Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 12, 2006. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purpose of judicial review nor does it extend the time within which petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental regulations, Reporting and recordkeeping requirements.

Dated: March 22, 2006.

Wayne Nastri,

Regional Administrator, Region IX.

[FR Doc. 06–3406 Filed 4–11–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0056; FRL–7770–4]

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-dinitrobenzenamine], and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenyzl alcohol in or on carrots; spearmint, tops; peppermint, tops; spearmint, oil; peppermint, oil; fruit, citrus, group 10, citrus, oil; almond, hulls; nut, tree group 14. Interregional Research Project Number 4 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 April 12, 2006. Objections and requests for hearings must be received on or before June 12, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number EPA–HQ–OPP–2005–0056. All documents in the docket are listed on the www.regulations.gov web site, (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enchanced Federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*. Follow the on-line instructions. Although listed in the index, some information is not publicly available, i.e., 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 electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This 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 (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5805; 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 and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.Follow the on-line instructions. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two a*thttp://www.epa.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of September 1, 1999 (64 FR 47797) (FRL–6096–8), and March 19, 2001, (66 FR 15464) (FRL–6766–8), 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 6E4603, PP 6E4787, PP 7E4878, and 0E6083 by Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902–390. The petitions requested that 40 CFR part 180 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-dinitrobenyzl alcohol, in or on carrots at 0.5 parts per million (ppm); (6E4603); peppermint and spearmint tops at 0.2 ppm; (7E4878); peppermint and spearmint oil at 1.0 ppm (7E4878); fruit, citrus, group 10 at 0.1 ppm (6E4787); citrus, oil at 0.5 ppm, (6E4787); almond, hulls at 0.4 ppm; (0E6083); and nut, tree group 14 at 0.1 ppm (0E6083). That notice included a summary of the petition prepared by IR-4, the registrant. There were no comments received in response to the notice of filing.

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 pendimethalin and its metabolite in or on carrots at 0.5 ppm; peppermint and spearmint tops at 0.2 ppm; peppermint and speamint oil at 1.0 ppm; fruit, citrus, group 10 at 0.1 ppm; citrus, oil at 0.5 ppm; almond, hulls at 0.4 ppm; and nuts, tree group 14 at 0.1 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic effects caused by pendimethalin and its metabolite 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 *www.fdms.gov*.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which 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 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or UFs may be used: ''Traditional UFs;'' the ''FQPA data safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional UFs,'' EPA is referring to those additional UFs used prior to FQPA passage to account for database deficiencies. These traditional UFs have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''FQPA data safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional UF or a FQPA data safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional UFs deemed appropriate (RfD = NOAEL/UF). Where a FQPA data safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the Level of Concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

The data base for pendimethalin does not indicate a potential for increased toxicological sensitivity from either prenatal or postnatal exposures. In the submitted rat and rabbit developmental studies, no adverse effects were observed at doses tested. These studies were considered adequate, and no additional developmental toxicity studies are required. There was no evidence of qualitative or quantitative susceptibility in a 2-generation reproduction study conducted in the rat. There was no neurotoxicity observed in the submitted studies, and no evidence of qualitative or quantitative susceptibility in the developmental and reproduction studies; therefore, a developmental neurototoxicity study has not been required, and the 10X Special FQPA factor has been reduced to 1X.

Hormonal changes (alterations in thyroid weights and histopathological lesions) were observed in several studies following oral administration of pendimethalin and it is likely that these changes 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, the Agency has 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. Pending receipt of the study, the Agency has retained a 10X data base UF to provide adequate protection of infants and children from potential thyroid effects.

The standard 10X intraspecies uncertainty factor and a 3X interspecies factor are applicable to pendimethalin risk assessments. The interspecies uncertainty factor of 10X was reduced to 3X due to the greater sensitivity of the adult rat to thyroid effects compared to the adult humans. Because of toxicodynamic differences in adult thyroid function that result in greater sensitivity of the adult rat to hypothyroidism compared to adult humans, the 3X toxicodynamic part of the 10X can be removed leaving the 3X portion for toxicokinetic interspecies differences based on the Agency's Interim Guidance on Thyroid Disrupting Pesticides, dated November 1, 2005. Thus, the usual 100X UF for intraspecies and interspecies differences is reduced to 30X. A data base UF of 10X was retained for residential exposures pending receipt of the developmental thyroid study. The level of concern (target MOE) for residential exposure is 300X.

A summary of the toxicological endpoints for pendimethalin used for human risk assessment is shown in the following Table 1:

TABLE 1.—TOXICOLOGICAL DOSES AND ENDPOINTS FOR PENDIMETHALIN HUMAN HEALTH RISK ASSESSMENTS

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA data SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Dietary exposure			
Acute dietary (females 13–49) General US pop.)	NA	NA	No appropriate acute endpoint identified for these groups. There were no toxic effects attributable to a single dose
Chronic dietary (all populations)	NOAEL = 10 mg/kg/day UF = 10X (intraspecies) UF = 3X (interspecies) UF = 10X (data base) Total UF = 300X Chronic RfD= 0.03 mg/kg/day	FQPA SF = 1X cPAD = Chronic RfD FQPA SF cPAD = 0.03 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
Oral ingestion			
Incidental oral short-term (1–30 days) Intermediate-term (1–6 months)	NOAEL = 10 mg/kg/day UF = 10X (intraspecies) UF = 3X (interspecies) UF = 10X (data base) Total UF = 300X	FQPA SF = 1X Residential LOC = 300	92–day thyroid function study in rats; 56–ay thyroid study in rats; 14–ay intra thyroid metabolism study in rats LOAEL= 31 mg/kg/day based on hormonal and histopathological changes in the thyroid
Dermal exposure			
Dermal short-term (1–30 days) Intermediate-term (1–6 months) Long-term (>6 months)	NOAEL = 10 mg/kg/day UF = 10X (intraspecies) UF = 3X (interspecies) UF = 10X (data base) Total UF = 300X Dermal absorption = 3%	FQPA SF = 10X Residential LOC = 300 Occupational LOC = 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
Inhalation exposure			
Inhalation short-term (1–30 days) Intermediate-term (1–6 months) Long-term (>6 months)	NOAEL = 10 mg/kg/day UF = 10X (intraspecies) UF = 3X (interspecies) UF = 10X (data base) Total UF = 300X Inhalation absorption = 100%	FQPA SF = 1X Residential LOC = 300	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			
Cancer (oral, dermal, inhalation)	Pendimethalin is considered to be a possible human carcinogen. The linear default risk methodology was not appropriate and non-linear, RfD approach was used	2–year chronic/carcinogenicity study in rats	

UF = uncertainty factor, FQPA SF = FQPA data safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable* Refer to discussion above

Pendimethalin is classified as a ''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. A non-quantitative approach (i.e., non-linear, RfD approach) was used by the Agency 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 cells. The cPAD from the 92–day thyroid function study in rats; 56–day thyroid study in rats; 14–day intra thyroid metabolism study in rats used for the chronic dietary assessment provide adequate MOE's for cancer.

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 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 1–day or single exposure.

No such effects were identified in the toxicological studies for pendimethalin therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the United State Department of Agriculture Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity (CSFII, 1994–1996, and 1998). 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-quantitative approach (i.e., non-linear, 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*. Pendimethalin dissipates in the environment by binding to soil, metabolizing by microbes, and by volatilizing into air. Persistence decreased with increased temperature, increased moisture and decreased soil organic carbon. Pendimethalin residues in laboratory and field studies are tightly bound to soil and sediment particles, which is consistent with the laboratory mobility studies.

The Agency estimated concentrations in drinking water using Tier II screening level surface water modeling (PRZM-EXAMS) for surface water and Tier I modeling screening concenteration for ground water (SCI-GROW^2). These Estimated Drinking Water Concentrations (EDWCs) may be used for acute, chronic (non-cancer), and chronic (cancer) exposure assessments. The PRZM-EXAMS concentrations to be used for drinking water ranged from 2.2 to 38.8 micrograms/liter (µ/L) for peak values, 0.1 to 4.8 µ/L for chronic (non-cancer), and 0.1 to 3.8 µ/L for chronic (cancer) exposures.

The I in 10–year annual peak (acute), 1 in 10–year annual mean (non-cancer chronic), and 36–year annual mean concentrations (cancer chronic) were derived from modeling pendimethalin on the Pennsylvania apple scenario.

Based on SCI-GROW modeling, the acute and chronic pendimethalin concentrations are not expected to exceed 0.024 µ/L parts per billion (ppb) from one application of 4 lbs active ingredient/A (ai/A). The estimated concentrations of up to 0.024 µ/L were actually lower than the detected concentrations in ground water, ranging from 0.2 to 0.9 ppb. However, the Agency does not consider pendimethalin to be a likely ground water contaminant in most environments based on its environmental fate property of tight sorption to soil.

Parent pendimethalin is the only significant non-volatile residue, therefore, the EDWCs were calculated for parent pendimethalin only.

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: Landscape, grounds plantings, ornamental crops, turf grass, and lawns. Residential handler exposure estimates of applying pendimethalin to residential turf were previously assessed in the 1996 re-registration eligibility decision document for pendimethalin. Since that time registered labels for use of pendimethalin on turf have been revised. Turf (ornamental, landscape, golf course, non-cropland) in commercial areas can be treated at a rate of 3 pounds of ai/A Treatment of turf at residential sites is limited to a rate of 2 pounds of ai/A.

There are two types of potential post-application risks: Dermal and incidental oral exposure. Chemical-specific WDG turf transferable residue (TTR) data have been submitted to the Agency and reviewed in support of assessing dermal exposure to adults and children.

Ingestion of pendimethalin granules is also a potential source of exposure because children can eat them if they are found in treated lawns or gardens. This scenario is considered to be episodic, and therefore, acute oral endpoints would be used to estimate the risk. A risk assessment for this exposure scenario for children was not conducted since an acute oral toxicological endpoint of concern was not identified for pendimethalin.

In evaluating the residential uses of pendimethalin, the Agency has combined all non-dietary sources of postapplication exposure to obtain an estimate of potential aggregate exposure. These scenarios are short-term in duration and consist of dermal (adults and children) and oral (hand-to-mouth, object-to-mouth and soil ingestion - children only) exposure. The Agency combines risk values resulting from separate exposure scenarios when it is likely they can occur simultaneously based on the use-pattern and the behavior associated with the exposed population.

A Tier I aggregate exposure estimate for adults (consisting of dermal exposure only) was conducted using the TTR from California test site and 3% dermal absorption factor. Since the California test site resulted in the lowest dermal margin of exposure (MOE), it was determined to represent the worst case scenario. In assessing the aggregate residential exposure for children, The Agency also used the California TTR data, hand press data and 3% dermal absorption factor for determining dermal exposure to children.

The LOC for non-occupational dermal exposure is 300. Using the TTR data for the Pendulum WDG formulation, children's short-term dermal MOEs calculated at a rate of 3.0 lb ai/A ranged from 440 to 910. For adults, short-term dermal MOEs ranged from 740 to 1,500. All dermal short-term MOEs were greater than 300 and therefore, did not exceed the Agency;s LOC.

All oral (hand-to-mouth, object-to-mouth, and soil ingestion) exposures were greater than 300 and therefore, did not exceed the Agency's LOC. The MOEs calculated for hand-to-mouth exposures using the rate of 2.0 lb ai/A resulted in an MOE of 7,700. The MOEs for object-to-mouth and soil ingestion exposure were 130,000 and 100,000 respectively. MOEs calculated for hand-to-mouth exposures using the rate of 3.0 lb ai/A resulted in an MOE of 5,300. The MOEs for object-to-mouth and soil ingestion exposure were 85,000 and 67,000 respectively.

A Tier I aggregate exposure estimate for adults (consisting of dermal exposure only) resulted in a total MOE of 740 which is greater than the level of concern of 300 and therefore not of concern. The adult total MOE of 740 was based on using the TTR from California test site and 3% dermal absorption factor. Since the California test site resulted in the lowest dermal MOE, it was determined to represent the worst case scenario. In assessing the aggregate residential exposure for children, The Agency also used the California TTR data, hand press data and 3% dermal absorption factor for determining dermal exposure to children. This resulted in a total MOE (dermal + oral) of 410 for an application rate of 2 lb ai/acre and 400 for an application rate of 3 lb ai/acre, both of which are greater than 300 and therefore not of concern.

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

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 MOE analysis or through using UF (safety) 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 UFs and/or FQPA data safety factors, as appropriate.

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, and 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. Since thyroid toxicity parameters were not measured in the developmental toxicity studies, the Agency has required additional data on comparative thyroid toxicity in young and adult rats. The Agency has retained a data base UF for the lack of the study, to be applied in determining residential and aggregate risks. The Agency has removed the Special FQPA Safety Factor (i.e., reduced it to 1X) because there was no evidence of qualitative or quantitative susceptibility in the submitted data, and because the endpoints and doses selected for risk assessment were based on thyroid effects. There is a concern that perturbation of thyroid homeostatis may lead to hypothyroidism, and possibly result in adverse effects on the developing nervous system. 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.

E. Aggregate Risks and Determination of Safety

1. *Acute aggregate risk.* No toxic effects attributable to a single dose were identified for pendimethalin. Therefore, an acute risk is not anticipated for this chemical.

2. *Short-term Aagregate risk.* In estimating short-term aggregate risk, the chronic dietary (food) exposure estimate and the total non-dietary (residential) exposure estimate have been combined for adults and children. The chronic dietary exposure estimate reflects average dietary exposure and serves as an estimate of dietary exposure that co-occurs with potential short-term non-dietary exposure to adults and children. The short-term aggregate exposures for adults and children at application rates of 3 and 2 lbs ai/acre were greater than the EDWC for ground water or surface water and therefore, were not of concern. Short-term aggregate risk estimates for pendimethalin are summarized in the following Table 2.

TABLE 2.—SHORT-TERM AGGREGATE RISK AND DWLOC CALCULATIONS

Population	Average Food Exposure mg/kg/day	Residential Exposure[1] mg/kg/day	Aggregate MOE (food and residential)[2]	Max Water Exposure[3] mg/kg/day	Ground Water EDWC (ppb)	Surface Water EDWC (ppb)	Short-Term DWLOC[4] (μ/L)
Adult male (U.S. population)	0.000710	0.014	699	0.013600	0.024	5	476
Adult Female (Females 13+)	0.000473	0.016	607	0.016000	0.024	5	480
Child (1-2 years) 21b rate	0.001787	0.024	383	0.024300	0.024	5	243
Child (1-2 years) 31b rate		0.025	370	0.006300	0.024	5	95

Target MOE = 300 based on a total UF of 100 (10X intraspecies, 3X interspecies).
Maximum Exposure (mg/kg/day) = NOAEL(10 mg/kg/day)/Target MOE (300)
[1]Residential Exposure = [Oral exposure + Dermal exposure + Inhalation Exposure]
[2]Aggregate MOE = [NOAEL ÷ (Avg Food Exposure + Residential Exposure)]
[3]Maximum Water Exposure (mg/kg/day) = Target Maximum Exposure - (Food Exposure + Residential Exposure)
[4]DWLOC(μ/L) = [maximum water exposure (mg/kg/day) x body weight (kg)]/ [water consumption (L) x 10^{-3} (microgram)]
Body Weight = 70 kg for adults, 10 Kg for children; Water consumption = 2L for adults, 1L for children.

3. *Intermediate-term aggregate risk*. Based on the currently requested uses, there are no scenarios that are likely to result in intermediate-term exposure (30 to 180 days, continuous). Therefore, an intermediate-term risk assessment for pendimethalin has not been conducted.

4. *Long-term aggregate risk*. The dietary exposure pathway is the only source of exposure to pendimethalin that is expected to be long-term (180 to 365 days). Therefore, the long term aggregate exposure estimates are equivalent to the chronic dietary exposure estimates discussed in the previous section. The chronic aggregate exposure is provided in Table 3 for convenience. The most highly exposed population subgroup from exposure to pendimethalin in food was children 1 to 2 years old. The chronic exposure estimate of approximately 0.002 mg/kg/day corresponds to 6% of cPAD. Risks for the general U.S. population (2.4% cPAD) and all other population subgroups were lower. For all population subgroups, the chronic DWLOC is greater than the chronic ground and surface water EDWC; therefore, aggregate chronic exposure to pendimethalin is not expected to exceed the level of concern.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PENDIMETHALIN.

Population Subgroup	Chronic Scenario					
		cPAD mg/kg/day	Chronic Food Exposure mg/kg/day	Max Chronic Water Exposure mg/kg/day[1]	Ground Water EDWC (ppb)[2]	Surface Water EDWC (ppb)[2]
U.S. population	0.03	0.000710	0.02929	0.024	4.8	1025
All Infants (<1 year old)		0.0001295	0.02987			448
Children 1-2 years		0.001787	0.028213			423
Children 3-5 years		0.001608	0.0284			426
Children 6–12		0.001105	0.028895			433
Youth 13–19		0.000742	0.02926			1024
Adults 20–49		0.000558	0.029442			1030
Females 13+		0.000473	0.0295			885
Adults 50+ years		0.000556	0.0294			1029

[1]Maximum chronic water exposure (mg/kg/day) = [chronic PAD (mg/kg/day) - chronic dietary exposure (mg/kg/day)]
[2] See section 2 for estimated surface water and ground water concentrations
[3]Chronic DWLOC(μ/L) = [maximum chronic water exposure (mg/kg/day) x body weight (kg)]/[water consumption (L) x 10^{-3} mg/μ]

Body weights (70 kg adult male; 60 kg adult female; 10 kg child)

5. *Cancer aggregate risk*. As discussed above 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 the Pesticide Analytical Manuel (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 Food and Drug Administration's PESTDATA data base (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 Maxium Residue Levels (MRLs) for pendimethalin residues. Therefore, there are no questions of compatibility with respect to Codex MRLs and U.S. tolerances.

V. Conclusion

Therefore, the tolerance is 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-dinitrobenyzl alcohol, in or on carrots at 0.5 ppm; peppermint, tops and spearmint, tops at 0.2 ppm; peppermint, oil and spearmint, oil at 1.0 ppm; fruit, citrus, group 10 at 0.1 ppm; citrus, oil at 0.5 ppm; almond, hulls at 0.4 ppm; and nuts, tree, group 14 at 0.1 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2005–0056 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 June 12, 2006.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number EPA–HQ–OPP–2005–0056, to: Public Information and Records Integrity Branch, Information Technology and Resource Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 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.

VIII. 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 in 40 CFR Part 180

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

Dated: March 30, 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 alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.361 Pendimethalin, Tolerance for Residues.

(a) * * *

Commodity	Parts per million
Almond, hulls	0.4
* * * * *	
Carrots	0.5
* * * * *	
Citrus, oil	0.5
* * * * *	
Fruit, citrus, group 10	0.1
* * * * *	
Nut, tree, group 14	0.1
* * * * *	
Peppermint, oil	1.0
Peppermint, tops	0.2
* * * * *	
Spearmint, oil	1.0
Spearmint, tops	0.2

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0486; FRL–7765–1]

FD&C Blue No. 1 PEG Derivatives; Exemptions from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.