Dated: September 6, 2005.

Donald S. Welsh,

Regional Administrator, Region III.

■ Accordingly, the added entry for Delaware's Regulation 1, Section 2, and revised entries for Regulation 3, Sections 1, 6, and 11 in 40 CFR 52.420(c) published at 70 FR 41147 are withdrawn as of September 16, 2005.

[FR Doc. 05–18565 Filed 9–15–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0129; FRL–7719–9]

Fluoxastrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, and its Z isomer, (1Z)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, in or on leaf petioles subgroup 4B; peanut; peanut, hay; peanut, refined oil; tomato, paste; vegetable, fruiting, group 8; and vegetable, tuberous and corm, subgroup 1C. This regulation also establishes tolerances for the indirect or inadvertent combined residues of fluoxastrobin and its Z isomer, in or on alfalfa, forage; alfalfa, hay; cotton, gin byproducts; grain, cereal, forage, fodder and straw, group 16; grass, forage; grass, hay; and vegetable, foliage of legume, group 7. This regulation additionally establishes tolerances for the combined residues of fluoxastrobin, its Z isomer, and its phenoxy-hydroxypyrimidine metabolite, 6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinol, expressed as fluoxastrobin, in or on cattle, fat; cattle, meat; cattle, meat byproducts; goat, fat; goat, meat; goat, meat byproducts; horse, fat; horse, meat; horse, meat byproducts; milk; milk, fat; sheep, fat; sheep, meat; and sheep, meat byproducts. Bayer CropScience 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 September 16, 2005. Objections and requests for hearings must be received on or before November 15, 2005.

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–2003–0129. 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: Tony Kish, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9443; e-mail address: *kish.tony@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. 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 April 23, 2003 (68 FR 19991) (FRL–7303–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F6556) by Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, North Carolina 27709. The petition requests that 40 CFR 180.609 be amended by establishing tolerances for the combined residues of the fungicide fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]-oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, in or on the raw agricultural commodities (RACs) alfalfa, forage at 0.05 parts per million (ppm); alfalfa, hay at 1.0 ppm; cotton, gin byproducts at 0.02 ppm; grain, cereal, forage at 0.10 ppm; grain, cereal, hay at 0.10 ppm; grain, cereal, stover at 0.10 ppm; grain, cereal, straw at 0.10 ppm; grass, forage at 0.10 ppm; grass, hay at 0.50 ppm; legume, forage at 0.05 ppm; legume, hay at 0.05 ppm; legume, seed at 0.01 ppm; peanut at 0.01 ppm; peanut, hay at 20 ppm; peanut, refined oil at 0.10 ppm; tomato, paste at 2.0 ppm; vegetable, foliage of legume, group 7 at 0.05 ppm; vegetable, fruiting, group at 1.0 ppm; vegetable, leafy, petioles, except brassica, subgroup at 5.0 ppm; and vegetable, tuberous and corm, subgroup at 0.01 ppm. The petition also requests that 40 CFR 180.609 be amended by establishing tolerances for

the combined residues of fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]-oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, and its phenoxy-hydroxypyrimidine metabolite, 6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinol, in or on the RACs cattle, fat at 0.10 ppm; cattle, meat at 0.05 ppm; cattle, meat byproducts at 0.20 ppm; milk at 0.01 ppm; and milk, fat at 0.10 ppm. That notice included a summary of the petition prepared by Bayer CropScience, the registrant. Several comments concerning the notice were received. They are described and discussed in Unit V.

Based on EPA's review, the aforementioned petition was revised by the petitioner by adjusting some tolerance levels, revising the tolerance expression, and revising the commodity nomenclature to reflect the correct commodity definitions. The tolerance expression was revised to reflect the fact that fluoxastrobin E-isomer, and not the mixture of E- and Z-isomers, is the proposed active ingredient. The petition was also revised, based on extensive field rotational crop data, to add indirect tolerances for the combined residues of fluoxastrobin and its Z-isomer in/on rotated crops. As revised, the petition seeks the establishment of tolerances for combined residues of fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, and its Z isomer, (1Z)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, in or on the RACs leaf petioles subgroup 4B at 4.0 ppm; peanut at 0.010 ppm; peanut, hay at 20.0 ppm; peanut, refined oil at 0.030 ppm; tomato, paste at 1.5 ppm; vegetable, fruiting, group 8 at 1.0 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.010 ppm, the establishment of tolerances for indirect or inadvertent residues for the combined residues of fluoxastrobin and its Z isomer, in or on the RACs alfalfa, forage at 0.050 ppm; alfalfa, hay at 0.10 ppm; cotton, gin byproducts at 0.020 ppm; grain, cereal, forage, fodder, and straw, group 16 at 0.10 ppm; grass, forage at 0.10 ppm; grass, hay at 0.50 ppm; and vegetable, foliage of legume, group 7 at 0.050 ppm; and the establishment of tolerances for the combined residues of fluoxastrobin, its Z isomer, and its phenoxy-hydroxypyrimidine metabolite, 6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinol, expressed as fluoxastrobin, in or on the RACs cattle, fat at 0.10 ppm; cattle, meat at 0.05 ppm; cattle, meat byproducts at 0.10 ppm; goat, fat at 0.10 ppm; goat, meat at 0.05 ppm; goat, meat byproducts at 0.10 ppm; horse, fat at 0.10 ppm; horse, meat at 0.05 ppm; horse, meat byproducts 0.10 ppm; milk at 0.02 ppm; milk, fat at 0.50 ppm; sheep, fat at 0.10 ppm; sheep, meat at 0.05 ppm; and sheep, meat byproducts at 0.10 ppm.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal upper limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for the fluoxastrobin tolerances described in Unit II. EPA's assessment of exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by fluoxastrobin are discussed in Table 1. of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity-rats	NOAEL was 70.4 milligrams/kilogram/day (mg/kg/day) for males; 162.9 mg/kg/day for females. LOAEL was 580.0 mg/kg/day for males based on reduced body weight gain and food intake, vacuolation in the zona fasciculate of the adrenal cortex, calculi in the urethra and kidney, and histological lesions in kidney, urinary bladder, and urethra; 1416.1 mg/kg/day for females based on increased liver weight (by 20%).
870.3100	90-Day oral toxicity-mice	Neither a NOAEL nor a LOAEL were assigned. There was a dose related increase in liver weight in both sexes and in kidney weight in females, in addition to other effects whose toxicological relevance was considered uncertain. Among these effects were increased hepatocellular hypertrophy with cytoplasmic changes in the high-dose males and minimal to moderate kidney tubular hypertrophy in mid- and high-dose females.

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

Guideline No.	Study Type	Results
870.3150	90-Day oral toxicity-dogs	NOAEL was 3.0 mg/kg/day (100 ppm) for both males and females. LOAEL was 24.8/24.2 mg/kg/day (800 ppm) for both males and females based on dose-related reductions in net body weight gain and food efficiency in addition to toxicity findings in the liver in both sexes (cholestasis) and in kidneys (increased relative weights in females and degeneration of the proximal tubular epithelium in males).
870.3200	28-Day dermal toxicity-rats	NOAEL was 1,000 mg/kg/day (the limit dose, for both systemic and dermal effects). No LOAEL was identified.
870.3700	Prenatal development-rats	Maternal NOAEL was greater than or equal to 1,000 milligrams per kilogram body-weight per day (mg/kg bw/day; limit dose). No maternal LOAEL was identified. Developmental NOAEL was greater than or equal to 1,000 mg/kg bw/day. No developmental LOAEL was identified.
870.3700	Prenatal development-rabbits	Maternal NOAEL was 100 mg/kg/day. Maternal LOAEL was 400 mg/kg/day based on cold ears, transient body weight loss, and decreased food consumption. Developmental NOAEL was greater than or equal to 400 mg/kg/day. No developmental LOAEL was identified.
870.3800	Reproduction and fertility effects-rats	Parental systemic NOAEL was 70.0 mg/kg/day for males and 84.7 mg/kg/day for females. Parental systemic LOAEL was 665.0 mg/kg/day for males and 825.4 mg/kg/day for females based on decreased premating body weight gain of the P-generation males and females and decreased premating absolute body weight of the F_1 males and females. Reproductive NOAEL was greater than 665.0 mg/kg/day for males and greater than 825.4 mg/kg/day for females. No reproductive LOAEL was identified. Offspring systemic NOAEL was 70.0 mg/kg/day for males and 84.7 mg/kg/day for females. Offspring systemic LOAEL was 665.0 mg/kg/day for males and 825.4 mg/kg/day for females based on decreased body weights, delayed preputial separation, and incomplete ossification in the F_1 and/or F_2 males and females.
870.4100	Chronic toxicity-dogs	NOAEL was 1.7 mg/kg/day for males and 1.5 mg/kg/day for females. LOAEL was 8.1 mg/kg/day for males and 7.7 mg/kg/day for females based on body weight reductions and hepatocytomegaly and cytoplasmic changes associated with increased serum liver alkaline phosphatase indicative of cholestasis.
870.4200	Carcinogenicity--mice	NOAEL was 775.6 mg/kg bw/day for males and 1265.1 mg/kg bw/day for females. No LOAEL was identified. There was no evidence of carcinogenicity.
870.4300	Combined chronic toxicity/carcinogenicity--rats	NOAEL was 53.0 mg/kg/day for males and 181.3 mg/kg/day for females. LOAEL was 271.9 mg/kg/day for males and 1083.2 mg/kg/day for females was based on decreased body weight, decreased body weight gain, and decreased food efficiency in both sexes; decreased spleen weight in males; and microscopic lesions in the uterus of females. The apparent increase in tumors in the uterus and thyroid were addressed and resolved by an Agency committee, which concluded that no carcinogenic concern exists for fluoxastrobin.
870.6200	Acute neurotoxicity screening battery--rats	Neurotoxicity NOAEL was greater than or equal to 2,000 mg/kg (limit dose). No LOAEL was identified.
870.6200	Subchronic neurotoxicity screening battery--rats	Systemic NOAEL (systemic and neurotoxic) was 473.9/582.4 mg/kg/day for males and females, respectively. No LOAEL was identified.
870.5100	Gene Mutation-*in vitro* bacterial reverse gene mutation	Negative (considered non-mutagenic in *Salmonella typhimurium* cultures treated up to cytotoxic/ precipitating levels).
870.5100	Gene Mutation--*in vitro* bacterial reverse gene mutation (the test substance was HEC 5725N (E:Z ratio of 90%:10%)	Negative (considered non-mutagenic in this *Salmonella typhimurium*/microsome test).

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

Guideline No.	Study Type	Results
870.5100	Gene Mutation--*in vitro* bacterial reverse gene mutation (the test substance was HEC 5725-phenoxy-hydroxy-pyrimidine)	Negative (considered non-mutagenic in this *Salmonella typhimurium*/mammalian activation gene mutation assay).
870.5100	Gene Mutation--*in vitro* bacterial reverse gene mutation (the test substance was HEC 5725-dihydroxy- pyrimidine)	Negative (considered non-mutagenic in this *Salmonella typhimurium*/mammalian activation gene mutation assay).
870.5300	Gene mutation-*in vitro* mammalian forward gene mutation	Negative (considered non-mutagenic in this in vitro forward mutation V79-HPRT test).
870.5375	Gene Mutation--*in vitro* mammalian chromosome aberrations in Chinese hamster lung (V79) cells	Negative (considered to be negative for clastogenicity in this in vitro mammalian cell test).
870.5395	Cytogenics-*in vivo* mammalian cytogenetics - micronucleus assay (mouse)	Negative (considered non-clastogenic, as indicated by no increases in micronuclei in bone marrow).
870.7485	Metabolism and pharmacokinetics-rat	Absorption, distribution, and metabolism were fully characterized in several rat metabolism studies using each of the three ^{14}C-radiolabeled rings in fluoxastrobin. Absorption was almost complete following a single oral low dose. Peak plasma concentrations were attained within 0.5 to 8 hours depending on the dose and label position. Fecal excretion was the major route of elimination while renal excretion was a secondary route and elimination via expired air was negligible. Fluoxastrobin was extensively metabolized as evidenced by the extensive metabolite profiles from urine, feces, and bile and the relative absence of parent compound (except in the feces of rats given the high dose).
870.7600	Dermal penetration--monkey	Following an 8-hour dermal application in a male monkey, absorption was negligible (1.16% preliminary, 2.16% main). The normalized absorption value for the main study was 2.31%.
870.7800	Immunotoxicity-mouse (subacute feeding study)	No clinical signs of toxicity or mortality were found and no treatment-related effects were found on body weight, food intake, or B-cell activated, T-cell mediated IgM response to SRBC. Based on these findings, and findings in the 90-day oral rat study (no difference between the control and treated animals in spleen cell count, macrophage activities after PMA stimulation and plaque-forming cell assay after challenge with sheep erythrocytes), it was concluded that fluoxastrobin is not immunotoxic. However, the study is considered unacceptable because of uncertainty in dietary test material intake, failure to report spleen weight of each mouse at necropsy, and failure of the laboratory to demonstrate its capability in performing this type of assay.

B. Toxicological Endpoints

The highest 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for fluoxastrobin used for human risk assessment is shown in Table 2. of this unit:

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

Exposure Scenario	Dose Used in Risk Assessment; Interspecies, Intraspecies, and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary	NOAEL = None	Not applicable	There was no indication of an adverse effect attributable to a single dose. An aRfD was not established.
Chronic Dietary (all populations)	NOAEL = 1.5 mg/kg/day UF = 100X	Special FQPA SF = 1X cPAD = 0.015 mg/kg/day	Chronic Toxicology-Dog LOAEL = 8.1 mg/kg/day for males and 7.7 mg/kg/day for females based on body weight reductions, hepatocytomegaly, and cytoplasmic changes associated with increased serum liver alkaline phosphatase that is indicative of cholestasis.
Incidental Short-Term Oral (1–30 days)	NOAEL = 3.0 mg/kg/day UF = 100X	Residential LOC for MOE = 100	90-Day Subchronic Oral Toxicology-Dog LOAEL = 24.8 mg/kg/day (800 ppm) for males and 24.2 mg/kg/day (800 ppm) for females based on dose-related reductions in net body weight gain and food efficiency; toxicity findings in the liver (cholestasis) in both sexes; and toxicity findings in the kidneys (increased relative weights in females and degeneration of the proximal tubular epithelium in males).
Incidental Intermediate-Term Oral (1–6 months)	NOAEL = 3.0 mg/kg/day UF = 100X	Residential LOC for MOE = 100	90-Day Subchronic Oral Toxicology-Dog LOAEL = 24.8 mg/kg/day (800 ppm) for males and 24.2 mg/kg/day (800 ppm) for females based on dose-related reductions in net body weight gain and food efficiency; toxicity findings in the liver (cholestasis) in both sexes; and toxicity findings in the kidneys (increased relative weights in females and degeneration of the proximal tubular epithelium in males).
Short-Term Dermal (1–30 days)	Not applicable	None	None: A 28-day dermal toxicity study in the rat was negative up to the limit dose and there are no developmental or neurotoxicity concerns.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUOXASTROBIN FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment; Interspecies, Intraspecies, and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Intermediate-Term Dermal (1–6 months)	NOAEL = 3.0 mg/kg/day UF = 100X Dermal absorption rate = 2.3%	Residential LOC for MOE = 100	90-Day Subchronic Oral Toxicology-Dog LOAEL = 24.8 mg/kg/day (800 ppm) for males and 24.2 mg/kg/day (800 ppm) for females based on dose-related reductions in net body weight gain and food efficiency; toxicity findings in the liver (cholestasis) in both sexes; and toxicity findings in the kidneys (increased relative weights in females and degeneration of the proximal tubular epithelium in males).
Long-Term Dermal (greater than 6 months)	NOAEL = 1.5 mg/kg/day UF = 100X Dermal absorption rate = 2.3%	Residential LOC for MOE = 100	Chronic Toxicology-Dog LOAEL = 8.1 mg/kg/day for males and 7.7 mg/kg/day for females based on body weight reductions, hepatocytomegaly, and cytoplasmic changes associated with increased serum liver alkaline phosphatase that is indicative of cholestasis.
Short-Term Inhalation (1–30 days)	NOAEL = 3.0 mg/kg/day UF = 100X	Residential LOC for MOE = 100	90-Day Subchronic Oral Toxicology-Dog LOAEL = 24.8 mg/kg/day (800 ppm) for males and 24.2 mg/kg/day (800 ppm) for females based on dose-related reductions in net body weight gain and food efficiency; toxicity findings in the liver (cholestasis) in both sexes; and toxicity findings in the kidneys (increased relative weights in females and degeneration of the proximal tubular epithelium in males).
Intermediate-Term Inhalation (1–6 months)	NOAEL = 3.0 mg/kg/day UF = 100X	Residential LOC for MOE = 100	90-Day Subchronic Oral Toxicology-Dog LOAEL = 24.8 mg/kg/day (800 ppm) for males and 24.2 mg/kg/day (800 ppm) for females based on dose-related reductions in net body weight gain and food efficiency; toxicity findings in the liver (cholestasis) in both sexes; and toxicity findings in the kidneys (increased relative weights in females and degeneration of the proximal tubular epithelium in males).
Long-Term Inhalation (greater than 6 months)	NOAEL = 1.5 mg/kg/day UF = 100X	Residential LOC for MOE = 100	Chronic Toxicology-Dog LOAEL = 8.1 mg/kg/day for males and 7.7 mg/kg/day for females based on body weight reductions, hepatocytomegaly, and cytoplasmic changes associated with increased serum liver alkaline phosphatase that is indicative of cholestasis.
Cancer (oral, dermal, inhalation)	Classification: Not likely to be carcinogenic to humans.		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* As is described in Unit II., tolerances for fluoxastrobin are being established on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from fluoxastrobin in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one-day or single exposure. The toxicological database for fluoxastrobin identified no adverse effect attributable to a single dose, therefore an acute dietary exposure assessment was not performed.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™ version 2.0) and the Lifeline™ model, version 2.0, both of which incorporate food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). The assumptions made for the chronic dietary exposure assessments were that residues, for all commodities, were present at 100% of the tolerance levels and fluoxastrobin was applied to 100% of each crop to which it may be applied.

2. *Dietary exposure from drinking water*. The Agency does not have drinking water monitoring exposure data to use in a comprehensive dietary exposure analysis and risk assessment for fluoxastrobin, a new pesticidal chemical. Because of this the Agency made drinking water concentration estimates by use of simulation or modeling, which takes into account data on the physical and chemical characteristics of fluoxastrobin.

The Agency used the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS (PRZM version 3.12 beta and EXAMS version 2.98.04)), to produce estimates of pesticide concentrations in an index reservoir (the surface water concentration estimates). The Screening Concentrations in Ground Water (SCI-GROW) model was used to predict pesticide concentrations in shallow ground water (the ground water concentration estimates). The surface water concentration analysis was based on the turf use, which has the highest labeled annual application rate and assumes the highest default value of 87% percentage cropped area (PCA) land use around the index reservoir. The assumptions in this analysis are therefore also conservative. The ground water concentration analysis was based on the maximum pesticide use rate (the turf use again), the persistence of fluoxastrobin in soil, and the ability of fluoxastrobin to leach.

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 levels of concern.

Estimated drinking water concentrations (EDWCs) derived from these models are used to calculate drinking water levels of comparison (DWLOCs). The DWLOCs are used as points of comparison against the EDWCs. DWLOCs are theoretical upper limits on the concentration of a pesticide that could occur in drinking water without exceeding the size of the risk cup, considering the aggregate exposure to that pesticide in food and from residential uses. Since DWLOCs represent maximum allowable exposure to fluoxastrobin in drinking water, they are further discussed in the aggregate risk sections in Unit III.E.

Based on the PRZM/EXAMS and SCI-GROW models, the EDWCs of fluoxastrobin for acute exposures are 28 parts per billion (ppb) for surface water and less than 1 ppb for ground water. The EDWCs for chronic exposures are 14 ppb for surface water and less than 1 ppb for ground water.

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

There is potential for homeowner exposure to fluoxastrobin in residential settings by entry to turf areas where this fungicide has previously been applied, such as lawns where children might play or golf courses that adults might be active on. Therefore, risk assessments have been performed for residential postapplication scenarios. However, only professional pest control operators will be allowed to make the turf applications so residential handler exposure was not evaluated.

Since chemical-specific data were unavailable, the Agency used general current approaches for non-occupational assessment and believes that the calculated risks represent screening level estimates. Maximum application rates have been used for all scenarios, and the risk estimates assume no dissipation of residues after day zero and do not consider removal of residues as a result of periodic cutting of the grass. Additionally, the intermediate-term endpoint was used for dermal risk estimates, even though the non-occupational exposure duration is believed to mostly be short-term (as a result of the use pattern), because no short-term dermal toxicity endpoint was identified.

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 fluoxastrobin and any other substances and fluoxastrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fluoxastrobin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. The toxicity database for fluoxastrobin, including acceptable developmental toxicity studies in rats and rabbits, as well as a two-generation reproduction toxicity study, provides no indication of prenatal and/or post-natal sensitivity.

3. *Conclusion*. There is a complete toxicity data base for fluoxastrobin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency therefore has recommended reducing the special FQPA SF to 1X, based on the following additional considerations. First, there are no low risk concerns indicated by the various hazard studies. The study data are of high quality, and there are no residual uncertainties with regard to the pre- and/or postnatal toxicity of this chemical. Second, the dietary food exposure assessment utilizes proposed tolerance level or higher residues and 100% crop treated information for all commodities. By using these screening-level assessments, chronic exposures and risks will not be underestimated.

Third, the dietary drinking water assessments utilize values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations. Fourth, the residential exposure assessment utilizes activity-specific transfer coefficients and turf transferable residues (TTR), as well as maximum application rates for the postapplication scenario. The residential assessment is based on reliable data and is unlikely to underestimate exposure/risk.

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 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, not regulatory standards for drinking water . 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 the source of the 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) would not result in unacceptable levels of aggregate human health risk at this time. 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.* The toxicological database for fluoxastrobin identified no adverse effect attributable to a single dose, therefore fluoxastrobin is not expected to pose an acute dietary risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fluoxastrobin from food will utilize 10% of the cPAD for the U.S. population, 6% of the cPAD for all infants less than 1 year old, and 25% of the cPAD for children 1 to 2 years old, the children subpopulation with the greatest exposure. Based on the use pattern, chronic residential exposure to residues of fluoxastrobin is not expected. However, there is the potential for chronic dietary exposure to fluoxastrobin 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 shown in Table 3. of this unit:

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

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EDWC (ppb)	Ground Water EDWC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.015	10	14	< 1	470
All infants (less than 1 year old)	0.015	6.0	14	< 1	140
Children 1 to 2 years old	0.015	25	14	< 1	110

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposures both take into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because all short- and intermediate-term quantitative hazard estimates (via the dermal and incidental oral routes) for fluoxastrobin are based on the same endpoint, a screening level, conservative aggregate risk assessment was conducted that combined the short-term incidental oral and intermediate-term dermal exposure estimates (i.e., the highest exposure estimates).

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 1,000 for the U.S. population, 1,100 for females 13–49 years old, and 180 for 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- and intermediate-term DWLOCs were calculated and compared to the EDWCs for chronic exposure to fluoxastrobin in ground and surface water. After calculating DWLOCs and comparing them to the EDWCs for surface and ground water, EPA does not expect short- and intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 4. of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT- AND INTERMEDIATE-TERM EXPOSURE TO FLUOXASTROBIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EDWC (ppb)	Ground Water EDWC (ppb)	Short- and Intermediate-Term DWLOC (ppb)
U.S. population	1,000	100	28	< 1	940
Females 13–49 years old	1,100	100	28	< 1	820
Children 1–2 years old	180	100	28	< 1	140

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography/mass spectrometry/mass spectrometry methods) is available to enforce the tolerance expression. The methods are LC/MS/MS Method No. 00604, entitled ''Analytical Determination of Residues of the Fungicide HEC 5725 In/On Cereals, Cereal Processed Products and Vegetables by HPLC-MS/MS [high-pressure liquid chromatography--mass spectrometry/mass spectrometry],'' and LC/MS/MS Method No. 00649, entitled ''Analytical Method 00649 for the Determination of Residues of HEC 5725 In/On Matrices of Plant Origin by HPLC-MS/MS.'' 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

There are currently no Mexican, Canadian, nor CODEX maximum residue limits established for fluoxastrobin.

C. Conditions

The following conditions are being imposed on Bayer CropScience (the petitioner) for the registration of fluoxastrobin.

1. Submit additional information concerning weather conditions, confirmatory raw data, and soil characteristics data for the crop field trial and field rotational crop studies.

2. Submit additional data concerning the chromatograms and chromatography in the goat metabolism study.

3. The enforcement methods must be rewritten to include instructions for the analysis of all crops, and to specify the additional ions to be monitored for quantitation.

4. A new peanut processing study must be submitted.

5. Submit reference standard materials for fluoxastrobin and several molecules related to it, including isotopically labeled internal standard reference materials, to the EPA National Pesticide Standards Repository.

6. Submit additional information concerning the grass forage and hay rotational crop field trials.

7. Submit confirmatory data and additional information concerning the storage stability data.

8. Submit additional information concerning the mouse immunotoxicity subacute feeding study.

V. Comments

In response to the notice of filing one communication was received from Susie Wilcher in the role of private citizen and one communication, undersigned by Ellen Connett, was received from the Fluoride Action Network (FAN). The communications objected to establishment of the proposed tolerances for several reasons, some of them specific and others involving generalized and unsubstantiated disagreement with EPA's risk assessment methodologies or safety findings.

Ms. Wilcher's comments contained general objections to the use of pesticides on food and to the use of animal testing to determine the safety of pesticides. The Agency understands the commentor's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, under the existing legal framework provided by section 408 of the FFDCA EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute.

The Agency disagrees with the commenter's objections to animal testing. Since humans and animals have complex organ systems and mechanisms for the distribution of chemicals in the body, as well as processes for eliminating toxic substances from their systems, EPA relies on laboratory animals such as rats and mice to mimic the complexity of human and higher-order animal physiological responses when exposed to a pesticide. EPA is committed, however, to reducing the use of animals whenever possible. EPA-required studies include animals only when the requirements of sound toxicological science make the use of an animal absolutely necessary. The Agency's goal is to be able to predict the potential of pesticides to cause harmful effects to humans and wildlife by using fewer laboratory animals as models and have been accepting data from alternative (to animals) test methods for several years. As progress is made on finding or developing non-animal test models that reliably predict the potential for harm to humans or the environment, EPA expects that it will need fewer animal studies to make safety determinations.

FAN submitted a number of different comments. First, FAN asked whether fluoxastrobin was already registered in the United States and what are the names of the fluoxastrobin products used on residential turf and golf courses. Fluoxastrobin is not currently registered but with the completion of this tolerance regulation that registration should be granted shortly. To the best of EPA's knowledge, the product name under which fluoxastrobin is marketed for turf and golf course use is HEC 480 SC Fungicide.

Second, FAN suggested that a 14-week feeding study using dogs showed an effect on the thyroid, which seems to conflict with the statement that ''...There is no evidence to suggest that fluoxastrobin has any primary

endocrine disruptive potential.'' FAN stated that a ''discussion or rationale'' addressing this should have been provided. EPA does believe that the thyroid effects seen in the dog study indicated that fluoxastrobin is an endocrine disruptor. An effect on the thyroid gland, even though this gland is part of the endocrine system, does not necessarily mean that endocrine disruption has or will occur. In this case, the effects observed in the thyroid gland were induced by effects fluoxastrobin had on liver enzymes and are therefore considered secondary.

Third, FAN claimed that a ''fuller discussion and description of the metabolites of fluoxastrobin should have been presented.'' The notice states: ''The residue of concern is parent fluoxastrobin (sum of E and Z isomers).'' According to the Compendium of Pesticide Common Names, Fluoxastrobin ''was provisionally approved for the (EZ)-isomer [193740–76–0] in April 2002. The definition was changed to the (E)-isomer in January 2003 at the request of the sponsor...Because of this change it is not clear from the information supplied in this notice what isomer/metabolite are of concern.''

Fluoxastrobin is the accepted common name for the pesticidally active E-isomer of (2-[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy phenyl)-5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime. The Z-isomer of fluoxastrobin is typically present at much lower levels (E:Z ratio of approximately 90:10). Additionally, the Z-isomer of fluoxastrobin is considered to be a metabolite (photo-degradate) of fluoxastrobin. The CAS Number Bayer CropScience initially obtained for fluoxastrobin pertained to both isomers combined. After consultation with the Agency, the petitioner requested that fluoxastrobin (the pesticidally active E-isomer only) be designated as the active ingredient. The tolerances that are being established today include both fluoxastrobin (i.e. the E-isomer) and the Z-isomer and the risk assessment for these tolerances was based on exposures resulting from both isomers.

Fourth, FAN requested that the Agency begin to incorporate the Chemical Abstract Service (CAS) numbers for ''every chemical, and its metabolite(s)'' in ''all future reports, especially those published in the **Federal Register**.'' EPA is evaluating the feasibility of such a step. EPA would note, however, that not every molecule or substance has a CAS number. Many metabolites do not have a CAS number, for example, because no application for a CAS number was made or is required. CAS is also often not willing to assign CAS numbers to substances it believes are not able to be characterized well enough (some petroleum distillates, for example). In addition, CAS numbers may be inappropriate in some types of reports. However, the CAS number could be a useful identifier in certain documents for molecules which have one.

FAN also commented that the data references cited in the notice of filing were not available in the docket, and that without this information, it was not possible to comment on the findings presented. In response, the Agency transmitted to FAN the human health risk assessment and the toxicological studies used in that risk assessment.

VI. Conclusion

Therefore, tolerances requested for fluoxastrobin in the revised petition are established.

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–2003–0129 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 15, 2005.

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. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2003–0129, 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 he 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 issue(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 tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

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 2, 2005.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 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 180.609 is added to read as follows:

§ 180.609 Fluoxastrobin; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, and its Z isomer, (1Z)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, in or on the following raw agricultural commodities:

Commodity	Parts per million
Leaf petioles subgroup 4B	4.0
Peanut	0.010
Peanut, hay	20.0
Peanut, refined oil	0.030
Tomato, paste	1.5
Vegetable, fruiting, group 8	1.0
Vegetable, tuberous and corm, subgroup 1C	0.010

(2) Tolerances are established for the combined residues of fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, its Z isomer, (1Z)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, and its phenoxy-

hydroxypyrimidine metabolite, 6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinol, in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.10
Cattle, meat	0.05
Cattle, meat byproducts	0.10
Goat, fat	0.10
Goat, meat	0.05
Goat, meat byproducts	0.10
Horse, fat	0.10
Horse, meat	0.05
Horse, meat byproducts	0.10
Milk	0.02
Milk, fat	0.50
Sheep, fat	0.10
Sheep, meat	0.05
Sheep, meat byproducts	0.10

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

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

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent combined residues of fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, and its Z isomer, (1Z)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimydinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime, in or on the following raw agricultural commodities when present therein as a result of the application of fluoxastrobin to the growing crops listed in paragraph (a)(1) of this section:

Commodity	Parts per million
Alfalfa, forage	0.050
Alfalfa, hay	0.10
Cotton, gin byproducts	0.020
Grain, cereal, forage, fodder, and straw, group 16	0.10
Grass, forage	0.10
Grass, hay	0.50
Vegetable, foliage of legume, group 7	0.050

[FR Doc. 05–18421 Filed 9–15–05; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF DEFENSE

48 CFR Part 205

[DFARS Case 2004–D025]

Defense Federal Acquisition Regulation Supplement; Provision of Information to Cooperative Agreement Holders

AGENCY: Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD has adopted as final, without change, an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement Section 816 of the National Defense Authorization Act for Fiscal Year 2005. Section 816 increased, from $500,000 to $1,000,000, the threshold at which a DoD contract must include a requirement for the contractor to provide to cooperative agreement holders, upon their request, a list of the contractor's employees who are responsible for entering into subcontracts.

DATES: Effective September 16, 2005.

FOR FURTHER INFORMATION CONTACT: Ms. Robin Schulze, Defense Acquisition Regulations Council, OUSD(AT&L)DPAP(DAR), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–3062. Telephone (703) 602–0326; facsimile (703) 602–0350. Please cite DFARS Case 2004–D025.

SUPPLEMENTARY INFORMATION:

A. Background

DoD published an interim rule at 70 FR 8536 on February 22, 2005, to implement Section 816 of the National Defense Authorization Act for Fiscal Year 2005 (Pub. L. 108–375). Section 816 amended 10 U.S.C. 2416(d) to increase, from $500,000 to $1,000,000, the threshold at which a DoD contract must include a requirement for the contractor to provide to cooperative agreement holders, upon their request, a list of the contractor's employees who are responsible for entering into subcontracts. The interim rule amended the prescription for use of the clause at DFARS 252.205–7000, Provision of Information to Cooperative Agreement Holders, to reflect the new dollar threshold.

DoD received no comments on the interim rule. Therefore, DoD has adopted the interim rule as a final rule without change.

This rule was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993.

B. Regulatory Flexibility Act

DoD certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* While the rule reduces administrative burdens for contractors, the economic impact is not expected to be substantial.

C. Paperwork Reduction Act

The information collection requirements of the clause at DFARS 252.205–7000, Provision of Information to Cooperative Agreement Holders, have been approved by the Office of Management and Budget, under Control Number 0704–0286, for use through September 30, 2007.

List of Subjects in 48 CFR Part 205

Government procurement.

Michele P. Peterson,

Editor, Defense Acquisition Regulations System.

Interim Rule Adopted as Final Without Change

■ Accordingly, the interim rule amending 48 CFR Part 205, which was published at 70 FR 8536 on February 22, 2005, is adopted as a final rule without change.

[FR Doc. 05–18476 Filed 9–15–05; 8:45 am]

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DEPARTMENT OF DEFENSE

48 CFR Part 217

[DFARS Case 2004–D024]

Defense Federal Acquisition Regulation Supplement; Multiyear Contracting

AGENCY: Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD has adopted as final, without change, an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement Section 8008 of the Defense Appropriations Act for Fiscal Year 2005 and Section 814 of the National Defense Authorization Act for Fiscal Year 2005. Sections 8008 and 814 contain requirements related to the funding of multiyear contracts.

DATES: Effective September 16, 2005.

FOR FURTHER INFORMATION CONTACT: Ms. Robin Schulze, Defense Acquisition Regulations Council, OUSD(AT&L)DPAP(DAR), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–3062. Telephone (703) 602–0326; facsimile (703) 602–0350. Please cite DFARS Case 2004–D024.

SUPPLEMENTARY INFORMATION:

A. Background

DoD published an interim rule at 70 FR 24323 on May 9, 2005, to implement Section 8008 of the Defense Appropriations Act for Fiscal Year 2005 (Pub. L. 108–287) and Section 814 of the