Dated: December 28, 2007.

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 180.475 is amended by revising paragraph (a) to read as follows:

§ 180.475 Difenoconazole; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole, in or on the following commodities:

Commodity	Parts per million
Apple, wet pomace	4.5
Banana[1]	0.2
Barley, grain	0.1
Barley, hay	0.05
Barley, straw	0.05
Beet, sugar	0.01
Beet, sugar, dried pulp	1.9
Canola, seed	0.01
Corn, sweet, forage	0.01
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.01
Cotton, gin byproducts	0.05
Cotton, undelinted seed	0.05
Fruit, pome group 11	1.0
Grape[1]	0.10
Papaya[1]	0.30
Potato, processed waste	0.04
Rye, grain[1]	0.1
Vegetable, fruiting, group 8	0.60
Vegetable, tuberous and corm, subgroup 1C	0.01

[1] There are no U.S. registrations.

(2) Tolerances are established for residues of the fungicide difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole, and its metabolite, CGA-205375, 1-[2-chloro-4-(4-chloro-phenoxy)phenyl]-2-[1,2,4]triazol-1-yl-ethanol, in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.10
Cattle, liver	0.20
Cattle, meat	0.05
Cattle, meat byproduct (except liver)	0.10
Eggs	0.10
Goat, fat	0.10
Goat, liver	0.20
Goat, meat	0.05
Goat, meat byproduct (except liver)	0.10
Hog, fat	0.10
Hog, liver	0.20
Hog, meat	0.05
Hog, meat byproduct (except liver)	0.10
Horse, fat	0.10
Horse, liver	0.20
Horse, meat	0.05
Horse, meat byproduct (except liver)	0.10
Milk	0.01
Sheep, fat	0.10
Sheep, liver	0.20
Sheep, meat	0.05
Sheep, meat byproduct (except liver)	0.10

* * * * *

[FR Doc. E8–15 Filed 1–8–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0093]; FRL–8344–3]

Mesotrione; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mesotrione in or on berry, group 13; flax, seed; cranberry; lingonberry; millet, grain; millet, forage; millet, hay; and millet, straw. Syngenta Crop Protection requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 9, 2008. Objections and requests for hearings must be received on or before March 10, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0093. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Kathryn V. Montague, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–1243; e-mail address: *montague.kathryn @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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2006–0093 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 March 10, 2008.

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–2006–0093, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of April 26, 2006 (71 FR 24695) (FRL–8063–7), 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 6F7023) by Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC. The petition requested that 40 CFR 180.571 be amended by establishing tolerances for residues of the herbicide mesotrione, 2–[4- (methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in or on flax, meal/seed at 0.01 parts per million (ppm); millet, forage/grain at 0.01 parts per million (ppm); millet, hay/straw at 0.02 ppm; Berry group and cranberry at 0.01 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, 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.

Based upon review of the data supporting the petition, to harmonize with the Food and Feed Commodity Vocabulary (*http://www.epa.gov/opphed01/foodfeed/index.htm*) EPA has amended the commodity listing to read: Flax, seed at 0.01 ppm; millet, grain at 0.01 ppm; millet, forage at 0.01 ppm; millet, hay at 0.02 ppm; millet, straw at 0.02 ppm; berry, group 13 at 0.01 ppm, lingonberry at 0.01 ppm and cranberry at 0.02 ppm

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....'' These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), 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 tolerance for residues of mesotrione on flax, seed at 0.01 ppm; millet, grain at 0.01 ppm; millet, forage at 0.01 ppm; millet, hay at 0.02 ppm; millet, straw at 0.02 ppm; berry group 13 at 0.01 ppm, lingonberry at 0.01 ppm and cranberry at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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. Specific information on the studies received and the nature of the adverse effects caused by mesotrione 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*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as ''Mesotrione: Petition 6F7023 Human Health Risk Assessment for Proposed Section 3 New Uses on Berries, Cranberries, Millet, Flax, Grain Sorghum (Section 18)'' in that docket. Additionally, mesotrione toxicological data are discussed in the final rule published in the **Federal Register** of June 21, 2001 (66 FR 33187) (FRL–6787–7).

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from 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) is sometimes

used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC 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 risks by comparing aggregate 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 LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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/fedrgstr/EPA-PEST/1997/November/Day–26/p30948.htm*.

A summary of the toxicological endpoints for mesotrione used for human risk assessment can be found at *http://www.regulations.gov* in document ''Mesotrione: Petition 6F7023 Human Health Risk Assessment for Proposed Section 3 New Uses on Berries, Cranberries, Millet, Flax, Grain Sorghum (Section 18)'' at page 16 in docket ID number EPA–HQ–OPP–2006–0093.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to mesotrione, EPA considered exposure under the petitioned-for tolerances as well as all existing mesotrione tolerances in (40 CFR 180.571). EPA assessed dietary exposures from mesotrione 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 mesotrione; 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 Agriculutre (USDA) 1994–1996, and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed all foods for which there are tolerances were treated and contain tolerance-level residues.

iii. *Cancer*. Mesotrione was negative for carcinogenicity in feeding studies in rats and mice and was classified as ''not likely'' to be a human carcinogen. Therefore, a quantitative exposure assessment to evaluate cancer risk is unnecessary.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for mesotrione in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of mesotrione. 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) for dry harvested cranberry and a modified Interim Rice Model for wet harvested cranberry and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of mesotrione for chronic exposures are estimated to be 4.7 parts per billion (ppb) for surface water and 0.18 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 4.7 ppb was used to assess the contribution to 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).

Mesotrione is not registered for use on any sites 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.''

Mesotrione, pyrasulfotole, isoxaflutole and topramezone belong to a class of herbicides that inhibit the liver enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD), which is involved in the catabolism (metabolic breakdown) of tyrosine (an amino acid derived from proteins in the diet). Inhibition of HPPD can result in elevated tyrosine levels in the blood, a condition called tyrosinemia. HPPD-inhibiting herbicides have been found to cause a number of toxicities in laboratory animal studies including ocular, developmental, liver and kidney effects. Of these toxicities, it is the ocular effect (corneal opacity) that is highly correlated with the elevated blood tyrosine levels. In fact, rats dosed with tyrosine alone show ocular opacities similar to those seen with HPPD inhibitors. Although the other toxicities may be associated with chemically-induced tyrosinemia, other mechanisms may also be involved.

There are marked differences among species in the ocular toxicity associated with inhibition of HPPD. Ocular effects following treatment with HPPD inhibitor herbicides are seen in the rat but not in the mouse. Monkeys also seem to be recalcitrant to the ocular toxicity induced by HPPD inhibition. One explanation of this species-specific response in ocular opacity may be related to the species differences in the clearance of tyrosine. A metabolic pathway exists to remove tyrosine from the blood that involves a liver enzyme called tyrosine aminotransferase (TAT). In contrast to rats where ocular toxicity is observed following exposure to HPPD-inhibiting herbicides, mice and humans are unlikely to achieve the levels of plasma tyrosine necessary to produce ocular opacities because the activity of TAT in these species is much greater compared to rats. HPPD inhibitors (e.g., nitisinone) are used as an effective therapeutic agent to treat patients suffering from rare genetic diseases of tyrosine catabolism. Treatment starts in childhood but is often sustained throughout patient's lifetime. The human experience indicates that a therapeutic dose (1 milligrams/kilogram/day (mg/kg/day) dose) of nitisinone has an excellent safety record in infants, children and adults and that serious adverse health outcomes have not been observed in a population followed for approximately a decade. Rarely, ocular effects are seen in patients with high plasma tyrosine

levels; however, these effects are transient and can be readily reversed upon adherence to a restricted protein diet. This indicates that an HPPD inhibitor in and of itself cannot easily overwhelm the tyrosine-clearance mechanism in humans.

Therefore, exposure to environmental residues of HPPD-inhibiting herbicides are unlikely to result in the high blood levels of tyrosine and ocular toxicity in humans due to an efficient metabolic process to handle excess tyrosine. The Agency continues to study the complex relationships between elevated tyrosine levels and biological effects in various species. Nonetheless, as a worst case scenario, EPA has assessed aggregate exposure to mesotrione based on ocular effects in rats. For similar reasons, a semi-quantitative screening cumulative assessment was conducted using the rat ocular effects and 100% crop treated information. The results of this screening analysis did not indicate a concern. In the future, assessments of HPPD-inhibiting herbicides will consider more appropriate models and cross species extrapolation methods. Therefore, EPA has not conducted cumulative risk assessment with other HPPD inhibitors. 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 of FFDCA provides that EPA shall apply an additional (''10X'') tenfold 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is quantitative evidence of increased susceptibility of the young in the oral prenatal developmental toxicity studies in rats, mice, and rabbits and in the multi-generation reproduction study in mice and lack of a developmental neurotoxicity study in mice. Quantitative evidence of increased susceptibility was not demonstrated in the multi-generation reproduction study in rats. However, no NOAEL was established for parental or offspring systemic toxicity. There is evidence of a qualitative increase in susceptibility since the tyrosinemia observed in the young was much more severe than that observed in the adults.

3. *Conclusion*. There are 2 deficiencies in the mesotrione toxicity database. First, a Developmental Neurotoxicity Study has been required to assess the effects on the developing nervous/ocular system from exposed to mesotrione. Second, the mouse 2–generation reproduction study, on which the Reference Dose/ Population Adjusted Dose (RfD/PAD) is based failed to identify a NOAEL. In light of this data gap, the necessity of a reliance on a LOAEL to calculate the RfD/PAD, and the quantitative and qualitative evidence of increased susceptibility of the young discussed above, EPA is raising the 10X FQPA safety factor to the value of 30X.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. There were no effects observed in oral toxicity studies including developmental toxicity studies in rats and rabbits that could be attributable to a single dose (exposure). Therefore, mesotrione 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 exposure to mesotrione from food and water will utilize 51% of the cPAD for the population group (All Infants (<1 year old)). There are no residential uses for mesotrione that result in chronic residential exposure to mesotrione.

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

Mesotrione is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water.

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

Mesotrione is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Mesotrione is classified as a ''not likely'' to be carcinogenic in humans based on the results of a carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in the rat. Therefore, mesotrione is not expected to pose a cancer risk to humans.

6. *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 mesotrione residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-pressure liquid chromatography fluorescence detector (HPLC/FLD)) 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 CODEX, Canadian, or Mexican tolerances/Maximum Residue Levels for mesotrione residues for the proposed crops.

V. Conclusion

Therefore, the tolerance is established for residues of mesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in or on flax, seed at 0.01 ppm; millet, grain at 0.01 ppm; millet, forage at 0.01 ppm; millet, hay at 0.02 ppm; millet, straw at 0.02 ppm; berry group 13 at 0.01 ppm, lingonberry at 0.01 ppm and cranberry at 0.02 ppm.

VI. 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 rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) 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 6, 2000) do not apply to this rule. In addition, This 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: December 28, 2007.

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 180.571 is amended by alphabetically adding the following commodities in the table in paragraph (a) to read as follows:

§ 180.571 Mesotrione; tolerances for residues.

(a) * * *

Commodity	Parts per million
Berry, group 13	0.01
* * *	* *
Cranberry	0.02
Flax, seed	0.01
Lingonberry	0.01
Millet, grain	0.01
Millet, forage	0.01
Millet, hay	0.02
Millet, straw	0.02

* * * * *

[FR Doc. E8–181 Filed 1–8–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0268; FRL–8345–8]

Poly(hexamethylenebiguanide) hydrochloride (PHMB); 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 insecticide, Poly(hexamethylenebiguanide) hydrochloride (PHMB) on all food when residues are the result of lawful application of a food contact surface sanitizer containing PHMB as a sanitizer solution in food handling establishments when applied as a sanitizer. Arch Chemicals Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of PHMB.

DATES: This regulation is effective January 9, 2008. Objections and requests for hearings must be received on or before March 10, 2008, 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–2005–0268. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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 either in the electronic docket at *http://www.regulations.gov*, or, if only