EPA APPROVED ALABAMA NON-REGULATORY PROVISIONS—Continued

| Name of nonregulatory SIP provision | Applicable geographic or nonattainment area | State submittal date/ effective date | EPA approval date | Explanation |
|---|---|---|---|---|
| 8-Hour Ozone Maintenance plan for the Birmingham area. | Jefferson County and Shelby County ..... | 1/26/06 | 5/12/06. | |

[FR Doc. E9–5732 Filed 3–17–09; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[EPA–HQ–OPP–2008–0513; FRL–8400–1]**

## Pendimethalin; Pesticide Tolerances for Emergency Exemptions

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances 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 Bermuda grass forage and hay. This action is in response to crisis exemptions issued by the Texas Department of Agriculture and the Oklahoma Department of Agriculture under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on Bermuda grass pastures and hay fields. This regulation establishes a maximum permissible level for residues of pendimethalin in these feed commodities. The time-limited tolerances expire and are revoked on December 31, 2009.

**DATES:** This regulation is effective March 18, 2009. Objections and requests for hearings must be received on or before May 18, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**.

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0513. 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 available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are 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:** Stacey Groce, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–2505; e-mail address: *Groce.Stacey@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Access Electronic Copies of this Document?*

In addition to accessing 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 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 the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0513 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before May 18, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2

may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2008–0513, 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. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of FFDCA, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited 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 Bermuda grass forage and hay at 25 parts per million (ppm) and 60 ppm, respectively. These time-limited tolerances expire and are revoked on December 31, 2009. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations (CFR).

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related time-limited tolerances to set binding precedents for the application of section 408 of FFDCA to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

## III. Emergency Exemptions for Pendimethalin on Bermuda Grass Forage and Hay and FFDCA Tolerances

The Texas and Oklahoma Departments of Agriculture requested emergency exemptions for use of pendimethalin on Bermuda grass to control common sandbur and other sandbur species (*Cenchrus echinatus*), and issued crisis exemptions for this use pursuant to 40 CFR part 166, subpart C. The states provided information indicating that sandbur species is a serious pest that commonly infests Bermuda grass forage and hay fields. Pendimethalin has been authorized under FIFRA section 18 for use on Bermuda grass forage and hay to control sandbur in Texas and Oklahoma under the crisis provision.

As part of its evaluation of the emergency exemption applications, EPA assessed the potential risks presented by residues of pendimethalin in or on Bermuda grass forage and hay. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerances under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemptions in order to address urgent non-routine situations and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although these time-limited tolerances expire and are revoked on December 31, 2009, under section 408(l) (5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on Bermuda grass forage and hay after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether pendimethalin meets FIFRA's registration requirements for use on Bermuda grass forage and hay or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these time-limited tolerance decisions serve as a basis for registration of pendimethalin by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for persons in any States other than Texas and Oklahoma to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for pendimethalin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

## IV. 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 the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of these actions. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of these emergency exemption requests and the time-limited tolerances 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 on Bermuda grass forage and hay at 25 ppm and 60 ppm, respectively. EPA's assessment of exposures and risks associated with establishing time-limited tolerances follows.

*A. Toxicological Endpoints*

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-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 pendimethalin used for human risk assessment can be found at *http://www.regulations.gov* in the May 20, 2008 document: *Pendamethalin. Human Health Risk Assessment for the Proposed Food/Feed Use of the Herbicide (associated with Section 18 Registration) on Bermuda Grass Forage and Hay Fields in Texas* on pages 6 and 7 of 22 in docket ID number EPA–HQ–OPP–2008–0513.

*B. Exposure Assessment*

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to pendimethalin, EPA considered exposure under the time-limited tolerances established by this action as well as exposures pursuant to existing tolerances in (40 CFR 180.361). EPA assessed dietary exposures from pendimethalin in food as follows:

i. *Acute exposure*. No acute effects were identified in the toxicological studies for pendimethalin; therefore, a quantitative assessment of acute dietary exposure was not conducted.

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 Survey of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance-level residues of pendimethalin in or on all current and proposed raw agricultural commodities in 40 CFR 180.361, empirical processing factors obtained from processing studies, maximum theoretical concentration factor of 8.0 for wheat bran and wheat germ, and 1.4 for wheat flour, Dietary Exposure Evaluation Model (DEEM) 7.81 default processing factors were used for the remaining processed commodities, 100% crop treated, and 0.006 ppm pendimethalin estimated drinking water concentration (EDWC).

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 assessment using the cPAD is considered to be protective of any potential cancer effects because mode of action studies are available, which demonstrate that the thyroid tumors are due to a thyroid-pituitary imbalance. Pendimethalin has 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 and/or PCT information in the dietary assessment for pendimethalin. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pendimethalin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport 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 EDWCs 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. For chronic exposures non-cancer assessments are estimated to be 6.0 ppb for surface water and 0.036 ppb for ground water.

Modeled EDWCs were directly entered into the dietary exposure model. An acute dietary endpoint was not identified; therefore a quantitative assessment of risk 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 uses that could result in residential exposures: Recreational and residential turf (including home lawns, golf courses, athletic fields, etc.), and ornamentals. EPA assessed residential exposure using the following assumptions: Exposures are short-term in duration, and consist of the following scenarios: (i) Dermal (adult and children) exposed to residential turf and (ii) oral exposure from hand-to-mouth, object-to-mouth, and soil ingestion for children only. The Agency combined all non-dietary sources of handler and post-

application exposure to obtain an estimate of potential aggregate exposure. The LOC for oral, dermal and inhalation exposure is an MOE of less than 300. The residential exposure estimate for adults (consisting of dermal exposure only) results in a total MOE of 740, and is therefore not of concern. Inhalation post-application was not assessed because there are no indoor residential uses associated with pendimethalin products, and inhalation exposure resulting from outdoor uses is expected to be negligible. The residential exposure for children results in total MOEs (dermal + oral) ≥400, based on application rates of 2 pounds active ingredient/acre (lbs. ai/acre) and 3 lbs. ai/acre. Residential aggregate exposure is not of concern.

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 pendimethalin to share a common mechanism of toxicity with 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 assumed that pendimethalin 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

*C. 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 pre-natal and post-natal 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 SF when reliable data available to EPA support the choice of a different factor.

2. *Pre-natal and post-natal sensitivity*. The pre- and post-natal toxicology database for pendimethalin includes rat and rabbit developmental toxicity studies and a 2–generation reproduction toxicity study in rats. There was no indication of pre-/or post-natal qualitative or quantitative increased susceptibility in the developmental studies in rats and rabbits or the 2-generation reproduction studies in rats. However, because developmental LOAELs could not be determined in the developmental studies, the Agency has requested developmental thyroid toxicity data in order to determine potential thyroid toxicity following pre- and/or post-natal exposure to pendimethalin.

The rabbit toxicity study with pendimethalin did not demonstrate maternal or developmental toxicity at doses up to 60 milligram/kilogram/day (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 decrease in number of 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 SF 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. The 10X database UF will be retained for non-occupational exposure scenarios pending receipt of the study.

ii. Although, there is no evidence that pendimethalin results in increased susceptibility in in-utero rats or rabbits in the pre-natal developmental studies or in young rats in the 2–generation reproduction study, 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.

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 UF 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 UF to account for intraspecies variation, result in a total uncertainty factor of 300X (10X, 3X, and 10X).

*D. 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. 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 was identified, therefore, dietary exposure presents no acute risks of concern.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic dietary exposure to

pendimethalin from food and water will utilize 15% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the use patterns, chronic residential exposure to residues of pendimethalin is not expected, so chronic risk is a function of dietary exposure alone. Thus the chronic aggregate exposure for the most exposed group is below EPA's LOC.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to 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 exposure through food and water with short-term residential exposures to pendimethalin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of 650 for adult males, 580 for adult females, and for children (1 to 2 years old) results in a total MOE of 350 or 340 depending on the application rate assessed at either 2 lbs. ai/acre or 3lbs. ai/acre. 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. Since the LOC for oral, dermal, and inhalation exposure is an MOE of less than 300, short-term aggregate exposure is not of concern for any of the population subgroups.

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

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

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. EPA concludes that the chronic dietary assessment is protective of any potential cancer effects.

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.

## V. Other Considerations

### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology is available to enforce the tolerance expression. Methods I through IV in the Pesticide Analytical Manual (PAM) Volume II are gas chromatography with electron capture detection (GC/ECD) methods for the determination of pendimethalin residues of concern in plant commodities. 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 currently no Canadian, Mexican, or Codex maximum residue limits for pendimethalin on the commodities for which tolerances are being established.

## VI. Conclusion

Therefore, time-limited tolerances are established 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 Bermuda grass forage and hay at 25 ppm and 60 ppm. These tolerances expire and are revoked on December 31, 2009.

## VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under sections 408(e) and 408(l)(6) of FFDCA on EPA's own initiative. 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, *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 in accordance with sections 408(e) and 408(l)(6) of FFDCA, such as the tolerances 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).

## VIII. 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 12, 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 180.361 is amended by revising paragraph (b) to read as follows:

**§ 180.361 Pendimethalin; tolerances for residues**

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established 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 the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

| Commodity | Parts per million | Expiration/revocation date |
|---|---|---|
| Bermuda grass, forage | 25 | 12/31/09 |
| Bermuda grass, hay | 60 | 12/31/09 |

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**BILLING CODE 6560–50–S**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[EPA–HQ–OPP–2008–0936; FRL–8402–8]**

## Pyraclostrobin; Pesticide Tolerances for Emergency Exemptions

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for combined residues of pyraclostrobin and its desmethoxy metabolite in or on sugarcane, cane and sugarcane, molasses. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on sugarcane. This regulation establishes a maximum permissible level for residues of pyraclostrobin and its desmethoxy metabolite in these food. The time-limited tolerances expire and are revoked on December 31, 2011.

**DATES:** This regulation is effective March 18, 2009. Objections and requests for hearings must be received on or before May 18, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**.

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0936. All documents in the docket are listed in the docket index available in *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:** Libby Pemberton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9364; e-mail address: *pemberton.libby@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Access Electronic Copies of this Document?*

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*.

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA),