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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0247; FRL-9973-03]

Pendimethalin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the tolerances for residues of pendimethalin in or on alfalfa, forage and alfalfa, hay. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0247, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703)

305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0247 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0247, by one of the following methods:

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

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

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 1, 2014 (79 FR 44729) (FRL-9911-67), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8245) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.361 be amended by increasing the tolerances for residues of the herbicide pendimethalin, [*N*- (1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine], and its metabolite, 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol, in or on alfalfa, forage to 80 parts per million (ppm) and alfalfa, hay to 150 ppm. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket EPA-HQ-OPP-2014-0397 at *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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a

determination on aggregate exposure for pendimethalin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pendimethalin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The target organ for pendimethalin is the thyroid. Thyroid toxicity in chronic and subchronic rat and mouse studies was manifested as alterations in thyroid hormones (decreased total T4 and T3, increased percent of free T4 and T3), increased thyroid weight, and microscopic thyroid lesions (including increased thyroid follicular cell height, follicular cell hyperplasia, as well as follicular cell adenomas). Due to these effects, the Agency required that a developmental thyroid assay be conducted to evaluate the impact of pendimethalin on thyroid hormones, structure, and/or thyroid hormone homeostasis during development. A developmental thyroid study was submitted and demonstrated that there is no potential thyroid toxicity following pre- and/or post-natal exposure to pendimethalin.

There is no evidence that pendimethalin is a developmental, reproductive, neurotoxic, or immunotoxic chemical. There is no evidence of increased qualitative or quantitative susceptibility in the young. EPA classified pendimethalin 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, reference dose (RfD) approach) was used to assess cancer risk since mode-of-action studies are available to demonstrate that the

thyroid tumors are due to a thyroid-pituitary imbalance, and also since pendimethalin was shown to be non-mutagenic in mammalian somatic cells and germ cells.

Specific information on the studies received and the nature of the adverse effects caused by pendimethalin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of December 21, 2015 (80 FR 79267) (FRL-9937-18).

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides*.

A summary of the toxicological endpoints for pendimethalin used for human risk assessment is shown in Table 1 of this unit.

Table 1. Summary of Toxicological Doses and Endpoints for Pendimethalin for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	NOAEL = 100 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 1 mg/kg/day aPAD = 1 mg/kg/day	Acute neurotoxicity study LOAEL = 300 mg/kg/day based on reduced motor activity for males and females on Day 0.
Chronic dietary (All populations)	NOAEL= 10 mg/kg/day UF_A = 3x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.3 mg/kg/day cPAD = 0.3 mg/kg/day	92- Day thyroid function study in rats; 56- day thyroid study in rats; 14- day intra thyroid metabolism study in rats. LOAEL = 31 mg/kg/day based on hormonal and histopathological changes in the thyroid.
Incidental oral short-term (1 to 30 days)	NOAEL= 10 mg/kg/day UF_A = 3x UF_H = 10x FQPA SF = 1x	LOC for MOE = 30	92- Day thyroid function study in rats; 56- day thyroid study in rats; 14- day intra thyroid metabolism study in rats. LOAEL = 31 mg/kg/day based on hormonal and histopathological changes in the thyroid.
Dermal short-term (1 to 30 days)	Dermal (or oral) study NOAEL = 10 mg/kg/day (dermal absorption rate = 3%	LOC for MOE = 30	92- Day thyroid function study in rats; 56- day thyroid study in rats; 14- day intra

	UF_A = 3x UF_H = 10x FQPA SF = 1x		thyroid metabolism study in rats. LOAEL = 31 mg/kg/day based on hormonal and histopathological changes in the thyroid.
Dermal intermediate-term (1 to 6 months)	Dermal (or oral) study NOAEL = 10 mg/kg/day (dermal absorption rate = 3% UF_A = 3x UF_H = 10x FQPA SF = 1x	LOC for MOE = 30	92- Day thyroid function study in rats; 56- day thyroid study in rats; 14- day intra thyroid metabolism study in rats. LOAEL = 31 mg/kg/day based on hormonal and histopathological changes in the thyroid.
Inhalation short-term (1 to 30 days)	Inhalation (or oral) study NOAEL= 10 mg/kg/day (inhalation absorption rate = 100%) UF_A = 3x UF_H = 10x FQPA SF = 1x	LOC for MOE = 30	92- Day thyroid function study in rats; 56- day thyroid study in rats; 14- day intra thyroid metabolism study in rats. LOAEL = 31 mg/kg/day based on hormonal and histopathological changes in the thyroid.
Inhalation (1 to 6 months)	Inhalation (or oral) study NOAEL= 10 mg/kg/day (inhalation absorption rate = 100%) UF_A = 3x UF_H = 10x FQPA SF = 1x	LOC for MOE = 30	92- Day thyroid function study in rats; 56- day thyroid study in rats; 14- day intra thyroid metabolism study in rats. LOAEL = 31 mg/kg/day based on hormonal and histopathological changes in the

			thyroid.
Cancer (Oral, dermal, inhalation)	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. The chronic RfD will be protective of cancer effects.		

FQPA SF = Food Quality Protection Act Safety Factor. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. LOAEL = lowest observed adverse effect level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment.

C. Exposure Assessment

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

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

Such effects were identified for pendimethalin. In estimating acute dietary exposure, EPA Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16. This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What

We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA used tolerance-level residues, and 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID, Version 3.16 software with 2003-2008 food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA used tolerance-level residues, and 100 PCT for all commodities.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to pendimethalin. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., chronic exposure.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for pendimethalin. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. In drinking water, the residue of concern is pendimethalin, parent only. 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide*.

Based on the Pesticide Root Zone Model Ground Water (PRZM GW) and Surface Water Concentration Calculator (SWCC) models, the estimated drinking water concentrations (EDWCs) of pendimethalin for acute exposures are estimated to be 96.4 parts per billion (ppb) for surface water and 4.38×10^{-9} ppb for ground water. For chronic exposures for non-cancer assessments, they are estimated to be 9.73 ppb for surface water.

For acute dietary risk assessment, the water concentration value of 96.4 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 9.73 ppb was used to assess the contribution to drinking water.

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

Pendimethalin is currently registered for the following uses that could result in residential exposures: turf, home gardens, and ornamentals. EPA assessed residential exposure using the following assumptions:

• For handlers, it is assumed that residential use will result in short-term (1 to 30 days) duration dermal and inhalation exposures.

• Residential post-application exposure is also assumed to be short-term (1-30 days) in duration, resulting from the following exposure scenarios:

• Gardening: Adults (dermal) and children 6<11 years old (dermal);

• Physical activities on turf: Adults (dermal) and children 1-2 years old (dermal and incidental oral);

• Mowing turf: Adults (dermal) and children 11<16 years old (dermal); and

• Exposure to golf courses during golfing: Adults (dermal), children 11<16 years old (dermal), and children 6<11 years old (dermal).

EPA did not combine exposure resulting from adult handler and post-application exposure resulting from treated gardens, lawns, and/or golfing because the conservative assumptions and inputs within each estimated exposure scenario would result in an overestimate of adult exposure. EPA selected the most conservative adult residential scenario (adult dermal post-application exposure from gardening) as the contributing source of

residential exposure to be combined with the dietary exposure for the aggregate assessment. The children's oral exposure is based on post-application hand-to-mouth exposures. To include exposure from object-to-mouth and soil ingestion in addition to hand-to-mouth would overestimate the potential for oral exposure. However, there is the potential for co-occurrence of dermal and oral exposure, since the toxicological effects from the dermal and oral routes of exposure are the same. As a result, the children's aggregate assessment combines post-application dermal and oral exposure along with dietary exposure from food and water. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found pendimethalin to share a common mechanism of toxicity with any other substances, and pendimethalin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pendimethalin does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

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*. There was no indication of pre- and/or post-natal qualitative or quantitative increased susceptibility in the developmental studies in rats and rabbits or the 2-generation reproduction studies in rats. A developmental thyroid toxicity study demonstrated that there is no potential thyroid toxicity following pre- and/or post-natal exposure to pendimethalin.

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

i. The toxicity database for pendimethalin is complete. Although a subchronic inhalation study was not available in the database, EPA determined that one is not needed at this time based on a weight-of-evidence analysis, considering the following: (1) all relevant hazard and exposure information, which indicates its low acute inhalation toxicity; (2) its physical/chemical properties, which indicate its low volatility; and (3) the use of an oral POD that results in a residential inhalation margin of exposure (MOE) more than 10X the level of concern (in the case of pendimethalin MOE = 30 based on thyroid POD).

ii. There is no indication that pendimethalin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that pendimethalin results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. In addition, a developmental thyroid toxicity study demonstrated that there is no potential thyroid toxicity following pre- and/or post-natal exposure to pendimethalin.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pendimethalin in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by pendimethalin.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pendimethalin will occupy 2% of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pendimethalin from food and water will utilize 2.4% of the cPAD for children one to two years old the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of pendimethalin is not expected.

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

Pendimethalin is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to pendimethalin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 130 for adults and 92 for children 1-2 years old, the two population subgroups receiving the greatest combined dietary and non-dietary exposure. Because EPA's level of concern for pendimethalin is a MOE of 30 or below, these MOEs are not of concern.

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

An intermediate-term adverse effect was identified; however, pendimethalin is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is

at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for pendimethalin**.**

5. *Aggregate cancer risk for U.S. population*. As discussed in Unit III.A., EPA has determined that an RfD approach based on the chronic point of departure is appropriate for evaluating cancer risk. As there are not chronic aggregate risks of concern, there are no cancer aggregate risk concerns.

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, gas chromatography with electron capture detection (GC/ECD), 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; email address: *residuemethods@epa.gov*.

B. International Residue Limits

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

international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are currently no established Codex MRLs for the residues of pendimethalin on alfalfa hay, although Codex has established an MRL for residues of pendimethalin in alfalfa fodder (which is equivalent to the US commodity of alfalfa forage) at 4 ppm. Harmonization is not possible because use of the Codex MRL would result in residues of pendimethalin exceeding tolerances in the U.S. as a result of use in accordance with the approved label.

V. Conclusion

Therefore, tolerances are established for plant residues by measuring only the sum of pendimethalin, [*N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine], and its metabolite, 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol calculated as the stoichiometric equivalent of pendimethalin, in or on alfalfa, forage at 80 ppm and alfalfa, hay at 150 ppm. In addition, the Agency is revising the tolerance expression for paragraph (a)(1) to clarify that the residues of the parent compound are to be summed with the residues of the metabolite in order to determine compliance with the tolerance. This revision does not substantively change the existing language; the current language already requires measurement of both residues. The insertion of the words "the sum" just provides a small clarification for measuring residues to determine compliance with the tolerance.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and

Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action 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); Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances 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 action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with

Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

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

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: January 30, 2018.

Daniel J. Rosenblatt,
Acting 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. In § 180.361:

a. Revise the introductory text of paragraph (a)(1).

b. Revise the entries for "Alfalfa, forage"; and "Alfalfa, hay" in the table in paragraph (a)(1).

The revisions read as follows:

§ 180.361 Pendimethalin; tolerances for residues.

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

Commodity	Parts per million
Alfalfa, forage	80
Alfalfa, hay	150
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