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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0521; FRL-9360-5]

Pendimethalin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pendimethalin in or on in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project No. 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-0521, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9367; email address: *ertman.andrew@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0521 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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 (excluding any CBI) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0521, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 20, 2011 (76 FR 43231) (FRL-8880-1), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7878) by 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 residues of the herbicide pendimethalin, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6dinitrobenzenamine, and its 3, 5-dinitrobenzyl alcohol metabolite (CL 202347), in or on lettuce, leaf at 3.0 parts per million (ppm); *Brassica,* leafy greens, subgroup 5B at 0.2 ppm; turnip greens at 0.2 ppm; melons subgroup 9A at 0.1 ppm; vegetable, soybean, succulent at 0.1 ppm; and small fruit vine climbing subgroup 13–07E, except grape at 0.1 ppm. That notice referenced a summary of the petition prepared by BASF, the registrant, which is available 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 modified the level for which the tolerance is being established for leaf lettuce. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with 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 pendimethalin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pendimethalin 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.

Pendimethalin has low acute oral, dermal, and inhalation toxicity, and is not a dermal sensitizer. The thyroid is a target organ for pendimethalin. Thyroid toxicity in chronic and subchronic rat and mouse studies was manifested as alterations in thyroid hormones, increased thyroid weight, and microscopic thyroid lesions. Due to these effects, the Agency required that a developmental thyroid assay be conducted to evaluate the impact of pendimethalin on thyroid hormones, structure, and/or thyroid hormone homeostasis during development. A developmental thyroid study was submitted and demonstrated that there is no potential thyroid toxicity following pre- and/or post-natal exposure to pendimethalin. The available prenatal and postnatal developmental toxicity data provided no indication of qualitative or quantitative susceptibility to the young. The overall weight of evidence suggests that this chemical does not directly target the immune system. There is no evidence of neurotoxicity for pendimethalin exposure.

The points of departure (PODs) used for the chronic and short-term risk assessments were based on a 92-day thyroid function study in rats, a 56- day thyroid study in rats, and a 14- day intra thyroid metabolism study in rats. Due to several important quantitative dynamic differences between rats and humans with respect to thyroid function, the interspecies uncertainty factor ((UF); used to account for animal to human differences in toxicokinetics and toxicodynamics) was reduced to 3X for the chronic and short-term risk assessments. A 10X interspecies UF was used in the acute risk assessment because the POD was based on an acute neurotoxicity study, not a thyroid study. The use of an oral POD, assuming 100 percent inhalation absorption is considered protective for assessing short-term inhalation exposure since pendimethalin has a low vapor pressure (1.24×10^{-8} Millimeter (mm) mercury (Hg) at 20ºC) and is not

likely to volatilize substantially. It also has a relatively low solubility in water (0.275 ppm at 25 ºC). Further the EPA has determined a subchronic inhalation study is not needed at this time.

Pendimethalin is considered a possible human carcinogen based on a statistically significant increased trend and pair-wise comparison between the high dose group and controls for thyroid folliculate cell adenomas in male and female rats. A threshold approach is being used to evaluate cancer risk because mode of action studies are available demonstrating that the thyroid tumors are due to a thyroid-pituitary imbalance (a threshold effect), and also because pendimethalin was shown to be non-mutagenic in mammalian somatic cells and germ cells.

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*, on pp. 51-54 in the document titled "*Revised Pendimethalin: Human Health Risk Assessment for Proposed Use on Leaf lettuce; Leafy brassica greens; Melons; Edamame; Kiwi and other small fruit vines*" in docket ID number EPA-HQ-OPP-2011-0521.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a

careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). 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 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 is shown in the Table of this unit.

Table —Summary of Toxicological Doses and Endpoints for Pendimethalin for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	NOAEL = 100 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	Acute RfD = 1 mg/kg/day aPAD = 1	Acute neurotoxicity study. LOAEL=300 mg/kg, based on reduced motor activity for males

		mg/kg/day	and females on Day 0.
Chronic dietary (All populations)	NOAEL= 10 mg/kg/day UF_A = 3X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.3 mg/kg/day cPAD = 0.3 mg/kg/day	92-day thyroid function study in rats; 56- day thyroid study in rats; 14-day intra thyroid metabolism study in rats. LOAEL = 31 mg/kg/day based on hormonal and histopathological changes in the thyroid.
Incidental oral short-term (1 to 30 days)	NOAEL= 10 mg/kg/day UF_A = 3X UF_H = 10X FQPA SF = 1X	LOC for MOE = 30	92-day thyroid function study in rats; 56- day thyroid study in rats; 14-day intra thyroid metabolism study in rats. LOAEL = 31 mg/kg/day based on hormonal and histopathological changes in the thyroid.
Dermal short-term (1 to 30 days)	Oral study NOAEL = 10 mg/kg/day (dermal	LOC for MOE = 30	92-day thyroid function study in rats; 56- day

	absorption rate = 3% UF_A = 3X UF_H = 10X FQPA SF = 1X		thyroid study in rats; 14-day intra thyroid metabolism study in rats. LOAEL = 31 mg/kg/day based on hormonal and histopathological changes in the thyroid.
Inhalation short-term (1 to 30 days)	Oral study NOAEL= 10 mg/kg/day (inhalation absorption rate = 100%) UF_A = 3X UF_H = 10X FQPA SF = 1X	LOC for MOE = 30	92-day thyroid function study in rats; 56- day thyroid study in rats; 14-day intra thyroid metabolism study in rats. LOAEL = 31 mg/kg/day based on hormonal and histopathological changes in the thyroid.
Cancer (Oral, dermal, inhalation)	Pendimethalin has been classified as a possible human carcinogen 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. A non-quantitative approach (i.e., non-linear, RfD approach) was used		

	since mode of action studies are available.

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

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.

Such effects were identified for pendimethalin. In estimating acute dietary exposure, EPA used food consumption information 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 100 percent crop treated (PCT) and tolerance-level residues for all current and proposed crops.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to

residue levels in food, EPA assumed 100 PCT and tolerance-level residues for all current and proposed crops.

iii. *Cancer*. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to pendimethalin. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure*.

iv. *Anticipated residue and 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 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 estimated drinking water concentrations (EDWCs) of pendimethalin for acute exposures are estimated to be 80.5 parts per billion (ppb) for surface water and 0.036 ppb for ground water; and for chronic exposures are estimated to be 6.2 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. For acute dietary risk assessment, the water concentration value of 80.5 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 6.2 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: Turf and ornamentals. EPA assessed residential exposure using the following assumptions: For handlers, it is assumed that most residential use will result in short-term (1 to 30 days) dermal and inhalation exposures. Residential handlers are assumed to be wearing short-sleeved shirts, short pants, shoes and socks during application of pendimethalin.

Residential post-application exposure is assumed to be short-term (1-30 days) in duration, resulting from the following: physical activities on turf: adults (dermal) and children 1-2 years old (dermal and incidental oral); mowing: adults (dermal) and children

11 < 16 years old (dermal); and golfing: adults (dermal), children 11 < 16 years old (dermal), and children 6 < 11 years old (dermal).

EPA did not combine exposure resulting from adult handler and post-application exposure resulting from treated lawns and/or golfing because of the conservative assumptions and inputs within each estimated exposure scenario. The Agency believes that combining exposures resulting from handler and post-application activities would result in an overestimate of adult exposure. EPA selected the most conservative adult residential scenario (adults 50+ years old; dermal post-application exposure) as the contributing source of residential exposure to be combined with the dietary exposure for the aggregate assessment.

The children's oral exposure is based on post-application hand-to-mouth exposures. To include exposure from object-to-mouth and soil ingestion in addition to hand-to-mouth could result in a very conservative estimation of exposure, as it would overestimate the potential for oral exposure. However, there is potential for co-occurrence of the dermal and oral exposure based on the use pattern and combining them is appropriate because risk estimated from the dermal and oral routes of exposure are based on the same toxicological study. As a result, the children's aggregate assessment combines post-application dermal and oral exposure along with dietary exposure from food and water.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

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 EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There was no indication of pre- and/or post-natal qualitative or quantitative increased susceptibility in the developmental studies in

rats and rabbits or the 2-generation reproduction studies in rats. In addition, a developmental thyroid toxicity study demonstrated that there is no potential thyroid toxicity following pre- and/or post-natal exposure to pendimethalin.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for pendimethalin is complete.

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. In addition, a developmental thyroid toxicity study demonstrated that there is no potential thyroid toxicity following pre- and/or post-natal exposure to pendimethalin

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. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pendimethalin in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by pendimethalin.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pendimethalin will occupy 2.0% of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pendimethalin from food and water will utilize 1.6% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of pendimethalin is not expected.

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 the combined short-term food, water, and residential exposures result in aggregate MOEs of 125 for adults and 93 for children 1-2 years old, the two population subgroups receiving the greatest combined dietary and non-dietary exposure. Because EPA's level of concern for pendimethalin is a MOE of 30 or below, these MOEs are not of concern.

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

An intermediate-term adverse effect was identified; however**,** pendimethalin is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for pendimethalin**.**

5. *Aggregate cancer risk for U.S. population*. Pendimethalin is considered a "possible human carcinogen" 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. A non-quantitative approach (i.e., non-linear, RfD approach) was used since mode of action studies are available to 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 cells. The chronic dietary risk assessment is considered to be protective of any 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.

IV. Other Considerations

A. Analytical Enforcement Methodology

PAM Volume II lists four Gas Chromatography/Electron Capture Detector (GC/ECD), methods for the determination of pendimethalin and its 3,5-dinitrobenzyl alcohol metabolite in plant commodities. Methods I and III determine residues of the parent, whereas Methods II and IV determine residues of the 3,5-dinitrobenzyl alcohol metabolite.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is

different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for pendimethalin on any of these new uses.

C. Revisions to Petitioned-For Tolerances

The proposed tolerance of 3.0 ppm on leaf lettuce is being increased to 4.0 ppm. This is because the Agency used the Organization of Economic Cooperation and Development (OECD) tolerance calculation procedures in determining appropriate tolerance levels, whereas the petitioner used the North American Free Trade Agreement (NAFTA) tolerance calculation procedures.

V. Conclusion

Therefore, tolerances are established for residues of pendimethalin, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6dinitrobenzenamine, and its 3, 5-dinitrobenzyl alcohol metabolite (CL 202347), in or on lettuce, leaf at 4.0 ppm; *Brassica,* leafy greens, subgroup 5B at 0.20 ppm; turnip greens at 0.20 ppm; melon subgroup 9A at 0.10 ppm; vegetable, soybean (edamame) at 0.10 ppm; and fruit, small vine climbing subgroup 13–07E, except grape at 0.10 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That

Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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) (2 U.S.C. 1501 *et seq*.).

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) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: August 17, 2012.

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
*****	*****
Brassica, leafy greens, subgroup 5B	0.20
*****	*****
Fruit, small vine climbing, except grape, subgroup 13-07E	0.10
*****	*****
Lettuce, leaf	4.0
Melon subgroup 9A	0.10
*****	*****
Turnip greens	0.20
*****	*****
Vegetable, soybean, succulent	0.10
*****	*****

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