

*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 as required by 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 other 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 104–13, section 12(d) (15 U.S.C. 272 note). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Agency previously assessed whether revocations of tolerances might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. This analysis was published on December 17, 1997 (62 FR 66020), and was provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticides listed in this rule, the Agency hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In a memorandum dated May 25, 2001, EPA determined that eight conditions must all be satisfied in order for an import tolerance or tolerance exemption revocation to adversely affect a significant number of small entity importers, and that there is a negligible joint probability of all eight conditions holding simultaneously with respect to any particular revocation. (This Agency document is available in the docket of this final rule). Furthermore, for the pesticides named in this final rule, the Agency knows of no extraordinary circumstances that exist as to the present revocations that would change EPA's previous analysis. 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 FFDCFA. 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.

#### VI. 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: April 11, 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.

**§§ 180.152, 180.174, 180.267, 180.488, 180.1024 and 180.1229 [Removed]**

■ 2. Sections 180.152, 180.174, 180.267, 180.488, 180.1024 and 180.1229 are removed.

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA–HQ–OPP–2006–0267; FRL–7772–6]

#### **Pantoea Agglomerans Strain C9–1; 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 C9–1 on pears and apples when applied or used as a microbial pesticide. Nufarm, Inc. 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 C9-1.

**DATES:** This regulation is effective April 26, 2006. Objections and requests for hearings must be received on or before June 26, 2006.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit X. of the **SUPPLEMENTARY**

**INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number EPA-HQ-OPP-2006-0267. All documents in the docket are listed on the *regulations.gov* website. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at <http://www.regulations.gov/>. Follow the on-line instructions). 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.

• **Important Note:** OPP will be moving to a new location the first week of May 2006. As a result, from Friday, April 28 to Friday, May 5, 2006, the OPP Regulatory Public Docket will NOT be accepting any deliveries at the Crystal Mall #2 address and this facility will be closed to the public. Beginning on May 8, 2006, the OPP Regulatory Public Docket will reopen at 8:30 a.m. and deliveries will be accepted in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202. The mail code for the mailing address will change to (7502P), but will otherwise remain the same. The OPP Regulatory Public Docket telephone number and hours of operation will remain the same after the move.

**FOR FURTHER INFORMATION CONTACT:** Leonard Cole, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5412; e-mail address: [cole.leonard@epa.gov](mailto:cole.leonard@epa.gov).

## SUPPLEMENTARY INFORMATION:

### I. General Information

#### A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. 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/>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

### II. Background and Statutory Findings

In the **Federal Register** of June, 13, 1997 (62 FR 32331) (FRL-5721-6), 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 7F4817) by Nufarm, Inc., (formerly Plant Health Technologies), 1333 Burr Ridge Parkway, Suite 125A, Burr Ridge, IL 60527. The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of *Pantoea agglomerans* (*P. agglomerans*) strain C9-1. This notice included a summary of the petition

prepared by the petitioner, Nufarm, Inc. There were no comments received in response to the notice of filing.

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.

*Pantoea agglomerans* strain C9-1 was originally isolated from apple stem tissue in an apple orchard in Michigan in 1981. Subsequently, a natural spontaneous mutant derived from the original strain was obtained which had

streptomycin and rifampicin resistance. This strain retained the designation C9-1 and was not derived through genetic engineering. When first isolated, this strain was identified as *Erwinia herbicola* based on GC-FAME (gas chromatography-fatty acid methyl ester) analysis and placed in GC subgroup B. Members of the group described as *E. herbicola/lathyri-Enterobacter agglomerans* are found in soil, water and air, and are associated with plants and animals, including humans as commensal microbes. Following GC-FAME and substrate utilization analyses, and most importantly, a restructuring of the bacterial taxonomy of this group of microbes, this isolate is now considered a strain of *Pantoea agglomerans*. No reports of plant pathogenicity exist for the *P. agglomerans* species.

The registrant is seeking to register *Pantoea agglomerans* strain C9-1 to control fire blight in apples and pears. 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.

1. *Acute oral toxicity – rats (OPPTS 870.1100)*. Sprague-Dawley Rats were dosed at 5g/kg with the test substance *Pantoea agglomerans* strain C9-1 and observed for 14 days Master Record Identification Number ((MRID) 442120-02 (Ref. 1)). All animals gained weight during the study and 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 C9-1 is not acutely toxic to rats following oral administration.

2. *Acute oral toxicity/pathogenicity – rat study (OPPTS 885.3050)*. Sprague-Dawley CD rats were challenged orally with *Pantoea agglomerans* C9-1 and heat killed cells (KTS) as an additional control group. Nine female and 9 male rats were also placed in a naive control (NC) group (no dosing) and 6 rats of each sex were placed into a shelf-control (SC) group (placed adjacent to treated animals, but not dosed) (MRID 442120-03 (Ref.2)). Organs were sampled on days 0, 3 and 7. Since no bacteria were recovered from the samples, the study was terminated on day 10. No deaths of animals occurred during the course of this study and no significant clinical findings were noted. All animals gained weight and relative organ weights were normal with no significant treatment effects observed.

*Pantoea agglomerans* strain C9-1 was considered to clear rapidly from the test animal in that it was never detected. *Pantoea agglomerans* strain C9-1 is considered to be non-toxic following oral challenge.

3. *Acute pulmonary toxicity/pathogenicity – rat (OPPTS 885.3150)*. Fifty rats, 25 female and 25 male) received, by intratracheal instillation, a dose of  $9.83 \times 10^7$  or  $9.00 \times 10^7$  colony forming units (cfu) of *Pantoea agglomerans* strain C9-1 in a 0.1 milliliter (mL) volume (MRID 442120-05 (Ref.4)). No adverse clinical signs were recorded for any of the animals during the study. Four rats died during dosing and were immediately replaced. The rats were sacrificed at 7 days and subjected to necropsy. No clinical signs related to the test organism or macroscopic abnormalities were observed in the rats. It can be concluded since no test substance was recovered from any animals that this organism does not appear to be toxic, infective, and/or pathogenic to rats at this high dose level. This study is considered acceptable and classified as Toxicity Category IV (BPPD DER 05/17/02).

4. *Acute dermal toxicity – rabbits (OPPTS 870.2500 and OPPTS 885.3100)*. Approximately 2 grams (g) of test material was applied to the dorsal epidermis of 10 New Zealand White Rabbits and maintained there for 24 hours (MIRD 442120-04 (Ref.3)). All rabbits exhibited very slight to well-defined erythema and three rabbits exhibited very slight edema. By day 10 all surviving rabbits (9 of 10) had cleared of any dermal irritations and remained this way throughout the end of the study (day 14). No edema scores greater than 1 and no erythema scores greater than 2 were recorded during the study. One rabbit, which died at day 10, revealed no gross lesions upon necropsy. This study is considered acceptable and classified as Toxicity Category IV for irritation and Toxicity Category III for Toxicity (BPPD DER 05/17/02)

5. *Primary eye irritation (OPPTS 870.2400)*. Six New Zealand White Rabbits were administered 0.1 g of test substance into the right eyelid which was washed out after 24 hours (MRID 442120-07 (Ref.5)). No mortality, corneal lesions or iridal effects were noted at any time during the study. *Pantoea agglomerans* C9-1 is considered to be a mild eye irritant. This study is considered acceptable and classified as Toxicity Category III (BPPD DER 05/17/02).

6. *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):

- (a) Acute Inhalation (OPPTS 870.1300);
- (b) Acute Intravenous (IV), Intracerebral (IC), Intraperitoneal (IP) injection Toxicity/Pathogenicity (OPPTS 885.3200);
- (c) Cell Culture (OPPTS 885.3500);
- (d) Immune Response (OPPTS 880.3800);
- (e) Hypersensitivity study;
- (f) Hypersensitivity Incidents (OPPTS 885.3400).

i. *Acute inhalation toxicity/pathogenicity*. The registrant cited the acute pulmonary toxicity/pathogenicity study (see Unit III.3., above) to justify waiving the acute inhalation study. In the acute pulmonary toxicity/pathogenicity study *Pantoea agglomerans* strain C9-1, 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. above), no clinical signs of toxicity were observed in rats and no *Pantoea agglomerans* strain C9-1 was recovered from organs or tissues. These data show that *Pantoea agglomerans* strain C9-1 was considered to clear rapidly from the test animal in that it was never detected. The active ingredient *Pantoea agglomerans* strain C9-1 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 C9-1. The request to waive this data requirement was granted.

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 C9-1. 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 C9-1 or the end use product, Blightban. 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.

vi. *Hypersensitivity incidents (OPPTS 885.3400)*. The registrant requested to waive reports of hypersensitivity incidents, because no incidents of hypersensitivity associated with the TGA I 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 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.

7. *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 the FFDC A 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 C9-1 is not likely to cause any harm via consumption of food or feed treated with the microbial pesticide, which is not applied directly to food as discussed below.

1. *Food*. Residues of *Pantoea agglomerans* strain C9-1 are not expected on treated food commodities from the proposed use patterns. The product, Blightban, containing *Pantoea agglomerans* strain C9-1, is applied at bloom followed by a second application at first petal fall-full bloom. After Blightban 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 C9-1 are not expected on treated fruit trees or their food commodities. Furthermore, as previously stated, *Pantoea agglomerans* strain C9-1 is found in soil, water and air. Data submissions to the Agency show that residues of the *Pantoea agglomerans* strain C9-1 are not found on the food commodities. Finally, as discussed 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 C9-1 is not likely 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 C9-1 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 *Pantoea agglomerans* strain C9-1 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 above (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 *Pantoea agglomerans* strain C9-1 is unlikely because the use sites are commercial and agricultural.

As previously discussed in Units III and IV, a lack of hypersensitivity incidents indicates *Pantoea agglomerans* strain C9-1 poses minimal risk to populations via non-occupational dermal exposure. Thus, the Agency does not expect pesticides containing *Pantoea agglomerans* strain C9-1 to pose a non-occupational dermal exposure risk.

2. *Inhalation exposure*. Non-occupational inhalation exposure to the active ingredient itself is not likely to pose an inhalation risk. No treatment-related effects associated with the active ingredient were observed in the pulmonary tests reported above. Based on the low potential for non-occupational inhalation exposure, the Agency does not expect *Pantoea agglomerans* strain C9-1 to pose an inhalation risk.

#### V. Cumulative Effects

The Agency has considered the potential for cumulative effects of *Pantoea agglomerans* strain C9-1 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 Unit IV.B., *Pantoea agglomerans* strain C9-1 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 C9-1, 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. above). Moreover, potential non-occupational inhalation or dermal exposure is not expected to pose any adverse effects to exposed populations via aggregate and cumulative exposure

(see Units IV. and V.). FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional ten-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 data base 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 factors, are incorporated into EPA risk assessments 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, based on all the available information (as discussed in detail above), the Agency concludes that the bacterium, *Pantoea agglomerans* strain C9-1, is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children and adults when *Pantoea agglomerans* strain C9-1 is used as labeled, the Agency has determined that the additional margin of safety is not necessary to protect infants and children, and that not adding any additional margin of safety will be safe for infants and children.

## VII. Other Considerations

### A. Endocrine Disruptors

EPA is required under section 408(p) of the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.” Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was 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 Method(s)

The acute oral studies discussed above demonstrate that the active ingredient, *Pantoea agglomerans* strain C9-1 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 C9-1. 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 C9-1

## VIII. Conclusions

The results of the studies discussed above are sufficient to comply with the requirements of the FQPA. They support an exemption from the requirement of a tolerance for residues of *Pantoea agglomerans* strain C9-1 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 C9-1 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 7F4817.

## IX. MRID Citation References

1. 442120-02. Johnson, W.D. Acute Oral Toxicity Study of *Erwinia herbicola* Strain C9-1 in Rats (Limit Test).
2. 442120-03. Mega, W.M. Toxicity/Pathogenicity Testing of *Erwinia herbicola* Strain C9-1 Following Acute Oral Challenge in Rats
3. 442120-04. Johnson, W.D. Acute Dermal Toxicity/Irritation Study of *Erwinia herbicola* Strain C9-1 in Rabbits
4. 442120-05. Mega, W.M. Toxicity/Pathogenicity Testing of *Erwinia herbicola* Strain C9-1 Following Acute Intratracheal Challenge in Rats.
5. 442120-07. Johnson, W.D. Primary Eye Irritation of *Erwinia herbicola* Strain C9-1 in Rabbits.

## X. 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 EPA-HQ-OPP-2006-0267 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 June 26, 2006.

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 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 IX.A.1., 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-2006-0267, to: Public Information and Records Integrity Branch, Information Technology and Resources Management 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

#### **XI. 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 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.

## XII. 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: April 7, 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 180.1267 is added to subpart D to read as follows:

#### § 180.1267 *Pantoea agglomerans* strain C9-1; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Pantoea agglomerans* strain C9-1 when used on apples and pears.

[FR Doc. 06-3856 Filed 4-25-06; 8:45 am]

BILLING CODE 6560-50-S

## GENERAL SERVICES ADMINISTRATION

### 41 CFR Parts 301-12, 301-13, and 301-70

[FTR Amendment 2006-03; FTR Case 2006-303]

RIN 3090-AI24

### Federal Travel Regulation; Travel of an Employee with Special Needs—Services of Attendants

**AGENCY:** Office of Governmentwide Policy, General Services Administration (GSA).

**ACTION:** Final rule.

**SUMMARY:** The General Services Administration (GSA) is amending the Federal Travel Regulation (FTR), to clarify existing authority under the Rehabilitation Act of 1973, as amended, 29 U.S.C. 701-7961, and 5 U.S.C. 3102, that allows agencies to reimburse employees with special needs for expenses incurred for the services of an attendant while on official travel. Specifically, this final rule amends the FTR by adding reimbursement for "services of an attendant traveling with an employee with special needs" as a miscellaneous expense item. The FTR and any corresponding documents may be accessed at GSA's website at <http://www.gsa.gov/fttr>.

**DATES:** Effective Date: This final rule is effective April 26, 2006.

**FOR FURTHER INFORMATION CONTACT:** The Regulatory Secretariat (VIR), Room 4035, GS Building, Washington, DC, 20405, (202) 208-7312, for information pertaining to status or publication schedules. For clarification of content, contact Umeki Thorne, Office of Governmentwide Policy, Travel Management Policy, at (202) 208-7636. Please cite FTR Amendment 2006-03; FTR case 2006-303.

### SUPPLEMENTARY INFORMATION:

#### A. Background

In order to provide reasonable accommodations for travel of an employee with special needs, agencies are authorized to pay for a variety of travel expenses as needed by the employee. Allowable expenses include the transportation and per diem expenses incurred by a family member or other attendant who must travel with the employee to make the trip possible. Although authorized by existing statutes, the FTR has not included a provision expressly addressing whether or not agencies may reimburse employees for expenses incurred for the actual services performed by an attendant while on travel with the employee. Accordingly, this final rule adds a provision stating that agencies may reimburse employees for the expenses of an attendant as a miscellaneous travel expense.

#### B. Executive Order 12866

This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

## C. Regulatory Flexibility Act

This final rule is not required to be published in the **Federal Register** for notice and comment; therefore, the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, does not apply.

## D. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the FTR do not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

## E. Small Business Regulatory Enforcement Fairness Act

This final rule is also exempt from congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.

### List of Subjects in 41 CFR Parts 301-12, 301-13, and 301-70

Government employees, Travel and transportation expenses.

Dated: March 7, 2006.

**David L. Bibb,**

*Acting Administrator of General Services.*

■ For the reasons set forth in the preamble, under 5 U.S.C. 5701-5709, GSA amends 41 CFR parts 301-12, 301-13, and 301-70 as set forth below:

### PART 301-12—MISCELLANEOUS EXPENSES

■ 1. The authority citation for 41 CFR part 301-12 continues to read as follows:

**Authority:** Authority: 5 U.S.C. 5707.

#### § 301-12.1 [Amended]

■ 2. Amend section 301-12.1, in the table, in the first column under the heading "General expenses", by adding the entry "Services of an attendant as described in § 301-13.3" after the entry "Services of guides, interpreters, and drivers".

### PART 301-13—TRAVEL OF AN EMPLOYEE WITH SPECIAL NEEDS

■ 3. The authority citation for 41 CFR part 301-13 continues to read as follows:

**Authority:** Authority: 5 U.S.C. 5707.

■ 4. Amend section 301-13.3 by revising the introductory sentence, paragraphs (e) and (f); and adding paragraph (g), and Note to paragraph (g) to read as follows: