ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0263; FRL–7275–7]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2002–0263, must be received on or before November 21, 2002.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Robyn Rose, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, 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–2002–0263. 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/.

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. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk

or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment, and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

2. *EPA Dockets—i.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2002–0263. The system is an, ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP–2002–0263. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency (7502C), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2002–0263.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2002–0263. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI To the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated:October 7, 2002.

Janet L. Andersen,

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

Summary of Petition

PP 2F06453

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by Taensa, Inc. and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

EPA has received a pesticide petition 2F06453 from Taensa, Inc., 26 Sherman Ct, P.O. Box 764, Fairfield, CT 06430, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the microbial pesticide *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Taensa, Inc. has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Taensa, Inc. EPA has not fully evaluated the merits of the

pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product Name and Proposed Use Practices

TAEGRO™ is currently registered with EPA for use on ornamentals in greenhouses and indoors (EPA Registration Number 72098–5). TAEGRO™ Technical (EPA Registration Number 72098–6) is also registered with EPA. Registration of TAEGRO™ is being proposed for the following sites (including those previously registered): Herbs and spices; ornamentals; shrubs, shade and forest trees; tree, vine, bush and other crops; turf; and vegetables.

Methods of application of TAEGRO™ will include seed treatment, incorporation into growth substrate as a dry powder or as an aqueous suspension, drenching, spraying, dipping (roots or cuttings), spraying, chemigation, and hydroponic use. As a plant strengthening agent, TAEGRO™ increases yield of many crops, improves flowering and plant quality, stimulates resistance of plants to disease, plant disease suppressant and can be used with fungicides. Directions for use of TAEGRO™ are as follows:

Apply TAEGRO™ as early as possible in the life cycle of the plant to enhance growth and disease resistance. TAEGRO™ should be applied to plants every few weeks for up to three to four applications as needed. For best results, apply TAEGRO™ to seedlings or to newly rooted cuttings.

1. *Transplants, including plugs.* TAEGRO™ may be applied to transplants by dipping or by drenching, making sure the root system is thoroughly soaked. For dipping, follow the instructions for ''Cutting and Root Dips'' before planting transplants into soil medium. For drenching, first plant the transplants into soil medium and then follow instructions for ''Drenching.''

2. *Drenching.* Apply TAEGRO™ to seedlings or to newly rooted cuttings. Drench plants with the TAEGRO™ suspension making sure the root system is thoroughly soaked. Allowing TAEGRO™ to work into the root zone.

Apply TAEGRO™ as follows:

- Per 100 gallons of water - by weight use 75 grams or 2.6 ounces; by volume use 3.5 fluid ounces of TAEGRO™.
- Per 1 gallon of water 5 grams - by weight use 0.75 gram; by volume use 0.2 teaspoon of TAEGRO™.

3. *Cutting and root dips.* Stir suspension for several minutes to ensure complete mixture and to eliminate clumps. Place rootstock in the suspension for 5 to 10 minutes allowing time for TAEGRO™ to penetrate the root zone. Ornamentals should receive at least one follow-up drench treatment 2 to 3 weeks following initial treatment.

Apply TAEGRO™ as follows:

- Per 10 gallons of water - by weight, use 40 grams; by volume, 1.8 fluid ounces of TAEGRO™.
- Per 1 gallon of water - by weight, use 4 grams; by volume, use 1 teaspoon of TAEGRO™.
- Per 1 Liter of water - by weight, use 1 gram of TAEGRO™.

4. *Turf.* As an overhead spray, mix 75 grams of TAEGRO™ in 100 gallons of water. Before applying, stir product for several minutes to ensure complete suspension. Apply solution with a conventional sprayer using at least 50 gallons of water per acre. Water-in TAEGRO™ immediately after application with a minimum of 1/10 inch of water. For best results, make two or three applications spaced 1 week apart.

5. *Row crops.* Mix 75 grams of TAEGRO™ in 100 gallons of water. Before applying, stir product for several minutes to ensure complete suspension. At time of (or just following) planting, apply as a spray over furrow. Water-in TAEGRO™ immediately after application with a minimum of 1/10 inch of water. For best results, make two or three applications spaced 1 week apart.

6. *Hydroponics.* Prepare a stock solution by adding 1 gram of TAEGRO™, for every 50 feet of irrigation tubing, in 1 gallon of water. Stir product for several minutes to ensure complete suspension. Add solution to circulating water system and allow to go through three to five watering cycles before clearing the system. For best results, make two or three applications spaced 1 week apart.

7. *Seed treatments.* Prior to planting, mix 4 grams of TAEGRO™ in 1 liter of water (or 3 teaspoons per gallon of water). Stir solution for several minutes to ensure complete suspension. Pour seeds into solution and allow to soak for 10 to 30 minutes. For very small seeds, soaking seedlings in plug trays after germination might be easier.

8. *Tubers, bulbs and corms.* Mix 4 grams of TAEGRO™ in 1 liter of water (or 3 teaspoons per gallon of water). Stir solution for several minutes to ensure complete suspension. Dip tubers (or bulbs, etc.) for 10 to 30 minutes before planting. For best results, make two or three applications spaced 1 week apart.

9. *Soil incorporation.* Mix TAEGRO™ into soil or soilless growing media at a rate of 250 grams per cubic yard. Thoroughly mix media, using mechanical mixing equipment, to ensure a uniform distribution of product. Incorporated into soil, TAEGRO™ can be raked into growing beds prior to planting.

10. *Mushrooms.* Mix TAEGRO™ into spawn medium at a rate of 10 grams per cubic foot. Thoroughly mix, using mechanical mixing equipment, to ensure a uniform distribution of product.

11. *Interiorscapes.* Before application, thoroughly moisten root zone with water. Mix 1 gram of TAEGRO™ per 1 liter of water (or 3/4 teaspoon per gallon of water). Stir solution for several minutes to ensure complete suspension. Drench solution onto root zone to ensure coverage to all roots. TAEGRO™ performs best when applied to seedlings or young plants. For best results, make two or three applications spaced 1 week apart.

12. *Orchids and ferns.* For potted orchids and ferns, follow directions for drenching. For orchids and ferns with exposed roots, prepare 4 grams of TAEGRO™ in 1 liter of water (or 3 teaspoons per gallon of water). Pour solution into spray container (or squirt bottle) and spray roots to point of drip. TAEGRO™ performs best when applied to seedlings or young plants. For best results, make two or three applications spaced 1 week apart.

B. Product Identity/Chemistry

1. *Identity of pesticide and corresponding residues.* The active ingredient in TAEGRO™ is *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. The mechanism by which *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 acts as a plant strengthening agent, increases yield of many crops, improves flowering and plant quality, stimulates resistance of plants to disease, plant disease suppressant appears to be primarily via secondary exudates. Suppression of plant disease by *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 may also be competitive. *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is not known to produce toxins or antibiotics. Further, *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is a naturally occurring microorganism. *Bacillus subtilis* var. *amyloliquefaciens* is widespread in the environment and occurs in most arable soils of the world.

2. *Magnitude of residue anticipated at the time of harvest and method used to determine the residue.* No residues of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 are anticipated in treated crops at harvest. Subdivision M - Series 153A-3(a) indicates that ''if Tier I toxicology tests indicate no toxic or other harmful properties, then no residue data would be indicated.'' Studies with *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 demonstrated low mammalian toxicity. No pathogenicity or infectivity was observed in any of the tests conducted with *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. Further, *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is a naturally occurring microorganism. *Bacillus subtilis* var. *amyloliquefaciens* is widespread in the environment.

3. *Statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* Subdivision M - Series 153A-3(a) indicates that '' if Tier I toxicology tests indicate no toxic or other harmful properties, then no residue data would be indicated and thus a recommendation for an exemption from the requirement of a tolerance can be made.'' Studies with *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 demonstrated low mammalian toxicity. No pathogenicity or infectivity was observed in any of the tests conducted with *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. Further, *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is a naturally occurring microorganism. *Bacillus subtilis* var. *amyloliquefaciens* is widespread in the environment.

C. Mammalian Toxicological Profile

Taensa, Inc. conducted the required toxicology studies to support its petition for an exemption from the requirement of tolerance and associated registrations of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. The studies conducted indicate a low mammalian toxicity for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. No pathogenicity or infectivity was observed in any of the tests conducted with *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. With the exception of an inhalation study for the end-use product (TAEGRO™), which is being submitted in support of this application, all toxicology data generated by Taensa have been reviewed by EPA's Biopesticides and Pollution Prevention Division (BPPD).

Toxicology data in support of the exemption from the requirement of a tolerance for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 included studies with spores (technical) and with the formulated product (water dispersible powder) as follows:

1. Acute toxicity and/or pathogenicity—a. *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 Spores (Technical):

- Acute oral toxicity/pathogenicity in rats - ''does not appear to be toxic and/or pathogenic when dosed at 1.3 x 10^8 cfu.'' BPPD Review December 20, 1999.
- Acute dermal toxicity/ pathogenicity in rabbits - ''The severity of irritation persisted 72 h, and slight irritation persisted for 10 d, and all resolved by day 11. No deaths observed. The acute lethal dose (LD_{50}) is greater than 2,000 mg/kg. . .Dermal irritation = Toxicity II; Dermal Toxicity = Toxicity III.'' BPPD Review December 20, 1999.
- Acute pulmonary toxicity/ pathogenicity in rats - ''does not appear to be toxic and/or pathogenic in rats, when dosed at 1.3 x 10^8 cfu/animal. No total clearance is seen form the lungs of treated test animals showed a distinct pattern of clearance from kidney, liver, and spleen.'' BPPD Review December 20, 1999.
- Acute intravenous toxicity/ pathogenicity in rats - ''does not appear to be toxic and/or pathogenic in rats, when dosed at 1.7 x 10^8 cfu/animal.'' BPPD Review December 20, 1999.
- Primary eye irritation - ''showed no signs of persistent irritation into day 21, when dosed at 4.7 x 10^{10} cfu/right eye/animal.'' BPPD Review December 20, 1999 - The initial review indicated Toxicity Category I, but was amended to Toxicity Category II (BPPD Review March 7, 2000).
- Hypersensitivity testing - ''Based on the submitted data does not appear to be a sensitizer when dosed at 3.6 x 10^{10} cfu.'' BPPD Review December 20, 1999.
- Hypersensitivity incident reporting - ''No recorded or reported hypersensitivity reaction based on handling MCPA in lab control setting, equating to 55 person years.'' BPPD Review December 20, 1999.
- Potential health effects - ''Based on information given, there are no apparent negative effects - cited literature on *B. Subtilis* indicate and/or support the development as a biological control.'' BPPD Review December 20, 1999.
- Growth parameters - ''is shown to grow at all tested temperatures (e.g., 30, 34, 37, and 50 ^oC). The enumeration shows a low 4.2 x 10^{11} cfu/g at 37 ^oC to a high 6.0 x 10^{11} cfu/g at 34 ^oC.'' BPPD Review December 20, 1999.

b. *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 WDG (formulation):

- Acute oral LD_{50} toxicity in rats - ''Toxic/limit dose greater than 2.8 g/kg body weight (6.7 x 10^{10} cfu/kg) Toxicity Category III.'' BPPD Review December 20, 1999.
- Acute dermal LD_{50} toxicity in rats - ''The severity of irritation persisted >72 h, but resolved by day 11. No deaths observed. The acute dose (LD_{50}) is greater than 2,000 mg/kg Dermal irritation = Toxicity Category II; Dermal Toxicity = Toxicity Category III.'' BPPD Review December 20, 1999.
- Acute inhalation LC_{50} toxicity in rats (formulation) - ''an acute inhalation medium lethal concentration (LC_{50}) in male and female rats is greater than 0.93 mg/L Toxicity Category II.'' IIT Research Institute (Document 2 of this submission)
- Primary eye irritation ''no corneal opacity, and no signs of irritation by day 7, when dosed at 3.6 x 10^{10} cfu/right eye/animal Toxicity Category III.'' BPPD Review December 20, 1999.

c. The inert ingredients contained in the *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 formulation, TAEGRO™ are all minimal risk (List 4).

2. *Genotoxicity.* Subdivision M Guidelines do not require the conduct of genotoxicity studies to support the registration of a microbial pest control agent, such as *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24.

3. *Reproductive and developmental toxicity.* Subdivision M Guidelines do not require the conduct of reproductive and developmental toxicity studies to support the registration of a microbial pest control agent, such as *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24.

4. *Subchronic toxicity.* Subdivision M Guidelines do not require the conduct of subchronic toxicity studies to support the registration of a microbial pest control agent, such as *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24.

5. *Chronic toxicity.* Subdivision M Guidelines do not require the conduct of chronic toxicity studies to support the registration of a microbial pest control agent, such as *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24.

According to Taensa, Inc., sufficient data exist to assess the hazards of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 and to make a determination on aggregate exposure, consistent with section 408(c)(2), for the exemptions from the requirement of a tolerance. The exposures, including dietary exposure, and risks associated with establishing the requested

exemption from the requirement of a tolerance follows.

D. Aggregate Exposure

Bacillus subtilis var. *amyloliquefaciens* is naturally occurring and widespread in the environment. The low toxicity and non-pathogenicity/infectivity of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is demonstrated by the data summarized herein. The product will be applied as a seed treatment and via incorporation, drenching, spraying, dipping, chemigation and hydroponics.

1. *Dietary exposure—a. Food.* It is not anticipated that residues of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 will occur in treated raw agricultural commodities.

b. *Drinking water.* It is not anticipated that residues of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 will occur in drinking water.

2. *Non-dietary exposure.* The potential for non-occupational, non-dietary exposure to the general population is not expected to be significant.

E. Cumulative Exposure

There is no anticipated potential for cumulative effects of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 and other substances that have a common mode of action.

F. Safety Determination

1. *U.S. population. Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is a naturally occurring microorganism. *Bacillus subtilis* var. *amyloliquefaciens* is widespread in the environment. The low toxicity of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is demonstrated by the data summarized above. Based on this information, the aggregate exposure to *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 over a lifetime should not pose appreciable risks to human health. There is a reasonable certainty that no harm will result from aggregate exposure to *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 residues. Exempting *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 from the requirement of a tolerance should be considered safe and pose insignificant risk.

2. *Infants and children.* The toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. There is a reasonable certainty that no harm will result to infants and children from aggregate exposure to *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 residues.

G. Effects on the Immune and Endocrine Systems

No specific tests have been conducted with *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 to determine whether it may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects. However, it is not likely that *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 would have estrogen or endocrine effects because:

- It is a naturally occurring microorganism. *Bacillus subtilis* is widespread in the environment
- It has demonstrated low mammalian toxicity. No pathogenicity or infectivity was observed in any of the tests conducted with *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24

The mechanism by which *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 controls diseases appears to be via exudates *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 does not produce toxins or antibiotics.

H. Existing Tolerances

No tolerances or exemptions from the requirement of tolerance have been established or applied for domestically or internationally other that subject petition.

I. International Tolerances

No maximum residue levels have been established for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 by codex Alimentarius Commission.

[FR Doc. 02–26844 Filed 10–21–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7396–9]

Proposed Modification of and Request for Additional Public Comment on the General National Pollutant Discharge Elimination System Permits for Log Transfer Facilities in Alaska: AK–G70–0000 and AK–G70–1000

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed modification of and request for additional public comments on general NPDES permits for log transfer facilities in Alaska.

SUMMARY: The Director, Office of Water, EPA Region 10, provides notice of and requests public comment on proposed modifications of the two general National Pollutant Discharge Elimination System (NPDES) permits for Alaskan log transfer facilities (LTFs), which include log storage areas (LSAs), that were issued on March 7, 2000 (65 FR 11999): NPDES permit no. AK–G70–0000, which modifies Clean Water Act (CWA) section 404 dredge-and-fill permits issued to LTFs by the U.S. Army Corps of Engineers (ACoE) prior to October 22, 1985, by adding CWA section 402 effluent limitations and conditions to those permits, and NPDES permit no. AK–G70–1000, which may cover all other log transfer facilities in Alaska.

The EPA issued two general permits for Alaskan log transfer facilities on March 7, 2000. In response to petitions to review the permits brought by the Natural Resources Defense Council and nine other petitioners, the United States Court of Appeals for the Ninth Circuit, on February 13, 2002, ruled that the EPA did not provide adequate notice of and opportunity to comment on the general NPDES permits AK–G70–0000 and AK–G70–1000 and remanded the permits to the EPA to take further comment on the project area Zone of Deposit (ZOD) authorized by the Alaska Department of Environmental Conservation (ADEC), and subsequently included in the final permits by the EPA. To comply with the Ninth Circuit's order, the EPA is seeking public comment on the authorization of a ''project area'' zone of deposit for trace, discontinuous, and continuous coverage in the general permits.

The EPA also is proposing to modify these permits. The most significant proposal would add a limit on continuous coverage within the project area zone of deposit, but would retain the project area zone of deposit limit for bark and woody debris for trace, discontinuous, and continuous coverage if less than one acre and less than 10 centimeters in depth. This notice seeks comment on the proposed major modifications. Finally, the notice describes various minor modifications the EPA is making to correct typographical errors.

DATES: Interested persons may submit written comments on the proposed modifications to general NPDES permits AK–G70–0000 and AK–G70–1000 and on the project area zone of deposit on or before December 23, 2002.

ADDRESSES: Comments must be sent to the attention of Alaskan LTF Public Comments, EPA Region 10 (OW–130), 1200 Sixth Avenue, Seattle, WA 98101. All comments should include the name of the commenter, a concise statement