Commodity	Parts per million
Wheat, straw	0.2

[1] There are no U.S. registrations for banana (whole) as of September 22, 1993.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

■ 25. Section 180.491 is amended by revising the tables in paragraphs (a)(1) and (a)(2) to read as follows:

§180.491 Propylene oxide; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Cacao bean, dried bean	200
Cacao bean, cocoa powder	200
Fig	3.0
Garlic, dried	300
Grape, raisin	1.0
Herbs and spices, group 19, dried	300
Nut, tree, group 14	300
Onion, dried	300
Plum, prune, dried	2.0

(2) * * *

Commodity	Parts per million
Basil, dried leaves	6000
Cacao bean, dried bean	20.0
Cacao bean, cocoa powder	20.0
Fig	3.0
Garlic, dried	6000
Grape, raisin	4.0
Herbs and spices, group 19, dried, except basil	1500
Nut, tree, group 14	10.0
Onion, dried	6000
Plum, prune, dried	2.0

* * * * *

■ 26. Section 180.523 is revised to read as follows:

§180.523 Metaldehyde; tolerances for residues.

(a) *General.* Tolerances are established for residues of the molluscicide metaldehyde in or on food commodities, as follows:

Commodity	Parts per million
Artichoke, globe	0.07
Berry group 13	0.15
Cactus	0.07
Fruit, citrus, group 10	0.26
Lettuce	1.73
Strawberry	6.25
Tomato	0.24
Vegetable, brassica, leafy, group 5	2.5
Watercress	3.2

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

■ 27. Section 180.540 is revised to read as follows:

§180.540 Fenitrothion; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide fenitrothion, *O,O*-dimethyl *O*-(4-nitro-*m*-tolyl) phosphorothioate, from the postharvest application of the insecticide to stored wheat in Australia, in or on the following food commodity:

Commodity	Parts per million
Wheat, gluten[1]	3.0

[1] There are no U.S. registrations on food commodities since 1987.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. E8–22078 Filed 9–23–08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0405; FRL–8368–8]

Pendimethalin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes 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, in or on crayfish at 0.05 parts per million (ppm), and cotton gin byproducts at 3.0 ppm. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 24, 2008. Objections and requests for hearings must be received on or before November 24, 2008, 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–2008–0405. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Jim Tompkins, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to 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 an electronic copy of this **Federal Register** document through the electronic docket 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 pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2008–0405 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 24, 2008.

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–2008–0405, 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'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 June 13, 2008 (73 FR 33814) (FRL–8367–3), 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 6F7098) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. 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, in or on crayfish at 0.05 ppm, and cotton byproducts at 3.0 ppm. 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*. No comments were received on 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 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 the raw agricultural commodity crayfish at 0.05 ppm, and cotton byproducts at 3.0 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 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. The thyroid is a target organ for pendimethalin in chronic studies. 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).

The data provided no indication of increased susceptibility following pre-/postnatal exposure in the two-generation reproduction study in rats. Pendimethalin is classified as a ''Group C'', possible human carcinogen, chemical based on a statistically significant increased trend and pair-wise comparison between the high dose group and controls for thyroid follicular cell adenomas in male and female rats. A non-quantitative cancer risk assessment approach is being followed since mode of action studies are available that demonstrate that the thyroid tumors are due to a thyroid-pituitary imbalance, and also since pendimethalin was shown to be non-mutagenic in mammalian somatic cells and germ cells. The chronic risk assessment is considered to be protective of any cancer effects.

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 chemical name used for human risk assessment is shown in the table of this unit.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR 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, FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Point of Departure	Dose Used in Risk Assessment, UF	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–49) (General U.S population)	NA	NA	NA	No appropriate acute endpoint identified for these groups. There were no toxic effects attributable to a single dose.
Chronic Dietary (All populations)	NOAEL = 10 mg/kg/day Chronic RfD = 0.03 mg/kg/day	UF_H = 10X UF_A = 3X UF_{DB} = 10X Total UF = 300X	Chronic RfD = 0.03 mg/kg/day cPAD = Chronic÷RfD cPAD = 0.03 mg/kg/day	92–day thyroid function study in rats; 56–day thyroid study in rats; 14–day intra thyroid metabolism study in rats. LOAEL = 31 mg/kg/day based on hormonal and histopathological changes in the thyroid.
Incidental Oral Short-Term (1–30 days) Intermediate-Term (1–6 months)	NOAEL = 10 mg/kg/day	UF_H = 10X UF_A = 3X UF_{DB} = 10X Total UF = 300X	Residential LOC = 300	92–day thyroid function study in rats; 56–day thyroid study in rats; 14–day intra thyroid metabolism study in rats. LOAEL = 31 mg/kg/day based on hormonal and histopathological changes in the thyroid.
Dermal Short-Term (1–30 days) Intermediate-Term (1–6 months) Long-Term (> 6 months)	NOAEL = 10 mg/kg/day	UF_H = 10X UF_A = 3X UF_{DB} = 10X Total UF = 300X Dermal Absorption = 3%	Residential LOC = 300	92–day thyroid function study in rats; 56–day thyroid study in rats; 14–day intra thyroid metabolism study in rats. LOAEL = 31 mg/kg/day based on hormonal and histopathological changes in the thyroid.
Inhalation Short-Term (1–30 days) Intermediate-Term (1–6 months) Long-Term (> 6 months)	NOAEL = 10 mg/kg/day	UF_H = 10X UF_A = 3X UF_{DB} = 10X Total UF = 300X Inhalation toxicity is assumed to be equivalent to oral toxicity.	Residential LOC = 300	92–day thyroid function study in rats; 56–day thyroid study in rats; 14–day intra thyroid metabolism study in rats. LOAEL = 31 mg/kg/day based on hormonal and histopathological changes in the thyroid.
Cancer (Oral, dermal, inhalation)	Pendimethalin is classified as a Group C possible human carcinogen. The chronic dietary assessment using the cPAD is considered to be protective of cancer effects.			2–year chronic/carcinogenicity study in rats.

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_{DB} = to account for the absence of key data (i.e., lack of a critical study). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to the herbicide pendimethalin, and its metabolite (CL 202347), EPA considered exposure under the petitioned-for tolerances as well as all existing tolerances for the herbicide pendimethalin, and its metabolite (CL 202347) in 40 CFR 180.361. EPA assessed dietary exposures from the herbicide pendimethalin, and its metabolite (CL 202347) 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 the herbicide pendimethalin, and its metabolite (CL 202347); therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment of the dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity (CSFII, 1994–1996, and 1998). Tolerance-level residues were assumed for all food commodities with current and proposed pendimethalin tolerances, and it was assumed that all of the crops included in the analysis were treated (i.e., 100 percent crop treated (PCT)). These assumptions result in highly conservative estimates of dietary exposure and risk.

iii. *Cancer.* Pendimethalin is classified as a ''Group C'' possible human carcinogen, chemical based on a statistically significant increased trend and pair-wise comparison between the high dose group and controls for thyroid follicular cell adenomas in male and female rats. A non-quantitative approach (i.e., non-linear, RfD approach) was used by the Agency since mode of action studies are available that demonstrate that the thyroid tumors are due to a thyroid-pituitary imbalance, and also since pendimethalin was shown to be non-mutagenic in mammalian somatic cells and germ cells. The cPAD from the 92–day thyroid function study in rats; 56–day thyroid study in rats; 14–day intra thyroid metabolism study in rats used for the chronic dietary assessment provide adequate protection for the pre-cancerous effect on the thyroid.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for the herbicide pendimethalin. 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 in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of the herbicide 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, drinking water concentrations (EDWCs) of the herbicide pendimethalin were estimated.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 77.7 parts per billion (ppb) was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 6 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 residential non-dietary sites: Landscape, grounds plantings, ornamental crops, turf grass, and lawns. EPA assessed residential exposure using the following assumptions: Exposures are short-term in duration, and consist of dermal (for adults and children), and oral (hand-to-mouth, object-to-mouth, and soil ingestion, for children only). The Agency combines risk values resulting from separate exposure scenarios when it is likely they can occur simultaneously, based on the use-pattern and the behavior associated with the exposed population. The LOC for oral, dermal and inhalation exposure is an MOE of less than 300. The residential exposure estimate for adults, consisting of dermal exposure only, results in a total MOE of 740, and is therefore not of concern. The residential exposure for children results in a total MOE (dermal + oral) of 410 at an application rate of 2 lb ai/acre, and an MOE of 400 for an application rate of 3 lb ai/acre. Residential aggregate exposure is not of concern.

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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pendimethalin and any other substances and pendimethalin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pendimethalin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

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 data base for pendimethalin does not indicate a potential for increased toxicological sensitivity from either prenatal or postnatal exposures. No

developmental toxicity was observed in either the rat or rabbit developmental toxicity studies, nor was there evidence in the 2–generation reproduction study of developmental or reproductive toxicity at dose levels below those in which parental toxicity was observed. There was no neurotoxicity observed in the submitted toxicity studies, and therefore a developmental neurotoxicity (DNT) study is not required.

3. *Conclusion*. EPA has determined that the FQPA safety factor of 10X must be retained. This decision is based on the following findings:

i. The toxicity database for pendimethalin contains all of the standard toxicity studies. However, there is uncertainty regarding potential thyroid effects seen in some of these studies. 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.

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. However, the developmental studies were not adequate to fully assess the potential for susceptibility. Consequently, there is concern for potential increased sensitivity or susceptibility in offspring regarding thyroid effects.

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. Conservative ground and surface water modeling estimates were used. Similarly, conservative Residential SOPs were used 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.

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. EPA has also determined that the traditional 10X uncertainty factor to account for interspecies variation may be reduced to 3X, 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*. No toxic effects attributable to a single dose were identified for pendimethalin. Therefore, a quantitative acute risk assessment was not conducted for pendimethalin.

2. *Chronic risk*. The dietary exposure (food and drinking water) pathway is the only source of exposure to pendimethalin that is expected to be of long term (180 to 365 days). Therefore, the long-term aggregate exposure and risk estimates are equivalent to the chronic dietary exposure and risk estimates.

Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to the herbicide pendimethalin from food and water will utilize 15% of the cPAD for (children 1–2 years of age) 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 the herbicide 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).

The herbicide 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 the herbicide 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 aggregated result in aggregate MOEs of the level of concern for oral, dermal, and inhalation exposure is an MOE of less than 300. The short-term aggregate exposure estimate for adult males results in an aggregate MOE of 650, while the short-term aggregate exposure estimate for adult females results in an aggregate MOE of 580. The aggregate exposure estimate for children results in a total MOE of 350 at an application rate (to residential turf) of 2 lbs ai/A, and a total MOE of 340 for an application rate of 3 lbs ai/A. Aggregate exposure is therefore not of concern for any of the population subgroups.

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).

The herbicide 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 the herbicide 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*. 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. EPA is following a non-quantitative approach since mode of action studies are available that demonstrate that the thyroid tumors are due to a thyroid-pituitary imbalance, and also since pendimethalin was shown to be non-mutagenic in mammalian somatic cells and germ cells. The chronic risk assessment is considered to be protective of any

cancer effects; therefore, a separate quantitative cancer aggregate risk assessment was not conducted.

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 the herbicide pendimethalin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate methods are available for data collection and tolerance enforcement for existing and proposed uses of pendimethalin. Methods I through IV in the Pesticide Analytical Manuel (PAM) Vol. II are gas chromatography/electron capture (GC/ECD) methods. Methods used for data collection are essentially the same as the PAM Vol. II methods, and have been adequately validated.

The Food and Drug Administration's PESTDATA data base (PAM Volume I, Appendix I) indicates that pendimethalin is completely recovered (>80%) by Multiresidue Methods Section 302 (Luke Method; Protocol D) and 303 (Mills, Onley, Gaither Method; Protocol E, nonfatty), and partially recovered (50–80%) by Multiresidue Method Section 304 (Mills Fatty Food Method; Protocol E, fatty).

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 no established or proposed Codex Maxium Residue Levels (MRLs) for pendimethalin residues. Therefore, there are no questions of compatibility with respect to Codex MRLs and U.S. tolerances.

C. Revisions to Petitioned-For Tolerances

Based on the submitted data, residues of pendimethalin in rice processed commodities are not expected to exceed those found in rice grain. Therefore, a tolerance for rice processing fraction at 0.1 ppm is not necessary.

V. Conclusion

Therefore, tolerances are established for combined residues of the herbicide pendimethalin, N-(1-ethylpropyl)-3,4-dimethyl-2,6- dinitro-benzenamine, and its metabolite, 4-[(1-ethylpropyl) amino]-2-methyl-3,5-dinitrobenzyl alcohol, in or on cotton, gin byproducts at 3.0 ppm, and crayfish at 0.05 ppm.

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 9, 2008.

Donald R. Stubbs,

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. Section 180.361 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.361 Pendimethalin, tolerance for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Cotton, gin byproducts ...	3.0
* * *	* *
Crayfish	0.05
* * *	* *

* * * * *

[FR Doc. E8–22434 Filed 9–23–08; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0337; FRL–8382–5]

Cyfluthrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes, revises, or deletes tolerances for residues of cyfluthrin in or on numerous raw agricultural commodities. It also establishes tolerances for residues of beta-cyfluthrin in or on all commodities for which cyfluthrin tolerances exist. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 24, 2008. Objections and requests for hearings must be received on or before November 24, 2008, 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–2007–0337. 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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 pilot e-CFR site 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–2007–0337 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 24, 2008.

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–2007–0337, 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 July 30, 2008 (73 FR 44264) (FRL–8375–1), 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 7F7200) by Bayer CropScience, 2 T.W. Alexander Dr., P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.436 be amended by:

- Establishing tolerances for residues of the insecticide, cyfluthrin, cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate, in or on food commodities barley, grain; buckwheat, grain; millet, grain; oat, grain; rye, grain; triticale, grain; and wheat, grain at 0.15 part per million (ppm); corn, field, grain; corn, pop, grain; and teosinte, grain at 0.05 ppm; sorghum, grain at 3.5 ppm; grain, cereal, forage, fodder and hay, group 16, forage, except rice at 25 ppm; grain, cereal, forage, fodder and hay, group 16, hay, except rice at 6.0 ppm; grain, cereal, forage, fodder and hay, group 16, stover, except rice at 30 ppm; and grain, cereal, forage, fodder and hay, group 16, straw, except rice at 7.0 ppm.