Paperwork Reduction Act of 1995

This rule does not contain collection of information requirements and would not be subject to the Paperwork Reduction Act of 1980, as amended (44 U.S.C. 3501–20).

List of Subjects in 28 CFR Part 0

Authority delegations (Government agencies), Government employees, Organization and functions (Government agencies), Whistleblowing.

■ Accordingly, Title 28, Part 0 of the Code of Federal Regulations is amended as follows:

PART 0—[AMENDED]

■ 1. The authority citation for Part 0 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 509, 510, 515–519.

§ 0.114 [Amended]

■ 2. In § 0.114, paragraph (a)(3) is amended by removing the fee ''$45'' and adding the fee ''$55'' in its place wherever it occurs.

Dated: November 12, 2008.

Michael B. Mukasey,

Attorney General.

[FR Doc. E8–27465 Filed 11–18–08; 8:45 am]

BILLING CODE 4410–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900–AM75

Schedule for Rating Disabilities; Evaluation of Residuals of Traumatic Brain Injury (TBI); Correction

AGENCY: Department of Veterans Affairs.

ACTION: Correcting amendment.

SUMMARY: This document contains a minor correction to the final rulemaking that the Department of Veterans Affairs (VA) published at 73 FR 54693 on September 23, 2008. The rulemaking relates to a revision of the portion of VA's Schedule for Rating Disabilities that addresses neurological conditions and convulsive disorders to provide detailed and updated criteria for evaluating residuals of traumatic brain injury (TBI).

DATES: *Effective Date:* November 19, 2008.

FOR FURTHER INFORMATION CONTACT: Rhonda F. Ford, Chief, Regulations Staff (211D), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–9739 (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: VA published a document in the **Federal Register** on September 23, 2008, at 73 FR 54693, revising the portion of the Rating Schedule regarding traumatic brain injury (TBI). In the **Federal Register** document, a period was left off the end of Note (4) of diagnostic code 8045 in 38 CFR 4.124a. Additionally, we provided updates to 38 CFR part 4, Appendices A and C to reflect the changes to the TBI rating criteria. An extra ''4.124a'' was erroneously added in Appendix A, and ''Traumatic Brain Injury residuals'' with diagnostic code 8045, was not added alphabetically. This document corrects those errors.

List of Subjects in 38 CFR Part 4

Disability benefits, Pensions, Veterans.

Approved: October 29, 2008.

William F. Russo,

Director, Regulations Management.

■ For the reasons set out in the preamble, VA is correcting 38 CFR part 4 as follows.

PART 4—SCHEDULE FOR RATING DISABILITIES

■ 1. The authority citation for part 4 continues to read as follows:

Authority: 38 U.S.C. 1155, unless otherwise noted.

■ 2. In § 4.124a, diagnostic code 8045, Note (4), add a period at the end of the paragraph.

■ 3. In Appendix A to Part 4, under the ''Sec.'' heading, remove from the table the second entry ''4.124a''.

■ 4. In Appendix C to Part 4—Alphabetical Index of Disabilities table, remove the entry ''Traumatic brain injury residuals'' and its diagnostic code ''8045'' and add it in alphabetical order after the entry ''Toxic nephropathy''.

[FR Doc. E8–27457 Filed 11–18–08; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0226; FRL–8389–1]

Ipconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of ipconazole from seed treatment in or on cotton, peanut, soybean, dry shelled pea and bean (Subgroup 6C), cereal grains (Group 15) except rice, and forage, fodder, and straw of cereal grains (Group 16) except rice. Chemtura Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

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–2007–0226. 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: Tawanda Maignan, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8050; e-mail address: *maignan.tawanda@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 those engaged in the following activities:

- 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 to provide 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 EPA's tolerance regulations at 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. 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–2007–0226 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 as required by 40 CFR part 178 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 this copy, identified by docket ID number EPA–HQ–OPP–2007–0226, 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. Petition for Tolerance

In the **Federal Register** of May 9, 2007 (72 FR 26374) (FRL–8121–5), 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 petition (PP 7F7180) by Chemtura Corporation, 199 Benson Rd., Middlebury, CT 06749. The petition requested that 40 CFR part 180 be amended by establishing permanent tolerances for residues of the fungicide ipconazole, (2-[(4-chlorophenyl)methyl]-5-(1-methylethyl)-1-(1H-1,2,4-triazole-1-ylmethyl) cyclopentanol) from treatment of seed prior to planting, in or on food commodities cereal grains (except rice), group 15; forage, fodder and straw of cereal grains (except rice), group 16; cotton; peanut; soybean; dry pea and bean (shelled) (Subgroup 6C) at 0.01 parts per million (ppm). That notice referenced a summary of the petition prepared by Chemtura Corporation, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(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. Section 408(b)(2)(C) of FFDCA requires 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....''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of ipconazole. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies 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. Ipconazole has low acute toxicity via the oral, dermal, and inhalation routes of exposure. It causes low to mild irritation to the eyes and skin; it is not a dermal sensitizer. Ipconazole may cause local, portal-of-entry irritation via all routes following repeated exposure. Systemic effects that were noted in dogs, mice, rabbits and/or rats following exposure to ipconazole were generally limited to decreased body weight, body weight gain, and food consumption; and liver and kidney effects. Developmental effects were observed only at the maternally-toxic dose. Ipconazole is classified as not likely to be a human carcinogen and there is no concern for mutagenicity. Specific information on the studies received and the nature of the adverse effects caused by ipconazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document *Ipconazole. Human Health Risk Assessment for the Requested Seed Treatment Uses on Cotton, Peanut, Soybean, Dry Shelled Pea and Bean (Subgroup 6C), Cereal Grains (Groups 15 and 16) Except Rice*, page number 16 in docket ID number EPA–HQ–OPP–2007–0226.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure

(POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for ipconazole used for human risk assessment is shown in Table 1 of this unit.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR IPCONAZOLE FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General Population Including Infants and Children)	No appropriate endpoint attributable to a single dose of ipconazole was identified for this population.		
Acute dietary (Females 13–50 years of age)	NOAEL = 10 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.1 mg/kg/day aPAD = 0.1 mg/kg/day	Developmental Toxicity Studies in Rats and Rabbits $LOAEL_{rats}$ = 30 mg/kg/day, based on increased visceral and skeletal variations $LOAEL_{rabbits}$ = 50 mg/kg/day, based on increased incidence of skeletal variations and malformations
Chronic dietary (All populations)	NOAEL = 1.5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.015 mg/kg/day cPAD = 0.015 mg/kg/day	Chronic Toxicity Study in Dogs LOAEL = 5 mg/kg/day, based on skin reddening (both sexes) and decreased body weight gain in females
Dermal Short-Term (1 to 30 days) And Intermediate-Term (1 to 6 months)	NOAEL = 150 mg/kg/day UF_A = 10x UF_H = 10x	LOC for MOE = 100	28–Day Dermal Toxicity Study in Rats LOAEL = 1,000 mg/kg/day, based on decreased body weight, body weight gain, and food consumption, as well as, increased incidences of dermal irritation
Inhalation Short-Term (1 to 30 days) And Intermediate-Term (1 to 6 months)	NOAEL = 26.1 mg/kg/day UF_A = 10x UF_H = 10x	LOC for MOE = 100	28–Day Inhalation Toxicity Study in Rats LOAEL = 78.3 mg/kg/day, based on decreased body weight, body weight gain, and food consumption in males; clinical findings, such as alopecia, in males and/or females; meta/hyperplasia and inflammatory cells in the respiration tract in males and/or females; and increased leukocytes in females
Cancer (Oral, dermal, inhalation)	Classification: Not likely to be a human carcinogen, based on two adequate rodent carcinogenicity studies.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = Not Applicable.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to ipconazole, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from ipconazole in food as follows:

i. *Acute and chronic exposure.* In conducting the acute and chronic dietary exposure assessments EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA acute and chronic assessments used tolerance-level residues, assumed 100% crop treated, and incorporated model-derived, conservative estimates of ipconazole residues in drinking water.

ii. *Cancer.* Ipconazole has been classified as not likely to be carcinogenic based on carcinogenicity

studies in the rat and mouse which showed no evidence of an increase in the incidence of tumors. Therefore a cancer dietary exposure assessment is not needed to assess cancer risk.

iii. *Anticipated residue and/or percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for ipconazole. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for ipconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of ipconazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Ipconazole is persistent and immobile in terrestrial and aquatic environments. Data are not available to estimate the leaching potential of ipconazole from treated seeds. Because ipconazole is persistent in soil, there is a potential for it to accumulate in soil on sites with use over consecutive years. Steady-state ipconazole concentrations in soil are predicted to plateau at 0.7 lbs a.i./A after 20 years of consecutive use.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of ipconazole from newly proposed seed uses on cotton, peanuts, soybean, cereal grains (except rice), and pea and bean (dry shelled) would not exceed the drinking water concentrations previously assessed for the seed treatment for potatoes. Potatoes are expected to yield the highest concentration of ipconazole due to the high seeding rates. Therefore, the Agency incorporated the drinking water concentrations from potatoes directly into the dietary analysis.

For acute dietary risk assessment, the surface water concentration value of 4.589 part per billion (ppb) was used to assess the contribution to drinking water.

For chronic (non-cancer) dietary risk assessment, the surface water concentration value of 1.840 ppb was used to assess the contribution of drinking water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Ipconazole is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Ipconazole is a member of the triazole-containing class of pesticides, often referred to as the conazoles. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events. In conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

Triazole-derived pesticides can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazole alanine and triazole acetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including ipconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazole alanine, and triazole acetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide as of September 1, 2005. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's September 1, 2005 risk assessment can be found in the propiconazole reregistration docket at *http://www.regulations.gov* (Docket ID EPA–HQ–OPP–2005–0497). An addendum to the risk assessment, *Dietary Exposure Assessments for the Common Triazole Metabolites 1,2,4-triazole, Triazolylalanine, Triazolylacetic Acid and Triazolylypyruvic Acid; Updated to Include New Uses of Fenbuconazole, Ipconazole, Metconazole, Tebuconazole, and Uniconazole; and a Change in Plant-back Restriction for Tetraconazole* can be found at *http://www.regulations.gov* in docket ID EPA–HQ–OPP–2007–0226.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. Offspring effects only occurred in the presence of maternal toxicity; offspring effects were not considered more severe than the parental effects. Therefore, HED concluded that there is no quantitative or qualitative evidence of increased susceptibility to rat or rabbit fetuses exposed *in utero* and/or post-natally to ipconazole.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for ipconazole is adequate for the purposes of this risk assessment.

ii. There is no indication that ipconazole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that ipconazole results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to ipconazole in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by ipconazole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions described in this unit for acute exposure, EPA has concluded that acute exposure to ipconazole from food and water will utilize <1% of the aPAD for the population group females 13–49 years old, the only population subgroup appropriate for inclusion in an acute dietary exposure assessment.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to ipconazole from food and water will utilize 1.2% of the cPAD for all infants (the population group receiving the greatest exposure).

3. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Ipconazole is not registered for any use patterns that would result in short-term and intermediate-term residential exposure. Therefore, the short-term and intermediate-term aggregate risk, individually is the sum of the risk from exposure to ipconazole through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population*. Ipconazole has been classified as not likely to be carcinogenic, and is not expected to pose a cancer risk to humans.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to ipconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) enforcement methodology (AC/3020) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

No Codex MRLs have been established for ipconazole. No Canadian or Mexican MRLs have been established.

C. Revisions to Petitioned-For Tolerances

The proposed tolerance for crop subgroup 6C has been modified to reflect the correct commodity definition: ''Pea and bean, dried shelled, except soybean, subgroup 6C.''

V. Conclusion

Therefore, tolerances are established for residues of ipconazole, (2-[(4-chlorophenyl)methyl]-5-(1-methylethyl)-1-(1H-1,2,4-triazole-1-ylmethyl) cyclopentanol) from treatment of seed prior to planting, in or on cotton, peanut, soybean, pea and bean, dried shelled, except soybean (Subgroup 6C), cereal grains (Group 15) except rice, and forage, fodder, and straw of cereal grains (Group 16) except rice at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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).

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