revisions if consistent with the Clean Air Act.

SIP requirements applicable to all areas are provided in section 110. Part D of title I the Clean Air Act specifies additional requirements applicable to nonattainment areas. Section 110 and part D describe the elements of a SIP and include, among other things, emission inventories, a monitoring network, an air quality analysis, modeling, attainment demonstrations, enforcement mechanisms, and regulations which have been adopted by the State to attain or maintain NAAQS. EPA has adopted regulatory requirements which spell out the procedures for preparing, adopting and submitting SIP's and SIP revisions; that are codified in 40 CFR part 51.

EPA's action on each State's SIP is promulgated in 40 CFR part 52. The first section in the subpart in 40 CFR part 52 for each State is generally the ''Identification of plan'' section which provides chronological development of the State SIP. Or if the state has undergone the new Incorporation by Reference format process (*see* 62 FR 27968, May 22, 1997), the identification of plan section identifies the State-submitted rules and plan elements which have been Federally approved. The goal of the State-by-State SIP compilation is to identify those rules under the ''Identification of plan'' section which are currently Federally-enforceable. In addition, some of the SIP compilations may include control strategies, such as transportation control measures, local ordinances, State statutes, and emission inventories, or may include regulations provided in other sections of the State-specific subpart of part 52. Some of the SIP compilations may not identify these other Federally-enforceable elements.

The contents of a typical SIP fall into three categories: (1) State-adopted control measures which consists of either rules/regulations or source-specific requirements (e.g., orders and consent decrees); (2) State-submitted ''non-regulatory'' components (e.g., attainment plans, rate of progress plans, emission inventories, transportation control measures, statutes demonstrating legal authority, monitoring networks, etc.); (3) additional requirements promulgated by EPA (in the absence of a commensurate State provision) to satisfy a mandatory section 110 or part D (Clean Air Act) requirement.

What Is Federally-Enforceable

Enforcement of the state regulation before and after it is incorporated into the Federally-approved SIP is primarily a state responsibility. However, after the regulation is Federally approved, EPA is authorized to take enforcement action against violators. Citizens are also offered legal recourse to address violations as described in section 304 of the Clean Air Act.

You should note that, when States have submitted their most current State regulations for inclusion into Federally-enforceable SIPs, EPA will begin its review process of submittals as soon as possible. Until EPA approves a submittal by rulemaking action, State-submitted regulations will be State-enforceable only; therefore, State-enforceable SIPs may exist which differ from Federally-enforceable SIPs. As EPA approves these State-submitted regulations, the regional offices will continue to update the SIP compilations to include these applicable requirements.

Dated: December 16, 2004.

Michael O. Leavitt,

Administrator.

[FR Doc. 04–27993 Filed 12–21–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0175; FRL–7682–6]

Bacillus pumilus GB34; 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 microbial pesticide *Bacillus pumilus* GB34 when used as a seed treatment in or on all food commodities. An exemption is also granted for such residues on treated but unplanted soybean seeds. Gustafson LLC 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), to amend and expand an existing exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus pumilus* GB34.

DATES: This regulation is effective December 22, 2004. Objections and requests for hearings must be received on or before February 22, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0175. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., 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.

FOR FURTHER INFORMATION CONTACT: Anne Ball, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8717; e-mail *address:ball.anne@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 (NAICS 111), e.g. crop production, vegetable and fruit farming
- Industry (NAICS 112), e.g. animal production
- Industry (NAICS 311), e.g. food manufacturing
- Industry (NAICS 32532), e.g. pesticide and other agricultural chemical 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in the NAICS listings which are published by the U. S. Census Bureau. 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 and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), 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 E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of March 3, 2004 (69 FR 10037) (FRL –7343–8), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1F6344) by Gustafson LLC, 1400 Preston Road, Suite 400, Plano, TX 75093. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus pumilus* GB34 when used as a seed treatment in or on all food commodities, which term for purposes of the tolerance exemption that is sought, includes all soybean seeds treated prior to planting, but not planted, but excludes all other non-soybean seeds that are treated, but not planted. This request would amend and expand an existing exemption from the requirement of a tolerance that the Agency had granted for residues of *Bacillus pumilus* GB34 when used as a seed treatment in or on soybeans, including once again, all soybean seeds treated prior to planting, but not planted and thereafter used as a food commodity. This notice included a summary of the petition prepared by the petitioner Gustafson LLC.

One comment was received in response to the notice of filing. The comment states that ''the material safety data sheet is horrific on this *bacillus*. It is listed as an irritant on Gustafson's own MSDS, with eye irritation, skin and lung sensitization, producing carcinogen (sic) in rats and scarring of lungs, with inhalation dangerous''. In response, it should be clarified that the purpose of the **Federal Register** notice of filing upon which comment was received is intended to inform the public about receipt of a petition for a tolerance exemption. Pursuant to the FFDCA, as amended by the FQPA, that **Federal Register** notice of filing included the company's interpretation of the data they submitted in support of the requested tolerance exemption. Importantly, however, the FR notice of filing is not the final Agency determination on the tolerance exemption request. Second, EPA has now evaluated the potential hazards posed by this microbial pesticide product in connection with its proposed seed treatment use pattern, including the toxicity of the cited filler, in the proposed seed treatment use pattern during the risk assessment undertaken in order to make a determination on this petition. The results of end product testing indicate low toxicity or irritation potential (toxicity category III or IV), and the active ingredient itself displays no infectivity, pathogenicity or toxicity. Therefore, use of the product as a seed treatment presents negligible concern. In addition, a fate study presented by the company showed that *Bacillus pumilus* GB34 treated soybean seeds, when processed by typical procedures for soybeans, had no greater level of *Bacillus* species present than ordinary untreated soybeans. This final rule includes EPA's assessment of the submitted data and discusses why the seed treatment application of this microbial agent, and the use as a food commodity of *Bacillus pumilus* GB34 treated but unplanted soybean seeds that are then processed, have a reasonable certainty of causing no harm considering the expected aggregate residues, if any, and the negligible to no dietary exposure resulting from these applications or uses.

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 exemption 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. Pursuant to 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 section 408(b)(2)(C), 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 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.

III. 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.

The *Bacillus pumilus* species was first described by Meyer and Gottheil in 1901. This naturally occurring species is one of the most numerous of the *Bacillus* species found on plant surfaces. The strain *Bacillus pumilus* GB34 is a naturally occurring soil colonizer. The mode of action of the strain, an antifungal agent, is to colonize the developing root system of the plant it is to protect, in this case the developing root system of plants of food crops including that of the soybean plant. The organism *Bacillus pumilus* GB34 then suppresses by competition, through the formation of a physical barrier, the continued formation of spores of the fungal diseases such as *Rhizoctonia* and *Fusarium*. Subsequently, *Bacillus pumilus* GB34 colonizes the remaining fungal disease spores themselves, thereby destroying them. On the basis of acute injection toxicity/pathogenicity tests on rats, *Bacillus pumilus* GB34 does not appear to be toxic, infective, or pathogenic in those mammals.

Toxicity studies in support of this tolerance exemption petition are summarized below. More detailed analyses of these studies may be found in the specific Agency reviews of the studies. Waivers from certain data requirements were requested and granted, and these are noted below as well.

Summarized below are toxicity studies relating to the *Bacillus pumilus* GB34 Concentrate (end use product), which initially were submitted to support an application for an experimental use permit (EUP) for *Bacillus pumilus* GB34 Concentrate and later were bridged to support a section 3 registration for the microbial product, as well as studies pertaining to *Bacillus pumilus* GB34 Technical. All of these studies supported the initial, more limited tolerance exemption for residues of *Bacillus pumilus* GB34 when used as a seed treatment in or on soybeans, including all soybean seeds treated prior to planting, but not planted and thereafter used as a food commodity. Additionally, all of these studies support the broader tolerance exemption considered in this Final Rule for residues of *Bacillus pumilus* GB34 when used as a seed treatment in or on all food commodities, which term, for purposes of this tolerance exemption, includes all soybeans treated prior to planting, but not planted, but excludes all other, non-soybean seeds that are treated but not planted. In addition to these studies, the company presented to the Agency a fate study supporting the use of soybean seeds, which had been treated but not planted, as a food commodity. The study demonstrated that *Bacillus pumilus* GB34 treated soybean seeds, when processed by typical procedures for soybeans, have no greater level of *Bacillus* species present than ordinary untreated and processed soybeans.

1. *Acute oral toxicity*—i. *Bacillus pumilus GB34 Concentrate*. (Originally submitted to support an application for an EUP for *Bacillus pumilus* GB34 Concentrate and subsequently bridged to support a section 3 registration for the microbial product (and its exemption from a tolerance.) (OPPTS 870.1100; Master Record Identification Number (MRID) 452940–01). Five male and five female young adult Sprague-Dawley rats each received a single 5,000 milligrams/kilogram (mg/kg) gavage dose of *Bacillus pumilus* GB34 Concentrate, previously diluted to a 40% weight/weight (w/w) solution with distilled water at a dosing volume of 1 milliliter (mL)/100 grams (g). The rats were observed for morbidity/moribundity, and behavior changes 1 and 3 hours after dosing and at least daily thereafter for 14 days. They were weighed on days 0, 7, and 14. At the end of the study the rats were all euthanized and necropsied. No morbidity, moribundity, or effects on body weight were found following treatment of rats with 5,000 mg/kg test material. Therefore, the Sprague-Dawley rat oral lethal $(LD)_{50}$ of *Bacillus pumilus* GB34 Concentrate for male, female, and male and female combined is >5,000 mg/kg, placing the test material in Toxicity Category IV.

ii. *Acute oral toxicity—Bacillus pumilus GB34 Technical*. (OPPTS 870.1100; MRID 454335–01 corrected as MRID 457225–01). Five male and five female Sprague-Dawley rats each received a single 5,000 mg/kg gavage dose of the *Bacillus pumilus* GB34 Technical, previously diluted to a 40% w/w solution with distilled water, at a dosing volume of 1ml/100g. The rats were observed for morbidity, moribundity, and behavioral changes 1 hour and 3 hours after dosing and at least daily thereafter for 14 days. They were weighed on days 0, 7, and 14. At the end of the study, the rats were euthanized and necropsied. No morbidity, moribundity, or effects on body weight were found following treatment of rats with 5,000 mg/kg test material. Therefore, the Sprague Dawley rat oral LD_{50} of *Bacillus pumilus* GB34 Technical for male, female and male and female combined is >5,000 mg/kg, placing the test material in Toxicity Category IV.

2. *Acute dermal toxicity—Bacillus pumilus GB34 Concentrate and Bacillus pumilus GB34 Technical*. (OPPTS 870.1200 and OPPTS 885.3100 (Acute dermal Toxicity/Pathogenicity); waiver request, no MRID). A waiver from this data requirement was requested and granted for a seed treatment use. The rationale for the waiver is that the rate of application of the product is 0.1 ounce per 100 pounds of seed. The seed treatment is to take place in a commercial seed treatment facility in which there is no exposure to the general population. After germination of the treated seed, the habit of the bacterium is to inhabit the root system of the plant. Thus there is expected to be minimal, if any, dermal exposure for the general population in a seed treatment use of the microbial pesticide. As stated above , with respect to its use as a food commodity, of any soybeans treated but not planted, a fate study presented by the company demonstrated that *bacillus pumilus* GB3 4 treated soybeans seeds, when processed by typical procedures for soybeans, had no greater level of *Bacillus* species present than ordinary untreated and processed soybeans.

3. *Acute inhalation toxicity—Bacillus pumilus GB34 Concentrate and Bacillus pumilus GB34 Technical*. (OPPTS 870.1300 and OPPTS 885.3150 (Acute Pulmonary Toxicity/Pathogenicity); waiver request, no MRID). A waiver from this data requirement was requested and granted for a seed treatment use. The use of *Bacillus pumilus* GB34 as a seed treatment will take place in a commercial seed treatment facility in which there is no potential for inhalation exposure by the general population. The rate of application of the pesticide is 0.1 oz per 100 lbs of seed. The habit of the bacterium is to gravitate to the root system of the developing plant. Thus, for a seed treatment use of *Bacillus pumilus* GB34 there is expected to be a negligible, if any, inhalation exposure. In addition, the fate study referred to above supports the use of any treated but not planted, soybean seeds as a food commodity, and the data waiver is applicable for that use as well.

4. *Acute oral toxicity/pathogenicity—Bacillus pumilus GB34 Technical and Bacillus pumilus GB34 Concentrate*. (OPPTS 885.3050). A waiver from this data requirement was requested and granted for a seed treatment use. The rationales include the following:

i. There is expected to be a low rate of application (0.1 oz per 100 lbs of seed).

ii. There is expected to be a minimal exposure to the general population since the seed treatment will take place in a commercial seed treating facility with mechanical treating equipment.

iii. The results of the toxicity tests submitted to date do not indicate that this strain is toxic or infective. Moreover, the results would suggest that the *Bacillus pumilus* GB34 strain does not express the 6,500 molecular weight toxin discussed in two papers in the literature. In addition, the habit of the bacterium to gravitate to the root system of the developing plant makes it unlikely that any would be present in the above ground parts of the mature plant, thus minimizing the the potential for oral exposure for humans. Finally, the fate study referred to above supports the use as a food commodity of any treated, but not planted, soybean seed that have been processed by typical procedures for soybeans.

5. *Primary eye irritation*—i. *Bacillus pumilus GB34 Concentrate*. (Originally submitted to support an application for an EUP for Bacillus pumilus GB34 Concentrate and subsequently bridged to support a section 3 registration for the microbial product and its exemption from a tolerance.) (OPPTS 870.2400; MRID 452940–02). Three male and three female young adult new Zealand whit rabbits were used in the experiment. Prior to test material instillation, both eyes were treated with 2% fluorscein and examined under ultraviolet (UV) light for ocular abnormalities. The test material, 0.1ml (equivalent to 0.05 to

0.07 g) was instilled into the everted lower lid of the right eye and the upper and lower lids held closed for one second. The contralateral eye acted as control. The eyes were examined and scored according to the Draize method 1, 24, 48 and 72 hours after test material instillation. The 24 hour examination also included a fluorescein staining examination.for corneal effects. All rabbits survived the study. All rabbits developed slight conjunctival irritation that cleared within 24 hours after treatment. No corneal opacity or iritis was noted. *Bacillus pumilus* GB34 Concentrate was minimally irritating to the eye and is placed in Toxicity Category IV.

ii. *Bacillus pumilus GB34 Technical.* (OPPTS 870.2400; MRID 454335–02, corrected as 457225–02). Prior to the test, three male and three female young adult New Zealand white rabbits were, treated in both eyes with 2% fluorscein and then examined under UV light for ocular abnormalities. The test material, in the amount of 0.1 mL was instilled into the everted lower lid of the right eye and the upper and lower lids were held closed for 1 second. The contralateral eye served as control. The eyes were examined and scored according to the Draize metnod 1, 24, 48 and 72 hours after test material instillation. The 24 hour examination also included a fluorescein staining examination for corneal efffects. All rabbits developed moderate conjunctival irritation that cleared up within 72 hours of treatment. No corneal opacity or irritis or non-ocular effects were noted. The *Bacillus pumilus* GB34 test substance was mildly irritating to the eye and is placed in Toxicity Category III.

6. *Primary Dermal Irritation*—i. *Bacillus pumilus GB34 Concentrate.* (Originally submitted to support an application for an EUP for *Bacillus pumilus* GB34 Concentrate and subsequently bridged to support a section 3 registration for the microbial product and its exemption from a tolerance) (OPPTS 870.2500; MRID 452940–03). Three male and three female young adult New Zealand white rabbits were received for the study. The fur on the dorsal-lumbar area of each rabbit was clipped. The rabbits were given a single 0.5 g dose of test material applied under a 1″x1″ 4-ply gauze pad on a 6 cm square clipped site. The gauze pad is then secured and Elizabethan collars were placed on the animals. Four hours later these were removed and the sites wiped with a moistened towel. The application sites were observed for dermal irritation 1, 24, 48 and 72 hours after patch removal. In addition, the rabbits were observed at least daily for clinical signs of toxicity during the 72–hour study period. All rabbits survived the study. No dermal irritation was observed on any rabbit at any site. Based on the study, *Bacillus pumilus* GB34 Concentrate is non-irritating to the New Zealand white rabbit and is placed in Toxicity Category IV.

ii. *Bacillus pumilus GB34 Technical.* (OPPTS 870.2500; MRID 454335–03 corrected as MRID 457225–03). Three male and three female New Zealand white albino rabbits were prepared by clipping the doesal area and the trunk. Only healthy animals without preexisting skin irritation had been selected for the test. The test substance in the amount of 0.5 g was placed on a 1 inch x 1 inch, 4-ply gauze pad which was applied and secured on each rabbit. After 4 hours exposure to the test substance, the pads were removed and the test site wiped with water and towel to remove any residual test substance. Individual test sites were scored according to the Draize scoring at approximately 1, 24, 48, and 72 hours after patch removal. The animals were observed for signs of gross toxicity and behavioral changes at least once daily during the test period. All animals appeared active and healthy. There were no signs of gross toxicity, adverse pharmacological effects or abnormal behavior. No dermal irritation was noted at any test site during the study. Under the conditions of the study, the *Bacillus pumilus* GB34 Technical is classified as non-irritating to the skin and placed in Toxicity Category IV.

7. *Acute injection toxicity/ pathogenicity, Bacillus pumilus GB34 Technical.* (originally submitted to support an application for an EUP for *Bacillus pumilus* GB34 Technical and subsequently bridged to support a section 3 registration for the microbial product and its exemption from a tolerance) (OPPTS 885.3200; MRID 453416–01). A total of 39 male and 39 female rats were used in the tests. The results showed:

i. *Mortality.* No deaths were observed in any of the dosed or control groups prior to scheduled sacrifice.

ii. *Body and organ weights.* Overall, both male and female rats gained weight for the duration of the study, demonstrating the continued health of the animals.

iii. *Clinical observation.* Overall, both male and female rats showed no abnormal clinical signs.

iv. *Gross necropsy.* No significant signs of abnormalities were seen except for a laceration on the left shoulder of a test-substance- treated male rat. An enlarged spleen was seen in one test-substance-treated male rat.

Based on the results of the acute injection toxicity/pathogenicity study, the Agency determined that *Bacillus pumilus* GB34 does not appear to be toxic, infective or pathogenic in rats when dosed at 1x 10^{7} cfu/animal. This test supports the requirements for both the technical grade active ingredient (the technical) and the end use product (the concentrate).

A hypersensitivity study, or dermal sensitization study is not required for registration of this product since, in the case of the use of the product as a seed treatment, there is not expected to be repeated human contact by inhalation or dermal routes (routes specified in footnote iii of the table in 40 CFR 158.740 (c)). In the case of the use as a food commodity of the treated but not planted soybean seeds, a fate study presented by the company, as mentioned elsewhere in this document, showed that *Bacillus pumilus* GB34 treated soybean seeds, when processed by typical procedures for soybeans, had no greater level of *Bacillus* species present than ordinary untreated soybeans. Furthermore, there have been no reports of incidents of hypersensitivity, allergies or other adverse effects in connection with the production or use of *Bacillus pumilus* GB34. Nonetheless, to comply with EPA's requirements under FIFRA section 6(a)(2) , any incident of hypersensitivity associated with the use of this pesticide must be reported. (See also 40 CFR 158.690(c)(iv)).

An immune response study is not required for registration of or exemption from the requirement of a tolerance for this product because the Acute I.V., I.C., or I.P. injection toxicity/pathogenicity study (OPPTS Guidelines 885.3200) previously submitted in support of an EUP for *Bacillus pumilus* GB34 and subsequently bridged to support a section 3 registration and an earlier, more limited in scope tolerance exemption for this microbial product, serves to address the endpoint of immune response. This injection study examines the normal functioning of the immune system when faced with the potentially most challenging exposure to this microbial pesticide active ingredient: direct injection into the bloodstream. If the test animal is able to withstand and survive the introduction of such a large number of microbes, bypassing the normal protective barriers of the skin, the pulmonary macrophages and the gastrointestinal lymphoid tissues, then the immune system is functioning normally. The normal functioning of the immune system

implies that it can recognize the introduced microbes as foreign and can clear them from the blood and other exposed organs. After the active ingredient, *Bacillus pumilus* GB34 , was intravenously injected into the test animals (rats), no deaths, adverse clinical signs or significant findings upon necropsy were seen 35 days after the injection.

The requirement for Tier II and Tier III data was not triggered based on the results of Tier I data which had been submitted or waived.

IV. 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

Bacillus pumilus GB34 is a naturally occurring and ubiquitous microorganism. It inhabits the root system of plants where it acts as an antifungal agent. Review of the available toxicology data submitted in support of the registration of this active ingredient indicate that it is non-toxic and non-pathogenic to animals. In its proposed use as a seed treatment, which will take place in a commercial seed treating facility with mechanical treating equipment, it is foreseen that it will not contribute to any additional dietary exposures over and above those exposures that already exist due to the fact that the organism is naturally occurring and ubiquitous. In connection with the proposed use of the treated but not planted soybean seeds as a food commodity, it has been shown that the pesticide *Bacillus pumilus* GB34 does not survive, except for negligible amounts, the processing customary for soybeans. A fate study presented to EPA by the company, as stated above, showed that *Bacillus pumilus* GB34 treated soybeans, after processing by typical procedures for soybeans, had no greater level of *Bacillus* species present than ordinary untreated soybeans. These uses, thus, are not expected to add in a significant measure to the density with which this naturally occurring, ubiquitous bacterium, which is non-toxic and non-pathogenic to animals, is found in soil, water, air and plant tissue.

1. *Food.* When used as a seed treatment in or on all food commodities, *Bacillus pumilus* GB34 migrates to and inhabits the roots of the plants. Accordingly, it is anticipated that negligible to no dietary exposure from food will result for humans from such uses. Similarly, with respect to the use of *Bacillus pumilus* GB34 as a seed treatment on soybean seeds that are not planted and thereafter used as a food commodity, based on the fate study discussed above, it is anticipated that negligible to no dietary exposure will result for humans from such use. To date, there have been no reports of any hypersensitivity incidents or reports of any known adverse reactions in humans resulting from exposure to *Bacillus pumilus* GB34.

2. *Drinking water exposure.* There is expected to be only insignificant or minimal human exposure to the organism in drinking water resulting from its use in the treatment of seeds or from the use as a food commodity of any treated, but not planted, soybean seeds that are processed using typical procedures for soybeans. The treatment of seeds is expected to take place in a commercial seed treatment facility before the farmer plants the seeds in the soil. As stated elsewhere in this document, the organism is ubiquitous, naturally occurring, already found in water, among other places, and is non-toxic and non-pathogenic to humans. Thus, even if insignificant additional amounts were to seep or otherwise find their way into the ground water as a result of its uses, there is expected to be no adverse effect on humans as a result of the uses of *Bacillus pumilus* GB34 contemplated in this tolerance exemption action.

B. Other Non-Occupational Exposure

The possibility for non-dietary exposure to residues of this *Bacillus pumilus* GB34 pesticide for the general population, including infants and children, is unlikely as a result of its use as a seed treatment or as a result of the use of any treated soybean seed that are not planted and thereafter used as a food commodity. Since the seed treatment is to take place in a commercial seed treating facility where mechanical treating equipment is used, it is not expected that dermal or inhalation exposure will occur in the general population, including infants and children. As stated elsewhere in this document, a fate study showed that the treated but not planted soybean seeds, when processed by typical procedures for soybeans, had no greater level of *Bacillus* species present than ordinary untreated soybeans. *Bacillus pumilus* GB34 is a ubiquitous, naturally-occurring bacterium that functions as an antifungal agent and already is found in soil, water, air and decomposing plant tissue. It is not known to be pathogenic, infective or toxic to any animal or plant species. The bacteria typically occur at 106 to 107 colony forming units (CFUs) per gram of soil. The added soil density from the proposed seed treatment use rates represents a very small proportion of the naturally occurring bacilli in the soil or water and therefore is not expected to add substantially to non-occupational dermal or inhalation exposure for the general population, including infants and children.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, 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.'' These considerations include the possible cumulative effects of such residues on infants and children. The Agency has considered the potential for cumulative effects of *Bacillus pumilus* GB34 and other substances in relation to a common mechanism of toxicity. Based on tests in mammalian systems, *Bacillus pumilus* GB34 does not appear to be toxic or pathogenic to humans. The product strain belongs to the bacterial genus of *Bacillus. Bacillus pumilus* Gb34 may have a similar mode of action in mammals as *Bacillus subtilis* that has been shown to be non-toxic and non-pathogenic to mammalian species. A similar mode of action of *Bacillus pumilus* GB34 and *Bacillus subtilis* would not be expected to result in any cumulative adverse effect since, in each case, intravenous toxicity and pathogenicity studies have demonstrated the organism to be non-toxic and non-pathogenic. Thus, the Agency does not expect any cumulative or incremental effects from exposure to residues of *Bacillus pumilus* GB34 when used as directed on the label and in accordance with good agricultural practices.

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

The Agency has determined that there is a reasonable certainty that no harm will result to the U. S. population, including infants and children, from aggregate exposures to residues of *Bacillus pumilus* GB34 as a result of or in connection with the uses described in this action. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously,

there is little to no potential for harm from this bacterium in its uses via dietary exposure since the organism is non-toxic and non-pathogenic to animals and humans. 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. Moreover, as mentioned above, no non-occupational inhalation or dermal exposure is expected.

FFDCA section 408 (b)(2)(C) provides that EPA shall apply an additional 10-fold 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 (safety) will be safe for infants and children. Margins of exposure (safety), which are often referred to as uncertainty (safety) 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. In this instance, and based on all the available information reviewed and discussed more fully above, the Agency concludes that the additional margin of exposure (safety) is not necessary to protect infants and children and that not adding any additional margin of exposure (safety) will be safe for infants and children.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under FFDCA section 408(p), as amended by FQPA, to develop a screening process to determine whether pesticide chemicals (and any other substance that may have an effect that is cumulative to an effect of a pesticide chemical) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone systems. 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 the 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 Endocrine Disruptor Screening Program have been determined, *Bacillus pumilus* GB34 may be subjected to additional screening and/or testing to better characterize any effects related to endocrine disruption. At this time, however, and based on the weight of available data, there is no basis for including this organism, since no endocrine system-related effects have been identified for *Bacillus pumilus* GB34.

B. Analytical Method(s)

The organism, *Bacillus pumilus* GB34, as mentioned above, is a naturally occurring soil microorganism which inhabits the root system of plants and acts as an antifungal agent in that area of the plant. The acute oral studies discussed above demonstrate that this active ingredient is non-toxic and non-pathogenic to animals and humans and thus, does not pose a dietary risk to humans in its uses. The Agency has concluded, therefore, that analytical methods are not needed for enforcement purposes.

C. Codex Maximum Residue Level

There are no Codex Maximum Levels nor any tolerances or exemptions issued for *Bacillus pumilus* GB34 outside the United States.

VIII. 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–2004–0175 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 February 22, 2005.

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 (1900L), 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 Suite 350, 1099 14th St., NW., Washington, DC 20005. 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 (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2004–0175, 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 **ADDRESSES**. 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).

IX. Statutory and Executive Order Reviews

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 tolerance 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.

X. Congressional Review Act

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: December 10, 2004.

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), 346a and 371.

■ 2. Section 180.1224 is revised to read as follows:

§ 180.1224 Bacillus pumilus GB34; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Bacillus pumilus* GB34 when used as a seed treatment in or on all food commodities. An exemption is also granted for such residues on treated but unplanted soybean seeds.

[FR Doc. 04–27982 Filed 12–21–04; 8:45 am]

BILLING CODE 6560–50–S