Commodity	Parts per million
* * * * *	

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■ 39. Section 180.517 is amended by removing the entries for ''Fat of cattle, goat, horse and sheep,'' ''Liver of cattle, goat, horse and sheep,'' ''Meat Byproducts, except liver of cattle, goat, horse, and sheep,'' and ''Meat of cattle, goat, horse and sheep'' and adding alphabetically the following entries to the table in paragraph (a) to read as follows:

§ 180.517 Fipronil; tolerances for residues.

(a) * * *

Commodity	Parts per million
Cattle, fat	0.40
Cattle, liver	0.10
Cattle, meat	0.04
Cattle, meat byproducts, except liver	0.04
* * * * *	
Goat, fat	0.40
Goat, liver	0.10
Goat, meat	0.04
Goat, meat byproducts, except liver	0.04
* * * * *	
Horse, fat	0.40
Horse, liver	0.10
Horse, meat	0.04
Horse, meat byproducts, except liver	0.04
* * * * *	
Sheep, fat	0.40
Sheep, liver	0.10
Sheep, meat	0.04
Sheep, meat byproducts, except liver	0.04

* * * * *

■ 40. Section 180.554 is amended by removing the entry for ''Apple pomace'' and by adding alphabetically the following entries to the table in paragraph (a)(1) to read as follows:

§ 180.554 Kresoxim-methyl; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
Apple, dry pomace	1.0
Apple, wet pomace	1.0
* * * * *	

* * * * *

■ 41. Section 180.615 is amended by removing the entry for ''Wheat, milled byproducts'' and adding alphabetically the following entries to the table in paragraph (d) to read as follows:

§ 180.615 Amicarbazone; tolerances for residues.

* * * * *

(d) * * *

Commodity	Parts per million
* * * * *	
Wheat, bran	0.15
Wheat, flour	0.15
* * * * *	
Wheat, germ	0.15
* * * * *	
Wheat, middlings,	0.15
Wheat, shorts	0.15
* * * * *	

[FR Doc. E9–21416 Filed 9–8–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0876; FRL–8431–2]

Pendimethalin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of the herbicide pendimethalin including its metabolites and degradates in or on olive at 0.1 parts per million (ppm). The Interregional Research Project Number 4 (IR–4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 9, 2009. Objections and requests for hearings must be received on or before November 9, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0876. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

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

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2008–0876 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before November 9, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0876, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA 22202. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of April 13, 2009 (74 FR 16866) (FRL–8396–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7404) by IR–4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.361 be amended by establishing tolerances for combined residues of the herbicide pendimethalin, *N*-(ethylpropyl)-3,4-di methyl-2,6-dinitrobenzenamine and its metabolite, 4-[(1-ethylpropyl)amino]-2-methyl-3, 5-dinitrobenzyl alcohol in or on olive at 0.1 parts per million (ppm). That notice referenced a summary of the petition prepared by BASF Corporation, the registrant, on behalf of IR–4 and is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

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 section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for the petitioned-for tolerances for combined residues of pendimethalin including its metabolites and degradates on olive at 0.1 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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 moderate oral and eye toxicity and low dermal and inhalation toxicity. Pendimethalin is not a dermal sensitizer. The target organ for pendimethalin in chronic and subchronic rat and mouse studies is the thyroid. Effects seen in these studies include alterations in thyroid hormones, increased thyroid weight, and microscopic thyroid lesions (including increased thyroid follicular cell height, follicular cell hyperplasia, as well as follicular cell adenomas).

Prenatal developmental toxicity studies in rats and rabbits show no indication of qualitative or quantitative susceptibility following prenatal and postnatal exposure in 2-generation reproduction studies in rats. A developmental thyroid study has been requested to provide additional information to evaluate thyroid toxicity in the developing fetus following prenatal and postnatal exposure.

In a combined chronic/carcinogenicity study in rats, the lowest-observed-adverse-effect level (LOAEL) of 250 milligrams/kilogram/day (mg/kg/day) is based on decreased survival, body weight gain and food consumption, increased gamma glutamyl transferase and cholesterol, increase in absolute and/or relative liver weight, generalized icterus, dark adipose tissue in females, diffusely dark thyroids and follicular cell hyperplasia of the thyroid. Thyroid tumors were observed in both male and female rats. In the carcinogenicity study in mice, the LOAELs of 622.1 and 806.99 mg/kg/day for males and females, respectivley, are based on increased mortality in females, decreased body weight in females, increased absolute thyroid, liver and gall bladder weights and/or relative body and brain weight ratios in males and females as well as amyloidosis in males. There were no tumors observed in mice.

Pendimethalin is classified as a ''Group C'', 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 employed by the Agency since mode of action studies are available that demonstrate that the thyroid tumors are due to a thyroid-pituitary imbalance. Pendimethalin was shown to be non-mutagenic in mammalian somatic cells and germ cells.

Based on concern for the hormonal changes (alterations in thyroid weights and histopathological lesions) seen in several studies following oral administration of pendimethalin for 14, 28, and 92 days as well as following chronic exposure and the likelihood that pendimethalin may cause disruption in the thyroid, the Agency

required a developmental thyroid study to be submitted to further characterize these effects.

There is no evidence of neurotoxicity or potential immunotoxicity for pendimethalin in the toxicology database. An immunotoxicity and acute and subchronic neurotoxicity studies are required as part of the revised 40 CFR part 158 toxicology data requirements for pendimethalin.

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 LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document ''Pendimethalin: Human Health Risk and Exposure Assessment for Proposed Section 3 Registration for Use on Olive,'' dated May 28, 2009, at page 10 in docket ID number EPA–HQ–OPP–2008–0876.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for pendimethalin used for human risk assessment can be found at *http://www.regulations.gov* in document ''Pendimethalin: Human Health Risk and Exposure Assessment for Proposed Section 3 Registration for Use on Olive,'' dated May 28, 2009, at page 10 in docket ID number EPA–HQ–OPP–2008-0876.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to pendimethalin, EPA considered exposure under the petitioned-for tolerances as well as all existing pendimethalin tolerances in 40 CFR 180.361. EPA assessed dietary exposures from pendimethalin in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

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

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used Dietary Exposure Evaluation Model (DEEM-FCID, version 2.00), which uses food consumption data from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, the chronic dietary exposure analysis was based on the following assumptions:

a. All currently registered raw agricultural commodities (RACs) and all proposed uses on RACs have tolerance level residues of pendimethalin; and

b. All crops for which tolerances exist or are proposed were treated, i.e., 100% crop treated (CT).

In estimating residues in processed commodities EPA used empirical processing factors obtained from the processing studies, where available; maximum theoretical concentration factors of 8.0 for the processed commodities of wheat bran and wheat germ and 1.4 for wheat flour; and DEEM 7.81 default-processing factors were used for the remaining processed commodities.

iii. *Cancer*. As explained in Unit II.A., EPA has concluded that the chronic risk assessment will be protective of the precursor events that have led to cancer effects in animal studies. Therefore, a separate quantitative dietary exposure assessment to evaluate cancer risk was not conducted.

iv. *Anticipated residue and percent crop treated*. The Agency did not use anticipated residue or percent crop treated (PCT) in the dietary assessment for pendimethalin. The assumption of 100% CT and tolerance level residues was made for all registered and proposed food commodity uses of pendimethalin.

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 were estimated. Modeled estimates of drinking water were entered into the dietary exposure model. For chronic exposures for non-cancer assessments, the concentration values of pendimethalin are estimated to be 6.0 ppb for surface water and 0.036 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

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

There is a potential for short-term exposure of homeowners applying products containing pendimethalin on home lawns. There is also a potential for short-term post-application exposure of adults and children entering lawn and

recreation areas previously treated with pendimethalin. Exposures from treated recreational sites are expected to be similar to, or lower than, those from treated residential turf sites; therefore, a separate exposure assessment for recreational turf sites was not conducted. EPA assessed exposures from the following residential turf post-application scenarios:

i. Adult and toddler post-application dermal exposure from contact with treated lawns.

ii. Toddlers' incidental ingestion of pesticide residues on lawns from hand-to-mouth transfer.

iii. Toddlers' object-to-mouth transfer from mouthing of pesticide-treated turfgrass.

iv. Toddlers' incidental ingestion of soil from pesticide-treated residential areas.

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

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of 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 Web site 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 safety factor (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*. The Agency concluded there is potential for prenatal and/or postnatal toxicity (thyroid) in developing offspring resulting from exposure to pendimethalin. There was no indication of prenatal and/or postnatal qualitative or quantitative increased susceptibility in the developmental studies in rats and rabbits or the 2-generation reproduction studies in rats. However, because developmental LOAELs for thyroid toxicity could not be determined in the developmental studies, the Agency has requested developmental thyroid toxicity data, in order to determine potential thyroid toxicity following prenatal and/or postnatal exposure to pendimethalin.

3. *Conclusion*. Based on the following considerations, EPA has determined that the FQPA safety factor should be retained for the subchronic and chronic thyroid endpoints:

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

In accordance with 40 CFR part 158 toxicology data requirements, acute and subchronic neurotoxicity studies and an immunotoxicity study are required for pendimethalin. However, since there was no evidence of neurotoxic clinical signs, changes in brain weight, or histopathology of the nervous system in any study with pendimethalin, the Agency determined that an additional factor for database uncertainties is not needed to account for lack of these data. Additionally, there is no need for a developmental neurotoxicity study. In the absence of specific immunotoxicity studies, EPA has evaluated the available pendimethalin toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. There are no indications in the available studies that organs associated with immune function, such as the thymus and spleen, are affected by pendimethalin, and pendimethalin does not belong to a class of chemicals (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic.

ii. There was no indication of pendimethalin neurotoxicity in subchronic or chronic toxicity studies and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There was no indication of prenatal and/or postnatal qualitative or quantitative increased susceptibility in the developmental studies in rats and rabbits or the 2-generation reproduction studies in rats. However, the developmental studies in rats and rabbits were not adequate to determine the potential for thyroid toxicity during development. Consequently, there is concern for potential increased sensitivity or susceptibility in offspring regarding thyroid effects, and, as discussed above, a developmental thyroid toxicity study has been required.

iv. The available studies do not indicate potential immunotoxicity and pendimethalin does not belong to the class of compounds (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be toxic to the immune system. Based on the available data the immunotoxicity is not expected to provide a Point of Departure (POD) lower than that currently used for overall risk assessments. Therefore, at this time a database uncertainty factor is not needed for the lack of these studies.

v. There are no residual uncertainties identified in the exposure databases. The chronic food exposure assessments are considered to be highly conservative, as they assume that all crops registered and proposed have residues at tolerance-level. The drinking water estimates were derived from conservative screening models. The residential exposure assessment utilizes reasonable high-end variables set out in EPA's Residential Exposure SOPs (Standard Operating Procedures). The aggregate assessment is based upon reasonable high-end residential exposure assumptions, and is also not likely to under estimate exposure to any subpopulation, including those comprised of infants and children.

Although the exposure estimate is very conservative and there are no neurotoxic concerns for pendimethalin, there is sufficient uncertainty regarding thyroid effects, particularly thyroid effects in the young, that EPA is retaining the 10X FQPA safety factor for all subchronic and chronic exposures whose endpoint is based on thyroid effects. Pendimethalin has not been shown to cause acute effects. EPA has also determined that the traditional 10X uncertainty factor to account for interspecies variation may be reduced to 3X for these subchronic and chronic exposures, since it has been established that rats are more susceptible to thyroid effects than humans. These factors, together with the traditional 10X uncertainty factor to account for intraspecies variation, result in a total uncertainty factor of 300X (10X, 3X and 10X).

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. No adverse effect resulting from a single-oral exposure was identified and no acute dietary endpoint was selected. Therefore, pendimethalin is not expected to pose an acute risk.

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 15% of the cPAD for children 1 to 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 use(s) that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to pendimethalin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that the combined short-term food, water, and residential exposures result in aggregate MOEs of 650 for adult males and 580 for adult females. The aggregate exposure estimate for children results in a total MOE of 350 at an application rate (to residential turf) of 2 lbs active ingredient/Acre (ai/A), and a total MOE of 340 for an application rate of 3 lbs ai/A. As the level of concern is for MOEs that are lower than 300, 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).

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

5. *Aggregate cancer risk for U.S. population*. As explained in Unit II.A., the chronic 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

Adequate enforcement methodology, liquid chromatography/mass spectrometry (LC/MS/MS), is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are currently no established or proposed Codex or Canadian Maximum Residue Levels (MRLs) for pendimethalin. Mexico has established MRLs (expressed as pendimethalin per se) for several crops but none for olives.

V. Conclusion

Therefore, a tolerance is established for combined residues of pendimethalin, [*N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine], including its metabolites and degradates, in or on olive at 0.1 ppm. Compliance with the tolerance levels specified is to be determined by measuring only pendimethalin [*N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine] and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol expressed as the stoichiometric equivalent of pendimethalin, in or on the commodity.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 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 section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions

of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 1, 2009.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.361 is amended by revising the introductory text to paragraph (a) and adding alphabetically an entry for ''olive'' to the table in paragraph (a) to read as follows:

§ 180.361 Pendimethalin; tolerance for residues.

(a) *General.* Tolerances are established for the combined residues of pendimethalin, [*N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine], including its metabolites and degradates. Compliance with the tolerance levels specified is to be determined by measuring only pendimethalin, [*N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine] and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol expressed as the stoichiometric equivalent of pendimethalin, in or on the following raw agricultural commodities.

Commodity	Parts per million
* * * * *	
Olive	0.1
* * * * *	

* * * * *

[FR Doc. E9–21719 Filed 9–8–09; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 74

[MB Docket No. 07–172; FCC 09–59].

Amendment of Service and Eligibility Rules for FM Broadcast Translator Stations

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the information collection requirements associated with 47 CFR 74.1284, FCC Form 303–S and FCC Form 345. Therefore, this rule and forms will take effect on October 1, 2009. On September 1, 2009, the Commission published the summary document of the Report and Order, In the Matter of the Amendment of Service and Eligibility Rules for FM Broadcast Translator Stations, MB Docket No. 07–172, FCC 09–59, at 74 FR 45126. The Ordering Clause of the Report and Order stated that the Commission would publish a notice in the Federal Register announcing when OMB approval for Section 74.1284 and information collection requirements (revisions to FCC Form 303–S and 345) have been received and when the revised rule and requirements will take effect. This notice is consistent with the statement in the Report and Order.

FCC Form 349 has not received OMB approval to date. The Commission will publish a notice in the Federal Register announcing when OMB approval has been received.

DATES: The amendments to 47 CFR 74.1284, published September 1, 2009 (74 FR 45130) are effective on October 1, 2009.

FOR FURTHER INFORMATION CONTACT: Cathy Williams, cathy.williams@fcc.gov or on (202) 418–2918.

SUPPLEMENTARY INFORMATION: This document announces that, on September 1, 2009, OMB approved, for a period of three years, the information collection requirement(s) contained in Section 74.1284 of the rules and revisions to FCC Forms 303–S and 345. The Commission publishes this notice to announce the effective date of this rule and requirements. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW, Washington, DC 20554. Please include OMB Control Numbers, 3060–0075 (Form 345), 3060–0110 (Form 303–S) and 3060–0250 (Section 74.1284) in your correspondence. The Commission will also accept your comments via the Internet if you send them to PRA@fcc.gov.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e–mail to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

SYNOPSIS

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Commission is notifying the public that it received OMB approval on September 1, 2009, for the information collection requirement(s) contained in the Commission's rules at 47 CFR 74.1284 and revisions to FCC Forms 303–S and 345.

Under 5 CFR 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.