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**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180****[EPA-HQ-OPP-2007-0106; FRL-8147-8]****Pendimethalin; Pesticide Tolerance****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of pendimethalin in or on artichoke, globe; asparagus; brassica head and stem, subgroup 5-A; and grape. Interregional Research Project Number 4 requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 19, 2007. Objections and requests for hearings must be received on or before November 19, 2007, 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-2007-0106. 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 [www.regulations.gov](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](mailto: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), 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; 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-2007-0106 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 November 19, 2007.

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-2007-0106, 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 4, 2007 (72 FR 16352-16356) (FRL-8119-2), 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 6E7129) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.361 be amended by establishing tolerances for combined residues of the herbicide pendimethalin, N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, and

its metabolite, 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol, in or on artichoke, globe at 0.05 parts per million (ppm); asparagus at 0.1 ppm; brassica head and stem, subgroup 5A at 0.05; and grape at 0.05 ppm. That notice referenced a summary of the petition prepared by BASF 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.

Based upon review of the data supporting the petition, EPA has revised the tolerances for artichoke, globe; asparagus; brassica, head and stem vegetables, subgroup 5-A; and grape. The reason for these changes is explained in Unit V.

### 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 combined residues of pendimethalin and its metabolite on artichoke, globe at 0.1 ppm; asparagus at 0.15 ppm; brassica head and stem, subgroup 5-A at 0.1; and grape at 0.1 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 pendimethalin, 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 Appendix A of the document *Pendimethalin. Human Health Risk Assessment for the Proposed Food Uses of the Herbicide on Artichoke, Globe; Asparagus; Brassica Head and Stem Vegetables, Subgroup 5A; and Grape (PP#6E7129)*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA-HQ-OPP-2007-0106-0003 in that docket.

#### 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-, intermediate-, 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/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for pendimethalin used for human risk assessment can be found at <http://www.regulations.gov> in document *Pendimethalin. Human Health Risk Assessment for the Proposed Food Uses of the Herbicide on Artichoke, Globe; Asparagus; Brassica Head and Stem Vegetables, Subgroup 5A; and Grape (PP#6E7129)* at pages 11–12. The referenced document is identified as EPA-HQ-OPP-2007-0106-0003 in that docket.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pendimethalin, EPA considered exposure under the petitioned-for tolerances as well as all existing pendimethalin tolerances in (40 CFR 180.361). EPA assessed dietary exposures from pendimethalin 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 pendimethalin; 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 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.* EPA has classified pendimethalin as a "Group C" (possible human) carcinogen, based on thyroid follicular cell adenomas observed in rats. The chronic dietary risk assessment based on the cPAD, however, is considered to be protective of any potential cancer effects, because mode of action studies are available that demonstrate that the thyroid tumors are due to a thyroid-pituitary imbalance, and also since pendimethalin was shown to be nonmutagenic in

mammalian somatic cells and germ cells. Therefore, a separate cancer exposure assessment was not conducted.

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

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for pendimethalin 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 pendimethalin. 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 Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of pendimethalin for acute exposures are estimated to be 77.7 parts per billion (ppb) for surface water and 0.036 ppb for ground water. The EECs for chronic exposures are estimated to be 6.0 ppb for surface water and 0.036 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. As explained in Unit III.C.1., an acute dietary risk assessment was not conducted for pendimethalin. For the chronic dietary risk assessment, the water concentration of value 6.0 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).

Pendimethalin is currently registered for the following residential non-dietary sites: Recreational and residential turf (including home lawns, golf courses, athletic fields, etc.) and ornamentals. EPA assessed residential exposure based on applications to residential turf (i.e., home lawns), since this use is expected to result in the greatest residential exposure.

There is a potential for short-term exposure of homeowners applying products containing pendimethalin on home lawns. There is also a potential for short-term post-application exposure of adults and children entering lawn and recreation areas previously treated with pendimethalin. Exposures from treated recreational sites are expected to be similar to, or lower than, those from treated residential turf sites; therefore, a separate exposure assessment for recreational turf sites was not conducted. EPA assessed exposures from the following residential turf post-application scenarios:

- Adult and toddler post-application dermal exposure from contact with treated lawns.
- Toddlers' incidental ingestion of pesticide residues on lawns from hand-to-mouth transfer.
- Toddlers' object-to-mouth transfer from mouthing of pesticide-treated turfgrass.
- Toddlers' incidental ingestion of soil from pesticide-treated residential areas.

The post-application risk assessment was conducted in accordance with the *Residential Standard Operating Procedures (SOPs)* and recommended approaches of the Health Effects Division's (HED's) Science Advisory Council for Exposure (ExpoSAC).

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCFA 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pendimethalin and any other substances and pendimethalin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pendimethalin has 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 of FFDCFA 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.* The pre- and postnatal toxicology database for pendimethalin includes rat and rabbit developmental toxicity studies and a 2-generation reproduction toxicity study in rats.

In the rat developmental study, there were no maternal or developmental effects noted at any dose level tested. However, the study is considered adequate and a new study is not required because in other rat studies, thyroid toxicity was seen at significantly lower doses than the highest dose tested (500 milligrams/kilograms/day (mg/kg/day)) in this study. If thyroid parameters had been measured, maternal toxicity would likely have been demonstrated.

The rabbit toxicity study with pendimethalin did not demonstrate maternal or developmental toxicity at doses up to 60 mg/kg/day (highest dose tested). Since neither maternal nor developmental toxicity was seen at the highest dose tested, potential for increased sensitivity of the offspring could not be determined.

In the 2-generation reproduction study in rats, there was no evidence of increased susceptibility of offspring. Effects in the pups (decreased pup body weight gain and possible decreased pups born alive and pup survival) were seen at doses that also resulted in parental toxicity (decreased body weight).

3. *Conclusion.* EPA has determined that the FQPA safety factor of 10X must be retained. This decision is based on the following findings:

- i. The toxicity database for pendimethalin contains all of the standard toxicity studies. However, there is uncertainty regarding potential thyroid effects seen in some of these

studies. Based on the hormonal changes (alterations in thyroid weights and histopathological lesions) observed in several studies following oral administration of pendimethalin, it is likely that pendimethalin may cause disruption in the endocrine system. There is concern that perturbation of thyroid homeostasis may lead to hypothyroidism and possibly result in adverse effects on the developing nervous system. Consequently, EPA has recommended that a developmental thyroid assay be conducted to evaluate the impact of pendimethalin on thyroid hormones, structure, and/or thyroid hormone homeostasis during development. This study has not yet been submitted.

ii. There is no indication that pendimethalin 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 pendimethalin 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. However, the developmental studies were not adequate to fully assess the potential for susceptibility. Consequently, there is concern for potential increased sensitivity or susceptibility in offspring regarding thyroid effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. Conservative ground and surface water modeling estimates were used. Similarly, conservative Residential SOPs were used 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 pendimethalin.

Although the exposure estimate is very conservative and there are no neurotoxic concerns for pendimethalin, there is sufficient uncertainty regarding thyroid effects, particularly thyroid effects in the young, that EPA is retaining the 10X FQPA safety factor. EPA has also determined that the traditional 10X uncertainty factor to account for interspecies variation may be reduced to 3X, since it has been established that rats are more susceptible to thyroid effects than humans. These factors, together with the traditional 10X uncertainty factor to account for intraspecies variation, result in a total uncertainty factor of 300X (10X, 3X, and 10X).

#### *E. Aggregate Risks and Determination of Safety*

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. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, 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.

1. *Acute risk.* None of the toxicology studies available for pendimethalin has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure; therefore, a quantitative acute dietary exposure assessment is unnecessary.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pendimethalin from food and water will utilize 16% of the cPAD for children, 1 to 2 years old, the population group with the greatest estimated exposure. Based on the use pattern, chronic residential exposure to residues of pendimethalin is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure from food and water (considered to be a background exposure level). Pendimethalin is currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for pendimethalin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water and residential exposures aggregated result in aggregate MOEs of 650 for adult males, 580 for adult females, and 390 to 410 for children, 1 to 2 years old (depending on the application rate assessed). The aggregate MOEs for adults are based on the residential turf scenario and include combined food, drinking water and post-application dermal exposures. The aggregate MOEs for children include food, drinking water, post-application dermal and incidental oral exposures from entering turf areas previously treated with pendimethalin.

#### 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). Pendimethalin is not registered for use on any sites that would result in intermediate-term 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.* Pendimethalin has been classified as a "Group C" (possible human) carcinogen, based on thyroid follicular cell adenomas observed in rats. As explained in Unit III.C.1., risk assessments based on the endpoint selected for the cPAD are considered to be protective of any potential carcinogenic risk from exposure to pendimethalin. Based on the results of the chronic risk assessment discussed above in Unit III.E.2., EPA concludes that pendimethalin is not expected to pose a cancer risk.

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 Pendimethalin residues.

### **IV. Other Considerations**

#### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology is available to enforce the tolerance expression. The PAM VII lists four gas chromatography, with electron capture detection (GC/ECD), methods for the determination of pendimethalin residues of concern in plant commodities. Methods I and III determine residues of the parent, whereas Methods II and IV determine residues of the regulated metabolite. An adequate confirmatory GC/MS method is also available and 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](mailto:residuemethods@epa.gov).

#### *B. International Residue Limits*

There are currently no Canadian, Mexican, or Codex maximum residue limits (MRLs) for pendimethalin on the commodities for which tolerances are being established.

### **V. Conclusion**

Based upon review of the data supporting the petitions, EPA has modified the proposed tolerances as

follows: Artichoke, globe from 0.05 ppm to 0.1 ppm; asparagus from 0.1 ppm to 0.15 ppm; brassica head and stem, subgroup 5-A from 0.05 ppm to 0.1 ppm; and grape from 0.05 ppm to 0.1 ppm.

The tolerances for artichoke, globe; brassica head and stem, subgroup 5-A; and grape were determined based on the sum of the method Limits of Quantitation (LOQ) for parent pendimethalin (0.05 ppm) and its regulated metabolite (0.05 ppm), since no detectable residues were found in the submitted residue field trials.

The tolerance for asparagus was determined using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*.

Therefore, tolerances are established for combined residues of pendimethalin, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, and its metabolite, 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol, in or on artichoke, globe at 0.1 ppm; asparagus at 0.15 ppm; brassica head and stem, subgroup 5-A at 0.1 ppm; and grape at 0.1 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: September 7, 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 180.361 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

**180.361 Pendimethalin; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Artichoke, globe .....	0.1
Asparagus .....	0.15
Brassica head and stem, subgroup 5-A .....	0.1
Grape .....	0.1

[FR Doc. E7-18259 Filed 9-18-07; 8:45 am]

**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2007-0539; FRL-8147-3]

**Trifloxystrobin; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for combined residues of Trifloxystrobin and the acid metabolite CGA-321113 in or on grass, forage and grass, hay. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 19, 2007. Objections and requests for hearings must be received on or before November 19, 2007, 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-2007-0539. To access the electronic docket, go to <http://>