

■ 4. Subpart G of part 82 is amended by adding Appendix P to read as follows:

**Appendix P to subpart G of part 82-
Substitutes listed in the September 27,
2006 Final Rule, effective November 27,
2006**

**FIRE SUPPRESSION AND EXPLOSION PROTECTION SECTOR—TOTAL FLOODING AGENTS—ACCEPTABLE SUBJECT TO
NARROWED USE LIMITS**

End-use	Substitute	Decision	Conditions	Further information
Total flooding	Gelled Halocarbon/Dry Chemical Suspension with any agent other than ammonium polyphosphate or sodium bicarbonate additive (Envirogel with sodium bicarbonate additive).	Acceptable subject to narrowed use limits.	For use only in normally unoccupied areas.	Use of this agent should be in accordance with the safety guidelines in the latest edition of the NFPA 2001 Standard for Clean Agent Fire Extinguishing Systems, for whichever hydrofluorocarbon gas is employed. Envirogel is listed as a streaming substitute under the generic name Gelled Halocarbon/Dry Chemical Suspension. Envirogel was also previously listed as a total flooding substitute under the same generic name. EPA has found Envirogel with the ammonium polyphosphate additive and Envirogel with the sodium bicarbonate additive to be acceptable as total flooding agents in both occupied and unoccupied areas. See additional comments 1, 2, 3, 4, 5

Additional comments:

1—Should conform to relevant OSHA requirements, including 29 CFR 1910, subpart L, Sections 1910.160 and 1910.162.

2—Per OSHA requirements, protective gear (SCBA) should be available in the event personnel should reenter the area.

3—Discharge testing should be strictly limited to that which is essential to meet safety or performance requirements.

4—The agent should be recovered from the fire protection system in conjunction with testing or servicing, and recycled for later use or destroyed.

5—EPA has no intention of duplicating or displacing OSHA coverage related to the use of personal protective equipment (e.g., respiratory protection), fire protection, hazard communication, worker training or any other occupational safety and health standard with respect to halon substitutes.

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**ENVIRONMENTAL PROTECTION
AGENCY**

40 CFR Part 180

[EPA-HQ-OPP-2006-0645; FRL-8092-6]

Pendimethalin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of pendimethalin, N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzamine, and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol in or on alfalfa, forage; alfalfa, hay; alfalfa, seed; apple, wet pomace; fruit, pome, group 11; fruit, stone, group 12; juneberry; leek; onion, green; onion, welsh; pomegranate; shallot; strawberry; vegetable, fruiting, group 8; wheat, grain; wheat, forage; wheat, hay; and wheat, straw. BASF Corporation and Interregional Research Project Number 4

(IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 27, 2006. Objections and requests for hearings must be received on or before November 27, 2006 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-2006-0645. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Jim Tompkins, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305 5697; e-mail address: tompkins.jim@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 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.

- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 28522), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 FFDCA, as amended by the 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-2006-0645 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 November 27, 2006.

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-2006-0645 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 Building), 2777 S. Crystal Drive, 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 telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of June 14, 2006 (71 FR 34341-34342) (FRL-8072-1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions PP 0E6175 (vegetable, fruiting, group 8), PP 2E6450 (fruit, pome, group 11; apple, wet pomace; and juneberry), PP 2E6464 (fruit, stone, group 12), PP 2E6449 (pomegranates), by Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, New Brunswick, NJ 08902-390.

In the **Federal Register** of June 14, 2006 (71 FR 34344-34345) (FRL-8072-7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions PP 5E6927 (onion, green; onion, welsh; leek; and shallot), PP 5E6928 (strawberry), by Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, New Brunswick, NJ 08902-390.

In the **Federal Register** of August 18, 2006 (71 FR 47810-47811) (FRL-8084-71), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions PP 4F6870 (wheat, grain; wheat, forage; wheat, hay; and wheat, straw), and PP 5F6961 (alfalfa, forage; alfalfa, hay; and alfalfa, seed) by BASF Corporation Agricultural Products, P.O. Box 13528, Research Triangle Park, NC 27709-3528.

These petitions requested that 40 CFR 180.361 be amended by establishing a tolerance 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 vegetables, fruiting, group 8 at 0.10 ppm (PP 0E6175), fruit, pome, group 11 at 0.10 ppm; apple, wet pomace at 0.20 ppm; and juneberry at 0.10 ppm (PP 2E6450), fruit, stone, group 12 at 0.10 ppm (PP 2E6464), pomegranate at 0.10 ppm (PP 2E6449), onion, green at 0.20 ppm; onion, welsh at 0.20 ppm, leek at 0.20 ppm; and shallot at 0.2 ppm (PP 5E6927), strawberry at 0.10 ppm (PP 5E6928), wheat, grain at 0.10 ppm; wheat, forage at 3.0 ppm; wheat, hay at 0.60 ppm; and wheat, straw at 0.30 ppm; (PP 4F6870), alfalfa, forage at 3.0 ppm; alfalfa, hay at 4.0 ppm; and alfalfa, seed at 0.10 ppm (PP 5F6961). These notices included a summary of the petition prepared by IR-4 and BASF Corporation, the registrant. One comment was received in response to the notices of filing. EPA's response to this comment is discussed in Unit IV.C.

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...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the

available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance 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 vegetables, fruiting, group 8 at 0.10 ppm; fruit, pome, group 11 at 0.10 ppm; apple, wet pomace at 0.20 ppm; junberry at 0.10 ppm; fruit, stone, group 12 at 0.10 ppm; pomegranate at 0.10 ppm; onion, green at 0.20 ppm; onion, welsh at 0.20 ppm; leek at 0.20 ppm; shallot at 0.2 ppm; strawberry at 0.10 ppm; wheat, grain at 0.10 ppm; wheat, forge at 3.0 ppm; wheat, hay at 0.60 ppm; wheat, straw at 0.30 ppm; alfalfa, forage at 3.0 ppm; alfalfa, hay at 4.0 ppm; and alfalfa, seed at 0.10 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 toxic 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/fdmspublic/component/main>, see Docket OPP-2005-0056-0002.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

A summary of the toxicological endpoints for pendimethalin used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 12, 2006, 70 FR 18628-18635 (FRL-7770-4)

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.361) for the 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 a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess 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 one-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 Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. Tolerance-level residues were assumed for all food commodities with current and proposed pendimethalin tolerances, and it was assumed that all of the crops included in the analysis were treated (i.e., 100% crop treated). These assumptions result in highly conservative estimates of dietary exposure and risk.

iii. *Cancer.* Pendimethalin is classified "Group C," possible human carcinogen, chemical based on a statistically significant increased trend and pair-wise comparison between the high dose group and controls for thyroid follicular cell adenomas in male and female rats. The Agency used a non-linear approach (i.e., reference dose (RfD) approach) since 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 non-mutagenic in mammalian somatic cells and germ.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure 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 physical 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 39 parts per billion (ppb) for surface water and 0.024 ppb for ground water. The EECs for chronic exposures are estimated to be 4.8 ppb for surface water and 0.024 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID™, Version 2.03). An acute dietary risk assessment for the peak water concentration value was not done because no such effects were identified in the toxicological studies for pendimethalin. For chronic dietary risk assessment, an estimated drinking water concentration (EDWC) of 0.039 ppm, the 1 in 10 year annual peak concentration in surface water as calculated by PRZM-EXAMS modeling, resulting from a single application of pendimethalin to apples at a rate of 4.0 lb of active ingredient/acre, was entered into DEEM.

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 use on the following residential non-dietary sites: Landscapes, grounds plantings, ornamental crops, turf grass, and lawns. The risk assessment for residential non-dietary sites is discussed in Unit III.C.3. of the final rule published in the **Federal Register** of April 12, 2006, FR Page 18628–18635 (FRL–7770–4)

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

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 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>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional 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 data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. 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 safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* The data base for pendimethalin does not indicate a potential for increased toxicological sensitivity from either prenatal or postnatal exposures. No developmental toxicity was observed in either the rat or rabbit developmental toxicity studies, nor was there evidence in the two-generation reproduction study of developmental or reproductive toxicity at dose levels below those in which parental toxicity was observed. There was no neurotoxicity observed in the submitted toxicity studies. Therefore, a developmental neurotoxicity (DNT) study is not required.

Available data show the thyroid is a target organ for pendimethalin. The endpoints and doses selected for risk assessment were based on the most sensitive effect, thyroid toxicity, which was well-characterized in both chronic and subchronic toxicity studies on the basis of clear NOAELs and LOAELs. In addition, the exposure data used to evaluate risks for the general U.S. population and infants and children are conservative, and therefore the calculated risks are considered to be protective.

3. *Conclusion.* There was no evidence of qualitative or quantitative susceptibility in the submitted data. Additionally, exposure estimates are based on very conservative data and assumptions that will overstate exposure to pendimethalin. There is, however, a concern that perturbation of thyroid homeostasis may lead to hypothyroidism, and possibly result in adverse effects on the developing nervous system. Since thyroid toxicity parameters were not measured in the developmental toxicity studies, the Agency has requested a developmental thyroid assay be conducted to evaluate the impact of pendimethalin on thyroid hormones, structure, and/or thyroid hormone homeostasis during development. The Agency has retained the additional 10X FQPA safety factor in the form of a database uncertainty factor (UF_{DB}) for the lack of the study, to be applied in determining pendimethalin risks.

E. Aggregate Risks and Determination of Safety

1. *Acute risk.* No toxic effects attributed to a single dose were identified for pendimethalin. Therefore

an acute risk is not anticipated for this chemical.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pendimethalin from food and drinking water will utilize 11% of the chronic population adjusted dose (cPAD) for the U.S. population, 19% of the cPAD for infants, and 26% of the cPAD for Children 1 to 2 years of age. 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 to food and water (considered to be a background exposure level).

Pendimethalin is currently registered for use 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, drinking water and residential exposures aggregated result in aggregate MOEs of 580 for adult males, 520 for females 13 years or older, and 310 for children 1 to 2 years old. These aggregate MOEs do not exceed the Agency’s level of concern (MOE 300) for aggregate exposure to food, drinking water and residential uses. See 71 FR 18628–18630, April 12, 2006.

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). Based on the currently registered and requested uses, there are no scenarios that are likely to result in intermediate-term exposure (30 to 180 days, continuously). Therefore an intermediate-term risk is not anticipated for pendimethalin.

5. *Aggregate cancer risk for U.S. population.* The Agency determined that the 0.10 mg/kg/day RfD for chronic risks, is protective of both the chronic, non-carcinogenic effects as well as the carcinogenic effect seen in the rat. Accordingly, based on the risk estimates for chronic risk above, EPA concludes that aggregate chronic exposure to pendimethalin is not expected to pose a cancer risk of concern.

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, and to infants and children from aggregate exposure to pendimethalin and its metabolite residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate methods are available for data collection and tolerance enforcement for existing and proposed uses of pendimethalin. Methods I through IV in PAM Vol. II are gas chromatography/electron capture (GC/ECD) methods. Methods used for data collection are essentially the same as the PAM Vol. II methods, and have been adequately validated.

The FDA PESTDATA database (PAM Volume I, Appendix I) indicates that pendimethalin is completely recovered (>80%) by Multiresidue Methods Section 302 (Luke method; Protocol D) and 303 (Mills, Onley, Gaither method; Protocol E, nonfatty), and partially recovered (50–80%) by Multiresidue Method Section 304 (Mills fatty food method; Protocol E, fatty). The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are no established or proposed Codex maximum residue limits (MRLs) for pendimethalin residues. Therefore, there are no questions of compatibility with respect to Codex MRLs and U.S. tolerances.

C. Response to Comments

One comment was received in response to the notices of filing for this action. The comment contained no scientific data or other substantive evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to pendimethalin from the establishment of these tolerances.

V. Conclusion

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 alfalfa, forage at 3.0 ppm; alfalfa, hay at 4.0 ppm; and alfalfa, seed at 0.10 ppm; fruit, pome, group 11 at 0.10 ppm; apple, wet pomace at 0.20 ppm and juneberry at 0.10 ppm; fruit, stone, group 12 at 0.10 ppm; pomegranate at 0.10 ppm; onion, green at 0.20 ppm; onion, welsh at 0.20 ppm; leek at 0.20 ppm; and shallot at 0.2 ppm; strawberry at 0.10 ppm; wheat, grain at 0.10 ppm; wheat, forge at 3.0 ppm; wheat, hay at 0.60 ppm; wheat, straw at 0.30 ppm;

and vegetables, fruiting, group 8 at 0.10 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to petitions 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 due to its lack of significance, 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). 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.*, or 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). 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), or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input

by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 19, 2006.

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 adding entries to the table in paragraph (a) to read as follows:

§ 180.361 Pendimethalin, Tolerances for Residues.

(a) * * *

Commodity	Parts per million
Alfalfa, Forage	3.0
Alfalfa, Hay	4.0
Alfalfa, Seed	0.10
Apple, wet pomace	0.20
* * * * *	
Fruit, pome, group 11	0.10
Fruit, stone, group 12	0.10
* * * * *	
Juneberry	0.10
Leek	0.20
* * * * *	
Onion, green	0.20
Onion, welsch	0.20
* * * * *	
Pomegranate	0.10
* * * * *	
Shallot	0.2
* * * * *	
Strawberry	0.10
* * * * *	
Vegetable, fruiting, group 8	0.10
Wheat, grain	0.10
Wheat, forage	3.0
Wheat, hay	0.60
Wheat, straw	0.30

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0204; FRL-8094-5]

Quizalofop ethyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of quizalofop ethyl in or on the raw agricultural commodities barley, grain; barley, hay; barley, straw; flax, seed; milk, fat; sunflower, seed; wheat, forage; wheat, grain; wheat, hay; and wheat, straw. Nissan Chemical Industries, Ltd requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 27, 2006. Objections and requests for hearings must be received on or before November 27, 2006, 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-2006-0204. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: James A. Tompkins, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 703-305-5697; e-mail address: Tompkins.jim@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 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 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 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 FFDCA, as amended by the 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