

Commodity	Parts per million
Poultry, meat byproducts	0.05
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Soybean, seed	2.5
Spinach	6.0
Sweet Potato, roots	0.05

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(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for residues of the herbicide, fluzafop-P-butyl,

butyl(R)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, and the free and conjugated forms of the resolved isomer of fluzafop, (R)-2-[4-

[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, expressed as fluzafop, in or on the following commodities:

Commodity	Parts per million
Asparagus	3.0
Coffee, bean	0.1
Pepper, tabasco	1.0
Rhubarb	0.5

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0065; FRL-8400-4]

Propoxycarbazone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of propoxycarbazone and its Pr-2-OH metabolite in or on grass, forage and grass, hay. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 4, 2009. Objections and requests for hearings must be received on or May 4, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0065. 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: Joanne I. Miller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6224; e-mail address: miller.joanne@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be

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

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

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gpo/opptsfrs/home/guidelin.htm>.

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-2008-0065 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 May 4, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2008-0065, 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 February 6, 2008 (73 FR 6964) (FRL-8350-9), 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 7F7304) by Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.600 be amended by establishing tolerances for combined residues of the herbicide propoxycarbazone, 2-[[[(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]benzoate in or on grass, forage and grass, hay at 20 parts per million (ppm) and 25 ppm and to amend the tolerances in 40 CFR 180.600 by increasing the established tolerances for residues of the herbicide propoxycarbazone, methyl 2-[[[(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]benzoate (Pr-2-OH MKH-6561) in or on the food commodities cattle, goat, horse, sheep

meat from 0.05 ppm to 0.1 ppm; meat byproducts from 0.3 ppm to 1.0 ppm; and milk from 0.03 ppm to 0.05 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available to the public in the docket, <http://www.regulations.gov>.

Based upon review of the data supporting the petition, EPA recalculated a maximum reasonable dietary burden (MRDB) for cattle that is lower than used previously. No changes are required in the established tolerances for milk or livestock commodities for this petition.

Comments were received on the notice of filing. EPA's response to these comments is discussed 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 propoxycarbazone and its Pr-2-OH metabolite on grass, forage and grass, hay at 20 ppm and 25 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.

Propoxycarbazone has low acute toxicity via the oral, dermal, and inhalation routes. It is not an eye or dermal irritant or a dermal sensitizer. No toxicity was seen at the limit dose in a 28-day dermal toxicity study in rats. The main target organ appears to be the gastrointestinal (GI) tract (gastric irritation), with irritation observed in the 2-generation reproduction toxicity study in rats, developmental toxicity study in rabbits, and the 90-day feeding study in rats. In the 64-day and 1-year toxicity studies in dogs, no toxicity was observed at doses $\geq 1,181$ milligram/kilogram/day (mg/kg/day) and, ≥ 605 mg/kg/day, respectively. Increased incidence of gastric irritation was observed at a very high-dose (limit dose) in a 90-day feeding study in rats. In a combined chronic toxicity/carcinogenicity study in rats, decreased body weight, increased urinary pH and histopathological changes in the kidney, indicate the kidney as the target organ. An effect on body weight was evident in both subchronic and chronic toxicity studies in mice.

There was no evidence of neurotoxicity in any study. No quantitative or qualitative evidence of increased susceptibility was seen following *in utero* exposure to rats or rabbits in developmental toxicity studies. No quantitative or qualitative evidence of increased susceptibility was seen following the prenatal or postnatal exposure to rats in a 2-generation reproduction toxicity study in rats. No evidence of carcinogenicity was observed in a carcinogenicity study in mice at doses up to the limit dose. In a chronic toxicity/carcinogenicity study in rats, there was an increase in the incidence of mononuclear cell leukemia (MNCL) in mid- and high-dose males; however, EPA concluded that MNCL was not treatment-related. Propoxycarbazone has been classified as "not likely to be carcinogenic to human" based on lack of carcinogenicity in mice and rats and negative findings in various mutagenicity assays.

Specific information on the studies received and the nature of the adverse effects caused by propoxycarbazone 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 document *Propoxycarbazone-sodium; Human-*

Health Risk Assessment for Proposed Section 3 New Use on Pasture and Rangeland Grasses at page 12 in docket ID number EPA-HQ-OPP-2008-0065 and in the **Federal Register** of July 7, 2004 (69 FR 40774) (FRL-7365-7).

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 (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 effect 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-term, intermediate-term, 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 propoxycarbazine used for human risk assessment can be found at <http://www.regulations.gov> in document *Propoxycarbazine-sodium; Human-Health Risk Assessment* for Proposed Section 3 New Use on Pasture and Rangeland Grasses at page 12 in docket ID number EPA-HQ-OPP-2008-0065 and in the **Federal Register** of July 7, 2004 (69 FR 40774) (FRL-7365-7).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to propoxycarbazine, EPA considered exposure under the petitioned-for tolerances as well as all existing propoxycarbazine tolerances in (40 CFR 180.600). EPA assessed dietary exposures from propoxycarbazine 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 propoxycarbazine; 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, EPA assumed that tolerance-level residues were for all food commodities at current or proposed propoxycarbazine tolerances, and that 100% of the crops included in the analysis were treated.

iii. *Cancer.* The Agency has determined that propoxycarbazine is "not likely to be carcinogenic to humans" based on the lack of evidence of carcinogenicity in mice and rats and no mutagenicity concerns. Therefore, a quantitative exposure assessment to evaluate cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for propoxycarbazine. Tolerance level residues and/or 100% crop treated (CT) 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 propoxycarbazine in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of propoxycarbazine. 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 First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of propoxycarbazine for chronic exposures

for non-cancer assessments are estimated to be 1.79 parts per billion (ppb) for surface water and 0.36 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 1.79 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).

Propoxycarbazine is not registered for any specific use patterns that would result in residential exposure.

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 propoxycarbazine to share a common mechanism of toxicity with any other substances, and propoxycarbazine does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that propoxycarbazine 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 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 is no evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure to propoxycarbazone. In the rat developmental toxicity study, no developmental or maternal toxicity was observed at doses up to 1,000 mg/kg/day (limit dose). In the developmental toxicity study in rabbits, developmental effects (abortion, post-implantation loss) were seen at a higher dose (limit dose) than the maternally toxic dose. There is no qualitative and/or quantitative evidence of increased susceptibility to propoxycarbazone following prenatal or postnatal exposure in a 2-generation reproduction study in rats. Although propoxycarbazone caused increased post implantation loss and decreased live litter size in the F2 litters at a dose level of 1,230.7–1,605.3 mg/kg/day, EPA did not consider this as evidence for increased susceptibility since it occurred in the presence of severe maternal toxicity (histopathological lesions in the stomach) and only at doses above the limit dose.

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 propoxycarbazone is complete, except for immunotoxicity testing. EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement went into effect well after the tolerance petition was submitted, these studies are not yet available for propoxycarbazone. In the absence of specific immunotoxicity studies, EPA has evaluated the available propoxycarbazone toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. There was no evidence of adverse effects on the organs of the immune system in any study with propoxycarbazone. In addition, propoxycarbazone 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. Based on these considerations, EPA does not believe that conducting a special series (Harmonized Guideline 870.7800) immunotoxicity study will result in a point of departure less than the NOAEL of 74.8 mg/kg/day used in calculating the cPAD for propoxycarbazone; therefore, an additional database uncertainty factor is not needed to account for potential immunotoxicity.

ii. There is no indication that propoxycarbazone 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 propoxycarbazone 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.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to propoxycarbazone in drinking water. These assessments will not underestimate the exposure and risks posed by propoxycarbazone.

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-term, intermediate-term, 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, propoxycarbazone 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 propoxycarbazone from food and water will utilize less than 1% of the cPAD for (children 1 to 2 years old) the population group receiving the greatest exposure. There are no residential uses for propoxycarbazone.

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).

Propoxycarbazone is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to propoxycarbazone through food and water and will not be greater than the chronic aggregate risk.

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).

Propoxycarbazone 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 propoxycarbazone 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. Propoxycarbazone is classified as “not likely to be a carcinogenic to humans” based on the lack of evidence of carcinogenicity in mice and rats and no mutagenicity concerns. Therefore, propoxycarbazone is not expected to pose a cancer risk to humans.

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 Propoxycarbazone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology—liquid chromatography with tandem mass spectrometry detection (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 Codex, Canadian or Mexican maximum residue limits established for propoxycarbazone.

C. Response to Comments

Public comments were received from B. Sachau who objected to the proposed tolerances because of the amounts of pesticides already consumed and carried by the American population. She further indicated that testing

conducted on animals have absolutely no validity and are cruel to the test animals. B. Sachau's comments contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to propoxycarbazone, including all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has responded to B. Sachau's generalized comments on numerous previous occasions. January 7, 2005, (70 FR 1349)(FRL-7691-4); October 29, 2004, (69 FR 63083) (FRL-7681-9).

V. Conclusion

Therefore, tolerances are established for combined residues of propoxycarbazone, methyl 2-[[[(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl] benzoate and its Pr-2-OH metabolite, methyl 2-[[[(4,5-dihydro-3-(2-hydroxypropoxy)-4-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl] benzoate in or on grass, forage and grass, hay at 20 ppm and 25 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.

February 12, 2009.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.600 is amended by adding alphabetically the following commodities to the table in paragraph (a)(1) to read as follows:

§ 180.600 Propoxycarbazone: tolerance for residue.

(a) * * * (1) * * *

Commodity	Parts per million
Grass, forage	20
Grass, hay	25
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[FR Doc. E9-4352 Filed 3-3-09; 8:45 am]

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