§ 180.169 [Amended]

■ 2. Section 180.169 is amended by removing paragraphs (a)(3) and (a)(4).

[FR Doc. E9–5223 Filed 3–10–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0301; FRL–8402–6]

Chlorimuron-ethyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of chlorimuron-ethyl in or on berry, low growing, except strawberry, subgroup 13-07H. Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 11, 2009. Objections and requests for hearings must be received on or before May 11, 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–2007–0301. 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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 cite 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–2007–0301 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 May 11, 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–2007–0301, 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 June 27, 2007 (72 FR 35237) (FRL–8133–4), 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 6E7153) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W., Princeton, NJ 08540–6635. The petition requested that 40 CFR 180.429 be amended by establishing tolerances for residues of the herbicide chlorimuron-ethyl, ethyl 2-[[[[(4-chloro-6-methoxypyrimidin-2yl) amino]carbonyl]sulfonyl]benzoate], in or on cranberry; bearberry; bilberry; lowbush berry; cloudberry; lingonberry; muntries; and partridgeberry, each at 0.02 parts per million (ppm). That notice referenced a summary of the petition prepared by E.I. du Pont de Nemours and Company, the registrant, on behalf of IR-4, 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.

EPA has determined that a tolerance of 0.02 ppm on berry, low growing, except strawberry, subgroup 13–07H is

appropriate in lieu of the proposed individual tolerances on berry commodities. The reason for this change is explained in Unit IV.C.

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 chlorimuron-ethyl on berry, low growing, except strawberry, subgroup 13–07H at 0.02 ppm. 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.

Chlorimuron-ethyl has low or minimal acute toxicity via the oral, dermal and inhalation routes of exposure. It is mildly irritating to the eye and non-irritating to the skin; it is not a skin sensitizer.

In subchronic toxicity studies with chlorimuron-ethyl, no adverse effects were observed up to the limit dose tested in mice; decreased body weight gain and liver pathology (margination of hepatocyte cytoplasmic content in the centrilobular areas) were observed in rats (males only); and mild hemolytic anemia, atrophy of the thymus and prostate and increased liver weights were seen in dogs. Chronic exposure of dogs to chlorimuron-ethyl also led to mild anemia (decreased erythrocyte count, hematocrit, and hemoglobin concentration), but atrophy of the thymus and prostate were not seen. In rats, treatment-related effects observed were limited to decreased body weight and body weight gain in both sexes after long-term exposure. Prostatitis (males) and fatty replacement in the pancreas (both sexes) were also observed but considered incidental occurrences; and biliary hyperplasia/fibrosis seen in females was attributed to aging. In mice, there were no treatment-related effects observed up to the highest dose tested (216 milligrams/kilograms/day (mg/kg/day)). There were no treatment-related increases in tumors in rat and mouse carcinogenicity studies after exposure to chlorimuron-ethyl. Chlorimuron-ethyl is classified as ''Not Likely to be Carcinogenic to Humans.''

In the developmental toxicity studies, decreases in maternal body weight gain and delayed ossification in fetuses were observed in rats at the same dose (150 mg/kg/day). In rabbits, decreases in maternal body weight gain were seen at 300 mg/kg/day, while delayed ossification was seen in fetuses at a lower dose of 48 mg/kg/day, indicating increased quantitative susceptibility. In a guideline 2–generation reproduction study in rats, decreased body weight and histopathology in the cerebellum (cellular changes in the internal granular and external germinal layers) were seen in pups at 177 mg/kg/day. These effects were seen in the absence of maternal toxicity, indicating potential increased quantitative susceptibility of the pups to chlorimuron-ethyl. However, these effects were not associated with any neurotoxicity or neurobehavioral changes and not observed in other reproduction studies in rats. In a non-guideline reproduction toxicity study (1–generation) in rats, decreased body weight (females) and liver histopathology (males) were seen in parental animals at 173 mg/kg/day, along with decreases in litter weights. In another reproduction study (1–year interim sacrifice) in rats, decreases in maternal and pup body weights were observed at 195 mg/kg/day.

There is no indication of neurotoxicity in the toxicity database for chlorimuron-ethyl. In a 2–generation reproduction study in rats, histopathological alterations were seen in the cerebellum (cellular changes in the internal granular and external germinal layers) of F2 pups at 177 mg/kg/day; however, these findings were not associated with any neurobehavioral changes or any indications of neurotoxicity. In addition, these histopathological alterations were not observed in two other reproduction studies, and there was no evidence of neurotoxicity observed in other rat toxicity studies or toxicity studies in other species (rabbits, mice, or dogs).

Hematological changes (indicative of mild anemia) and atrophy of the thymus were observed in dogs after subchronic exposure. However, atrophy of the thymus was not associated with any histopathology and not seen after chronic exposure. No other potential immunotoxic effects were observed in the toxicology database.

Specific information on the studies received and the nature of the adverse effects caused by chlorimuron-ethyl 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 *Chlorimuron-ethyl: Human Health Risk Assessment for Proposed Uses on Cranberry and Low-growing Berry Subgroup 13–07H, except Strawberry, PP# 6E7153*, page 36 in docket ID number EPA–HQ–OPP–2007–0301.

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 NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, 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-term, intermediate-term, 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 chlorimuron-ethyl used for human risk assessment can be found at *http://www.regulations.gov* in document *Chlorimuron-ethyl: Human Health Risk Assessment for Proposed Uses on Cranberry and Low-growing Berry Subgroup 13–07H, except Strawberry, PP# 6E7153*, page 16 in docket ID number EPA–HQ–OPP–2007–0301.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to chlorimuron-ethyl, EPA considered exposure under the petitioned-for tolerance as well as all existing chlorimuron-ethyl tolerances in 40 CFR 180.429. EPA assessed dietary exposures from chlorimuron-ethyl in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. No such effects were identified in the toxicological studies for chlorimuron-ethyl; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT) for all existing and new uses of chlorimuron-ethyl.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice, EPA classified chlorimuron-ethyl as ''Not Likely to be Carcinogenic to Humans.'' Therefore, an exposure assessment for evaluating cancer risk is not needed for this chemical.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for chlorimuron-ethyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of chlorimuron-ethyl. 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*.

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 chlorimuron-ethyl for chronic exposures for non-cancer assessments are estimated to be 2.4 parts per billion (ppb) for surface water and 1.76 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the only dietary exposure scenario for which a toxicological endpoint of concern was identified, the water concentration value of 2.4 ppb was used to assess the contribution to chlorimuron-ethyl dietary exposure from 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). Chlorimuron-ethyl 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.''

EPA has not found chlorimuron-ethyl to share a common mechanism of toxicity with any other substances, and chlorimuron-ethyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that chlorimuron-ethyl does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

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*. The prenatal and postnatal toxicity database for chlorimuron-ethyl includes guideline rat and rabbit developmental toxicity studies and a 2–generation reproduction toxicity study in rats, as well as two additional non-guideline reproduction studies in rats (a 1–generation study and 1–year interim sacrifice study). No evidence of increased prenatal or postnatal susceptibility was seen in the developmental toxicity study in rats or in the non-guideline reproduction toxicity studies in rats. In the rabbit developmental study, delayed ossification was observed in fetuses at 48 mg/kg/day, while maternal effects (decreased body weight gain) were seen at 300 mg/kg/day, suggesting increased quantitative susceptibility of fetuses. In the 2–generation rat reproduction study, decreased body weight and histopathology findings in the cerebellum were observed in pups at 177/214 mg/kg/day (male/female) in the absence of maternal toxicity, also suggesting increased quantitative susceptibility of the pups.

Although the data suggest increased quantitative susceptibility in the developmental rabbit study and the 2–generation rat reproduction study, there are no residual uncertainties with regard to prenatal toxicity following *in utero* exposure of rats or rabbits or prenatal and/or postnatal exposures of rats. The fetal effect seen in rabbits was limited to delayed ossification, and, although effects (histopathology in the cerebellum) were seen in a rat reproduction study, there was no evidence of increased susceptibility observed in two additional reproduction studies in rats. Additionally, there are clear NOAELs for the offspring effects

seen in rabbits (NOAEL=13 mg/kg/day) and rats (17 mg/kg/day). Finally, the NOAEL (9 mg/kg/day) used to establish the cRfD of 0.09 mg/kg/day is considered protective of potential developmental effects observed at the higher doses. Considering the overall toxicity database and doses selected for risk assessment, the degree of concern for the effects observed in the studies is low.

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 chlorimuron-ethyl is adequate to characterize potential prenatal and postnatal risk for infants and children. Acceptable/guideline studies for developmental toxicity in rats and rabbits and reproduction toxicity in rats are available for FQPA assessment.

On December 26, 2007 EPA began requiring functional immunotoxicity testing and acute and subchronic neurotoxicity testing of all food and non-food use pesticides. Since these requirements went into effect after the tolerance petition was submitted, these studies are not yet available for chlorimuron-ethyl. In the absence of specific immunotoxicity and neurotoxicity studies, EPA has evaluated the available chlorimuron-ethyl toxicity data and determined that an additional uncertainty factor is not required to account for potential neurotoxicity or immunotoxicity. The reasons for this determination are explained below:

a. Hematological changes (indicative of mild anemia) and atrophy of the thymus were observed in dogs following subchronic exposure to chlorimuron-ethyl at a dose of 45.8/42.7 (M/F) mg/kg/day, indicating potential immunotoxicity. However, atrophy of the thymus was not associated with any histopathology and was not seen after chronic exposure; and no other potential immunotoxic effects were observed in the toxicology database. Therefore, EPA does not believe that conducting immunotoxicity testing will result in a NOAEL less than the NOAEL of 9 mg/kg/day already established for chlorimuron-ethyl, and an additional factor for database uncertainties (UFDB) is not needed to account for potential immunotoxicity.

b. There is no indication in the toxicity database that chlorimuron-ethyl is a neurotoxic chemical, and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

ii. Although there is evidence of increased quantitative susceptibility in the developmental rabbit study and the 2–generation rat reproduction study, the degree of concern for the effects observed in the studies is low, and there are no residual uncertainties with regard to prenatal toxicity following *in utero* exposure of rats or rabbits or prenatal and/or postnatal exposures of rats.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on the assumptions of 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to chlorimuron-ethyl in drinking water. Residential exposure to chlorimuron-ethyl is not expected. These assessments will not underestimate the exposure and risks posed by chlorimuron-ethyl.

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-term, intermediate-term, 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. No adverse effect resulting from a single-oral exposure was identified and no acute dietary endpoint was selected. Therefore, chlorimuron-ethyl is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to chlorimuron-ethyl from food and water will utilize less than 1% of the cPAD for the general population and all population subgroups, including infants and children. There are no residential uses for chlorimuron-ethyl.

3. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposure take into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Chlorimuron-ethyl is not registered for any use patterns that would result in residential exposure. Therefore, the short-term/intermediate-term aggregate risk is the sum of the risk from exposure to chlorimuron-ethyl through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population*. EPA has classified chlorimuron-ethyl into the category ''Not Likely to be Carcinogenic to Humans''. Chlorimuron-ethyl is not expected to pose a cancer risk.

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 chlorimuron-ethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (a high performance liquid chromotography (HPLC) photoconductivity method) 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

There are no established or proposed Canadian, Mexican or Codex MRLs for residues of chlorimuron-ethyl on berry commodities.

C. Revisions to Petitioned-For Tolerances

IR-4 petitioned for individual tolerances on bearberry, bilberry, lowbush berry, cloudberry, cranberry, lingonberry, muntries and partridgeberry. In the **Federal Register** of December 7, 2007 (72 FR 69150) (FRL–8340–6), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA expanded and revised berries group 13. Changes to crop group 13 included adding new commodities, revising existing subgroups and creating new subgroups (including a low growing berry, except strawberry, subgroup (13–07H) consisting of the commodities requested in this petition and cultivars, varieties, and/or hybrids of these). EPA indicated in the December 7, 2007 final rule as well as the earlier May 23, 2007 proposed rule (72 FR 28920) that, for

existing petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA is establishing a tolerance on low growing berry, except strawberry, subgroup 13–07H. EPA concludes it is reasonable to establish the tolerance on the newly created subgroup, since the individual commodities for which tolerances were requested are identical to those which comprise low growing berry, except strawberry, subgroup 13–07H.

V. Conclusion

Therefore, a tolerance is established for residues of chlorimuron-ethyl, ethyl 2-[[[[(4-chloro-6-methoxypyrimidin-2yl) amino]carbonyl]sulfonyl]benzoate], in or on berry, low growing, except strawberry, subgroup 13–07H at 0.02 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: February 24, 2009.

Lois Rossi,

Director, Registration Division, 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 180.429 is revised to read as follows:

§ 180.429 Chlorimuron ethyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide chlorimuron ethyl, ethyl 2-[[[[(4-chloro-6-methoxypyrimidin-2yl) amino]carbonyl]sulfonyl]benzoate], in or on the following raw agricultural commodities:

Commodity	Parts per million
Berry, low growing, except strawberry, subgroup 13–07H	0.02
Peanut	0.02
Soybean	0.05

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

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

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

[FR Doc. E9–5192 Filed 3–10–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0303; FRL–8400–2]

Bacillus Mycoides Isolate J; Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the *Bacillus mycoides* isolate J in or on pecans, potatoes, sugar beets, tomatoes, and peppers when used in accordance with good agricultural practices. Montana Microbial Products, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting to amend the existing temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus mycoides* isolate J in or on pecans, potatoes, sugar beets, tomatoes, and peppers on a time-limited basis. The temporary tolerance exemption expires on March 31, 2011.