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 FIFRA section 18 exemption under section 408 of the 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. 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.

VIII. 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: September 8, 2006.

James Jones,

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 180.620 is added to read as follows:

§ 180.620 Etofenprox; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of etofenprox (2-[ethoxyphenyl]-2-methylpropyl-3-phenoxy benzyl ether) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ revocation date
Rice, grain	0.01	12/31/09
Rice, straw	0.02	12/31/09

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 06–8004 Filed 9–19–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0617; FRL–8091–6]

Pantoea Agglomerans Strain E325; 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 *Pantoea agglomerans* strain E325 on apples and pears when applied/used as a microbial pesticide. Northwest Agricultural Products 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 *Pantoea agglomerans* strain E325.

DATES: This regulation is effective September 20, 2006. Objections and requests for hearings must be received on or before November 20, 2006, 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–2006–0617. All documents in the docket are listed in the index for the docket. 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: Leonard Cole, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5412; e-mail address: *cole.leonard@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Document 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. 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–2006–0617 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 November 20, 2006.

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–2006–0617, 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 July 26, 2006 (71 FR 42395) (FRL–8080–6), 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 6F7086) by Northwest Agricultural Products, 821 South Chestnut Ave., Pasco, Washington 99301. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Pantoea agglomerans* strain E325. This notice included a summary of the petition prepared by the petitioner Northwest Agricultural Products. 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.

Pantoea agglomerans strain E325 was originally isolated from apple blooms in Wenatchee, Washington. *Pantoea agglomerans* strain E325 was isolated from an apple flower stigma by washing the flower in buffer and plating dilutions on agar media. The Microbial Pest Control Agent (MPCA) was selected from among more than 1,000 bacteria and yeast isolates evaluated for potential use in the control of fire blight. Screening assays were based on the ability of test organisms to colonize the stigma and preemptively exclude the disease organism which was introduced 24 hours after treatment with the test organism.

Pantoea agglomerans is ubiquitous in the environment, and is recognized as an epiphyte of a wide variety of plants, such as buckwheat, weeds, oilseed rape, sweet potato, rice, and trees of the Rosaceae family. *Pantoea agglomerans* is found on a wide variety of plant parts, including the rhizosphere, leaves, and seeds. The species is also a heavy colonizer of cotton plants, grass and silage and is the prominent species in organic dust. The organism has also been isolated from soil and water. Recent reports have also identified *P. agglomerans* on retail salad vegetables.

Pantoea agglomerans is a common organism of the gut microbiota of mosquitos and locusts. In fecal pellets of the locust, the organism is responsible for the release of guaiacol and phenol, essential components of the locust cohesion pheromone. These components are not produced in germ-free locusts. *Pantoea agglomerans* (*Enterobacter agglomerans*) was also identified in association with sheep scab mites, and as an intracellular symbiotic bacteria of the cereal weevil and the apple maggot fly. It has been demonstrated that *Enterobacter agglomerans* (in the gut of the fly) is able to detoxify the defense chemical (phloridzin) of the apple tree, which would otherwise kill the fly.

Fire blight is caused by the phytopathogenic bacterium *Erwinia amylovora* which colonizes predominately on the stigmatic surfaces of the apple or pear. The pathogen may enter the tree through the blossoms, leaves, or stem wounds. Usually the disease is spread by bacteria that over winter in holdover cankers in the main stem and branches or infected twigs. In the spring, when the blossoms begin to open, the cankers exude drops of bacterial ooze that are disseminated to the blossoms and young leaves by rain, heavy dew, or windblown mist. Fire blight may also be spread by pollinating insects such as bees, sucking, chewing, or boring insects, and unsanitary pruning tools. Warm temperatures (24–28°C) and high humidity are the optimal conditions for infection and disease development.

The disease becomes apparent in the spring, when infected blossoms suddenly wilt and turn brown. Later, twigs and leaves also turn brown and appear to be scorched by fire. The affected leaves usually remain on the tree well into the winter. Young infected fruits become watery or oily in appearance and exude droplets of clear, milky, or amber colored ooze. They later become leathery and turn brown, dark brown, or black, depending on the species. The shriveled fruit usually remains attached to the tree.

Fire blight is considered one of the most destructive diseases of fruit trees in North America. It occurs sporadically and unpredictably and occasionally reaches epidemic levels. A severe outbreak can seriously damage or kill mature pear, apple, or crab apple trees in one season. Other ornamentals such as hawthorn, plum, chokecherry, saskatoon, cotoneaster, and spirea may also be affected.

1. *Acute oral toxicity/pathogenicity—rats (OPPTS 885.3050).* Nineteen male and 19 female Sprague-Dawley rats were dosed with the test substance, *Pantoea agglomerans* strain E325, at a rate of 1.05×10^8 colony forming unit (CFU) per animal. (Master Record Identification Number (MRID) 464678–02) (Ref 1). Three animals were sacrificed on day 3, 7, and 14. All rats survived to the scheduled sacrifice. There was no change in organ weights (brain, blood, cecum contents, kidneys, liver, lungs, lymph nodes, and spleen) of male and female test animals from beginning of testing to sacrifice. The MPCA was detected at high levels in the organs of all test animals. Clearance of the MPCA from the blood and lymph node was achieved in all test animals. Counts of the MPCA had fallen in the lungs and kidney of test animals by day 7. Results from day 14 showed that the MPCA was cleared from all organs in all test animals. No clinical manifestations of treatment were noted. Gross necropsy revealed no indications of treatment-related pathology or any unusual findings. It is concluded that *Pantoea agglomerans* strain E325 is not acutely toxic to rats following oral administration.

2. *Acute pulmonary toxicity/pathogenicity—rat (OPPTS 885.3150).* Forty-eight male and 48 female Sprague-Dawley rats were dosed with the test substance, *Pantoea agglomerans* strain E325 at a rate of 1.8×10^{11} CFU per animal. (MRID 464678–03) Ref 2. The test material was determined to be below 100 CFU per animal at all time points tested. The test organism (*Pantoea agglomerans* strain E325) was cleared from the cecum contents by day 7 and from the lungs by day 14. The MPCA was detected in the kidney and lymph nodes, spleen, and brain up to day 14, but had cleared in all animals by day 21. Therefore, based on the presented/submitted data, the test organism was not toxic nor pathogenic to the test animals.

3. *Acute dermal toxicity—rabbits (OPPTS 870.2500 and OPPTS 885.3100).* The registrant has requested that the dermal irritation study be waived. *Pantoea agglomerans* is found on a wide variety of plant parts, including the rhizosphere, leaves, and seeds. The species is also a heavy colonizer of cotton plants, grass, and silage, and is the prominent species in organic dust. The organism has also been isolated from soil and water. Recent reports have also identified P. agglomerans on retail salad vegetables. There have been no adverse dermal effects or dermal irritation reported in any cited literature for *Pantoea agglomerans* strain E325. In light of the strong evidence indicating no adverse effects due to dermal exposure to *Pantoea agglomerans*, EPA has agreed to waive dermal toxicity testing. Further, data show that exposure from ambient populations is sufficiently high that it indicates there would be no adverse dermal effects from pesticidal use no matter what the residue level is.

4. *Primary eye irritation (OPPTS 870.2400).* The registrant has requested a waiver for the primary eye irritation study. Due to the fact that *Pantoea agglomerans* is found in food and drinking water, and there have been no adverse eye irritation effects reported, *Pantoea agglomerans* is not considered to be an eye irritant. Additionally *Pantoea agglomerans* is ubiquitous in the environment, and it is recognized as an epiphyte of a wide variety of plants such as sweet potato, rice, and organic

dust. No reports of eye irritation have been reported for this organism.

5. *Data waiver requests*. Data waiver requests were made for the following requirements for the Technical Grade of the Active Ingredient/Manufacturing-use Product (TGAI/MP) and Experimental Product (EP):

- Acute Intravenous (IV), Intracerebral (IC), Intraperitoneal (IP) injection Toxicity/Pathogenicity (OPPTS 885.3200).
- Cell Culture (OPPTS 885.3500).
- Immune Response (OPPTS 880.3800).
- Hypersensitivity study.
- Hypersensitivity Incidents (OPPTS 885.3400).

i. *Acute inhalation toxicity/pathogenicity*. The registrant cited the acute pulmonary toxicity/pathogenicity study (see Unit III.?.3.) to justify waiving the acute inhalation study. In the acute pulmonary toxicity/pathogenicity study *Pantoea agglomerans* strain E325, was not found in any organs or tissues which indicates that the active ingredient cleared tissues and was not toxic, infective, or pathogenic to rats when instilled intratracheally. Additionally, when this product is applied, applicators will be required to wear the necessary protective equipment to prevent inhalation, and this justifies granting this request to waive acute-inhalation data requirements.

ii. *Acute IV/IP/IC study*. In an acute oral toxicity/pathogenicity study (see Unit III.1. and 2.), no clinical signs of toxicity were observed in rats and no *Pantoea agglomerans* strain E325 was recovered from organs or tissues. These data show that *Pantoea agglomerans* strain E325 was considered to clear rapidly from the test animal in that it was never detected. The active ingredient *Pantoea agglomerans* strain E325 is considered to be non-toxic. Based on the low toxicity potential indicated by these observations, the request to waive the acute IP study was granted.

iii. *Cell culture*. This study is required for a virus and is not required for a bacterial active ingredient such as *Pantoea agglomerans* strain E325.

iv. *Immune response*. The lack of pathogenicity seen in the acute oral toxicity/pathogenicity study with the active ingredient indicates the immune system was not adversely affected by *Pantoea agglomerans* strain E325. Based on these considerations, the justifications to support the request to waive data requirements for the immune response studies for the TGAI/MP are acceptable.

v. *Hypersensitivity study*. No incidents of hypersensitivity have occurred during the research, development, or testing of *Pantoea agglomerans* strain E325 or the end use product, Bloomtime. A hypersensitivity study is not required at this time, but may be required in the future if there are reports of hypersensitivity incidents associated with this active ingredient used in pesticides. If a person is abnormally physiologically susceptible to a specific agent, there are a number of symptoms that the individual will exhibit. This organism has been in nature for many years, and there have been no reports of any human or animal exhibiting any symptoms after having been in contact with the organism.

vi. *Hypersensitivity incidents (OPPTS 885.3400)*. The registrant requested to waive reports of hypersensitivity incidents, because no incidents of hypersensitivity associated with the TGAI or the EP have been reported. However, the registrant agreed to report hypersensitivity incidents, should they occur in the future. This guideline requirement is satisfied at this time. In order to comply with the Federal Insecticide, Fungicide, and Rotenticide Act (FIFRA) requirements under section 6(a)(2), any incident of hypersensitivity associated with the use of this pesticide must be reported to the Agency. This data requirement has not been waived.

6. *Subchronic, chronic toxicity and oncogenicity, and residue data*. Based on the data generated in accordance with the Tier I data requirements set forth in 40 CFR 158.740(c), the Tier II and Tier III data requirements were not triggered and, therefore, not required in connection with this action. In addition, because the Tier II and Tier III data requirements were not required, the residue data requirements set forth in 40 CFR 158.740(b) also were not required.

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

Use of *Pantoea agglomerans* strain E325 is not expected to cause any harm via consumption of food or feed treated with the microbial pesticide, which is not applied directly to food as discussed in this unit.

1. *Food*. Residues of *Pantoea agglomerans* strain E325 are not expected on treated food commodities from the proposed use patterns. The product, Bloomtime, containing *Pantoea agglomerans* strain E325, is applied at bloom followed by a second application at first petal fall-full bloom. After Bloomtime is applied, the pesticide becomes non-viable very rapidly, which causes the need for more than one application. The pesticide itself is not in direct contact with the food commodities. This pesticide is applied prior to fruiting. There is no post-harvest treatment directly to the food commodities. Furthermore, the active ingredient is not a systemic pesticide. Thus, detectable residues of *Pantoea agglomerans* strain E325 are not expected on treated fruit trees or their food commodities. Furthermore, as previously stated, *Pantoea agglomerans* strain E325 is found in soil, water, and air. Data submissions to the Agency show that residues of the *Pantoea agglomerans* strain E325 are not found on the food commodities. Finally, as discussed previously in Unit III., the acute oral tests demonstrate low toxicity potential via dietary exposure to this Toxicity Category IV pesticide. Hence, even if the pesticide was present in or on food commodities, exposure via the dietary route is not expected to cause any harm. Therefore, the Agency has decided that dietary exposure from the proposed uses of *Pantoea agglomerans* strain E325 is not expected to adversely affect the U.S. adult population, infants, and children.

2. *Drinking water exposure*. No drinking water exposure is anticipated because of the use pattern and use sites. There are no aquatic use sites permitted for this pesticide, so exposure to drinking water is not expected. Further, there is no evidence of adverse effects from exposure to this organism. Exposure from the proposed use of *Pantoea agglomerans* strain E325 is not likely to pose any incremental risk via consumption of drinking water to adult humans, infants and children.

B. Other Non-Occupational Exposure

The proposed product is an end-use product to be commercially used in apple and pear orchards. No non-occupational residential, school or day care exposure is anticipated because of the use pattern of this product. The use of *Panteoa agglomerans* strain E325 should result in minimal to non-existent, non-occupational risk. No indoor residential, school, or daycare uses are permitted on the label of this product.

1. *Dermal exposure*. The low toxicity potential observed in the acute dermal studies discussed in Unit III., the low exposure potential based on low application rates, and the lack of persistence of the active ingredient, leads EPA to conclude that this pesticide poses minimal risk to human populations via non-occupational dermal exposure. Moreover, potential non-occupational dermal exposure to *Panteoa agglomerans* strain E325 is unlikely because the use sites are commercial and agricultural.

As previously discussed in Units III. and IV., a lack of hypersensitivity incidents indicates *Panteoa agglomerans* strain E325 poses minimal risk to populations via non-occupational dermal exposure. Thus, the Agency does not expect pesticides containing *Panteoa agglomerans* strain E325 to pose a non-occupational dermal exposure risk.

2. *Inhalation exposure*. Non-occupational inhalation exposure to the active ingredient itself is not expected to pose an inhalation risk. No treatment-related effects associated with the active ingredient were observed in the pulmonary tests reported in Unit II. Based on the low potential for non-occupational inhalation exposure, the Agency does not expect *Pantoea agglomerans* strain E325 to pose an inhalation risk.

V. Cumulative Effects

The Agency has considered the potential for cumulative effects of *Pantoea agglomerans* strain E325 and other substances in relation to a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. As demonstrated in the toxicity assessment, *Pantoea agglomerans* strain E325 is non-toxic and non-pathogenic to mammals. Because no mechanism of pathogenicity or toxicity in mammals has been identified for this organism, 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

There is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposures to residues of *Pantoea agglomerans* strain E325, as a result of its proposed uses. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, there appears to be no potential for harm, from this bacterium in its use as a microbial pesticide in apple and pear orchards. Furthermore, 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 for acute oral, pulmonary, and dermal effects with no toxicity or infectivity at the doses tested (see Unit III.). Moreover, potential non-occupational inhalation or dermal exposure is not expected to pose any adverse effects to exposed populations via aggregate and cumulative exposure.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under section 408(p) of 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 scientific basis for including, as part of the program, the androgen and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority, to require 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). The Agency is not requiring information on the endocrine effects of this active ingredient at this time. The Agency has considered, among other relevant factors, available information concerning whether the microorganism may have an effect in humans similar to an effect produced by a naturally-occurring estrogen or other endocrine effects.

There is no known metabolite produced by this bacterium that acts as an endocrine disruptor. The submitted and cited toxicity/pathogenicity studies in rodents indicate that following injection and pulmonary routes of exposure, no test substance was found in organs or tissues of test animals. This indicates that the body is able to process and clear the active ingredient. The Agency concludes that there will be no incremental adverse effects to the endocrine system.

B. Analytical Methods

The acute oral studies discussed in Unit II. demonstrate that the active ingredient, *Pantoea agglomerans* strain E325 does not pose a dietary risk. In addition, the active ingredient is not likely to come into contact with food commodities. 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 *Pantoea agglomerans* strain E325. 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 *Pantoea agglomerans* strain E325.

VIII. Conclusions

The results of the studies discussed in Unit II. are sufficient to comply with the requirements of FQPA. They support an exemption from the requirement of a tolerance for residues of *Pantoea agglomerans* strain E325 on apples and pears. In addition, the Agency is of the opinion that, if the microbial active ingredient is used as labeled, aggregate and cumulative exposures are not likely to pose any undue risk. Submitted and cited data show that *Pantoea agglomerans* strain E325 do not pose an incremental dietary and non-dietary risk to the adult human U.S. population, children, and infants. Therefore, an exemption from tolerance is granted in response to pesticide petition 6F7087.

MRID Citation References

1. 464678–02, Kuhn, J.O., Acute Oral Toxicity/Pathogenicity Study in Rats With A Microbial Pest Control Agent (MPCA).

2. 464678–03, Kuhn, J.O., Acute Pulmonary Toxicity/Pathogenicity Study In Rats With A Microbial Pest Control Agent (MPCA).

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of 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 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, entitled *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 FFDCA, such as the exemption from the requirement of a 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. 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 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: September 11, 2006.

James J. Jones,

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 180.1272 is added to subpart D to read as follows:

§ 180.1272 Pantoea agglomerans strain E325; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Pantoea agglomerans* strain E325 when used on apples and pears.

[FR Doc. 06–8005 Filed 9–19–06; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[FEMA Docket No. D–7642]

Withdrawal of Final Flood Elevation Determination for the Listed Communities in Yuma and Coconino Counties, AZ

AGENCY: Federal Emergency Management Agency (FEMA), Department of Homeland Security (DHS).

ACTION: Final rule; withdrawal.

SUMMARY: The Federal Emergency Management Agency (FEMA) withdraws the final flood elevation determination published in 71 FR 33647, June 12, 2006 for the Unincorporated Areas of Yuma County and Cities of San Luis and Yuma, and the Unincorporated Areas of Coconino County, and City of Flagstaff, Arizona, hereafter referred to as ''listed communities.'' A final flood elevation determination will be made at a later date.