to support Tier II and Tier III requirements for the TGAI.

The following rationales were provided to support requests to waive submission of the studies

1. The active ingredient, *Bacillus firmus* strain I-1582, is a naturally occurring microorganism.

2. No reports of adverse effects of *Bacillus firmus* or its metabolites to humans or mammals were found in literature searches.

3. The proposed uses of the proposed End-use Product (EP) are not expected to result in increased exposure or adverse effects to humans or mammals.

4. The bacteria count falls to sub-effective levels in the environment within 90 days of treatment.

5. The submitted studies, MRIDs 46933007, 46933008, 46933009, and 46933010, did not show pathogenicity to animals treated by oral gavage, dermal application, pulmonary instillation, or intravenous injection.

6. *Bacillus firmus* was not found on any of eleven lists of pathogens searched.

Based on these acceptable rationales and there being no toxicological, infectivity or pathogenicity concerns in the Tier I mammalian toxicity data submitted, the Agency granted the request to waive studies required for Tier II and Tier III testing.

i. *Waiver requests: EP and hypersensitivity incidents (OPPTS 885.3400; DER 03/05/2008).* The applicant has submitted rationales to waive data for acute oral toxicity/ pathogenicity, acute pulmonary toxicity/pathogenicity, acute dermal, primary eye, hypersensitivity study, acute inhalation, and primary dermal, primary eye studies. These rationales were based on the results of tests for the TGAI discussed in the toxicological profile in Unit III of this document. In addition to the rationales in Unit III.h., the applicant reiterated that there were no reports of adverse effects of *Bacillus firmus* or its metabolites to humans or mammals in literature searches.

The request to waive toxicity testing for the EP was based on acceptable data reviews of the TGAI and the nature of the inert ingredients which are exempt from the requirement of a tolerance. The Agency decided to grant the request to waive the test for primary eye irritation based on the acceptable low acute dermal toxicity category IV classification of the pesticide. Any potential primary eye irritation to this low toxcity pesticide can be mitigated by goggles or personal protective eye equipment. In addition the application rate and types of soil application and seed treatments indicate minimal to non-existent risk via eye exposure. The request to waive the requirement for hypersensitivity incidents for the EP is not granted. As required for all pesticides, the Agency requires that hypersensitivity incidents, should adverse effects occur, must be reported to comply with section 6(a)(2) (40 CFR 159.152).

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

1. *Food.* Dietary exposure to the microbial pesticide is likely to occur to this ubiquitous microbe. The lack of acute oral toxicity/pathogenicity, based on the toxicology test in rats, supports the exemption from the requirement of a tolerance for this active ingredient. The pesticide is intended to be applied to the soil or to be used as seed treatments, mainly for control of nematodes. It is not systemic. Thus, dietary exposure by direct contact with food is not expected. The acute oral study described in Unit III indicates that the active ingredient is not toxic, infective or pathogenic when administered to mammals (rats) via the oral route. In addition to this acute oral study, other toxicology studies indicated that the microbe cleared all organs within the time allotted for the studies.

There is no direct post-harvest treatment of food commodities with *Bacillus firmus* I-1582. Thus, detectable residues of *Bacillus firmus* I-1582 are not expected on agricultural crops or food commodities as a result of the proposed use of this active ingredient. All inerts in the proposed EP are exempt from the requirement of a tolerance. Based on these observations, the Agency concluded that dietary exposure to *Bacillus firmus* I-1582 is not expected to cause harm to human adults, infants and children.

2. *Drinking water exposure.* Drinking water is not being screened for *Bacillus firmus* I-1582 as a potential indicator of microbial contamination. The pesticide is not intended for application to aquatic agricultural crops. In the unlikely event that *Bacillus firmus* I-1582 was transferred to ground water, the microbe would not survive the conditions of drinking water treatment, such as chlorination, pH adjustments, and other water processing conditions. However, because of the lack of mammalian toxicity, even if negligible oral exposure should occur through drinking water, the Agency concludes that such exposure would present no risk.

B. Other Non-Occupational Exposure

The Agency expects non-occupational dermal and inhalation exposure to pose no harm if the pesticide is used as labeled. The proposed product is anEP that is intended to be used commercially for seed and soil treatments of agricultural crops. Other homeowner and residential uses are also for soil applications outdoors at very low rates. No indoor residential, school, or daycare uses are currently permitted for this active ingredient. Even if there is non-occupational residential, school or day care exposure from the proposed uses of *Bacillus firmus* I-1582, the risk posed by this low toxicity microbe is likely to be minimal.

1. *Dermal exposure*. As discussed in Unit III. *Bacillus firmus* I-1582 is not toxic, infective, or pathogenic via the dermal route of exposure, and the active ingredient is placed in Toxicity Category IV for acute dermal effects. The pesticide is proposed for use as soil and seed treatments to agricultural crops. For these exposure scenarios, non-occupational dermal exposure is not expected. The potential for non-occupational exposure exists for residential and home and garden use. However, low application rates, soil applications and the low toxicity potential of the active ingredient indicate that non-occupational exposure through these uses is not likely to cause harm to the exposed population if the pesticide is used as labeled.

2. *Inhalation exposure*. A similar rationale supports the Agency's conclusion that non-occupational inhalation exposure is not likely to cause harm to the exposed population if the pesticide is used as labeled. The active ingredient is placed in Toxicity Category IV on the basis of the acute pulmonary study (see Unit III.) and is non-volatile.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to *Bacillus firmus* I-1582 and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. *Bacillus firmus* I-1582 is not toxic or pathogenic to mammals via several routes of exposure (Unit III.) There are no other *Bacillus firmus* strains registered. Consequently, no cumulative effects from the residues of this product with other related microbial pesticides are anticipated.

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

See Unit III. for acute toxicological evaluations of *Bacillus firmus* I-1582. Further, 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 on toxicity and exposure, unless EPA determines that a different margin of exposure (MOE) (safety) will be safe for infants and children. Margins of exposure (safety), which often are referred to as uncertainty factors, are incorporated into EPA risk assessment either directly or through the use of a margin of exposure analysis or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk. Actual exposures to adults and children through diet are expected to be several orders of magnitude less than the doses used in the toxicity and pathogenicity tests referenced in Unit III. Thus, the Agency has determined that an additional margin of safety for infants and children is unnecessary.

VII. Other Considerations

A. Endocrine Immunotoxicity

EPA is required under section 408(p) of 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 was a scientific basis for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that it include evaluations of potential effects in wildlife.

The Agency has no knowledge of *Bacillus firmus* I-1582 being an endocrine disruptor, nor if this microbe is related to any class of known endocrine disruptors. Consequently, endocrine-related concerns did not impact the Agency's safety finding for these *Bacillus firmus* I-1582 strains. Additional data specifically on the endocrine effects of this microbial pesticide are not required at this time. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupter Screening Program (EDSP) have been developed and implemented, *Bacillus firmus* I-1582 may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

As discussed in this document in Unit III. Tier I toxicology data evaluated for this active ingredient showed clearance in a variety of tissues and did not trigger Tier III data requirements for immunotoxicity testing.

B. Analytical Methods

The acute oral studies discussed in Unit III. demonstrate that the active ingredient does not pose a dietary risk. In addition, the active ingredient is not likely to come into contact with the treated food commodities. Furthermore, the low application rate and non-persistence on food during applications suggests very low exposure potential via the dietary route. Since residues are not expected on treated commodities, the Agency has concluded that an analytical method to detect residues of this pesticide on treated food commodities for enforcement purposes is not needed.

Nevertheless, the Agency has concluded that for analysis of the pesticide itself, microbiological and biochemical methods exist and are acceptable for enforcement purposes for product identity of *Bacillus firmus* I-1582. Other appropriate methods are required for quality control to assure that product characterization, the control of human pathogens and other unintentional metabolites or ingredients are within regulatory limits, and to ascertain storage stability and viability of the pesticidal active ingredient.

C. Codex Maximum Residue Level

There is no Codex maximum residue level for residues of *Bacillus firmus* I-1582.

VIII. Conclusions

The results of the studies discussed in Unit III. meet the safety standards of the 1996 FQPA. They support an exemption from the requirement of a tolerance for residues of *Bacillus firmus* I-1582, on treated food or feed commodities. In addition, the Agency is of the opinion that, if the microbial active ingredient is used as allowed, aggregate and cumulative exposures are not likely to harm the adult human U.S. population, children and infants. Therefore, an exemption from tolerance is granted for residues of *Bacillus firmus* I-1582 when used as soil and seed treatments in/on all food/feed commodities in response to pesticide petition 6F7111.

IX. 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, *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).

X. 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: April 23, 2008.

Debra Edwards,

Director, Office of Pesticide Programs

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.1282 is added to read as follows:

§ 180.1282 Bacillus firmus I-1582; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established in/on all food/feed commodities, for residues of *Bacillus firmus* I-1582 when used as a soil application or seed treatment.

[FR Doc. E8–10121 Filed 5–6–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2004–0306; FRL–8361–4]

Pyridalyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyridalyl in or on vegetables, leafy, except *Brassica*, group 4; *Brassica*, head and stem, subgroup 5A; vegetables, fruiting, group 8; mustard greens; and turnip greens. Valent U.S.A. Corporation and the International Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 7, 2008. Objections and requests for hearings must be received on or before July 7, 2008, 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–2004–0306. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Olga Odiott, Registration Division (7505P),