duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 5, 2008.

Debra Edwards,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.646 is added to subpart C to read as follows:

§ 180.646 Ipconazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of ipconazole, (2-[(4-chlorophenyl)methyl]-5-(1-methylethyl)-1-(1H-1,2,4-triazole-1-ylmethyl) cyclopentanol) from seed treatment in or on the following commodities:

Commodity	Parts per million
Cotton, gin byproducts	0.01
Cotton, undelinted seed	0.01
Grain, cereal, forage, fodder and straw, group 16, except rice	0.01
Grain, cereal group 15, except rice	0.01
Pea and bean, dried shelled, except soybean, subgroup 6C	0.01
Peanut	0.01
Soybean, forage	0.01
Soybean, seed	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

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

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

[FR Doc. E8–27310 Filed 11–18–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0417; FRL–8389–5]

Polyoxin D Zinc Salt; 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 polyoxin D zinc salt (zinc 5-[[2-amino-5-o-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2*H*)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronatein) on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes and strawberries when applied/used as a biochemical pesticide to control and suppress fungal diseases. Arysta LifeScience North America Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of polyoxin D zinc salt (zinc 5-[[2-amino-5-o-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2*H*)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronatein).

DATES: This regulation is effective November 19, 2008. Objections and requests for hearings must be received on or before January 20, 2009, 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–2008—0417. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Chris Pfeifer, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0031; e-mail address: *pfeifer.chris@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?

In addition to accessing electronically available documents 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 e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, 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–2008–0417 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 January 20, 2009.

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–2008–0417, 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 Facility'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 31, 2008 (73 FR 44719) (FRL–8374–3), 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 7F7252) by Arysta LifeScience North America Corporation, 15401 Weston Parkway, Suite 150, Cary, NC 27513. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of polyoxin D zinc salt (zinc 5-[[2-amino-5-o-(aminocarbonyl)-2-deoxy-L-xylonoyl]amino]-1-(5-carboxy-3,4-dihydro-2,4-dioxo-1(2*H*)-pyrimidinyl)-1,5-dideoxy-β-D-allofuranuronatein). This notice included a summary of the petition prepared by the petitioner Arysta LifeScience North America Corporation. 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.

Polyoxin D zinc salt is a brown musty smelling powder derived through the fermentation of the microbe *Streptomyces cacaoi var. asoensis*, which was isolated from a soil sample collected in Japan. It is registered with EPA's Biopesticides and Pollution Prevention Division (BPPD) as a biochemical active ingredient, intended for incorporation into sprayable fungicides for turf. As an active ingredient, it has a non-toxic mode of action, which acts against fungi; not by killing it, but by inhibiting chitin growth in the cell walls, and thus precluding the development of fungal colonies. Its effects are considered fungi-exclusive in that it has no mode of action relative to mammals. Polyoxin D zinc salt does not persist in the environment, biodegrading readily within 2 to 3 days. Finally, polyoxin D zinc salt has a well understood low toxicity profile.

Polyoxin-D zinc salt was first assessed by EPA in 1997 with regard to the

human health risks associated with its fungicidal use on turf. The risk assessment concluded that the commercial turf uses of polyoxin D zinc salt posed no health risks to either occupational users or to any non-occupational populations that might be exposed. A battery of acute and chronic toxicological studies, submitted in support of this non-food use, showed that polyoxin D zinc salt induced ''minimal toxic affects to humans through oral, dermal, ocular or inhalation routes of exposure.'' These studies included all acute toxicity studies, mutagenicity studies, developmental studies, and exposure and oncogenicity studies. Additionally, EPA's risk assessment considered the active ingredient in light of the requirements of the Food Quality Protection Act (FQPA) and made a determination of ''reasonable certainty of no harm to human health.'' Altogether, the Agency's 1997 risk assessment of polyoxin D zinc salt concluded that there are no risks expected for acute, subchronic, chronic, immune, endocrine, or non-dietary cumulative exposures due to the negligible toxicity associated with the active ingredient.

New toxicity data have since been submitted in support of the request by the applicant to allow food uses (detailed in this rule) of this registered non-food use active ingredient. These data have been incorporated into a comprehensive risk assessment on polyoxin D zinc salt and provide sufficient grounds for this exemption from the requirement of a tolerance. The new data include a new mutagenicity study, a 90–day subchronic oral toxicity study, a 2–generation developmental toxicity study, an immunotoxicty study, and calculations for terrestrial residues. All new data confirm a lack of human health hazard associated with dietary exposures. These new toxicity data, coupled with the data to support the original non-food uses, allow for a comprehensive dietary risk analysis, and fully demonstrate polyoxin D zinc salt's lack of acute, subchronic, and/or chronic toxicity with regard to dietary exposure. All data substantiate the lack of dietary risk associated with the food use of polyoxin D zinc salt.

All data supporting the use of polyoxin D zinc salt on the food crops mentioned in this rule confirm that the dietary risks to humans are negligible for the following reasons:

i. The fungistatic mode of action of this active ingredient is specific to fungi and poses no risk to mammals.

ii. Polyoxin D zinc salt is not digestible by mammals and passes through the digestive system.

iii. Theoretical (potential) residues are substantially less than the doses that were actually used in polyoxin D zinc salts' toxicity studies, which showed virtual non-toxicity.

iv. A complete battery of toxicological studies show no toxicological endpoints and confirm the active ingredient's very low toxicity. For the reasons listed in this unit, any potential residues of polyoxin D zinc salt are considered to be safe with regard to dietary risk. Summaries of the supporting toxicological information are found in this unit.

1. *Acute toxicity*. Acute toxicity studies were submitted to support the initial registration of polyoxin D zinc salt. These studies show a lack of significant acute toxicological endpoints, and support the finding that polyoxin D zinc salt poses no significant human health risk with regard to food uses listed in the summary section of this document. A précis of the acute toxicity studies follows:

i. The acute oral LD_{50} is greater than 10,000 milligrams/kilograms (mg/kg) in rats, a result that confirms acute non-toxicity through the oral route, and undergirds the risk assessment finding that any amount of residues of polyoxin D zinc salt, if consumed, is not a health concern.

ii. The acute dermal LD_{50} in rats is greater than 2,000 mg/kg in rats, and demonstrates very low toxicity through dermal exposure. While no significant dermal exposure is expected as a result of pesticidal applications associated with these new food uses, these data substantiate polyoxin D zinc salt's relative non-toxicity to both occupational users and the general public.

iii. The acute inhalation LC_{50} is greater than 2.17 mg/L in rats, and shows no significant inhalation toxicity. Again, no significant new inhalation exposure is expected; and relatedly, no risks are expected for occupational users or the general public as a result of these new food uses.

iv. Primary dermal irritation in rabbits was considered slight, which finding bolsters the information presented in the acute dermal toxicity study.

v. A hypersensitivity study on guinea pigs further demonstrated that the active ingredient was not a dermal sensitizer. The acute toxicity studies demonstrate that even if there were residues present in food, there would be negligible toxic effects associated with polyoxin D zinc salt.

2. *Mutagenicity*. Data demonstrate that polyoxin D zinc salt is non-mutagenic. Accordingly, residues associated with the new pesticidal food uses of polyoxin D zinc salt are not expected to pose any risk to humans with regard to mutagenicity. Studies submitted in support of the original 1997 registration of polyoxin D zinc salt first showed the active ingredient to be without mutagenic effect. While an Ames Assay (Master Record Identification Number (MRID 433230–01)) showed polyoxin D to be weakly mutagenic, a battery of three complementary mutagenicity tests supported negative conclusions for mutagenicity. In further support of that finding of non-mutagenicity, no maternal toxicity or developmental toxicity were observed in a developmental toxicity study submitted at that time (MRID 432618–36). More recently, two additional studies were submitted in support of non-mutagenicity with regard to a food use. A Tier II Mammalian Erythrocyte Micronucleus Study (OPPTS 870.5395; MRID 47145102) showed no mutagenic effect. The test material was not toxic to male mice at any dose tested, and there were no reported sex differences in response to the test. In a second study, polyoxin D zinc salt was tested to the limit dose of 2,000 mg/kg on mice. The mice showed no clinical signs or mortality, and there was no significant increase in the frequency of micronucleated PCEs, further indicating no mutagenic effect. The mutagenicity studies are sufficient to confirm that there are no expected dietary, occupational, or non-occupational risks of mutagenicity with regard to new food uses.

3. *Subchronic toxicity*. Polyoxin D zinc salt has very low subchronic oral toxicity, and demonstrates a lack of dietary risk at the subchronic level. In a 90–Day Oral Toxicity study on rats (OPPTS 870.3100; MRID 47145101), polyoxin D zinc salt technical was administered to ten rats. There were no toxicologically significant treatment-related effects on mortality. Neurological assessments, urinalysis, ophthalmology, hematology, clinical chemistry, and gross and histologic pathology found no clinical signs of toxicologically significant treatment-related effects. The no-observed-adverse-effect level (NOAEL) in this study is 20,000 parts per million (ppm) (1,333 mg/kg/day) in females and 2,000 ppm (119 mg/kg/day) in males. The lowest-observed-adverse-effect level (LOAEL) in males is 20,000 ppm (1,166 mg/kg/day) based on decreased body

weight (bw) gain, food consumption and food efficiency; a LOAEL was not observed in females. Based on the lack of meaningful subchronic toxicological endpoints for the technical grade active ingredient (TGAI), the fungi-exclusive mode of action as a chitin synthetase inhibitor, and the related lack of toxic oral effect in mammals, there are no subchronic oral toxicity concerns with polyoxin D zinc salt. It is further noted that the proposed use patterns for this active ingredient are not expected to result in any repeated and/or long-term exposure by either the dermal or inhalation routes; and as a result, no dermal or inhalation subchronic studies are required to establish this food use.

4. *Developmental toxicity*. Data demonstrate that polyoxin D zinc salt is not a developmental or reproductive toxicant. These findings further confirm polyoxin D zinc salt's lack of mammalian toxicity, and demonstrate a lack of dietary effect consistent with its fungi-exclusive mode of action. A Tier III Two Generation Reproduction Toxicity Study (OPPTS 870.3800; MRID 47120904) on rats showed no parental systemic toxicity or differences in bw gain of either generation. No abnormal clinical signs were observed during the study period in any generation. No significant differences were found between treated and control groups with regard to the average number of live births per litter, average bw of live pups, ossification failure of the chest ossification center, or bone variation. No differences were found in the number of stillbirths and weaning rate. No specific abnormalities in postnatal growth or general behavior was found between treated and control groups. No differences were detected in mating, pregnancy, delivery, or nursing rate by generation between the treated and control groups. No chemical effects were found in males or females. The reproductive NOAEL for polyoxin D zinc salt is 1%; a LOAEL was not identified. Again, the data indicate the fungistatic nature of active ingredient and the capacity of polyoxin D zinc salt to pass through mammalian digestive systems. In sum, the study demonstrated a clear lack of reproductive toxicity regarding dietary exposure and supports the Agency's conclusion that there is no risk of developmental toxicity associated with the new food uses.

5. *Immunotoxicity*. Polyoxin D zinc salt is not immunotoxic on a dietary basis. No meaningful immunotoxicity endpoints (i.e., dietarily possible) for polyoxin D zinc salt were identified. In an immunotoxicity study based on dietary exposure (OPPTS 870.7800; MRID 47120901), polyoxin D zinc salt technical was administered to mice in their diet for 28 days at various concentrations. There were no compound-related deaths or effects on clinical observations, bw or food consumption. There were no compound-related macroscopic findings noted, and organ weights were unaffected. There were no compound-related effects on the humoral immune response to the T-dependent antigen, sRBC. This study shows the lack of dietary risk posed by the immunotoxicity of polyoxin D zinc salt residues, and supports the exemption from the requirement of a tolerance by further demonstrating a lack of toxic endpoints.

6. *Chronic exposure/oncogenicity*. Based on the data, polyoxin D zinc salt is not a chronic toxicant or oncogen. Results of chronic toxicity/oncogenicity studies (MRIDs 432618–38 and -39) indicated that there were no significant toxicity or oncogenic responses in mice dosed with polyoxin D zinc salt over 2 years. The NOAEL was determined to be 2,058.7 mg TGAI/kg bw/day in males and 2,469.8 mg TGAI/kg bw/day in females. The data show the lack of chronic toxicity/oncogenicity posed by dietary exposure to polyoxin D zinc salt, and further demonstrate the fungistatic nature of the active ingredient – i.e. polyoxin D zinc salt can pass through the mammalian digestive system regularly without toxic effect.

7. *Effects on immune and endocrine systems*. There is no available evidence demonstrating that polyoxin D zinc salt acts is an endocrine disruptor in humans. Based on negative responses obtained from developmental toxicity studies, chronic exposure studies, and oncogenicity studies (MRIDs 432618–36, -38 and -39), no adverse effects to the endocrine or immune systems are known or expected. The lack of evidence of endocrine disruption is consistent with polyoxin D zinc salt's non-toxic profile, and supports this exemption from the requirement of a tolerance.

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

Dietary risks to humans are considered negligible based on the lack of dietary toxicological endpoints for polyoxin D zinc salt, and its non-toxic mode of action as a fungi-specific chitin synthetase inhibitor that passes through mammalian digestive systems. No acute, subchronic, mutagenic, immunotoxic, reproductive, or chronic dietary toxicity hazards were identified in any of the studies used to support this exemption from the requirement of a tolerance. Based on polyoxin D zinc salt's virtual dietary non-toxicity for mammals, no aggregate dietary exposure concerns are expected.

1. *Food*. A Terrestrial Exposure Model (T-Rex, v. 1.2.3; EPA, 2005) used to calculate terrestrial residue data confirms that it is highly unlikely that there will be adverse effects resulting from the use of polyoxin D zinc salt via the oral route of exposure. EPA's T-Rex calculations delimit aggregate consumption of residues to no more than 40 ppm polyoxin D zinc salt, a level that is far below the highest doses used in any of the toxicity testing. T-Rex residue modeling, findings of negligible toxicity, and information confirming polyoxin D zinc salt's fungi-specific mode of action demonstrate a lack of aggregate dietary risk sufficient to support this exemption from the requirement of a tolerance.

2. *Drinking water exposure*. There is a small potential for trace amounts of polyoxin D zinc salt to enter ground water or other drinking water sources after a significant rainfall and surface water runoff, and from incidental spray drift. While the active ingredient does degrade in water over days, it still has the remote potential to reach drinking water sources. Nonetheless, any residues resulting from the scenarios in this unit are expected to be so diluted as to be negligible. As a result, even if there is drinking water exposure, a health risk to humans is considered negligible. Again, based on the lack of toxicological endpoints for polyoxin D zinc salt, and its non-toxic fungi-specific mode of action as a chitin synthetase inhibitor, no dietary risks are expected with regard to drinking water exposure.

B. Other Non-Occupational Exposure

No new non-occupational exposure is expected to result from the new agricultural uses of polyoxin D zinc salt. However, the Agency notes that no health risks are expected from any exposure to this active ingredient in any event. A 1997 risk assessment of polyoxin D zinc salt makes clear that

even the expected non-agricultural non-occupational exposures that are associated with this active ingredient pose negligible risks. Polyoxin D zinc salt is characterized by its negligible toxicity; it has a non-toxic, fungistatic, fungi-specific mode of action, and it demonstrates no mammalian dietary effects.

1. *Dermal exposure*. No new non-occupational dermal exposures are expected to result from the new agricultural uses of polyoxin D zinc salt. Any new dermal exposure associated with this new agricultural use pattern is expected to be occupational in nature.

2. *Inhalation exposure*. No new non-occupational inhalation exposures are expected to result from the new agricultural uses of polyoxin D zinc salt. Any new inhalation exposure associated with this new agricultural use pattern is expected to be occupational in nature.

V. Cumulative Effects

Pursuant to section 408(b)(2)(D)(v) of FFDCA, EPA has considered available information concerning the cumulative effects of polyoxin D zinc salt residues and other substances that have a common mechanism of toxicity. These considerations include the cumulative effects on infants and children of polyoxin D zinc salt residues and other substances with a common mechanism of toxicity. Because there is no indication of mammalian toxicity, the Agency concludes that there are no cumulative effects arising from polyoxin D zinc salt residues in or on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes and strawberries.

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

Health risks to humans, including infants and children are considered negligible. There is a lack of meaningful toxicological endpoints for polyoxin D zinc salt. Moreover, polyoxin D zinc salt is defined by its fungistatic non-toxic mode of action, and demonstrates no mammalian effect. Accordingly, it is considered to have negligible toxicity, and there are no acute or chronic dietary risk concerns for sensitive subpopulations.

1. *U.S. population*. The Agency has determined that there is reasonable certainty that no harm will result to the U.S. population from aggregated exposure to residues of polyoxin D zinc salt. This includes all dietary exposures and other exposures for which there is reliable information. The Agency has arrived at this conclusion based on polyoxin D zinc salt's non-toxic fungi-specific mode of action, and its observed non-toxic effect on mammals. The Agency finds that the combination of registered turf use and the proposed crop uses of polyoxin D zinc salt has a reasonable certainty of no harm to the U.S. population.

2. *Infants and children*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless the EPA determines that a different margin of exposure (safety) will be safe for infants and children. Based on all the reliable available information the Agency reviewed on polyoxin D zinc salt, the Agency concludes that there are no residual uncertainties for prenatal/postnatal toxicity resulting from polyoxin D zinc salt, and that polyoxin D zinc salt has relatively low toxicity to mammals from a dietary standpoint, including infants and children. Accordingly, there are no threshold effects of concern and an additional margin of safety is not necessary to protect infants and children. Indeed, the available data indicate that polyoxin D zinc salt has very low toxicity, including to infants and children, and no increased sensitivity of infants or children was indicated in any of the laboratory studies. In sum, there is a reasonable certainty of no harm to infants and children with regard to the proposed food uses of polyoxin D zinc salt.

VII. Other Considerations

A. Endocrine Disruptors

Based on available data, no endocrine system-related effects have been identified with the consumption of polyoxin D zinc salt. No evidence of endocrine system effects was observed in the immunotoxicity, subchronic, chronic, teratology or reproduction studies.

B. Analytical Method

Through this action, the Agency proposes an exemption from the requirement of a tolerance of polyoxin D zinc salt when used on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes and/or strawberries, without any numerical limitations for residues. EPA has determined that residues resulting from the pesticidal uses of polyoxin D zinc salt would as a matter of viable application be low, and that there are no significant toxicity concerns regarding this active ingredient. As a result, the Agency has concluded that an analytical method is not required for enforcement purposes for this proposed use of polyoxin D zinc salt.

C. Codex Maximum Residue Level

Through this action, the Agency proposes an exemption from the requirement of a tolerance of polyoxin D zinc salt when used on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes and/or strawberries, without any numerical limitations for residues. EPA has determined that residues resulting from the pesticidal uses of polyoxin D zinc salt would as a matter of viable application be low, and that there are no significant toxicity concerns regarding this active ingredient. As a result, the Agency has concluded that an analytical method is not required for enforcement purposes for this proposed use of polyoxin D zinc salt.

VIII. Conclusions

Based on the information submitted, and other information available to the Agency, EPA is establishing an exemption from the tolerance requirements pursuant to section 408(c) of FFDCA for residues of polyoxin D zinc salt in or on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes and strawberries.

IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 11, 2008.

Debra Edwards,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.1285 is added to subpart D to read as follows:

§ 180.1285 Polyoxin D zinc salt; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of the biochemical pesticide polyoxin D zinc when used as a fungicide on almonds, cucurbit vegetables, fruiting vegetables, ginseng, grapes, pistachios, pome fruits, potatoes and strawberries.

[FR Doc. E8–27485 Filed 11–18–08; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 65

[Docket No. FEMA–B–1019]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the Base (1% annual-chance) Flood Elevations (BFEs) is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified BFEs for new buildings and their contents.

DATES: These modified BFEs are currently in effect on the dates listed in the table below and revise the Flood Insurance Rate Maps (FIRMs) in effect prior to this determination for the listed communities.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Mitigation Assistant Administrator of FEMA reconsider the changes. The modified BFEs may be changed during the 90-day period.

ADDRESSES: The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: William R. Blanton, Jr., Engineering Management Branch, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3151.

SUPPLEMENTARY INFORMATION: The modified BFEs are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection is provided.

Any request for reconsideration must be based on knowledge of changed conditions or new scientific or technical data.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by the other Federal, State, or regional entities. The changes BFEs are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This interim rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility