EPA APPROVED LOUISIANA REGULATIONS IN THE LOUISIANA SIP

State citation	Title/subject	State approval date	EPA date approval	Comments
*	*	*	*	*
Chapter 21—Control of Emissions of Organic Compounds				
*	*	*	*	*
Table 8	Untitled [List of Synthetic Organic Chemicals].	Dec. 1987, LR13:741	05/05/94, 59 FR 2311666	Ref 52.999(c)(49) and (60). Table approved at (c)(49) included CAS numbers. Table approved at (c)(60) did not include CAS numbers.
Chapter 22—Control of Emissions of Nitrogen Oxides (NO_X)				
Section 2201—Affected Facilities in the Baton Rouge Nonattainment Area and the Region of Influence				
Subsection A	Applicability	Feb. 27, 2002 July 25, 2002.	September 27, 2002 and FR cite	
Subsection B	Definitions	Feb. 27, 2002 July 25, 2002.	September 27, 2002 and FR cite	
Subsection C	Exemptions	Feb. 27, 2002 July 25, 2002.	September 27, 2002 and FR cite	
Subsection D	Emission Factors	Feb. 27, 2002 July 25, 2002.	September 27, 2002 and FR cite	Cutoff size for lean burn engines lowered to 320 Hp on July 25, 2002, for the ozone nonattainment parishes. Cutoff size for lean burn engines in the Region of Influence is 1500 Hp.
Subsection E	Alternative Plans	Feb. 27, 2002 July 25, 2002.	September 27, 2002 and FR cite	
Subsection F	Permits	Feb. 27, 2002 July 25, 2002.	September 27, 2002 and FR cite	
Subsection G	Initial Demonstration of Compliance.	Feb. 27, 2002 July 25, 2002.	September 27, 2002 and FR cite	
Subsection H	Continuous Demonstration of Compliance.	Feb. 27, 2002 July 25, 2002.	September 27, 2002 and FR cite	
Subsection I	Notification, Record-keeping, and Reporting Requirements.	Feb. 27, 2002 July 25, 2002.	September 27, 2002 and FR cite	
Subsection J	Effective Dates	Feb. 27, 2002 July 25, 2002.	September 27, 2002 and FR cite	
Chapter 23—Control of Emissions From Specific Industries				
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0225; FRL–7200–7]

Pyraclostrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester and its desmethoxy metabolite methyl 2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl carbamate, expressed as parent compound, in or on almond, hulls and various other fruits and vegetables and agricultural products, and combined residues of pyraclostrobin, carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester and its metabolites convertible to 1-(4-chlorophenyl)-1H-pyrazol-3-ol and 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazol-3-ol, expressed as parent compound, in or on cattle, fat and various other animal products. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0225, must be received on or before November 26, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0225 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7740; e-mail address: *giles-parker.cynthia@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet home page at *http://www.epa.gov/*. To access this document, on the home page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

2. *In person*. The Agency has established an official record for this action under docket ID number OPP–2002–0225. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of May 23, 2001 (66 FR 28470) (FRL–6780–7), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 0F6139) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709–3528. This notice included a summary of the petition prepared by BASF Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.582 be amended by establishing tolerances for combined residues of the fungicide pyraclostrobin, (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl 2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl carbamate), expressed as parent compound, in or on almond, hulls at 1.6 parts per million (ppm); banana at 0.04 ppm; barley, grain at 0.4 ppm; barley, hay at 25 ppm; barley, straw at 6.0 ppm; bean, dry at 0.3 ppm; beet, sugar, dried pulp at 1.0 ppm; beet, sugar, roots at 0.2 ppm; beet, sugar, tops at 8.0 ppm; berry, group at 1.3 ppm; citrus, dried pulp at 5.5 ppm; citrus, oil at 4.0 ppm; fruit, citrus, group at 0.7 ppm; fruit, stone, group at 0.9 ppm; grain, aspirated fractions at 2.5 ppm; grape at 2.0 ppm; grape, raisin at 7.0 ppm; grass, forage at 10 ppm; grass, hay at 4.5 ppm; grass, seed screenings at 27 ppm; grass, straw at 14 ppm; nut, tree, group at 0.04 ppm; peanut, nutmeat at 0.05 ppm; peanut, refined oil at 0.1 ppm; pistachio at 0.7 ppm; radish, tops at 16 ppm; rye, grain at 0.04 ppm; rye, straw at 0.5 ppm; strawberry at 0.4 ppm; vegetable, bulb, group at 0.9 ppm; vegetable, cucurbit, group at 0.5 ppm; vegetable, fruiting, group at 1.4 ppm; vegetable, root, except sugar beet, subgroup at 0.4 ppm; vegetable, tuberous and corm, subgroup at 0.04 ppm; wheat, grain at 0.2 ppm; wheat, hay at 6.0 ppm; and wheat, straw] at 8.5 ppm, and combined residues of pyraclostrobin, (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its metabolites convertible to 1-(4-chlorophenyl)-1H-pyrazol-3-ol and 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazol-3-ol, expressed as parent compound, in or on cattle, fat at 0.1 ppm; cattle, liver at 1.5 ppm; cattle, meat at 0.1 ppm; cattle, meat byproducts, except liver at 0.2 ppm; goat, fat at 0.1 ppm; goat, liver at 1.5 ppm; goat, meat at 0.1 ppm; goat, meat byproducts, except liver at 0.2 ppm; hog, fat at 0.1 ppm; hog, liver at 1.5 ppm; hog, meat at 0.1 ppm; hog, meat byproducts, except liver at 0.2 ppm; horse, fat at 0.1 ppm; horse, liver at 1.5 ppm; horse, meat at 0.1 ppm; horse, meat byproducts, except liver at 0.2 ppm; milk at 0.1 ppm; sheep, fat at 0.1 ppm; sheep, liver at 1.5 ppm; sheep, meat at 0.1 ppm; and sheep, meat byproducts, except liver at 0.2 ppm.

Section 408(b)(2)(A)(i) of the 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) 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) 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 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), 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), for the establishment of tolerances for combined residues of pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl 2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl carbamate), expressed as parent compound in or on almond, hulls at 1.6 ppm; banana at 0.04 ppm; barley, grain at 0.4 ppm; barley, hay at 25 ppm; barley, straw at 6.0 ppm; bean, dry at 0.3 ppm; beet, sugar, dried pulp at 1.0 ppm; beet, sugar, roots at 0.2 ppm; beet, sugar, tops at 8.0 ppm; berry, group at 1.3 ppm; citrus, dried pulp at 5.5 ppm; citrus, oil at 4.0 ppm; fruit, citrus, group at 0.7 ppm; fruit, stone, group at 0.9 ppm; grain, aspirated fractions at 2.5 ppm; grape at 2.0 ppm; grape, raisin at 7.0 ppm; grass, forage at 10 ppm; grass, hay at 4.5 ppm; grass, seed screenings at 27 ppm; grass, straw at 14 ppm; nut, tree, group at 0.04 ppm; peanut, nutmeat at 0.05 ppm; peanut, refined oil at 0.1 ppm; pistachio at 0.7 ppm; radish, tops at 16 ppm; rye, grain at 0.04 ppm; rye, straw at 0.5 ppm; strawberry at 0.4 ppm; vegetable, bulb, group at 0.9 ppm; vegetable, cucurbit, group at 0.5 ppm; vegetable, fruiting, group at 1.4 ppm; vegetable, root, except sugar beet, subgroup at 0.4 ppm; vegetable, tuberous and corm, subgroup at 0.04 ppm; wheat, grain at 0.2 ppm; wheat, hay at 6.0 ppm; and wheat, straw] at 8.5 ppm, and combined residues of pyraclostrobin, (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its metabolites convertible to 1-(4-chlorophenyl)-1H-pyrazol-3-ol and 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazol-3-ol, expressed as parent compound], in or on [cattle, fat at 0.1 ppm; cattle, liver at 1.5 ppm; cattle, meat at 0.1 ppm; cattle, meat byproducts, except liver at 0.2 ppm; goat, fat at 0.1 ppm; goat, liver at 1.5 ppm; goat, meat at 0.1 ppm; goat, meat byproducts, except liver at 0.2 ppm; hog, fat at 0.1 ppm; hog, liver at 1.5 ppm; hog, meat at 0.1 ppm; hog, meat byproducts, except liver at 0.2 ppm; horse, fat at 0.1 ppm; horse, liver at 1.5 ppm; horse, meat at 0.1 ppm; horse, meat byproducts, except liver at 0.2 ppm; milk at 0.1 ppm; sheep, fat at 0.1 ppm; sheep, liver at 1.5 ppm; sheep, meat at 0.1 ppm; and sheep, meat byproducts, except liver at 0.2 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 acute toxicity of pyraclostrobin is presented in the following table 1:

TABLE 1.—ACUTE TOXICITY OF PYRACLOSTROBIN

Guideline Number	Study Type	Results/Toxicity Catergory
870.1100	Acute oral toxicity	LD_{50} = > 5,000 milligrams per kilogram (mg/kg) Toxicity category = IV
870.1200	Acute dermal toxicity	LD_{50} = > 2,000 mg/kg; toxicity category = III
870.1300	Acute inhalation toxicity	LC_{50} = < 0.31 milligrams per liter (mg/L) LC_{50} = < 1.07 mg/L; toxicity category = II
870.2400	Acute eye irritation	Minimal eye irritation; toxicity category = III
870.2500	Acute dermal irritation	Moderate skin irritation; toxicity ccategory = III
870.2600	Skin sensitization	Not a sensitizer

The subchronic and chronic toxic effects caused by pyraclostrobin, as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed, are discussed in the following Table 2.

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY OF PYRACLOSTROBIN

Guideline Number	Study Type	Study Classification; Dosing	Results
Number guideline number	28–day feeding study - rat	Acceptable/nonguideline; 0, 20, 100, 500, or 1,500 ppm (0, 1.8, 9.0, 42.3, or 120.2 mg/kg/day in males; 0, 2.0, 9.6, 46.6, or 126.3 mg/kg/day in females	The LOAEL = 500 ppm for both males and females, based on changes in hematology parameters, increased absolute and relative spleen weight, histopathology in spleen and liver, and increased duodenal mucosal hyperplasia The NOAEL = 100 ppm for both sexes
870.3100	13–week feeding study - rat	Acceptable/guideline; 0, 50, 150, 500, 1,000, or 1,500 ppm (0, 3.5, 10.7, 34.7, 68.8, or 105.8 mg/kg/day for males; 0, 4.2, 12.6, 40.8, 79.7, or 118.9 mg/kg/day for females)	The LOAEL for both sexes = 500 ppm, based on reduced body weight and body weight gain in males, reduced food intake in both sexes, increased relative liver weight and spleen weight in females, histopathology of duodenum and liver in males, and histopathology of spleen in both sexes The NOAEL = 150 ppm for both sexes
870.3150	13–week feeding study - dog	Acceptable/guideline; 0, 100, 200, and 450 ppm (0, 2.8, 5.8, and 12.9 mg/kg/day for males; 0, 3.0, 6.2, and 13.6 mg/kg/day for females)	The LOAEL for both males and females = 450 ppm, based on an increased incidence of diarrhea, clinical chemistry changes, and mucosal hypertrophy of the duodenum in both sexes; and body weight loss, decreased food intake, and decreased food efficiency in females The NOAEL = 200 ppm for both sexes
870.3150	13–week feeding study - mouse	Acceptable/guideline; 0, 50, 150, 500, 1,000, or 1,500 ppm (0, 9.2, 30.4, 119.4, 274.4, or 475.5 mg/kg/day for males; 0, 12.9, 40.4, 162.0, 374.1, or 634.8 mg/kg/day for females)	The LOAEL = 150 ppm for both sexes, based on reduced body weight and body weight gain in males; changes in clinical chemistry (increased urea and decreased triglyceride) in both sexes; and increased incidences of lymph node apoptosis, thymus atrophy, and ulceration/erosionin the glandular stomach in females The NOAEL = 50 ppm for both sexes
870.3200	28–day dermal toxicity - rat	Unacceptable/guideline; 0, 40, 100, or 250 mg/kg for 5 days/week	The LOAEL was > 250 mg/kg The NOAEL = 250 mg/kg The study is unacceptable because a higher dose could have been tolerated and the limit dose is 1,000 mg/kg/day
870.3700	Prenatal developmental toxicity study in rodents - rat	Acceptable/guideline; 0, 10, 25 or 50 mg/kg/day	The Maternal LOAEL = 25 mg/kg/day, based on reduced body weight, reduced body weight gain, reduced food intake, and reduced food efficiency Maternal NOAEL = 10 mg/kg/day The Developmental LOAEL = 50 mg/kg/day, based on increased incidences of dilated renal pelvis and cervical ribs with no cartilage The Developmental NOAEL = 25 mg/kg/day

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY OF PYRACLOSTROBIN—Continued

Guideline Number	Study Type	Study Classification; Dosing	Results
870.3700	Prenatal developmental toxicity study in nonrodents - rabbit	Acceptable/guideline; 0, 1, 3, 5, 10, or 20 mg/kg/day	The maternal LOAEL = 10 mg/kg/day, based on reduced body weight gain, reduced food consumption, and reduced food efficiency The maternal NOAEL = 5 mg/kg/day The developmental LOAEL = 10 mg/kg/day, based on increased resorptions/litter, increased post- implantation loss, and dams with total resorptions The Developmental NOAEL was 5 mg/kg/day
870.3800	2-generation reproduction and fertility effects - rat	Unacceptable/guideline; 0, 25, 75, or 300 ppm (0 to 29.0 mg/kg/day for F0 males; 0 to 30.4 mg/kg/day F0 females; 0 to 35.0 mg/kg/day for F1 males; 0 to 36.0 mg/kg/day for F1 females)	The parental systemic, reproductive, and offspring LOAELs were all > 300 ppmThe parental systemic, reproductive, and offspring NOAELs all = 300 ppm. The study is unacceptable because higher doses could be tolerated
870.4100	1–year feeding study - dog	Acceptable/guideline; 0, 100, 200, or 400 ppm (0, 2.7, 5.4, or 10.8 mg/kg/day in males; 0, 2.7, 5.4, or 11.2 mg/kg/day in females)	The LOAEL = 400 ppm for both sexes, based on increased diarrhea in both sexes, clinical chemistry changes in both sexes, decreased body weight gain in females, and decreased food intake and food efficiency in females The NOAEL = 200 ppm for both sexes
870.4200	18–month carcinogenicity - mouse	Unacceptable/guideline; 0, 10, 30, or 120 ppm in males (0, 1.4, 4.1, and 17.2 mg/kg/day); 0, 10, 30, 120, or 180 ppm in females (0, 1.6, 4.8, 20.5, or 32.8 mg/kg/day); 97.09% pure a.i.	The LOAEL was > 120 ppm for males and > 180 ppm for females, because no clearly and significantly dose-related adverse effects were observed. There were no increased incidences of tumors; under the conditions of the study, there was no evidence of carcinogenic potential. However, the study is considered to be unacceptable because the maximum dosing levels were too low to satisfy the requirements for a carcinogenicity study in mice

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY OF PYRACLOSTROBIN—Continued

Guideline Number	Study Type	Study Classification; Dosing	Results
870.4200	24–Month carcinogenicity - rat	Acceptable/guideline; 0, 25, 75, or 200 ppm (0, 1.2, 3.4, 9.2 mg/kg/day for males and 0, 1.5, 4.7, and 12.6 mg/kg/day for females)	The LOAEL = 200 ppm for both males and females, based on decreases in body weight and body weight gains in males and females; increased incidence of kidney tubular casts and atrophy in males and females; and increased incidence of necrosis of the liver, gross and microscopic evidence of erosion/ulceration of the glandular stomach, and increased incidence of acanthosis and ulcers of the forestomach in males. The NOAEL = 75 ppm for both males and females. As to carcinogenicity, histiocytic sarcoma and lymphoma of the hemolymphoreticular system was observed in males at 25, 75, and 200 ppm, as well as in controls. There was an increase in incidence of mammary gland adenocarcinoma in females at 200 ppm, compared to controls. Testicular leydig cell tumors were observed in all male groups, but had a slightly higher incidence in each treated group than in controls. Under the conditions of this study there is evidence that pyraclostrobin may be carcinogenic
870.4100	24–Month chronic toxicity - rats	Unacceptable/guideline; 0, 25, 75, or 200 ppm (0, 1.1, 3.4, or 9.0 mg/kg/day in males; 0, 1.5, 4.6, or 12.3 mg/kg/day in females)	The LOAEL was > 200 ppm The NOAEL = 200 ppm. The study is unacceptable because a higher dose could have been tolerated
870.5100	Gene mutation: Bacterial reverse mutation	Acceptable/guideline; 0 to 5,000 micrograms (µg)/plate tested up to precipitating concentrations	Negative. There was no evidence of treatment-induced mutant colonies above background levels in any assay, including in the presence or absence of an Aroclor 1,254-stimulated rat liver metabolic activation system or using the preincubation test
870.5300	Other genotoxic effect mammalian cells in culture gene mutation assay	Acceptable/guideline; (see test summary in results)	Negative. Chinese hamster ovary (CHO) cells were cultured *in vitro.* They were exposed to pyraclostrobin at concentrations of 0.625, 1.25, 2.5, 5.0, 10.0, and 20.0 µg/ml in the presence and absence of metabolic activation; concentrations of 3, 4, 5, 6, 7, and 8 µg/mL in the absence of metabolic activation; and concentrations of 1.25, 2.5, 5.0, 10.0, and 20.0 µg/mL in the presence and absence of metabolic activation. There was no evidence of induced mutant colonies over background

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY OF PYRACLOSTROBIN—Continued

Guideline Number	Study Type	Study Classification; Dosing	Results
870.5375	*In vitro* mammalian chromosome aberrations	Acceptable/guideline; (see test summary in results)	Negative. Chinese hamster V79 cell cultures were tested at concentrations of 0, 6.25, 12.5, or 25.0 micrograms per milliliter (μg/mL) in the presence and absence of an Aroclor 1,254-stimulated rat liver metabolic activation system; at 0, 3.125, 6.25, or 12.5 μg/mL in the presence of metabolic activation; and at 0, 0.005, 0.010, 0.050, or 0.100 μg/mL in the absence of metabolic activation. There was no evidence of an increase in the number of structural or numerical chromosomal aberrations induced over background
870.5395	*In vivo* mammalian cytogenetics	Acceptable/guideline; 0, 75, 150, or 300 mg/kg body weight	Negative. Mouse bone marrow micronucleus was assayed *in vitro.* There was no significant increase in the frequency of micronucleated polychromatic erythrocyte in the bone marrow at any dose level tested, at any time after treatment. It is therefore concluded that pyraclostrobin did not induce a clastogenic effect in either sex at any sacrifice time
870.5550	Unscheduled DNA syntheses	Acceptable/guideline; (see test summary in results)	Negative. Primary rat hepatocyte cultures were exposed to pyraclostrobin at up to cytotoxic concentrations: in one test at concentrations of 0.01, 0.03, 0.1, 0.3, or 1.0 μg/mL and in a second test at 0.004, 0.02, and 0.5 μg/mL. There was no evidence that pyraclostrobin induced unscheduled DNA synthesis, as determined by net nuclear silver grain counts
870.6100	Acute oral neurotoxicity - rat	Acceptable/guideline; single doses of 0, 100, 300, or 1,000 mg/kg before sacrifice after 14 days	The Systemic Toxicity LOAEL for males was 1,000 mg/kg body weight, based on 33% decreased body weight on days 0-7 (no similar effect was detected on days 0-14). The systemic toxicity NOAEL for males was 300 mg/kg body weight. The systemic toxicity LOAEL for females could not be determined since there were no adverse, treatment-related effects. Thus, the systemic toxicity NOAEL for females was 1,000 mg/kg body weight. The neurotoxicity LOAEL could not be determined because there were no treatment-related neurotoxic effects at any dose level tested. The neurotoxicity NOAEL was 1,000 mg/kg body weight

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY OF PYRACLOSTROBIN—Continued

Guideline Number	Study Type	Study Classification; Dosing	Results
870.6200	Subchronic neurotoxicity - rats	Acceptable/guideline; 0, 50, 250, or 750 (males)/1,500 (females) ppm (0, 3.5, 16.9, or 49.9 mg/kg/day for males and 0, 4.0, 20.4, or 111.9 mg/kg/day for females) for 3 months	Systemic toxicity: The LOAEL was 750 ppm for males and 1,500 ppm for females, based (for both sexes) on decreased body weight gain, decreased food intake, and decreased food efficiency. The NOAEL was 250 ppm for both males and females. Neurotoxicity: The LOAEL could not be determined because there were no treatment-related neurotoxic effects noted at any dose level. Therefore, the NOAEL was 750 ppm for males and 1,500 ppm for females
870.7600	Dermal penetration - rats	Unacceptable/guideline; 0.375 mg/cm^2	The absorption rate could not be accurately determined because at 8 hours after dermal exposure initiation 76.4% of the administered dose remained on the dressing and only 23.6% was available for absorption. However, a conservative upper bound dermal absorption rate estimate of 14% can be calculated from the study results

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 lowest dose at which adverse effects of concern are identified (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. That is the case in the pyraclostrobin risk assessment.

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 the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, 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 FQPA 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 is expressed as 1 X 10^{-6} or one in a million). 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 pyraclostrobin used for human risk assessment is shown in the following Table 3:

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYRACLOSTROBIN FOR USE IN HUMAN RISK ASSESSMENT*

Exposure Scenario	Dose used in Risk Assessment UF	FQPA SF and Endpoint for Risk Assessment	Study; Toxicological Endpoint
Acute dietary (general population)	NOAEL = 300 mg/kg/day UF = 100 Acute RfD = 3 mg/kg/day	Acute RfD = 3 mg/kg/day FQPA SF = 1X aPAD = 3 mg/kg/day	Rat acute oral neurotoxicity; the systemic toxicity NOAEL of 300 mg/kg based on decreased body weight gain in males at 1,000 mg/kg (the LOAEL)

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYRACLOSTROBIN FOR USE IN HUMAN RISK ASSESSMENT*—Continued

Exposure Scenario	Dose used in Risk Assessment UF	FQPA SF and Endpoint for Risk Assessment	Study; Toxicological Endpoint
Acute dietary (females 13-50 years)	NOAEL = 5 mg/kg/day UF = 100 Acute RfD = 0.05 mg/kg/day	Acute RfD = 0.05 mg/kg/day FQPA SF = 3x aPAD = 0.017 mg/kg/day	Rabbit prenatal developmental toxicity; developmental toxicity findings of increased resorptions/litter and increased total resorptions (i.e., dams with complete litter loss) at 10 mg/kg/day (the LOAEL)
Chronic dietary	NOAEL = 3.4 mg/kg/day UF = 100 Chronic RfD = 0.034 mg/kg/day	Chronic RfD = 0.034 mg/kg/day FQPA SF = 3x cPAD = 0.011 mg/kg/day	Rat oral carcinogenicity; decreased body weight and body weight gain, kidney tubular casts and atrophy in both sexes, increased incidence of liver necrosis and erosion and ulceration of the glandular stomach and forestomach in males in addition to hemolymphoreticular tumors in males and mammary adenocarcinoma in females at 9.2 mg/kg/day (the LOAEL)

* The reference to the FQPA SF refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances are being established (40 CFR 180.582) for the residues of pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and one or more of its metabolites, expressed as parent compound], in or on a variety of raw agricultural commodities. These tolerances include almond, hulls at 1.6 ppm; Banana at 0.04 ppm; barley, grain at 0.4 ppm; barley, hay at 25 ppm; barley, straw at 6.0 ppm; bean, dry at 0.3 ppm; beet, sugar, dried pulp at 1.0 ppm; beet, sugar, roots at 0.2 ppm; beet, sugar, tops at 8.0 ppm; berry, group at 1.3 ppm; cattle, fat at 0.1 ppm; cattle, liver at 1.5 ppm; cattle, meat at 0.1 ppm; cattle, meat byproducts, except liver at 0.2 ppm; citrus, dried pulp at 5.5 ppm; citrus, oil at 4.0 ppm; fruit, citrus, group at 0.7 ppm; fruit, stone, group at 0.9 ppm; goat, fat at 0.1 ppm; goat, liver at 1.5 ppm; goat, meat at 0.1 ppm; goat, meat byproducts, except liver at 0.2 ppm; grain, aspirated fractions at 2.5 ppm; grape at 2.0 ppm; grape, raisin at 7.0 ppm; grass, forage at 10 ppm; grass, hay at 4.5 ppm; grass, seed screenings at 27 ppm; grass, straw at 14 ppm; hog, fat at 0.1 ppm; hog, liver at 1.5 ppm; hog, meat at 0.1 ppm; hog, meat byproducts, except liver at 0.2 ppm; horse, fat at 0.1 ppm; horse, liver at 1.5 ppm; horse, meat at 0.1 ppm; horse, meat byproducts, except liver at 0.2 ppm; milk at 0.1 ppm; nut, tree, group at 0.04 ppm; peanut, nutmeat at 0.05 ppm; peanut, refined oil at 0.1 ppm; pistachio at 0.7 ppm; radish, tops at 16 ppm; rye, grain at 0.04 ppm; rye, straw at 0.5 ppm; sheep, fat at 0.1 ppm; sheep, liver at 1.5 ppm; sheep, meat at 0.1 ppm; sheep, meat byproducts, except liver at 0.2 ppm; strawberry at 0.4 ppm; vegetable, bulb, group at 0.9 ppm; vegetable, cucurbit, group at 0.5 ppm; vegetable, fruiting, group at 1.4 ppm; vegetable, root, except sugar beet, subgroup at 0.4 ppm; vegetable, tuberous and corm, subgroup at 0.04 ppm; wheat, grain at 0.2 ppm; wheat, hay at 6.0 ppm; and wheat, straw at 8.5 ppm. Risk assessments were conducted by EPA to assess dietary exposures from pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester)] 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. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following determinations and assumptions were made for the acute exposure assessments: The aPAD for the subgroup females (13-50 years old) is much lower than the aPAD for the U.S. population group and the other subgroups assessed (see table 3 of this preamble) because of the much lower NOAEL used for the females (13-50 years old) subgroup and the 3x FQPA SF applied only to this subgroup, to protect against effects seen following *in utero* exposure in the developmental rabbit study. In these assessments percent crop treated data were used for a number of commodities but anticipated residues were not, so the assessments are considered to be partially refined and somewhat conservative. Concentration factors for processed commodities were also used. Refinements such as the use of anticipated residue estimates would potentially produce much lower estimates of dietary exposure. The results, at the 95th percentile, of the acute dietary exposure analysis were that the general U.S. population and all subgroups except females (13-50 years old) had dietary exposures that were < 1.0% of the aPAD. Females (13-50 years old) had a dietary exposure that was 41% of the aPAD.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the valuation DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The same cPAD was applicable to the general U.S. population and all subgroups in the chronic dietary exposure analysis. In this assessment PCT data were used for a number of commodities but anticipated residues were not, so the assessments are considered to be partially refined and somewhat conservative. Concentration factors for processed commodities were also used. Refinements such as the use of anticipated residue estimates would potentially produce much lower estimates of dietary exposure. The chronic pyraclostrobin dietary exposure analysis estimated the following exposures: (a) General U.S. population - 27% of the cPAD, (b) children (1-6 years old) - 74% of the cPAD, and (c) children

(7-12 years old) - 41% of the cPAD, infants (< 1–year old) - 31% of the cPAD. All other subgroups analyzed had exposures lower than that of the general U.S. population.

iii. *Cancer*. The database for carcinogenicity for pyraclostrobin is incomplete because the maximum dose levels for female mice and rats in the carcinogenicity studies are inadequate. The Agency considered a method of expressing potential cancer risk using a linear (Q1*) method based on mammary tumors in female rats, to put an upper limit on any possible cancer risk. However, statistical analyses of the tumor data from the combined results of the rat carcinogenicity and chronic toxicology studies showed neither a significant increasing trend nor a significant difference in the pair-wise comparison of the dosed groups with the controls. In Consultation with the Pest Management Regulatory Agency (PMRA), Canada, with whom pyraclostrobin has been jointly reviewed, it was decided that a MOE method would be more appropriate. The reason is that the genotoxicity data show that pyraclostrobin is not mutagenic and the highest dosage level in female rats can be interpreted as a NOAEL for cancer. The Agency therefore believes that it can make a reasonable certainty of no harm determination for carcinogenicity by calculating MOEs, based on the following endpoints: (a) NOAELs of 3.4 (for males) and 12.6 (for females) mg/kg/day from the 2–year carcinogenicity rat feeding study and (b) the NOAEL of 9.0 mg/kg/day from the 28–day rat feeding study.

The NOAEL of 3.4 mg/kg/day is based upon chronic toxicity findings at the LOAEL of 9.2 mg/kg/day, including decreased body weight and body weight gain, kidney tubular casts, and kidney atrophy in both sexes; increased incidence of liver necrosis, erosion/ulceration of the glandular stomach and forestomach, and hemolymphoreticular tumors in males; and mammary adenocarcinoma in females. However, the observed increase in incidences of kidney tubular casts atrophy are commonly found in this strain of rat and were considered by the Agency to be strain and/or age related. The increased incidence of acanthosis and ulcers of the forestomach in both sexes were seen at necropsy late in the study and were considered to be of equivocal toxicological significance, but could not be ruled out as treatment-related effects. The NOAEL of 12.6 mg/kg/day for a cancer scenario is the highest tested dose in the rat oral carcinogenicity study and, though it is considered to be inadequate for assessing carcinogenicity in female rats because they could have tolerated a higher dose, it still is suitable for use as a NOAEL for the possibility of cancer induction in female rats. The dosing in males at 200 ppm (9.2 mg/kg/day) is considered to approach an adequate level because there was a (minimal) decrease of 7% of body weight and a reduction of up to 10% in body weight gain in addition to the slightly increased incidence of erosion/ulceration of glandular stomach and forestomach. The rat carcinogenicity study, rather than the mouse carcinogenicity study, was used for endpoint selection because the NOAELs in the latter study are higher.

The NOAEL of 9.0 mg/kg/day from the 28–day rat feeding study, based on increased incidences of duodenal mucosal hyperplasia in rats of both sexes at the LOAEL of 42.3 mg/kg/day, was selected based on the hypothesis that the observed hyperplasia would progress to duodenal neoplasia following long-term exposure to pyraclostrobin. This endpoint was also noted in the 13–week rat feeding study, with a NOAEL of 10.7 mg/kg bodyweight per day, and in the range-finding reproductive toxicity study.

The dietary MOEs from residues in food and water that were calculated from the above three endpoints were 1,100 for the NOAEL of 3.4 mg/kg/day, 3,200 for the NOAEL of 9.6 mg/kg/day, and 4,200 for the NOAEL of 12.6 mg/kg/day.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

In the pyraclostrobin risk assessment the Agency used PCT data as follows. PCT values of 100% were assumed where no more-refined data were available. EPA utilized PCT values of less than 100% for the following commodities: Beet, sugar; berry, group; fruit, citrus, group; fruit, stone, group; grain, cereal, group; grape; nut, tree, group; pea and bean, dried shelled, except soybean, subgroup; peanut; pistachio; potato; strawberry; tomato; vegetable, bulb, group; vegetable, cucurbit, group; and vegetable, root and tuber, group. These PCT values are based on projected market share information. The registrant provided the Agency with their anticipated market share projections. The Agency estimated market share projections comparing the efficacy spectrum of the registered alternatives to the spectrum of pyraclostrobin. In conducting its risk assessment, the Agency utilized the EPA-derived estimates. The Agency believes that this approach is conservative and will overestimate the potential risk. To further ensure the reliability of these data, as a condition of registration, the registrant will be required to provide annual reports on the market penetration and market share of pyraclostrobin for each of the registered crops.

The Agency believes that the three conditions listed above have been met. With respect to condition 1, PCT estimates are derived from company-provided anticipatory data that have been reviewed by the Agency and are believed to be reliable and to have a valid basis. Since there are not any use data for a new pesticidal active ingredient prior to its initial registration, the Agency believes that company anticipatory estimates provide the best initial estimation of PCT data and is reasonably certain that the percentage of the food treated is not likely to be an underestimation. Conditions 2 and 3 are satisfied by the use of regional consumption data and consumption data for significant subpopulations in EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of these consumption data in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which [pyraclostrobin] may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks monitoring

exposure data to allow it to complete a comprehensive dietary exposure analysis and risk assessment for pyraclostrobin 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 pyraclostrobin.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce surface water 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 groundwater. 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. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop treated (PCT) 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 coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as points 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 pyraclostrobin they are further discussed in the aggregate risk sections.

Based on the FIRST and SCI-GROW models the EECs of pyraclostrobin for acute exposures are estimated to be 20.4 parts per billion (ppb) for surface water and 0.009 ppb for ground water. The EECs for chronic exposures are estimated to be 0.79 ppb for surface water and 0.009 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). However, pyraclostrobin is not registered for use on any sites that would result in residential exposure. .

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) 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 pyraclostrobin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, pyraclostrobin 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 pyraclostrobin 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. FFDCA section 408 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 database on toxicity and exposure unless EPA determines 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.

2. *Prenatal and postnatal sensitivity*. Qualitative (but not quantitative) evidence of increased susceptibility to pyraclostrobin of infants and children, as compared to adults, was seen in the prenatal development study in rabbits, but neither qualitative nor quantitative evidence of increased susceptibility to pyraclostrobin was seen in rats.

3. *Conclusion*. There is an incomplete toxicity database for pyraclostrobin, but exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency concluded, despite the 2-generation reproduction study of rats data gap, that the FQPA SF can be reduced to 3x for pyraclostrobin because: (a) Only qualitative susceptibility was seen and this occurred in only one species, (b) there is no qualitative or quantitative evidence of increased susceptibility following *in utero* exposure to pyraclostrobin in the prenatal development study in rats, (c) a developmental neurotoxicity study is not required, and (d) the dietary (food and drinking water) and residential exposure assessments do not underestimate the potential exposure for infants, children, or women of childbearing age. The 3x FQPA SF was derived prior to finalizing the FQPA SF guidance document on January 31, 2002. A formal reconsideration of the FQPA SF was not made but the Agency did consider the effect of the application of the ''weight of evidence'' approach described in the guidance document on the value of the safety factor. It was concluded that the 3x FQPA SF established prior to the completion of the guidance document would not increase since the developmental effects in the rabbit prenatal developmental toxicity study are well characterized and the NOAEL for these effects is established. Therefore, there is no need for an additional FQPA SF to address potential prenatal or postnatal toxicity. In other words, for acute dietary and residential exposure assessment of the females 13-50 years old population subgroup, the 3x FQPA SF would likely be reduced to 1x. Also, the 3x FQPA SF for assessing chronic dietary and residential exposures would not increase because of the data base deficiency of the 2-generation reproduction study. The reproduction study that was submitted was rejected solely because it did not test at a high enough dose to identify toxicity. In that study, there was no parental systemic, reproductive, or offspring toxicity at any dose including the top dose of 29–36

mg/kg/day, which is well above the NOAELs of other repeated dose toxicity studies. Thus, conduct of another reproduction study will better define reproductive effects at high doses but, in all likelihood, will have no effect on the RfD.

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 the model estimates of a pesticide's concentration in water (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 USEPA are used to calculate DWLOCs: 2L/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.* Using the exposure assumptions discussed in this unit for acute exposure, at the 95th percentile the acute dietary exposure to pyraclostrobin from food will occupy < 1.0% of the aPAD for the U.S. population, 41% of the aPAD for females 13-50 years old, < 1.0% of the aPAD for infants (< 1–year old), and < 1.0% of the aPAD for children (1-6 years old). In addition, there is potential for acute dietary exposure to pyraclostrobin 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 aPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO PYRACLOSTROBIN.

Population Subgroup[1]	aPAD mg/kg/day	Food Exposure mg/kg/day (95th percentile)	Maximum Water Exposure (mg/kg/day)[2]	Acute Ground Water EEC[3] (µg/L)	Acute Surface Water EEC[4] (µg/L)	DWLOC (µg/L)[5]
U.S. population	3.0	0.0094	3.0	0.009	0.009	1.0×10^5
All Infants	3.0	0.014	3.0			3.0×10^4
Females (13-50 years old)	0.017	0.0068	0.043			1.3×10^3
Children (1-6 years old)	3.0	0.022	3.0			3.0×10^4
Males (13-19 years old)	3.0	0.0083	3.0			1.0×10^5

[1]Population subgroups chosen were the female subgroup with the highest food exposure (60 kg/ body weight assumed) the male subgroup with the highest food exposure (70 kg body weight assumed) and infant/child subgroups with the highest food exposure (10 kg/ body weight assumed).

[2] Maximum Water Exposure (mg/kg/day) = PAD (mg/kg/day) - Food Exposure from DEEM (mg/kg/day).

[3]Based upon SCI-GROW modeling results.

[4] Based upon FIRST (version 2) modeling results.

[5] DWLOC(µg/L) = maximum water exposure (mg/kg/day) x body weight (kg)/water consumption (L) x 10^3 mg/µg

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to [pyraclostrobin] from food will utilize 27% of the cPAD for the U.S. population, 31% of the cPAD for infants < 1–year old, and 74% of the cPAD for children (1-6 years old). There are no residential uses for pyraclostrobin that result in chronic residential exposure to pyraclostrobin. However, there is potential for chronic dietary exposure to pyraclostrobin 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 the following Table 5:

TABLE 5.—SUMMARY OF CHRONIC DRINKING WATER LEVELS OF COMPARISON FOR PYRACLOSTROBIN.

Population Subgroup[1]	cPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Maximum Water Exposure[2] (mg/kg/day)	Chronic Ground Water EEC3 (µg/L)	Chronic Surface Water EEC4 (µg/L)	DWLOC5 (µg/L)
U.S. population	0.011	0.0030	8.0×10^{-3}	0.009	0.79	280
All infants	0.011	0.0034	7.6×10^{-3}			76
Children (1-6 years)	0.011	0.0082	2.8×10^{-3}			28
Females (13-50 years old)	0.011	0.0022	8.8×10^{-3}			290
Males (13-19 years old)	0.011	0.0028	8.2×10^{-3}			290

[1]Population subgroups chosen were U.S. population (70 kg body weight assumed), the female subgroup with the highest food exposure (60 kg body weight assumed), the male subgroup (70 kg body weight assumed) with the highest food exposure, and infant/child subgroups with the highest food exposure (10 kg body weight assumed).
[2]Maximum Water Exposure (mg/kg/day) = PAD (mg/kg/day) - Food Exposure from DEEM (mg/kg/day)
[3]Based upon PRZM/EXAMS Index Reservoir modeling results.
[4]Based upon SCI-GROW modeling results.
[5]DWLOC(µg/L) = maximum water exposure (mg/kg/day) x body weight (kg)/water consumption (L) x 10^{-3} mg/µg

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). Pyraclostrobin 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 level of concern.

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). Pyraclostrobin 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 level of concern.

5. *Aggregate cancer risk for U.S. population*. The database for carcinogenicity is incomplete. MOEs have been calculated for chronic (cancer) food exposure based on NOAELs of 3.4 and 12.6 mg/kg/day from the 2–year carcinogenicity feeding study in rats and a NOAEL of 9.0 mg/kg/day from the 28–day rat feeding study. MOEs for drinking water exposure, using the SCI-GROW model chronic estimate of 0.009 ppb pyraclostrobin in ground water, are presented in the following table 6 as are the MOEs for food plus drinking water.

TABLE 6.—MARGINS OF EXPOSURE (MOES) BASED UPON CHRONIC (CANCER) AGGREGATE EXPOSURE (FOOD PLUS WATER ONLY) TO PYRACLOSTROBIN FOR THE U.S. POPULATION

NOAEL (mg/kg/day)	Exposure from food (mg/kg/day)	MOE (food)	Exposure from water (mg/kg/day)	MOE (water)	MOE (food + water)
3.4	0.0030	1,100	2.3×10^{-5}	1.5×10^{5}	1,100
9.0		3,000		4.2×10^{5}	3,000
12.6		3,000		4.2×10^{5}	4,200

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, and to infants and children from aggregate exposure to pyraclostrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Two tolerance enforcement methods have been proposed by BASF for the determination of pyraclostrobin and its desmethoxy metabolite (BF 500–3) in or on plant commodities: (a) The Liquid Chromatography/Mass Spectrometry (LC/MS) method number D9808 and (b) the HPLC/UV method number D9904. The validated method limits of quantitation for pyraclostrobin and BF 500–3 for both methods are 0.02 ppm for each analyte in plant matrices. Adequate independent method validation and radiovalidation data have been submitted for both methods. These methods have been forwarded to the Agency's Analytical Chemistry Laboratory for validation.

The Agency has also received two tolerance enforcement methods for ruminant commodities: HPLC/UV method number 439/0 and 446, which consists of Gas Chromatography (GC)/MS method number 446/0 and LC/MS/MS method number 446/1. The HPLC/UV method determines residues of pyraclostrobin per se. Method number 446 has a hydrolysis step and determines residues of pyraclostrobin and its metabolites as the molecules BF 500–5 and BF 500–8. These methods have also been forwarded to the Agency's Analytical Chemistry Laboratory for validation.

The petitioner must make any modifications or revisions to the proposed methods resulting from the Agency's validation. Upon successful

completion of the validation, the methods will be forwarded to FDA for publication in a future revision of the Pesticide Analytical Manual, Volume II (PAM-II). Before publication and upon request, the methods will be available, prior to the harvest season, from the Analytical Chemistry Branch (ACB), Biological and Economic Analysis Division (7503C), Environmental Science Center, 701 Mapes Road, Ft. George C. Meade, MD 20755–5350. Contact Francis D. Griffith, Jr., telephone (410) 305–2905, e-mail: *griffith.francis@epa.gov*. The analytical standards are also available from the EPA National Standard Repository at the same location.

Pyraclostrobin was successfully evaluated through several of the FDA multiresidue method protocols, while BF 500–3 was unsuccessful in all protocols. Pyraclostrobin was completely recovered through Protocol D (in grape) and E (in grape), and partially recovered through Protocol F (in peanut). Metabolite BF 500–3 had poor peak shape and inadequate sensitivity with Protocol C columns and therefore was not further analyzed under Protocols D, E, and F. The results of the multiresidue testing for pyraclostrobin will be forwarded to FDA for inclusion in PAM Volume I.

B. International Residue Limits

No Codex or Mexican maximum residue levels (MRLs) have been proposed or are established for residues of pyraclostrobin. Therefore, no tolerance discrepancies exist between countries for this chemical. Since the application for registration of pyraclostrobin was reviewed jointly with the Pest Management Regulatory Agency (PMRA) of Canada, several Canadian MRLs for pyraclostrobin are proposed and are expected to be established soon. However, the joint review is expected to have eliminated the potential for discrepancies between U.S. tolerances and Canadian MRLs.

V. Conclusion

Therefore, tolerances are established for combined residues of pyraclostrobin carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester and its desmethoxy metabolite methyl 2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl carbamate, expressed as parent compound, in or on almond, hulls at 1.6 ppm; Banana at 0.04 ppm; barley, grain at 0.4 ppm; barley, hay at 25 ppm; barley, straw at 6.0 ppm; bean, dry at 0.3 ppm; beet, sugar, dried pulp at 1.0 ppm; beet, sugar, roots at 0.2 ppm; beet, sugar, tops at 8.0 ppm; berry, group at 1.3 ppm; citrus, dried pulp at 5.5 ppm; citrus, oil at 4.0 ppm; fruit, citrus, group at 0.7 ppm; fruit, stone, group at 0.9 ppm; grain, aspirated fractions at 2.5 ppm; grape at 2.0 ppm; grape, raisin at 7.0 ppm; grass, forage at 10 ppm; grass, hay at 4.5 ppm; grass, seed screenings at 27 ppm; grass, straw at 14 ppm; nut, tree, group at 0.04 ppm; peanut, nutmeat at 0.05 ppm; peanut, refined oil at 0.1 ppm; pistachio at 0.7 ppm; radish, tops at 16 ppm; rye, grain at 0.04 ppm; rye, straw at 0.5 ppm; strawberry at 0.4 ppm; vegetable, bulb, group at 0.9 ppm; vegetable, cucurbit, group at 0.5 ppm; vegetable, fruiting, group at 1.4 ppm; vegetable, root, except sugar beet, subgroup at 0.4 ppm; vegetable, tuberous and corm, subgroup at 0.04 ppm; wheat, grain at 0.2 ppm; wheat, hay at 6.0 ppm; and wheat, straw at 8.5 ppm, and combined residues of pyraclostrobin carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester and its metabolites convertible to 1-(4-chlorophenyl)-1H-pyrazol-3-ol and 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazol-3-ol, expressed as parent compound, in or on cattle, fat at 0.1 ppm; cattle, liver at 1.5 ppm; cattle, meat at 0.1 ppm; cattle, meat byproducts, except liver at 0.2 ppm; goat, fat at 0.1 ppm; goat, liver at 1.5 ppm; goat, meat at 0.1 ppm; goat, meat byproducts, except liver at 0.2 ppm; hog, fat at 0.1 ppm; hog, liver at 1.5 ppm; hog, meat at 0.1 ppm; hog, meat byproducts, except liver at 0.2 ppm; horse, fat at 0.1 ppm; horse, liver at 1.5 ppm; horse, meat at 0.1 ppm; horse, meat byproducts, except liver at 0.2 ppm; milk at 0.1 ppm; sheep, fat at 0.1 ppm; sheep, liver at 1.5 ppm; sheep, meat at 0.1 ppm; and sheep, meat byproducts, except liver at 0.2 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the 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 the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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–2002–0225 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 November 26, 2002.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your written request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall # 2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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.

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.

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 Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0225, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this 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 FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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. Submission to Congress and the Comptroller General

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 record keeping requirements.

Dated: September 20, 2002.

James Jones,

Acting 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), 346(a) and 374.

2. Section 180.582 is added to read as follows:

§ 180.582 Pyraclostrobin; tolerances for residues.

(a) *General.* (1)Tolerances are established for combined residues of the fungicide pyraclostrobin carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester and its desmethoxy metabolite methyl 2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl carbamate, expressed as parent compound, in or on the following raw agricultural commodities.

Commodity	Parts per million
Almond, hulls	1.6
Banana	0.04
Barley, grain	0.4
Barley, hay	25
Barley, straw	6.0
Bean, dry	0.3
Beet, sugar, dried pulp	1.0
Beet, sugar, roots	0.2
Beet, sugar, tops	8.0
Berry group	1.3
Citrus, dried pulp	5.5
Citrus, oil	4.0
Fruit, citrus, group	0.7
Fruit, stone, group	0.9
Grain, aspirated fractions	2.5
Grape	2.0
Grape, raisin	7.0
Grass, forage	10
Grass, hay	4.5
Grass, seed screenings	27
Grass, straw grown for seed	14
Nut, tree, group	0.04
Peanut	0.05
Peanut, refined oil	0.1
Pistachio	0.7
Radish, tops	16
Rye, grain	0.04
Rye, straw	0.5
Strawberry	0.4
Vegetable, bulb	0.9
Vegetable, cucurbit, group	0.5
Vegetable, fruiting, group	1.4
Vegetable, root, except sugarbeet, subgroup	0.4
Vegetable, tuberous and corm, subgroup	0.04
Wheat, grain	0.02
Wheat, hay	6.0
Wheat, straw	8.5

(2) Tolerances are established for combined residues of the fungicide pyraclostrobin carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester and its metabolites convertible to 1-(4-chlorophenyl)-1H-pyrazol-3-ol and 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazol-3-ol, expressed as parent compound, in or on the following raw agricultural commodities.

Commodity	Parts per million
Cattle, fat	0.1
Cattle, liver	1.5
Cattle, meat	0.1
Cattle, meat byproducts, except liver	0.2
Goat, fat	0.1
Goat, liver	1.5
Goat, meat	0.1
Goat, meat byproducts, except liver	0.2
Hog, fat	0.1
Hog, liver	1.5

Commodity	Parts per million
Hog, meat	0.1
Hog, meat byproducts, except liver	0.2
Horse, fat	0.1
Horse, liver	0.1
Horse, meat	0.1
Horse, meat byproducts, except liver	0.2
Milk	0.1
Sheep, fat	0.1
Sheep, liver	1.5
Sheep, meat	0.1
Sheep, meat byproducts, except liver	0.2

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

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

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

[FR Doc. 02–24487 Filed 9–26–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0204; FRL–7200–1]

Lambda-cyhalothrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of lambda-cyhalothrin in or on almond, hulls and various other food commodities in 40 CFR 180.438. Syngenta Crop Protection, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0204, must be received on or before November 26, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0204 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: William G. Sproat, Jr., Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: 703–308–8587; e-mail address: *sproat.william@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet home page at *http://www.epa.gov/*. To access this document, on the home page select ''Laws and Regulations'', ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0204. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of October 8, 1997 (62 FR 52588–52563) (FRL–5748–6) and May 12, 2000 (65 FR 30591–30596) (FRL–6497–1), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of pesticide petitions (PP 7F4875 and 0F6092) by Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419–8300.