combusted, the nitrogen oxides emission limit is 215 ng/J (0.5 lb/million Btu).

(2) *Emission monitoring for nitrogen oxides.* (i) The nitrogen oxides emissions shall be determined by the compliance and performance test methods and procedures for nitrogen oxides in § 60.46b.

(ii) The monitoring of the nitrogen oxides emissions shall be performed in accordance with § 60.48b.

(3) *Reporting and recordkeeping requirements.* (i) The owner or operator of the No. 2 Power Boiler shall submit a report on any excursions from the limits required by paragraph (x)(2) of this section to the Administrator with the quarterly report required by § 60.49b(i).

(ii) The owner or operator of the No. 2 Power Boiler shall keep records of the monitoring required by paragraph (x)(3) of this section for a period of 2 years following the date of such record.

(iii) The owner or operator of the No. 2 Power Boiler shall perform all the applicable reporting and recordkeeping requirements of § 60.49b.

[FR Doc. 04–15204 Filed 7–6–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0172; FRL–7365–7]

Propoxycarbazone-sodium; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of propoxycarbazone-sodium and its metabolite in or on meat, meat byproducts, wheat and milk. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective July 7, 2004. Objections and requests for hearings must be received on or before September 7, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket ID number OPP–2004–0172. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 Bell Street, Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Joanne I. Miller, Registration Division (7505C), 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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides 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 and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. The OPPTS Harmonized Test Guidelines referenced in this document are avaiable at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of August 21, 2002 (67 FR 54188) (FRL–7195–2), 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 0F6094) by Bayer Corporation, 8400 Hawthorn Road, Kansas City MO, 64120–0013. That notice included a summary of the petition prepared by Bayer Corporation, the registrant. There were no comments received in response to the notice of filing. The company name and address were subsequently changed to Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709.

The petition requested that 40 CFR 180 be amended by establishing tolerances for residues of the herbicide, propoxycarbazone-sodium, methyl 2-[[[(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]benzoate, sodium salt and its metabolite, methyl 2-[[[(4,5-dihydro-4-methyl-5-oxo-3-(2′-hydroxy-propoxy)-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]benzoate, in or on the raw agricultural commodities (RACs) wheat forage, wheat hay, wheat straw, wheat grain, meat, and meat byproducts, (cattle, sheep, goats, horses, hogs), and milk at 1.5, 0.15, 0.05, 0.01, 0.05, and 0.002 parts per million (ppm); respectively. Bayer CropScience subsequently amended the petition by requesting that 40 CFR 180 be amended establishing 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, sodium salt and its 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 Wheat, forage at 1.5 ppm, Wheat, hay at 0.15 ppm, Wheat, straw at 0.05 ppm, and Wheat, grain at 0.02 ppm and 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 in or on the Meat of cattle, sheep, goat and horse at 0.05 ppm, Meat byproducts of cattle, sheep, goat and horse at 0.05 ppm and Milk at 0.004 ppm.

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 * * *.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for tolerances for combined residues of propoxycarbazone-sodium and its metabolite on Wheat, forage at 1.5 ppm, Wheat, hay at 0.15 ppm, Wheat, straw at 0.05 ppm, and Wheat, grain at 0.02 ppm and for residues of propoxycarbazone-sodium in or on the Meat of cattle, sheep, goat and horse at 0.05 ppm, Meat byproducts of cattle, sheep, goat and horse at 0.05 ppm and Milk at 0.004 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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 nature of the toxic effects caused by propoxycarbazone-sodium are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity—rodents (rat)	NOAEL = 286.4 males (M) and 350.6 females (F) milligrams/kilogram/day (mg/kg/day) LOAEL = 1507.5 (M) and 1769.9 (F) mg/kg/day based on gastric irritation
870.3100	90–Day oral toxicity—rodents (mouse)	NOAEL = 205 (M) and 1159 (F) mg/kg/day LOAEL = 860 (M) and 5109 (F) mg/kg/day based on decreased body weight, body weight gain and food efficiency
870.3150	64–Day oral toxicity—nonrodents (dog)(range-finding)	NOAEL = 1,407 (M) and 1,181 (F) mg/kg/day Highest Dose Tested (HTD) LOAEL not determined
870.3200	21/28–Day dermal toxicity	NOAEL = 1,000 mg/kg/day (HTD) LOAEL not determined
870.3700	Prenatal developmental—rodents (rat)	Maternal NOAEL equal or greater than (≥) 1,000 mg/kg/day (HTD) Maternal LOAEL not determined Developmental NOAEL ≥ 1,000 mg/kg/day (HTD) Developmental LOAEL not determined
870.3700	Prenatal developmental—nonrodents (rabbit)	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = 500 mg/kg/day based on reduced body weight gain and food consumption, GI toxicity and decreased water consumption and urination Developmental NOAEL = 500 mg/kg/day Developmental LOAEL = 1,000 mg/kg/day based on an abortion, decrease in mean fetal weights, and elevated pre- and post-implantation loss.
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 74.8–79.6 (M) and 373.5–413.5 (F) mg/kg/day Parental/Systemic LOAEL = 297.1–322.9 (M) and 1605.3–1907.5 (F) mg/kg/day based on microscopic lesions of the stomach. Reproductive NOAEL = 1230.7–1313.9 (M) and 373.5–413.5 (F) mg/kg/day Reproductive LOAEL = 1605.3–1907.5 (F) mg/kg/day based on increased in diestrous/metestrous Offspring NOAEL = 297.1–322.9 (M) and 373.5–413.5 (F) mg/kg/day Offspring LOAEL = 1230.7–1313.9 (M) and 1605.3–1907.5 (F) mg/kg/day based on increased postimplantation loss and decreased live litter size in the F_2 litters

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.4100	Chronic toxicity—dogs	NOAEL = 630.7 mg/kg/day LOAEL > 630.7 mg/kg/day
870.4300	Combined chronic toxicity carcinogenicity - rodents (rats)	NOAEL = 43 (M) and 49 (F) mg/kg/day LOAEL = 459 (M) and 525 (F) mg/kg/day based on decreased body weight and increased urinary pH (preceding histological changes in the kidney of rats in the mid- and high-dose groups such as: Foci of mineralization of pelvis, dilated and cystic renal tubules filled with proteinaceous material, regenerative tubular epithelium, glomerular and interstitial fibrosis, and hyperplasia of the pelvic epithelium). No evidence of carcinogenicity
870.4300	Carcinogenicity—mice	NOAEL = 369.0 (M) mg/kg/day and 3,106.1 (F) mg/kg/day (HTD) LOAEL = 1,880.9 (M) mg/kg/day based on decreased body weight gain combined with lower food efficiency. No evidence of carcinogenicity
870.5100	Gene mutation—Ames	Negative
870.5100	Gene mutation—Ames	Negative
870.5100	Gene mutation—Ames	Negative
870.5300	Gene mutation—*In vitro* Chinese hamster V79-HPRT	Negative
870.5375	Cytogenetics—*In vitro* Chinese hamster	Negative
870.5375	Cytogenetics—*In vitro* Chinese hamster	Negative
870.5395	Cytogenetics—Hsd/Win: NMRI mouse bone marrow micronucleus	Negative
870.5550	Other effects—UDS	Negative
870.6200	Acute neurotoxicity screening battery	NOAEL = 2,000 (M) and 800 (F) mg/kg (HDT) LOAEL = 2,000 (F) mg/kg/day based on decrease in body weight gains
870.6200	Subchronic neurotoxicity screening battery	NOAEL ≥ 1,321 (M) and 1,651 (F) mg/kg/day (HDT) LOAEL not established
870.7485	Metabolism and pharmacokinetics	Based on the amount of radiolabel recovered in the urine, 23–26% of the radiolabeled test material was absorbed by the males, with females absorbing slightly more (~31%). Absorption in male rats that received 200 mg/kg was ~21%. Radiolabel position did not influence absorption. Plasma T_{max} was rapid, being ~0.33 hours regardless of radiolabel position in rats that received 2 mg/kg and ~0.81 hours in rats that received 200 mg/kg. No bioaccumulation or tissue reservoirs were found; this result confirmed by whole body autoradiography. Plasma clearance was biphasic and rapid, with a $T_{\frac{1}{2}}$ for the first phase of ~1.1 hours for the compound labeled in the triazol position and ~0.6 hours for the compound labeled in the phenyl position, regardless of dose. No radiolabel effects were noted in the second phase plasma $T_{\frac{1}{2}}$ which was ~11 hours at 2 and 200 mg/kg of test material. Plasma area under the curve (AUC) was 3.6 µg/mL•hour for rats that received 2 mg/kg radiolabeled propoxycarbazone-sodium and ~ 45 times greater (169 µg/mL•hour) in rats that received 200 mg/kg. The radiolabeled test material was primarily eliminated unchanged in the urine and feces (~75–88% of the administered dose), with essentially none eliminated by the lungs. Of the absorbed radiolabeled test material, ~90% was excreted into the urine while the remaining was recovered from the bile. However, radiolabel position influenced the metabolic products. Two minor metabolites that contributed <2% of the administered radiolabel were identified in the urine, MKH 7284 and MKH 7283, of rats dosed with propoxycarbazone-sodium labeled in the phenyl position. No metabolites were found in the urine of rats that received propoxycarbazone-sodium labeled in the triazol position. One metabolite, STJ 4934, was recovered in the feces of rats that received propoxycarbazone-sodium labeled in the phenyl position and accounted for 2–9% of the fecal radioactivity. The primary fecal metabolite found from rats treated with the triazol-labeled test material was identified as MKH 7017 and accounted for ~3% of the recovered radioactivity. The metabolite Pr-2-OH MKH 6561, a product of wheat metabolism, was essentially not found in the urine or feces of treated rats.

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for propoxycarbazone-sodium used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PROPOXYCARBAZONE-SODIUM FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary	An endpoint of concern attributable to a single dose (exposure) was not identified from the available studies. An acute RfD was not established		
Chronic dietary (all populations)	NOAEL= 74.8 mg/kg/day UF = 100X Chronic RfD = 0.748 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD ÷ Special FQPA SF = 0.748 mg/kg/day	Two-generation reproduction study in rats LOAEL = 297.1 mg/kg/day based on microscopic lesions of the stomach in parental male rats
Cancer (oral, dermal, inhalation)	Not likely to be a carcinogen for humans based on the lack of carcinogenicity in a rat carcinogenicity study, an mouse carcinogenicity study and a battery of mutagenic studies.		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have not been previously established (40 CFR 180) for the residues of propoxycarbazone-sodium in or on raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from propoxycarbazone-sodium in food as follows:

i. *Acute exposure.* Acute dietary 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.

An effect of concern attributable to a single exposure (dose) was not identified from the oral toxicity studies including the developmental toxicity studies in rat and rabbits. Abortions seen in the developmental toxicity study in rabbits at 1,000 mg/kg/day during GD 19–28, were not considered to be a single dose effect. Since they occur late in gestation after repeated exposures.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-

FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: For the chronic analyses, tolerance-level residues were assumed for all food commodities with current or proposed propoxycarbazone-sodium tolerances, and it was assumed that all of the crops included in the analysis were treated. Percent Crop Treated (PCT) and/or anticipated residues were not used in the chronic risk assessment.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for propoxycarbazone-sodium in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of propoxycarbazone-sodium.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in ground water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health LOC.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to propoxycarbazone-sodium they are further discussed in the aggregate risk sections in Unit E.

Based on the FIRST and SCI-GROW models, the EECs of propoxycarbazone-sodium for acute exposures are estimated to be 2.3 parts per billion (ppb) for surface water and 0.4 ppb for ground water. The EECs for chronic exposures are estimated to be 0.9 ppb for surface water and 0.4 ppb for ground water.

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

Propoxycarbazone-sodium is not registered for use on any sites 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 does not have, at this time, available data to determine whether propoxycarbazone-sodium has a common mechanism of toxicity with other substances. 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 propoxycarbazone-sodium and any other substances and propoxycarbazone-sodium 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 propoxycarbazone-sodium 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 OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Conclusion*. The toxicology database is complete for FQPA purposes and there are no residual uncertainties for pre-/post-natal toxicity. Based on the quality of the exposure data, EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is removed based on the following:

(i) There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to in utero exposure to propoxycarbazone-sodium in developmental toxicity studies. There is no quantitative or qualitative evidence of increased susceptibility to propoxycarbazone-sodium following pre-/post-natal exposure to a 2–generation reproduction study.

(ii) There is no concern for developmental neurotoxicity resulting from exposure to propoxycarbazone-sodium. A developmental neurotoxicity study (DNT) study is not required.

(iii) The toxicological database is complete for FQPA assessment.

(iv) The chronic dietary food exposure assessment utilizes HED-recommended tolerance level residues and 100% CT information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.

(v) The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. An effect of concern attributable to a single exposure (dose) was not identified from the oral toxicity studies including the developmental toxicity studies in rat and rabbits. No acute risk is expected from exposure to propoxycarbazone-sodium.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to propoxycarbazone-sodium from food will utilize < 1% of the cPAD for the U.S. population, < 1% of the cPAD for all infant subpopulations, and < 1% of the cPAD for all children subpopulations. There are no residential uses for propoxycarbazone-sodium that result in chronic residential exposure to propoxycarbazone-sodium. In addition, there is potential for chronic dietary exposure to propoxycarbazone-sodium in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PROPOXYCARBAZONE-SODIUM

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.748	< 1%	0.9	0.4	26,200
All infants (< 1 year old)	0.748	< 1%	0.9	0.4	7,480
Children (1–2) years old	0.748	< 1%	0.9	0.4	7,480
Females (13–49 years old)	0.748	< 1%	0.9	0.4	22,400

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

Propoxycarbazone-sodium is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

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

Propoxycarbazone-sodium is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

5. *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, and to infants and children from aggregate exposure to propoxycarbazone-sodium residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography/mass spectroscopy) 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-sodium on wheat, meat, meat byproducts or milk.

V. Conclusion

Therefore, the tolerance is 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, sodium salt and its 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 wheat, forage at 1.5 ppm, wheat, hay at 0.15 ppm, wheat, straw at 0.05 ppm, and wheat, grain at 0.02 ppm and 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 in or on the meat of cattle, sheep, goat and horse at 0.05 ppm, meat byproducts of cattle, sheep, goat and horse at 0.05 ppm and milk at 0.004 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0172 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 on or before September 7, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099, 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0172, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: June 24, 2004.

James Jones,

Director, 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 added to read as follows:

§ 180.600 Propoxycarbazone; tolerances for residues

(a) *General.* (1) Tolerances are established for combined 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 and its 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/on the following raw agricultural commodities:

Commodity	Parts per million
Wheat, forage	1.5
Wheat, grain	0.02
Wheat, hay	0.15
Wheat, straw	0.05

(2) Tolerances are established 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 in/on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Goat, meat	0.05
Goat, meat byproducts	0.05
Horse, meat	0.05
Horse, meat byproducts	0.05
Milk	0.004
Sheep, meat	0.05
Sheep, meat byproducts	0.05

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

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

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

[FR Doc. 04–15210 Filed 7–6–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0190; FRL–7364–4]

Sulfuric Acid; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of sulfuric acid (CAS Reg. No. 7664–93–9) when used as an inert ingredient. Magna Bon Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, requesting an exemption from the requirement of a tolerance. This