Use classification	Applicable criteria
(2)(A)(i), (2)(B)(i), and (2)(B)ii, (2)(C), (2)(D)	Column D2—#s 14, 16, 18–21, 22, 23, 26, 27, 29, 30, 32, 37, 38, 42–44, 46, 53, 54, 55, 59–62, 64, 66, 68, 73, 74, 78, 82, 85, 88–93, 95, 96, 98, 102–105, 107–111, 115–126.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0325; FRL–7681–9]

Pyraclostrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the 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-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl] carbamate), expressed as parent compound in or on apple, wet pomace; brassica, head and stem, subgroup; brassica, leafy greens, subgroup; corn, field, grain; corn, field, forage; corn, field, stover; corn, field, refined oil; corn, pop, grain; corn, pop, stover; corn, sweet, kernel plus cob with husks removed; corn, sweet, forage; corn, sweet, stover; fruit, pome, group; hop, dried cones; legume, forage, except peanut and soybean; pea, succulent; pea and bean, dried shelled, except soybean, subgroup; peppermint; soybean, forage; soybean, hay; soybean, hulls; soybean, seed; spearmint; sunflower; vegetable, leafy, except brassica, group; vegetable, leaves of root and tuber, except sugar beet; and vegetable, legume, edible podded, subgroup. This regulation also increases the tolerances for citrus, dried pulp; citrus, oil; fruit, citrus, group; and strawberry and removes the currently existing tolerance for bean, dry, seed. The latter tolerance is superseded by the tolerance for pea and bean, dried shelled, except soybean, subgroup. BASF Corporation and Interregional Research Project Number 4 (IR-4) requested these tolerances 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 October 29, 2004. Objections and requests for hearings must be received on or before December 28, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0325. 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., 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 S. Bell St., 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: Dennis McNeilly, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–6742; e-mail address: *mcneilly.dennis@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; commercial applicators; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., food manufacturing plant employees; produce truck drivers; waste disposal truck drivers; consumers.
- Pesticide manufacturing (NAICS 32532), e.g., pesticide manufacturing plant employees; pesticide distribution employees; agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers.

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/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/.*

II. Background and Statutory Findings

In the **Federal Register** of August 13, 2003 (68 FR 48367) (FRL–7320–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of three pesticide petitions (PP 2E6473, 3E6548, and 3E6553) by Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. The petitions requested that 40 CFR 180.582 be amended by establishing tolerances for the combined residues of the fungicide carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester], pyraclostrobin, and methyl-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl] carbamate, the desmethoxy metabolite of pyraclostrobin, expressed as parent compound], in or on brassica, head and stem, subgroup at 5 ppm (PP 3E6553); lettuce, head at 22 ppm (PP 2E6473); lettuce, leafy at 22 ppm (PP

2E6473); and vegetable, leaves of root and tuber, group at 16 ppm (PP 3E6548).

In the **Federal Register** of August 27, 2004 (69 FR 52670) (FRL–7676–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of three pesticide petitions (PP 0F6139, 2F6431, and 3F6581) by BASF Corporation, Research Triangle Park, NC 27709 and one pesticide petition (PP 3E6774) by Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. The petitions requested that 40 CFR 180.582 be amended by establishing tolerances for the combined residues of the fungicide carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester, pyraclostrobin, and methyl-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl] carbamate, the desmethoxy metabolite of pyraclostrobin, expressed as parent compound, in or on apple, wet pomace at 8.0 ppm (PP 2F6431); brassica, leafy greens, subgroup at 16.0 ppm (PP 3F6581); corn, field, grain at 0.1 ppm (PP 2F6431); corn, field, forage at 5.0 ppm (2F6431); corn, field, stover at 17.0 ppm (PP 2F6431); corn, field, refined oil at 0.2 ppm (PP 2F6431); corn, pop, grain at 0.1 ppm (PP 2F6431); corn, pop, stover at 17.0 ppm (PP 2F6431); corn, sweet, kernel plus cob with husks removed at 0.04 ppm (PP 2F6431); corn, sweet, forage at 5.0 ppm (PP 2F6431); corn, sweet, stover at 23.0 ppm (PP 2F6431); fruit, pome, group 11 at 1.5 ppm (PP 2F6431); hop, dried, cones at 23.0 ppm (PP 2F6431); legume, forage, except peanut and soybean at 25.0 ppm (PP 2F6431); pea, succulent at 0.2 ppm (PP 2F6431); pea and bean, dried shelled, except soybean, subgroup at 0.3 ppm (PP 0F6139); peppermint at 8.0 ppm (PP2F6431); soybean, forage at 5.0 ppm (PP 3F6581); soybean, hay at 7.0 ppm (PP 3F6581); soybean, hulls at 0.06 ppm (PP 3F6581); soybean, seed at 0.04 ppm (PP 3F6581); spearmint at 8.0 ppm (PP 2F6431); sunflower at 0.3 ppm (PP 2F6431); vegetable, leafy, except brassica, group at 29.0 ppm (PP 3E6774); and vegetable, legume, edible podded, subgroup at 0.5 ppm (PP 2F6431). Tolerance petition 3F6581 also requests that 40 CFR 180.582 be amended by increasing the tolerances for the combined residues of pyraclostrobin and the desmethoxy metabolite of pyraclostrobin, expressed as parent compound, in or on citrus, dried pulp to 12.5 ppm (PP 3F6581); citrus, oil to 9.0 ppm (PP 3F6581); and fruit, citrus, group to 2.0 ppm (PP 3F6581). Tolerance petition 0F6139 also requests that 40 CFR 180.582 be amended by removing the tolerance for the combined residues of pyraclostrobin and the desmethoxy metabolite of pyraclostrobin, expressed as parent compound, in or on bean, dry, seed at 0.3 ppm. The latter tolerance has been superseded by the tolerance for pea and bean, dried shelled, except soybean, subgroup at 0.3 ppm.

In the **Federal Register** of August 30, 2004 (68 FR 52891) (FRL–7676–8), 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 4F6850) by BASF Corporation, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.582 be amended by increasing the tolerance for the combined residues of the fungicide carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-,methyl ester, pyraclostrobin, and methyl-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl] carbamate, the desmethoxy metabolite of pyraclostrobin, expressed as parent compound, in or on strawberry to 1.5 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, to establish (or increase) tolerances for the combined residues of carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester, pyraclostrobin, and methyl-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl] carbamate, the desmethoxy metabolite of pyraclostrobin, expressed as parent compound in or on apple, wet pomace 8.0 ppm; brassica, head and stem, subgroup at 5.0 ppm; brassica, leafy greens, subgroup at 16.0 ppm; citrus, dried pulp at 12.5 ppm (increased from 5.5 ppm); citrus, oil at 9.0 ppm (increased from 4.0 ppm); corn, field, grain at 0.1 ppm; corn, field, forage at 5.0 ppm; corn, field, stover at 17.0 ppm; corn, field, refined oil at 0.2 ppm; corn, pop, grain at 0.1 ppm; corn, pop, stover at 17.0 ppm; corn, sweet, kernel plus cob with husks removed at 0.04 ppm; corn, sweet, forage at 5.0 ppm; corn, sweet, stover at 23.0 ppm; fruit, citrus, group at 2.0 ppm (increased from 0.7 ppm); fruit, pome, group at 1.5 ppm; hop, dried cones at 23.0 ppm; legume, forage, except peanut and soybean at 25.0 ppm; pea, succulent at 0.2 ppm; pea and bean, dried shelled, except soybean, subgroup at 0.3 ppm; peppermint at 8.0 ppm; soybean, forage at 5.0 ppm; soybean, hay at 7.0 ppm; soybean, hulls at 0.06 ppm; soybean, seed at 0.04 ppm; spearmint at 8.0 ppm; strawberry at 1.5 ppm (a temporary increased tolerance with an expiration date of December 31, 2005); sunflower at 0.3 ppm; vegetable, legume, edible podded, subgroup at 0.5 ppm; vegetable, leafy, except brassica, group at 29.0 ppm; and vegetable, leaves of root and tuber, except sugar beet at 16.0 ppm ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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 pyraclostrobin 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 PROFILE

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity-rat	The study is acceptable/guideline. Dosing levels were 0, 50, 150, 500, 1,000, and 1,500 ppm (males: 0, 3.5, 10.7, 34.7, 68.8, and 105.8 mg/kg/day; females: 0, 4.2, 12.6, 40.8, 79.7, and 118.9 mg/kg/day). The NOAEL was 10.7 mg/kg/day. The LOAEL was 34.7 mg/kg/day based on reduced body weight and weight gain in males, reduced food intake in both sexes, increased relative liver weight and spleen weight in females, the histopathology of the duodenum and liver in males, and the histopathology of the spleen in both sexes.
870.3100	90-Day oral toxicity-mouse	The study is acceptable/guideline. Dosing levels were 0, 50, 150, 500, 1,000, and 1,500 ppm (males: 0, 9.2, 30.4, 119.4, 274.4, and 475.5 mg/kg/day; females: 0, 12.9, 40.4, 162.0, 374.1, and 634.8 mg/kg/day). The NOAEL was 9.2 mg/kg/day. The LOAEL was 30.4 mg/kg/day based on reduced body weight and body weight gain in males, changes in clinical chemistry (increased urea and decreased triglycerides) in both sexes, and increased incidences in females of lymph node apoptosis, thymus atrophy, and ulceration and erosion in the glandular stomach.
870.3150	90-Day oral toxicity-dog	The study is acceptable/guideline. The dosing levels were 0, 100, 200, and 450 ppm (males: 0, 2.8, 5.8, and 12.9 mg/kg/day; females: 0, 3.0, 6.2, and 13.6 mg/kg/day). The NOAEL was 5.8 mg/kg/day. The LOAEL was 12.9 mg/kg/day based on increased diarrhea, clinical chemistry changes, and increased incidence of thickening and mucosal hypertrophy of the duodenum in both sexes; and body weight loss, reduced food intake, and reduced food efficiency in females.
870.3050	28-Day oral toxicity-rat	The study is acceptable/guideline. The dosing levels were 0, 20, 100, 500, and 1,500 ppm (males: 0, 1.8, 9.0, 42.3, and 120.2 mg/kg/day; females: 0, 2.0, 9.6, 46.6, and 126.3 mg/kg/day. The NOAEL was 9.0 mg/kg/day. The LOAEL was 42.3 mg/kg/day based on changes in hematology parameters, increased absolute and relative spleen weight, histopathology in spleen and liver, and increased duodenal mucosal hyperplasia in both sexes.
870.3200	28-Day dermal toxicity-rat	This study was judged to be unacceptable/guideline because a higher dose could have been tolerated and the limit dose is 1,000 mg/kg/day. The dosing levels were 0, 40, 100, 250 mg/kg for 5 days/wk The dermal NOAEL was 40 mg/kg/day. The dermal LOAEL was 100 mg/kg/day based on scale formation, hyperkeratosis, and epidermal thickening.
870.3465	28-Day inhalation toxicity-rat	Study pending. Required due to the potential for occupational/residential exposure via this route.
870.3700	Prenatal development-rat	The study is acceptable/guideline. The dosing levels were 0, 10, 25, 50 mg/kg/day. The maternal NOAEL was 10 mg/kg/day; the maternal LOAEL was 25 mg/kg/day based on reduced body weight, body weight gain, food intake, and food efficiency. The developmental NOAEL was 25 mg/kg/day; the developmental LOAEL was 50 mg/kg/day based on increased incidences of dilated renal pelvis and cervical ribs with no cartilage.
870.3700	Prenatal development-rabbit	This study is acceptable/guideline. The dosing levels were 0, 1, 3, 5, 10, and 20 mg/kg/day. The maternal NOAEL was 5 mg/kg/day The maternal LOAEL was 10 mg/kg/day based on reduced body weight gain, reduced food intake, and reduced food efficiency. The developmental NOAEL was 5 mg/kg/day; the developmental LOAEL was 10 mg/kg/day based on increased resorption and post-implantation loss.

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

Guideline No.	Study Type	Results
870.3800	Two generation reproduction study-rat	This study is acceptable/guideline when combined with the one generation preliminary study (below). The dosing levels were 0, 25, 75, and 300 ppm (F0 males: 0, 2.5, 7.4, and 29.0 mg/kg/day; F0 females 0, 2.6, 7.8, and 30.4 mg/kg/day; F1 males: 0, 2.8, 8.6, and 35.0 mg/kg/day; F1 females: 0, 3.0, 9.0, and 36.0 mg/kg/day. The parental/systemic NOAEL was 29 mg/kg/day. The parental/systemic LOAEL was greater than 29 mg/kg/day based on no observed effects. The reproductive NOAEL was 29 mg/kg/day. The reproductive LOAEL was greater than 29 mg/kg/day based on no observed effects. The offspring NOAEL was 29 mg/kg/day. The offspring LOAEL was greater than 29 mg/kg/day based on no observed effects.
870.3800	One-generation reproduction study-rat	The dosing levels were 0, 200, 400, and 600 ppm (F0 males: 0, 20.5, 39.9, and 59.1 mg/kg/day; F0 females: 0, 21.3, 42.5, and 60.4 mg/kg/day). The offspring NOAEL was less than 20.5 mg/kg/day. The offspring LOAEL was 20.5 mg/kg/day based on decreased pup body weight and body weight gain on and after post-natal day 7.
870.4100	Chronic toxicity-rat	This study was judged to be unacceptable/guideline. The dosing levels were 0, 25, 75, and 200 ppm (males: 0, 1.1, 3.4, and 9.0 mg/kg/day; females: 0, 1.5, 4.6, and 12.3 mg/kg/day. The NOAEL was 9.0 mg/kg/day and the LOAEL was greater than 9.0 mg/kg/day, so the Agency judged the study to be unacceptable because the highest dosing level was insufficient to produce a significant toxicological response.
870.4100	Chronic toxicity-dog	This study is acceptable/guideline. The dosing levels were 0, 100, 200, and 400 ppm (males: 0, 2.7, 5.4, and 10.8 mg/kg/day; female: 0, 2.7, 5.4, and 11.2 mg/kg/day. The NOAEL was 5.4 mg/kg/day. The LOAEL was 10.8 mg/kg/day based on increased diarrhea and clinical chemistry changes in both sexes (decreased cholesterol, protein, albumin, and globulin); and reduced body weight gain and food intake and efficiency in females.
870.4200	Carcinogenicity-rat	This study is acceptable/guideline. The dosing levels were 0, 25, 75, and 200 ppm (males: 0, 1.2, 3.4, and 9.2 mg/kg/day; females: 0, 1.5, 4.7, and 12.6 mg/kg/day). The NOAEL was 3.4 mg/kg/day. The LOAEL was 9.2 mg/kg/day based on reduced body weight and body weight gain, kidney atrophy and tubular casts in both sexes, and hepatic necrosis plus gross and microscopic ulcerations and lesions in the glandular and fore-stomachs in males. There was no evidence of carcinogenicity.
870.4300	Carcinogenicity-mouse	This study was judged to be unacceptable/guideline. The dosing levels for males were 0, 10, 30, and 120 ppm (0, 1.4, 4.1, and 17.2 mg/kg/day). The dosing levels for females were 0, 10, 30, 120, and 180 ppm (0, 1.6, 4.8, 20.5, and 32.8 mg/kg/day). The NOAEL for males was 4.1 mg/kg/day and for females was 32.8 mg/kg/day. The LOAEL for males was 17.1 mg/kg/day based on decrease of 20% in body weight gain at 13 weeks that was supported by the results of a 90-day study. The LOAEL for females was greater than 32.8 mg/kg/day. The Agency judged the highest dosing level to be inadequate in females because it did not produce a significant toxicological response. There was no evidence of carcinogenicity
870.5100	Gene mutation: Bacterial reverse mutation assay	This study is acceptable/guideline. The results were negative ± S9 up to 5,000 μg/plate by standard plate and tube preincubation. There was no cytotoxicity at any dose but there was precipitation at ≥2,500 μg/plate.
870.5300	Gene mutation: Mammalian cell culture	This study is acceptable/guideline. The results were negative ± S9 up to cytotoxic and precipitating concentration of 20 μg/mL.
870.5375	Cytogenetics (*in vitro*): Chromosomal aberrations	This study is acceptable/guideline. The results were negative ± S9 for clastogenic/aneugenic activity up to 25 μg/mL. Precipitation and cytotoxicity (reduced cell attachment and poor quality of metaphases) were seen at concentrations ≥+50 μg/mL.

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

Guideline No.	Study Type	Results
870.5395	Cytogenetics: Micronucleus test in mouse	This study is acceptable/guideline. The results were negative for clastogenic/aneugenic activity up to the highest dose tested (HDT) (300 mg/kg). In a preliminary study, doses ≥400 mg/kg caused death.
870.5550	Unscheduled DNA synthesis: Rat hepatocyte culture	This study is acceptable/guideline. The results were negative up to a cytotoxic concentration of 1.0 μg/mL.
870.6200	Acute neurotoxicity screening-rat	This study is acceptable/guideline. The dosing levels were 0, 100, 300, and 1,000 mg/kg. The neurotoxicity NOAELs were 1000 mg/kg and the LOAELS were greater than 1,000 mg/kg for both males and females. The systemic NOAEL was 300 mg/kg for males and 1,000 mg/kg for females. The systemic LOAEL was greater than 1,000 mg/kg for females; it was 1,000 mg/kg for males based on reduced body weight gain in males.
870.6200	Subchronic neurotoxicity screening-rat	This study is acceptable/guideline. The dosing levels were 0, 50, 250, and 750 (males)/1500 (females) ppm (males: 0, 3.5, 16.9, 49.9 mg/kg/day; females: 0, 4.0, 20.4, 111.9 mg/kg/day). The neurotoxicity NOAEL for males was 49.9/111.9 mg/kg/day and for females was 111.9 mg/kg/day. The neurotoxicity LOAEL for males was greater than 49.9 mg/kg/day and for females was greater than 111.9 mg/kg/day. The systemic NOAEL for males was 16.9 mg/kg/day and for females was 20.4 mg/kg/day. The systemic LOAEL for males was 49.9 mg/kg/day and for females was 111.9 mg/kg/day based on reduced body weight gain, food intake and food efficiency.
870.7485	Metabolism and pharmacokinetics-rat	This study is acceptable/guideline. Nearly 35% of an oral dose of pyraclostrobin is absorbed, with urinary and fecal excretion accounting for about 15% and 85% of excretion, respectively. Bile elimination accounted for about 30%. Two peak plasma concentrations were reached at 0.5 - 1 and at 8 hours with 16 to 38% lower plasma concentrations in males than females during the early peak phase. Elimination was biphasic at a low dose with plasma half lives of nearly 10 and 35 hours and monophasic at a high dose with a half-life of nearly 20 hours. Tissue distribution was fast, peaking at 0.5 hours, and was slightly higher among females. Some of the highest concentrations were found in the liver, thyroid, kidney, lung, adrenal glands, and pancreas but all levels dropped by more than 20-fold within 72 hours. About 33 metabolites were identified in urine, feces, and bile with no sex- or dose-related differences but the position of the label seemed to alter the profile, particularly in the urine. Desmethoxy pyraclostrobin is one of the major metabolites (labeled 500M07) in rat and is also found in large amounts in plants (labeled BF 500-3) and livestock (also labeled 500M07). The rat metabolic pathway included phase I reactions such as N-demethoxylation, various hydroxylations, and cleavage of the ether bond with subsequent oxidation; these reactions were followed by phase II glucuronidation and sulfation.
870.7600	Dermal penetration-rat	This study was judged to be unacceptable/guideline because most of the test material was retained on the dressing and was therefore unavailable for absorption. This makes it very difficult to determine the actual dose. However, the Agency was able to calculate a maximum possible dermal penetration rate of 14%.

Notes: Mg/kg = milligram(s) per kilogram; mg/kg/day = milligram(s) per kilogram per day; mL = milliliter(s); days/wk = days per week; μg = microgram(s)

B. Toxicological Endpoints

The dose at which no adverse effects are observed (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.

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). Examples of how such a probability risk is expressed are description of 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 pyraclostrobin that were used for human risk assessment is shown in Table 2 below.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYRACLOSTROBIN

Exposure Scenario	Dose Used in Risk Assessment; Inter- species, Intraspecies, and UF; RfD	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13-50 years of age)	NOAEL= 5 mg/kg/day UF = 100 Acute RfD = 0.05 mg/kg/day	FQPA SF = 1X aPAD = 0.05 mg/kg/day	Rabbit prenatal developmental toxicity study. LOAEL = 10 mg/kg/day based on developmental toxicity findings of increased resorptions per litter and increased total resorptions (i.e., dams with complete litter loss).
Acute Dietary (General population including infants and children)	NOAEL = 300 mg/kg UF = 100 Acute RfD = 3.0 mg/kg/day	FQPA SF = 1X aPAD = 3.0 mg/kg/day	Rat acute oral neurotoxicity study. LOAEL = 1000 mg/kg/day based on decreased body weight gain in males.
Chronic Dietary (All populations)	NOAEL= 3.4 mg/kg/day UF = 100 Chronic RfD = 0.034 mg/kg/day	FQPA SF = 1X cPAD = 0.034 mg/kg/day	Rat oral carcinogenicity study. LOAEL = 9.2 mg/kg/day based on decreased body weight and body weight gain, and kidney tubular casts and atrophy in both sexes, increased incidence of liver necrosis and erosion/ulceration of the glandular stomach and forestomach in males, plus hemolymphoreticular tumors in males and mammary adenocarcinoma in females.
Short-Term Incidental Oral (1-30 days)	NOAEL= 5.8 mg/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = NA	13-Week dog feeding study. LOAEL = 12.9 mg/kg/day based on increased incidence of diarrhea, clinical chemistry changes, duodenum mucosal hypertrophy, and decreased body weight, food intake, and food efficiency.
Intermediate-Term Incidental Oral (1- 6 months)	NOAEL= 5.8 mg/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = NA	13-Week dog feeding study. LOAEL = 12.9 mg/kg/day based on increased incidence of diarrhea, clinical chemistry changes, duodenum mucosal hypertrophy, and decreased body weight, food intake, and food efficiency.
Short-Term Dermal (1 to 30 days)	Oral study NOAEL = 5.0 mg/kg/day (dermal absorption rate = 14 %)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Rabbit prenatal developmental toxicity study. LOAEL = 10.0 mg/kg/day based on developmental toxicity findings of increased resorptions per litter and increased total resorptions (i.e., dams with complete litter loss).

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYRACLOSTROBIN—Continued

Exposure Scenario	Dose Used in Risk Assessment; Inter- species, Intraspecies, and UF; RfD	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Intermediate-Term Dermal (1 to 6 months)	Oral study NOAEL = 5.0 mg/kg/day (dermal absorption rate = 14 %)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Rabbit prenatal developmental toxicity study. LOAEL = 10.0 mg/kg/day based on developmental toxicity findings of increased resorptions per litter and increased total resorptions (i.e., dams with complete litter loss).
Long-Term Dermal (>6 months)	Oral study NOAEL = 3.4 mg/kg/day (dermal absorption rate = 14 %)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Rat oral carcinogenicity study. LOAEL = 9.2 mg/kg/day based in males on decreased body weight and body weight gain, and 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, plus hemolymphoreticular tumors in males and mammary adenocarcinoma in females.
Short-Term Inhalation (1 to 30 days)	Oral study NOAEL = 5.0 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Rabbit prenatal developmental toxicity study. LOAEL = 10.0 mg/kg/day based on developmental toxicity findings of increased resorptions per litter and increased total resorptions (i.e., dams with complete litter loss).
Intermediate-Term Inhalation (1 to 6 months)	Oral study NOAEL = 5.0 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Rabbit prenatal developmental toxicity study. LOAEL = mg/kg/day based on developmental toxicity findings of increased resorptions per litter and increased total resorptions (i.e., dams with complete litter loss).
Long-Term Inhalation(>6 months)	Oral study NOAEL = 3.4 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Rat oral carcinogenicity study. LOAEL = 9.2 mg/kg/day based in both sexes on decreased body weight and body weight gain, and 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, plus hemolymphoreticular tumors in males and mammary adenocarcinoma in females.
Cancer (MOE Approach)	NOAEL = 32.8		Mouse oral carcinogenicity study. Results were that mortality, clinical signs, body weight, body weight gain, food consumption, food efficiency, hematology, organ weights, and gross and microscopic findings for both sexes at all doses were unaffected by treatment. The HDT was 32.8 mg/kg/day in females.

Note: NA = Not Applicable

The Agency has concluded that the rat carcinogenicity study is acceptable for both sexes and did not show either a significant increasing tumor trend or a significant difference in tumor incidence in the pair-wise comparison of the dosed groups with the controls. The Agency has also concluded that the mouse carcinogenicity study was acceptable for males, in which there was no evidence of carcinogenicity. In general, acceptable study results indicate that pyraclostrobin is unlikely to be a carcinogen. However, the Agency has also concluded that the carcinogenicity data available for pyraclostrobin are inadequate to allow full assessment of the human carcinogenic potential of this pesticide because the highest dosing levels for females in the mouse carcinogenicity study were not great enough to produce significant toxicological effects (that is, the HDT is the NOAEL for female mice in this study). The company is performing an additional carcinogenicity study in female mice to remedy this deficiency. Because neither of the cancer studies show any evidence of carcinogenicity, a non-threshold (Q-star) approach cannot be used to estimate cancer risk. Instead, a regulatory MOE has been chosen as a tool for bounding any potential chronic dietary cancer risk from pyraclostrobin that may exist. The regulatory MOE is derived from the HDT in female mice (a NOAEL of 32.8 mg/kg/day) and is 10 times higher than the NOAEL used for chronic non-cancer risk. This is not the traditional MOE approach used to assess the risks of using threshold carcinogens but is believed by the Agency to be appropriate in this situation for the following reasons:

- The genotoxicity data indicate that pyraclostrobin is not mutagenic,

- Both sex groups in the rat study and the male group in the mouse study showed no treatment-related increase in tumors, and
- Two structural analogs of pyraclostrobin have been found ''not likely to be carcinogenic to humans.'' It is, as well, commonly accepted that developing cancers which have been triggered by non-genotoxic substances are reversible if exposure is discontinued prior to complete propagation of the pre-neoplastic lesions or the full expression of cancer.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have previously been established (see 40 CFR 180.582) for the 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-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl] carbamate), expressed as parent compound, in or on a variety of raw agricultural commodities, including barley, grain; beet, sugar, roots; berry, group; fruit, citrus, group; fruit, stone, group; nut, tree, group; peanut; rye, grain; vegetable, bulb, group; vegetable, cucurbit, group; vegetable, fruiting, group; vegetable, root, except sugar beet, subgroup; vegetable, tuberous and corm, subgroup; and wheat, grain. Tolerances have also been established for the 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 the fat, liver, meat, and meat byproducts except liver of cattle, goat, hog, horse, and sheep, and in milk. Risk assessments to assess dietary exposures from pyraclostrobin in food were conducted by EPA 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 one-day or single exposure.

In conducting the acute dietary risk assessments EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.0), which accumulates food consumption (exposure) data directly from reports 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. EPA also used the Lifeline™, Version 2.0 model to conduct the acute dietary risk assessments. Lifeline™ also uses the CSFII, 1994–1996 and 1998 food consumption database but accumulates exposure data using statistical and random samplings of the database. The following assumptions were made for the acute exposure assessments. Tolerance level pyraclostrobin residues, default processing factors, and a 100% crop treated assumption were used for all commodities, as appropriate, except as follows. The highest average field trial residue data were used for leafy vegetables. Mango and papaya, on which no action has yet been taken, were also included in this analysis.

ii. *Chronic exposure.* Chronic dietary risk assessments are performed for a food-use pesticide if a toxicological study and the use pattern of the pesticide have indicated the possibility of an effect of concern occurring as a result of a long-term exposure.

In conducting the chronic dietary risk assessment EPA used the DEEM-FCID™ model, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 CSFII and accumulated exposure to the chemical for each commodity. EPA also used the Lifeline™, Version 2.0 model to conduct the chronic dietary risk assessments. Lifeline™ also uses the CSFII, 1994–1996 and 1998 food consumption database but accumulates exposure data using statistical and random sampling of the database. The following assumptions were made for the chronic exposure assessments. Tolerance level pyraclostrobin residues and default processing factors were used for raw and processed agricultural commodities, as appropriate, except as detailed below. Percent crop treated (PCT) data were used for most crop plant commodities but 100% crop treated values were assumed for banana commodities, mango and papaya (on which no action has been taken yet) commodities, and all animal commodities. The highest average field trial residue data (instead of tolerance level residues) were used for vegetables, leafy, except brassica, group. A proposed tolerance level residue value of 1.5 ppm was used for strawberries instead of the current tolerance level value of 0.4 ppm because BASF Corporation has petitioned for an increase in the pyraclostrobin tolerance in or on strawberries based on additional field trial data. No action has been taken on this petition yet but inclusion of the higher value adds to the conservatism of the exposure estimate. Finally, as noted above, mango and papaya, for which no action has yet been taken on proposed tolerances, were also included in this analysis.

iii. *Cancer.* The chronic dietary risk assessment for cancer utilized the same models, food consumption data, and PCT and residue assumptions as the chronic dietary risk assessment.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated pesticide residue levels in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate.

Section 408(b)(2)(F) of FFDCA 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, that 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) of FFDCA, EPA may require registrants to submit data on PCT.

Below is a description of how the Agency used PCT information, including a list of the PCT data used in the chronic cancer and noncancer PCT values. The value for each crop or crop group also applies to all raw or processed agricultural commodities that are encompassed by that crop or crop group. For example, the value for fruit, pome, group applies to such commodities as apple fruit, dried apples, apple juice and sauce, pear fruit, and pear juice.

Barley— 2%
Beet, sugar—55%
Berry group—2%
Brassica, head and stem, subgroup—1%
Brassica, leafy greens, subgroup—2%

Cherry, sweet—53%
Cherry, tart—53%
Corn, field—1%
Corn, pop—1%
Corn, sweet—1%
Fruit, citrus, group—6%
Fruit, pome, group—7%
Fruit, stone, group—28%
Grape—16%
Hop, dried cones—2%
Nut, tree, group—1%
Pea and bean, dried shelled, except soybean, subgroup—1%
Pea, succulent—1%
Peanut—19%
Peppermint—2%
Pistachio—6%
Rye— 2%
Soybean—1%
Spearmint—2%
Strawberry—80%
Sunflower—1%
Vegetable, bulb, group—17%
Vegetable, cucurbit, group—37%
Vegetable, fruiting, group—18%
Vegetable, leafy, except brassica, group—5%
Vegetable, leaves of root and tuber, except sugar beet—2%
Vegetable, root, except sugar beet, subgroup—6%
Vegetable, tuberous and corm, subgroup—25%
Wheat— 2%

The PCT data that were used in the chronic cancer and noncancer dietary risk analyses were derived as follows. (Note: For the acute analysis the Agency used 100% crop treated.) For crops that were already registered, the Agency used current usage data. These data were determined to be the best data available and were found to be reliable by the Agency.

For crops pending registration, the Agency generally uses projected PCTs based on the highest or second highest current PCT of relatively new fungicide alternatives that target the same diseases as pyraclostrobin, while also taking into account the corresponding market projections for the new pyraclostrobin uses. For corn, the Agency notes that the use of fungicides is negligible. Even the commodity sweet corn, with has the highest use rate of the alternative strobilurin, has a percent crop treated of only 2%. Therefore, the Agency believe for use on corn and sweet corn a 1% estimate is conservative. The use of fungicides on soybean and sunflower is also negligible. The highest use for any alternative is only <1% and therefore, the Agency used 1%. For Pome fruit, the Agency used an estimated percent crop treated of 7%, there are two alternative one with a percent crop treated of <1% and another with a percent crop treated of 15%. The Agency used 7% which is the Agency's estimate of the likely maximum percent crop treated for pyraclostrobin on Pome fruit. It is possible that use could increase beyond this estimated percentage; however, the Agency is requiring annual reports that would detect this increase. For leafy vegetable, the two major alternatives attained a 5% crop treated; therefore, the Agency used a 5% crop treated estimate for leafy vegetables. For Brassica, head and stem, one alternative had a percent crop treated of 2% for broccoli, cabbage and cauliflower and therefore a 2% crop treated estimate was used. For Vegetables, leaves of root and tubers, the best alternative had a maximum percent treated of 3% and the Agency used 2%. There are a few instances where the Agency did not use the maximum percent crop treated of any alternative, such as Vegetables, leaves of root and tubers. In these few instances (Sweet corn, Tree Nuts, Pome Fruit and Vegetables, leaves of roots and tubers) it is because in the past the Agency has found the registrants estimates of percent crop treated to be very reliable, more reliable that estimates based on the maximum percent crop treated of an alternative. The Agency conducted this same analysis of the major alternatives for all the other crops/crop groups to derive these estimates.

As indicated above, for existing uses 2003 PCT data provided by the registrant were accepted as provided for use in the dietary analysis. The 2003 data provided by the registrant were the only actual data available for the registered crops and the registrant best knew, based on its product sales during 2003, how pyraclostrobin was allocated across those crops. Usage data for 2003 from USDA/NASS (National Agricultural Statistics Service), the Agency's proprietary source, and the California Department of Pesticide Regulation were not available to the Agency at the time of analysis. These 2003 data from the registrant were initially presented as market share data—the shares of acre-treatments of pyraclostrobin in total fungicide treatments for each crop—as a check on the registrant's previous projections of the same prior to registration of these crops. These 2003 market shares were based on actual sales of pyraclostrobin allocated to registered crops during eleven months of 2003. Since dietary analysis requires PCTs, not market shares, the Agency converted these 2003 market shares to 2003 PCTs by taking into account the numbers of applications and the total fungicide treatments to acres planted ratio for each crop. At about the same time the registrant did the same conversions. Each of the two sets of 2003 PCTs converted from 2003 market shares were almost identical, with small differences mainly due to different numbers of applications used in their calculations by each party. Since the registrant's 2003 PCT data used numbers of applications that were consistent with those used in its corresponding 2003 market shares data, the registrant's PCTs were considered to be the more consistent of the two and thus were used for the dietary analysis. As a condition of registration, the registrant also will provide corresponding market share or PCT data for 2004 based on sales of its products during 2004 (and, similarly, for following years) for these same registered crops. Generally, chronic dietary analysis utilizes actual PCT data, based on either usage data sources and/or registrant product sales, for registered uses and projected PCT data for pending uses.

The Agency believes that the three conditions previously discussed for PCT data have been met. With respect to Condition 1, EPA finds that the PCT data that are listed above for pyraclostrobin use on a number of agricultural crops are reliable and have a valid basis. Since initial registration of this pesticide the Agency has required annual data submissions concerning the PCT of crops pyraclostrobin is registered for use on and the same requirement will be a condition of registration for crops for which tolerances are being established by this rule.

As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of the consumption information 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 currently lacks sufficient monitoring exposure data 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 used the Pesticide Root Zone Model/Exposure Analysis Modeling System model (PRZM/EXAMS) to estimate pesticide concentrations in surface water and the Screening Concentration in Groundwater (SCI-GROW) model to predict pesticide concentrations in ground water. PRZM/EXAMS incorporates an index reservoir environment in its analysis and includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin. The SCI-GROW model estimates pesticide concentrations in shallow groundwater.

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 LOCs.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated drinking water concentrations (EDWCs), which are the model estimates of a pesticide's concentration in water. EDWCs 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 pyraclostrobin they are further discussed in the aggregate risk sections in Unit E.

Based on the (Tier II) PRZM/EXAMS and SCI-GROW models, the peak EDWCs of pyraclostrobin for acute exposures are estimated to be 22.6 parts per billion (ppb) in surface water and 0.02 ppb in shallow ground water. The peak EDWCs for chronic exposures are estimated to be 1.9 ppb in surface water and 0.2 ppb in shallow ground water. The 36-year average concentration of pyraclostrobin in surface water that was estimated by PRZM-EXAMS for use in the chronic/cancer risk assessment is 1.2 ppb. These concentrations are based on maximum applications to turf, which has the highest labeled application rate of any pyraclostrobin use.

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).

Pyraclostrobin is proposed for application to residential turfgrass and recreational sites. The risk assessment was conducted using the following residential exposure assumptions. Turf applications will be made by professional pest control operators (PCOs) only, so residential handler exposure is not expected and was not evaluated. Postapplication scenarios evaluated assumed that exposure via the dermal route is likely for both adults and children entering treated lawns. Toddlers may also experience exposure via hand-to-mouth contact, object-to-mouth contact, and soil ingestion. The postapplication risk assessment is based on generic assumptions specified in the Recommended Revisions to the Residential SOPs (Standard Operating Procedures) and recommended approaches by an EPA science advisory council. It is also assumed that postapplication turf exposure can occur over periods of from one day to multiple weeks because of pyraclostrobin residue decline times and multiple treatments being made in a season. Thus, these exposures are classified as short-term (one day to one month) and intermediate-term (one to six months).

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pyraclostrobin and any other substances. Pyraclostrobin also does not appear to produce a toxic metabolite that is 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's 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. *Prenatal and postnatal sensitivity.* There was no substantial evidence of increased prenatal or postnatal susceptibility following *in utero* exposure to rats. That is, the lowest-dose adverse developmental effects were seen at a higher dose than that which caused maternal toxicity. However, in the rabbit developmental toxicity study there was qualitative evidence of higher prenatal susceptibility: Increases in resorptions per litter and post-implantation losses were seen in the presence of maternal toxicity (decreases in body weight gain and food consumption). In the 2–generation reproduction study the HDT did not elicit maternal systemic, reproductive, or offspring toxicity. In the 1-generation toxicity study there was an apparent quantitative susceptibility in pups (not seen in the 2–generation reproduction study) that is based on a possible marginal decline (threshold effect) in body weight and body weight gain at the lowest dose level of 21 mg/kg/day (developmental LOAEL) while the parental systemic toxicity NOAEL and LOAEL were 40 and 60 mg/kg/day, respectively, based

on decreased body weight and body weight gain.

3. *Conclusion*. There is an adequate toxicity data base for the selection of doses and endpoints for use in risk assessment for pyraclostrobin. Exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA has evaluated and reevaluated the potential for increased susceptibility of infants and children to pyraclostrobin and has concluded that the special FQPA safety factor (FQPA SF) should be reduced to 1X for all potential pyraclostrobin exposure scenarios because there are no residual uncertainties for pre- or post-natal toxicity and no substantial evidence of increased sensitivity of infants and children to pyraclostrobin. There is low concern for the qualitative susceptibility seen in the rabbit prenatal development study and no residual uncertainties because the developmental effects were seen in the presence of maternal toxicity and there are no clear NOAELs for maternal and developmental toxicities. There is also low concern for the quantitative susceptibility seen in the one-generation rat reproduction study and no residual uncertainties because:

i. The offspring effects seen in this study were not repeated in the two-generation reproduction study.

ii. The marginal increase in pup weights seen at or after post-natal day 7 may be due to higher exposure via their diet.

iii. The dose used for risk assessment would address the effects of concern seen in the offspring.

iv. Even though the mouse cancer study must be repeated, the MOE approach used for cancer risk assessment provides an adequate margin of safety because a NOAEL was established. The repeated study will be done at higher doses.

The Agency therefore concludes that the dietary (food and drinking water) and residential exposure assessments will not underestimate the potential exposure of infants, children, or women of childbearing age.

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 EDWCs. 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 EDWCs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) will not result in unacceptable levels of aggregate human health risk. Because OPP 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, OPP 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, the acute dietary exposure from food to pyraclostrobin is estimated to occupy 2% of the aPAD for the U.S. population in the DEEM-FCID™ model run and 1% of the aPAD for the U.S. population in the Lifeline™ model run; 74% of the aPAD for females 13 - 49 years old in the DEEM-FCID™ model run and 85% of the aPAD for females 13 - 49 years old in the Lifeline™ model run; 3% of the aPAD for all infants (less than one year old) in the DEEM-FCID™ model run and 3% of the aPAD for all infants (less than one year old) in the Lifeline™ model run; and 4% of the aPAD for children 1-2 years old in the DEEM-FCID™ model run and 3% of the aPAD for children 1-2 years old in the Lifeline™ model run. In addition, there is the potential for acute dietary exposure to pyraclostrobin in drinking water. After calculating DWLOCs and comparing them to the EDWCs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 below.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO PYRACLOSTROBIN

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)*	Surface Water EDWC (ppb)	Ground Water EDWC (ppb)	Acute DWLOC (ppb)
U.S. population	3.0	1	22.6	0.02	1.0×10^5
All Infants (less than 1 year old)	3.0	3	22.6	0.02	2.9×10^4
Children 1-2 years old	3.0	3	22.6	0.02	2.9×10^4
Children 3-5 years old	3.0	3	22.6	0.02	2.9×10^4
Children 6-12 years old	3.0	1	22.6	0.02	3.0×10^4
Youths 13-19 years old	3.0	1	22.6	0.02	8.9×10^4
Females 13-49 years old	0.05	85	22.6	0.02	230

The Lifeline™ model results

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure and the Lifeline™ model, EPA has concluded that exposure to pyraclostrobin from food will utilize 6% of the cPAD for the U.S. population, 10% of the cPAD for the subgroup all infants (less than 1 year old), 16% of the cPAD for the subgroup children 3-5 years old, and 5% of the cPAD for the subgroup females 13-49 years old. Based on the use pattern, chronic residential exposure to residues of pyraclostrobin is not expected. In addition, there is the potential for chronic dietary exposure to pyraclostrobin in drinking water. After calculating DWLOCs and comparing them to the EDWCs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as Table 4 demonstrates.

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PYRACLOSTROBIN

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)*	Surface Water EDWC (ppb)	Ground Water EDWC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.034	6	1.9	0.02	1100
All Infants (less than 1 year old)	0.034	10	1.9	0.02	310
Children 1-2 years old	0.034	21	1.9	0.02	270
Children 3-5 years old	0.034	16	1.9	0.02	290
Children 6-12 years old	0.034	9	1.9	0.02	310
Youths 13-19 years old	0.034	4	1.9	0.02	980
Females 13-49 years old	0.034	5	1.9	0.02	970

* The Lifeline™ model results

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 proposed to be registered for application, by professional pest control operators only, to residential and recreational turfgrass sites that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for pyraclostrobin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that aggregated food and residential exposures result in aggregate MOEs of 230 for the U.S. population as a whole and 130 for the subgroup children 1-2 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EDWCs for chronic exposure of pyraclostrobin in ground and surface water. After calculating DWLOCs and comparing them to- the EDWCs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 5 below.

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO PYRACLOSTROBIN

Population Subgroup	Aggregate MOE (Food + Residential)	Target MOE	Surface Water EDWC (ppb)	Ground Water EDWC (ppb)	Short-Term DWLOC (ppb)
U.S. population	230	100	22.6	0.02	980
Children 1-2 years old	130	100	22.6	0.02	110

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 currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for pyraclostrobin.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 230 for the U.S. population as a whole and 130 for the subgroup children 1-2 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EDWCs for chronic exposure of pyraclostrobin in ground and surface water. After calculating DWLOCs and comparing them to the EDWCs for surface and ground water, EPA does not expect (see Table 6) intermediate-term aggregate exposure to exceed the Agency's level of concern.

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO PYRACLOSTROBIN

Population Subgroup	Aggregate MOE (Food + Residential)	Target MOE	Surface Water EDWC (ppb)	Ground Water EDWC (ppb)	Intermediate-Term DWLOC (ppb)
U.S. population	230	100	22.6	0.02	980
Children 1-2 years old	130	100	22.6	0.02	110

5. *Aggregate cancer risk for U.S. population*. The Agency has calculated aggregate MOEs (food and drinking water exposure) for pyraclostrobin. The SCI-GROW model estimates that the chronic concentration of pyraclostrobin in shallow ground water from the proposed use on turf grasses is 0.2 ppb. The PRZM/EXAMS model estimates that the 36-year average chronic/cancer concentration is 1.2 ppb. The aggregate regulatory bounded MOE for food plus drinking water is therefore estimated to be 17,000, as detailed in Table 7 below.

TABLE 7.— MARGINS OF EXPOSURE (MOES) FOR CANCER BASED UPON CHRONIC AGGREGATE EXPOSURE (FOOD PLUS WATER) 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)	Total MOE (food + water)
32.8	0.00198	17,000	3.5×10^{-5}	950,000	17,000

6. *Determination of safety*. Based on these risk assessments, EPA therefore concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to pyraclostrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

1. *Enforcement methods for plant commodities*. The petitioner has proposed two tolerance enforcement methods for the determination of residues of pyraclostrobin and its desmethoxy metabolite (BF 500-3) in/on plant commodities: Liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) method D9808 and high pressure liquid chromatography/ultraviolet (HPLC/UV) method D9904. The validated method levels of quantitation (LOQs) for pyraclostrobin and BF 500-3 for both the LC/MS/MS and HPLC/UV methods are 0.02 ppm for each analyte in plant matrices. Adequate independent method validation and radiovalidation data have been submitted for both methods.

2. *Enforcement methods for livestock commodities*. The proposed enforcement methods were used for data collection in the ruminant and poultry feeding studies. The concurrent method validation recoveries demonstrate that the methods are adequate for data collection. The petitioner has proposed two tolerance enforcement methods for ruminant commodities: HPLC/UV method 439/0 and Method 446, consisting of gas chromatography/mass spectrometry (GC/MS) method 446/0 and LC/MS/MS method 446/1. Radiovalidation data submitted for the GC/MS and LC/MS/MS methods are adequate for liver, milk, and muscle. The HPLC/UV method determines residues of pyraclostrobin per se. Method 446 has a hydrolysis step and determines residues of pyraclostrobin and its metabolites as BF 500-5 and BF 500-8. Independent method validation data for the HPLC/UV and LC/MS/MS methods are acceptable.

3. *Multiresidue methods*. Pyraclostrobin was successfully evaluated through several of the FDA protocols, while recovery of 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 have been forwarded to FDA for inclusion in PAM (Pesticide Analytical Methods) Volume I.

Adequate enforcement methodology (such as gas chromatography) is therefore available to enforce the tolerance expression. The methods 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

No Codex or Mexican maximum residue limits (MRLs) have been proposed or are established for residues of pyraclostrobin. It appears that Canadian MRLs for pyraclostrobin have not yet been published.

C. Conditions

The following conditions are placed upon the initial registration of the uses that are the subject of this rule.

1. *Additional data requirements*.

i. A 28-day inhalation toxicity study that follows the 90-day inhalation toxicity protocol is required due to the potential occupational exposure via this route.

ii. A new carcinogenicity study in female mice, using higher dosing, because no systemic toxicity was seen in the initial study at the HDT.

iii. To support the tolerance for vegetable, leafy, except brassica, group, six additional analyses of residue samples of head lettuce with wrapper leaves are required from the submitted field trials and one additional field trial from either Region 1 or 2 is required for leaf lettuce.

iv. To support the tolerance for brassica, head and stem, subgroup, analyses of four more samples of cabbage with wrapper leaves are required from the submitted field trials.

v. To support the tolerance for brassica, leafy greens, subgroup, three additional field trials on mustard greens

are required, one each from Regions 2, 3, and 10.

vi. To support the tolerance for pea and bean, dried shelled, subgroup, one additional field trial is required from Region 11.

vii. To support the tolerances for soybean, forage and soybean, hay, two additional field trials from Region 5 and one more from Region 4 are required.

viii. To support the increased tolerance for strawberry, one final study of residues from field trials in California is required.

ix. Percent crop treated data will be required at the end of each year for 5 years after registration of the new crop uses for which tolerances are established in this final rule.

2. *Other*.

A reasonable amount of new analytical standard for pyraclostrobin (BAS 500 F) and the desmethoxy metabolite of pyraclostrobin (BF 500-3) must be submitted to the Agency.

V. Comments

Two communications were received from B. Sachau of New Jersey in response to the notices of filing. The communications objected to establishment of the proposed tolerances for several reasons and mostly involve generalized and unsubstantiated disagreement with EPA's risk assessment methodologies or safety findings. Each comment is listed below, followed by the Agency response.

1. Ms. Sachau feels that establishment of these tolerances would add to the pesticide body load that is already carried by the human population.

Agency response: When new or amended tolerances are requested for the presence of the residues of a pesticide and its toxicologically significant metabolite(s) in food or feed, the Agency, as is required by Section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), estimates the risk of the potential exposure to these residues by performing an aggregate risk assessment. Such a risk assessment integrates the individual assessments that are conducted for food, drinking water, and residential exposures. Additionally, the Agency, as is further required by Section 408 of the FFDCA, considers available information concerning what are termed the cumulative toxicological effects of the residues of that pesticide and of other substances having a common mechanism of toxicity with it. The Agency has concluded after this assessment that there is a reasonable certainty that no harm will result from exposure to the residues of interest. Therefore, the proposed tolerance(s) are found to be acceptable. These assessments consider body residue loads of the pesticide, as well as available information concerning the potential that other substances have a common mechanism of toxicity, in reaching a conclusion as to whether or not the reasonable certainty of no harm decision can be made.

2. Ms. Sachau does not want American universities to use tax dollars to promote pesticides (Interregional Research Project Number 4 is affiliated with Rutgers University).

Agency response: Although Ms. Sachau's concerns regarding use of tax dollars to seek pesticide tolerances and registrations are not germane to EPA's statutory basis for acting on the pyraclostrobin tolerance petitions, and thus technically no response is required to this comment, EPA can provide the following information regarding the Interregional Research Project Number4 (IR-4). The Interregional Research Project Number 4 (IR-4) Program was created by Congress in 1963 to assist the growers of minor crops in obtaining registration of pesticides for those uses that might otherwise be uneconomic for pesticide companies to pursue. The IR-4 National Coordinating Headquarters is located at Rutgers University in New Jersey and receives the majority (90%) of its funding from the U.S. Department of Agriculture (USDA). It is the only publicly funded program that conducts research, submits petitions for tolerances, and operates in collaboration with USDA, the Land Grant University System, the agrochemical industry, commodity associations, and the EPA. The IR-4 program takes the lead in identifying and prioritizing minor crop pesticide needs, and in conducting the research needed to obtain the tolerances for use on these crops. Under the Pesticide Registration Improvement Act (PRIA), IR-4 works in cooperation with the pesticide registrant to request a waiver of the fees that are charged for the registration services provided by EPA. The waiver will be granted if the labeling containing the use(s) of interest is closely associated with submission of a tolerance petition by IR-4 and if it is in the public interest. This fee waiver serves as an incentive to the IR-4 program to pursue registration of minor uses. In addition to the work performed for minor use crop pesticide registration, IR-4 also develops risk mitigation measures for existing registered products.

3. Ms. Sachau feels that animal testing is cruel to the animals, is inaccurate, and is potentially even irrelevant to the issue being researched.

Agency response: Animal testing is used because it is currently the only reasonably accurate and acceptable way in which the potential impacts of the use of new chemicals (including pesticides) on humans can be determined. The EPA Test Guidelines recommend the types of animals to be used as test animals in acute irritation studies as well as in longer term, subchronic and chronic, studies such as developmental toxicity, reproduction, and carcinogenicity studies. Results obtained from these animal studies are generally felt by the scientific community to be relevant to humans because the cells and molecules of the selected test species are very similar to those of humans. Therefore, if a pesticide causes toxicity in the test animals, it is likely to do so in humans as well. That said, EPA supports efforts to use the least possible number of animals in the studies that are required to support pesticide registration actions. Concerning alternatives, the use of humans as test subjects is widely felt to be morally unacceptable and there are no *in vitro* type studies that can adequately address the concerns the animal studies satisfy. The EPA is currently working with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) to investigate *in vitro* methods that can acceptably investigate the toxicological concerns associated with the use of pesticides but the use of animal tests is still necessary if the Agency is to make the reasonable certainty of no harm decisions that it is legally required to make.

4. Ms. Sachau feels that the end point effects noted for pyraclostrobin are, by themselves, sufficient that the Agency should reject use of pyraclostrobin for any pesticidal purpose in the U.S.

Agency response: As is the case with almost all conventional pesticides, numerous tests have been performed to study the toxicological effects of pyraclostrobin. The various tests use doses that range from quite low to many times higher than virtually any member of the population of the U.S. could ever be exposed to. The highest doses are, in fact, deliberately chosen to try to elicit toxicological symptoms because a description of these symptoms and the dose levels at which they occur is one of the desired outcomes of the studies. Virtually any chemical (vitamins, for example) is toxic if taken in excessively large doses. Risk, however, is a function of the exposure levels that actually occur in the population in comparison to the threshold exposure level at which

adverse symptoms begin to be elicited . For a toxicologically average person, if actual exposure is less than the adverse symptom exposure threshold, no such symptoms are expected to be seen. However, in order to make the reasonable certainty of no harm determination the Agency requires more assurance than this that the use of animals (instead of humans) for testing, variations in susceptibility among members of the U.S. population, greater sensitivity of infants and children, etc., has been accounted for in the risk assessment process. Therefore, safety factors are used in conjunction with dosing levels at which no or only the first symptoms of exposure to the pesticide were seen to provide a substantial additional margin of safety. This mechanism helps assure that toxicological symptoms will not be elicited in members of the U.S. population by beneficial, labeled uses of the pesticide. The fact that very high doses of a pesticide cause toxicological symptoms is not, by itself, enough to make approval of uses of that pesticide unreasonable.

5. Ms. Sachau feels that if all data are not available, the Agency should not proceed with establishment of the tolerances.

Agency response: The studies the Agency still requires for reasonably complete data support of the currently registered uses and the additional uses that will be enabled by the establishment of the tolerances in this rule are as follow, along with the reasons why they do not interfere with the completion of this rule. It should also be noted that there are always more data that could theoretically be required, and that data requirements do change through time. Data gaps such as those discussed below are, in general, considered to simply be supplementary or confirmatory to the large body of acceptable data that has already been submitted to the Agency in support of the tolerances and uses that are contemplated by this rule.

- A 28-day inhalation toxicity study. - This study has been required so that the Agency can confirm that repeated exposure of the lungs to pyraclostrobin, an irritating chemical, is reasonably safe. Since no incidents are known to the Agency, after two years of registration, where exposure to pyraclostrobin has lead to lung damage, continued use of this fungicide while this study is being completed does not seem unreasonable.
- A new carcinogenicity study of female mice. - Two carcinogenicity studies of pyraclostrobin have been completed. One, testing both sexes of rats, was acceptable for both sexes and produced no evidence of carcinogenicity. The other, testing both sexes of mice, was acceptable for males and produced no evidence of carcinogenicity. It was unacceptable for females because there was no evidence of carcinogenicity and no significant evidence of toxicity even at the highest dose. Because of this, and despite the lack of evidence of carcinogenicity to date, the Agency wants confirmation that pyraclostrobin is not a carcinogen. Despite the lack of carcinogenicity in the acceptable carcinogenicity studies to date, the Agency performed an MOE threshold-type analysis based on the NOAEL for female mice to produce a worst-case cancer risk assessment and found there to be no risk of concern.
- Six more residue samples from previous studies of head lettuce with wrapper leaves, one more residue field trial on head lettuce, and one more residue field trial on leaf lettuce. - A total of 6 acceptable head lettuce and 6 acceptable leaf lettuce residue field trials were submitted and, along with 12 acceptable celery and 8 acceptable spinach residue field trials, provide strong support for establishment of a pyraclostrobin tolerance of 29 ppm on leafy vegetables (except brassica). The Agency therefore believes that the additional studies, while required by our standard operating procedure, will simply serve to confirm the results of the acceptable data we have already evaluated.
- Four more treated samples of cabbage with wrapper leaves. - A total of 8 acceptable residue field trials on cabbage have already been submitted and, together with 7 broccoli field trials, provide strong support for establishment of pyraclostrobin tolerances of 16 ppm in/on brassica head and stem vegetables. The Agency therefore believes that the additional studies, while required by our standard operating procedure, will simply serve to confirm the results of the acceptable data we have already evaluated.
- Three more residue field trial on mustard greens. - A total of 5 acceptable residue field trials on mustard greens have already been submitted and provide strong support for establishment of pyraclostrobin tolerances of 16 ppm in/on brassica leafy greens. The Agency therefore believes that the additional studies, while required by our standard operating procedure, will simply serve to confirm the results of the acceptable data we have already evaluated.
- One more residue field trial on dried shelled peas. - A total of 9 acceptable residue field trials on dried shelled peas have already been submitted and, along with acceptable residue data previously submitted for dried shelled beans, provide substantial support for establishment of a pyraclostrobin tolerance of 0.3 ppm in/on dried shelled peas and beans. The Agency therefore believes that the additional study, while required by our standard operating procedure, will simply serve to confirm the results of the acceptable data we have already evaluated.
- Three more residue field trials on soybean forage and hay. - A total of 17 acceptable residue field trials on soybean forage and hay have already been submitted and provide strong support for establishment of pyraclostrobin tolerances of 5 ppm in/on soybean forage and 7 ppm in/on soybean hay. The Agency therefore believes that the additional studies, while required by our standard operating procedure, will simply serve to confirm the results of the acceptable data we have already evaluated.

6. Ms. Sachau feels that the lack of data on endocrine disruption show that the ''product'' is not ready to be used in the U.S.

Agency response: EPA is required by the FFDCA, as amended by the Food Quality Protection Act (FQPA), to develop a screening program to determine whether certain substances (including all pesticide product active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the [EPA] Administrator may designate.'' Following the recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects on wildlife. For pesticide chemicals EPA will use Federal Fungicide, Insecticide and Rodenticide Act (FIFRA) and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). In the available toxicity studies on pyraclostrobin, there was no estrogen, androgen, and/or thyroid mediated toxicity. When additional appropriate

screening and/or testing protocols being considered under the Agency's EDSP have been developed, pyraclostrobin may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption. The Agency will respond to new information in such a way as is appropriate at that time, but currently has no evidence that pyraclostrobin is an endocrine disruptor.

Furthermore and in conclusion, Ms. Sachau's comments contained no scientific data or other substantive evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to pyraclostrobin from the establishment of these tolerances.

VI. Conclusion

Therefore, tolerances are established for the combined residues of carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester, pyraclostrobin, and methyl-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl] carbamate, the desmethoxy metabolite of pyraclostrobin, expressed as parent compound, in or on apple, wet pomace at 8.0 parts per million (ppm); brassica, head and stem, subgroup at 5.0 ppm; brassica, leafy greens, subgroup at 16.0 ppm; corn, field, grain at 0.1 ppm; corn, field, forage at 5.0 ppm; corn, field, stover at 17.0 ppm; corn, field, refined oil at 0.2 ppm; corn, pop, grain at 0.1 ppm; corn, pop, stover at 17.0 ppm; corn, sweet, kernel plus cob with husks removed at 0.04 ppm; corn, sweet, forage at 5.0 ppm; corn, sweet, stover at 23.0 ppm; fruit, pome, group at 1.5 ppm; hop, dried cones at 23.0 ppm; legume, forage, except peanut and soybean at 25.0 ppm; pea, succulent at 0.2 ppm; pea and bean, dried shelled, except soybean, subgroup at 0.3 ppm; peppermint at 8.0 ppm; soybean, forage at 5.0 ppm; soybean, hay at 7.0 ppm; soybean, hulls at 0.06 ppm; soybean, seed at 0.04 ppm; spearmint at 8.0 ppm; sunflower at 0.3 ppm; vegetable, leafy, except brassica, group at 29.0 ppm; vegetable, leaves of root and tuber, except sugar beet at 16.0; and vegetable, legume, edible podded, subgroup at 0.5 ppm. Tolerances are increased for the combined residues of carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester, pyraclostrobin, and methyl-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl] carbamate, the desmethoxy metabolite of pyraclostrobin, expressed as parent compound, in or on citrus, dried pulp to 12.5 ppm; citrus, oil to 9.0 ppm; and fruit, citrus, group to 2.0 ppm, and deletes the currently existing tolerance in 40 CFR 180.582 for the 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-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl] carbamate), expressed as parent compound in or on bean, dry, seed at 0.3 ppm. The latter tolerance is superseded by the tolerance for pea and bean, dried shelled, except soybean, subgroup at 0.3 ppm. A temporary tolerance is established for the combined residues of (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester), pyraclostrobin, and methyl-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl] carbamate, the desmethoxy metabolite of pyraclostrobin, expressed as parent compound, in or on strawberry at 1.5 ppm, the increased tolerance expiring on December 31, 2005.

VII. 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–2004–0325 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 December 28, 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 PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0325, 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).

VIII. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this 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 tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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.

IX. 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: September 30, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.582 is amended as follows:

i. In paragraph (a)(1) by alphabetically adding commodities to the table; by revising the tolerance levels for ''Citrus, dried pulp, '' ''Citrus, oil'' and ''Fruit, citrus, group'', and by removing the commodity ''Bean, dry, seed''.

ii. By adding paragraph (a)(3).

The amendments to paragraph (a) read as follows:

§ 180.582 Pyraclostrobin; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
* * *	* *
Apple, wet pomace	8.0
* * *	* *
Brassica, head and stem, subgroup	5.0
Brassica, leafy greens, subgroup	16.0
Citrus, dried pulp	12.5
Citrus, oil	9.0
Corn, field, forage	5.0
Corn, field, grain	0.1
Corn, field, refined oil	0.2
Corn, field, stover	17.0
Corn, pop, grain	0.1
Corn, pop, stover	17.0
Corn, sweet, forage	5.0
Corn, sweet, kernel plus cob with husks removed	0.04
Corn, sweet, stover	23.0
Fruit, citrus, group	2.0
Fruit, pome, group	1.5
* * *	* *
Hop, dried cones	23.0
Legume, forage, except peanut and soybean, subgroup	25.0
* * *	* *
Pea, succulent	0.2
Pea and bean, dried shelled, except soybean, subgroup	0.3
* * *	* *
Peppermint	8.0
* * *	* *
Soybean, forage	5.0
Soybean, hay	7.0
Soybean, hulls	0.06
Soybean, seed	0.04
Spearmint	8.0
* * *	* *
Sunflower	0.3
* * *	* *
Vegetable, leafy, except brassica, group	29.0
Vegetable, leaves of root and tuber, except sugar beet	16.0
Vegetable, legume, edible podded, subgroup	0.5
* * *	* *

* * * * *

(3) 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 commodity:

Commodity	Parts per million	Expiration/Revocation Date
Strawberry	1.5	12/31/05

* * * * *

[FR Doc. 04–24247 Filed 10–28–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–7832–2]

Indiana: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA is granting Indiana final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The Agency published a proposed rule on April 20, 2004 and provided for public comment. The public comment period ended on May 20, 2004. We received no comments. No further opportunity for comment will be provided. EPA has determined that Indiana's revisions satisfy all the requirements needed to qualify for final authorization, and is authorizing the State's changes through this final action.

DATES: This final authorization will be effective on October 29, 2004.

ADDRESSES: You can view and copy Indiana's application from 9 a.m. to 4 p.m. at the following addresses: Indiana Department of Environmental Management, 100 North Senate, Indianapolis, Indiana, (mailing address P.O. Box 6015, Indianapolis, Indiana 46206) contact Steve Mojonnier (317) 233–1655, or Lynn West (317) 232–3593, and EPA Region 5, contact Gary Westefer at the following address.

FOR FURTHER INFORMATION CONTACT: Gary Westefer, Indiana Regulatory Specialist, U.S. EPA Region 5, DM–7J, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–7450.

SUPPLEMENTARY INFORMATION: On April 20, 2004, U.S. EPA published a proposed rule (69 FR 21077) proposing to grant Indiana authorization for changes to its Resource Conservation and Recovery Act program, listed in section F of that notice, which was subject to public comment. No comments were received. We hereby determine that Indiana's hazardous waste program revisions satisfy all of the requirements necessary to qualify for final authorization.

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

B. What Decisions Have We Made in This Rule?

We conclude that Indiana's application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we propose to grant Indiana Final authorization to operate its hazardous waste program with the