Commodity	Parts per million
Vegetable, fruiting, group 8	1.0

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[FR Doc. 2010–1609 Filed 1–26–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0876; FRL–8804–2]

Pendimethalin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues or residues of pendimethalin, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, in or on grass forage, fodder, and hay crop group 17, forage; grass forage, fodder, and hay crop group 17, hay; and grass forage, fodder, and hay crop group 17, straw. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 27, 2010. Objections and requests for hearings must be received on or before March 29, 2010, 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: Phil Errico, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6663; e-mail address: *errico.philip@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 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 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 March 29, 2010.

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. 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 8F7396) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709–3528. The petition requested that 40 CFR 180.361 be amended by establishing tolerances for combined residues of the herbicide, pendimethalin, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol, expressed as the stoichiometric equivalent of pendimethalin, in or on grass forage, fodder, and hay crop group 17, forage; grass forage, fodder, and hay crop group 17, hay; and grass forage, fodder, and hay crop group 17, straw at 40 parts per million (ppm), 80 ppm, and 4.5 ppm, respectively. That notice referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available to the public in the docket, at *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 changed the requested tolerances for the combined residues for pendimethalin and its metabolite in or on grass forage, fodder, and hay, crop group 17, forage; grass forage, fodder, and hay, crop group 17, hay; and grass forage, fodder, and hay crop group 17, straw from 40 ppm, 80 ppm, and 4.5 ppm, respectively, to 20 ppm, 13 ppm, and 4.0 ppm, respectively. EPA also changed the commodities names to reflect the regulatory names as stated in 40 CFR 180.41(c). The reason for these changes are 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 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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, on grass forage, fodder, and hay crop group 17, forage; grass forage, fodder, and hay crop group 17, hay; grass forage, fodder, and hay, crop group 17, straw at 20 ppm, 13 ppm, and 4.0 ppm, respectively. EPA's assessment of exposures and risks associated with establishing tolerances 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. The available prenatal and postnatal developmental toxicity data provided no indication of qualitative or quantitative susceptibility to the young. 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 mammaliam somatic cells and germ cells. Specific information on the studies received and the nature of the adverse effects caused by pendimethalin, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, 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* in the document titled "Pendimethalin: Human Health Risk and Exposure Assessment for Proposed Section 3 Registration for use on Grasses for Seed Production and Dormant Bermudagrass Pasture and Hay Fields," 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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, used for human risk assessment can be found at *http://www.regulations.gov* in the document titled "Pendimethalin: Human Health Risk and Exposure Assessment for Proposed Section 3 Registration for use on Grasses for Seed Production and Dormant Bermudagrass Pasture and Hay Fields," page 29 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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, EPA considered exposure under the petitioned-for tolerances as well as all existing pendimethalin, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, tolerances in (40 CFR 180.361). EPA assessed dietary exposures from pendimethalin, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, 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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the 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 its metabolite, 4-[(1-ethylpropy)amino]-2-methyl-3,5-dinitrobenzyl alcohol.

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

iii. *Cancer*. Pendimethalin is classified as a "Group C," possible human carcinogen, based on a statistically significant increase 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. Cancer risk was assessed using the same estimates as discussed in Unit III.C.1.ii., chronic exposure. 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 the following chronic exposure and the likelihood that pendimethalin may cause disruption in the thyroid, the Agency has required a developmental thyroid study to further characterize these effects. This study has not been submitted.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for pendimethalin, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pendimethalin, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pendimethalin, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine. 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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, acute exposures are estimated to be 77.7 parts per billion (ppb) for surface water and 0.036 ppb for ground water. Chronic exposures for non-cancer assessments are estimated to be 6.0 ppb for surface water and 0.036 ppb for ground water, and for chronic exposures for cancer assessments are estimated to be 4.8 ppb for surface water. Due to the tight sorption to soil, pendimethalin is not considered a cancer risk in ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model for PRZM-EXAMS concentrations.

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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, is currently registered for the following uses that could result in residential exposures: Turf grass. EPA assessed residential exposure using the following assumptions: The scenarios used were short-term in duration and consisted of dermal (for adults and children), and oral (hand-to-mouth, and soil ingestion, for children only) exposure. The level of concern for oral, dermal, and inhalation exposure is an MOE of less than 300.

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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, to share a common mechanism of toxicity with any other substances, and pendimethalin, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, 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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, 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 Food Quality Protection Act (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 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 SF 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.

Therefore, the Agency determined that an additional uncertainty factor for database uncertainties is not need to account for lack of these data.

ii. 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 a developmental thyroid toxicity study has been required.

iii. 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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, 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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine.

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 SF 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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, 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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, 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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, is not expected to exceed the MOEs of concern.

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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, 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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures aggregated 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 and 340 due to a residential exposure estimate of 0.024 mg/kg/day and 0.025 mg/kg/day when children are exposed to application rates (to residential turf) of 2 lbs ai/Acre and 3 lbs ai/Acre, respectively. The level of concern is a value less than 300, therefore 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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, 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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, 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 III.C.iii, the chronic risk assessment is considered to be protective of any cancer effects since available studies demonstrate that the thyroid tumors are due to a thyroid pituitary imbalance, and pendimethalin was shown to be non-mutagenic in mammalian somatic cells and germ cells.

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, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, using liquid chromatography/mass spectrometry analysis (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 Maximum Residue Levels (MRLs) for pendimethalin.

C. Revisions to Petitioned-For Tolerances

EPA has revised the requested tolerances to reflect the residue chemistry data submitted to support the proposed label for the use of pendimethalin on grass grown for seed and dormant Bermuda grass as requested by the petitioner. The commodity names were also changed to coincide with the regulatory Crop Group names as stated in 40 CFR 180.41(c).

V. Conclusion

Therefore, tolerances are established for combined residues of pendimethalin, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol, expressed as the stoichiometric equivalent of pendimethalin, in or on grass forage, fodder, and hay, crop group 17, forage; grass forage, fodder, and hay, crop group 17, hay; grass forage, fodder, and hay, crop group 17, straw at 20 ppm, 13 ppm, and 4.0 ppm, respectively.

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: January 19, 2010.

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
* * * * *	
Grass forage, fodder, and hay crop group 17, forage	20
Grass forage, fodder, and hay crop group 17, hay	13

Commodity	Parts per million
Grass forage, fodder, and hay crop group 17, straw	4.0

* * * * *

[FR Doc. 2010–1610 Filed 1–26–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0276; FRL–8808–6]

Triticonazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of triticonazole in or on grain, cereal, group 15, except rice, and grain, cereal, forage, fodder and straw, group 16, except rice. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 27, 2010. Objections and requests for hearings must be received on or before March 29, 2010, 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–2009–0276. 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: Tawanda Maignan, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308-8050; e-mail address: *Maignan.Tawanda@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 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 cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/oppts* and select "Test Methods & Guidelines" on the left-side navigation menu.

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–2009–0276 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 March 29, 2010.

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–2009–0276, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket 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 August 19, 2009, (74 FR 41900) (FRL–8426–7), 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 8F7420) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709-3528. The petition requested that 40 CFR 180.583 be amended by establishing tolerances for residues of the fungicide triticonazole, (1RS)-(E)-5-[(4-chlorophenyl)methylene]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol, in or on grain, cereal, group 15, except rice, and grain, cereal, forage, fodder and straw, group 16, except rice, at 0.05 and 0.10 parts per million (ppm), respectively. That notice referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available to the public 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 both the crop group terminology, and tolerance levels for