

American Society of Testing and Materials (ASTM) Method D3063–94 or D3074–94 for analysis of the propellant portion of the coating; South Coast Air Quality Management District (SCAQMD) Method 318–95, Determination of Weight Percent Elemental Metal in Coatings by X-ray Diffraction, July, 1996, for metal content; and ASTM D523–89 (Reapproved 1999), Standard Test Method for Specular Gloss for specular gloss of flat and nonflat coatings.

EPA Method 311—Analysis of Hazardous Air Pollutant Compounds in Paints and Coatings by Direct Injection into a Gas Chromatograph (40 CFR part 63, appendix A) also is a compilation of voluntary consensus standards. The following are incorporated by reference in EPA Method 311—Analysis of Hazardous Air Pollutant Compounds in Paints and Coatings by Direct Injection into a Gas Chromatograph (40 CFR part 63, appendix A): ASTM D1979–91, ASTM D3432–89, ASTM D4457–85, ASTM D4747–87, ASTM D4827–93, and ASTM PS9–94.

For the methods required by the final rule, a source may apply to EPA for permission to use alternative test methods or alternative monitoring requirements in place of any required testing methods, performance specifications, or procedures under §§ 63.7(f) and 63.8(f) of subpart A of the General Provisions.

*J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

Executive Order 12898 (59 FR 7629, Feb. 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income populations. Further, it

establishes national emission standards for VOC in aerosol coatings.

*K. 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. The EPA will submit a report containing the final rule amendment 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 amendment in the **Federal Register**. The final rule amendment is not a “major rule” as defined by 5 U.S.C. 804(2). This final rule is effective on June 23, 2008.

**List of Subjects in 40 CFR Part 59**

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: March 13, 2008.

**Stephen L. Johnson**,  
*Administrator.*

■ For the reasons set out in the preamble, part 59 of Title 40 of the Code of Federal Regulations is amended as follows:

**PART 59—[AMENDED]**

■ 1. The authority citation for part 59 continues to read as follows:

**Authority:** 42 U.S.C. 7414 and 7511b(e).

**Subpart E—[Amended]**

■ 2. Section 59.501 is amended by revising paragraphs (a) and (b)(1), (b)(2) and (b)(3) to read as follows:

**§ 59.501 Am I subject to this subpart?**

(a) The regulated entities for an aerosol coating product are the manufacturer or importer of an aerosol coating product and a distributor of an aerosol coating product if it is named on the label or if it specifies the formulation of the product. Distributors include retailers who fall within the definition of “distributor” in § 59.503.

(b) \* \* \*

(1) If you are a manufacturer or importer, you are a regulated entity responsible for ensuring that all aerosol coatings manufactured or imported by you meet the PWR limits presented in

§ 59.504, even if your name is not on the label.

(2) If you are a distributor named on the label, you are a regulated entity responsible for compliance with all sections of this subpart except for the limits presented in § 59.504. If you are a distributor that has specified formulations to be used by a manufacturer, then you are a regulated entity responsible for compliance with all sections of this subpart.

(3) If there is no distributor named on the label, then the manufacturer or importer is a regulated entity responsible for compliance with all sections of this subpart.

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[FR Doc. E8–5583 Filed 3–21–08; 8:45 am]

BILLING CODE 6560–50–P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA–HQ–OPP–2007–0906; FRL–8355–4]

**Pyraclostrobin; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of pyraclostrobin and its desmethoxy metabolite in or on avocado; canistel; oat, grain; oat, hay; oat, straw; sapodilla; sapote, black; sapote, mamey; and star apple. It also increases the existing tolerances in or on barley, grain from 0.4 parts per million (ppm) to 1.4 ppm; mango and Papaya from 0.1 ppm to 0.6 ppm. Interregional Research Project Number 4 (IR–4) and BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective March 24, 2008. Objections and requests for hearings must be received on or before May 23, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0906. To access the electronic docket, go to <http://www.regulations.gov>, select “Advanced Search,” then “Docket Search.” Insert the docket ID number where indicated and select the “Submit” button. Follow the instructions on the regulations.gov website to view the docket index or

access available documents. All documents in the docket are listed in the docket index available in [www.regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5218; e-mail address: [stanton.susan@epa.gov](mailto:stanton.susan@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 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 to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining

whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

###### C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2007-0906 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before May 23, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2007-0906, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket’s

normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

##### II. Petition for Tolerance

In the **Federal Register** of April 4, 2007 (72 FR 16352) (FRL-8119-2); May 9, 2007 (72 FR 26372) (FRL-8121-5); and October 24, 2007 (72 FR 60369) (FRL-8150-8), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 6E7165, PP 6F7105 and PP 7E7245) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W, Princeton, NJ 08540 and BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709. The petitions requested that 40 CFR 180.582 be amended by establishing tolerances for combined residues of the fungicide pyraclostrobin, carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester; and its desmethoxy metabolite; methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenylcarbamate, in or on herbs, fresh at 30.0 parts per million (ppm); avocado at 0.7 ppm; mango at 0.7 ppm; papaya at 0.7 ppm; sapote, black at 0.7 ppm; sapote, mamey at 0.7 ppm; canistel at 0.7 ppm; sapodilla at 0.7 ppm; and star apple at 0.7 ppm (PP#6E7165); in or on oat, grain at 1.0 ppm; oat, hay at 17.0 ppm; oat, straw at 17.0 ppm; and oilseed, group at 0.4 ppm (PP#6F7105); and in or on barley, grain at 1.3 ppm; and barley, straw at 9.0 ppm (PP#7E7245). The notices referenced summaries of the petitions prepared by BASF Corporation, the registrant, which are available to the public in docket ID numbers EPA-HQ-OPP-2007-0117 (PP 6E7165); EPA-HQ-OPP-2007-0214 (PP 6F7105); and EPA-HQ-OPP-2007-0906 (PP 7E7245); available at <http://www.regulations.gov>. There were no comments received in response to the April 4, 2007 or October 24, 2007 notices of filing; comments were received from a private citizen in response to the May 9, 2007 notice of filing of pesticide petition 6F7105. EPA’s response to these comments is discussed in Unit IV.C.

IR-4 has withdrawn its request for a tolerance for combined residues of pyraclostrobin and its desmethoxy metabolite in or on fresh herbs; and EPA is deferring to a later date the decision regarding the proposed tolerances in or on oilseed commodities. Based upon review of the data supporting the

petitions, EPA has revised the tolerance levels for the remaining commodities. The reason for these changes is explained in Unit IV.D.

### III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ." These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for combined residues of pyraclostrobin and its desmethoxy metabolite on avocado at 0.6 ppm; barley, grain at 1.4 ppm; canistel at 0.6 ppm; mango at 0.6 ppm; oat, grain at 1.2 ppm; oat, hay at 18 ppm; oat, straw at 15 ppm; papaya at 0.6 ppm; sapodilla at 0.6 ppm; sapote, black at 0.6 ppm; sapote, mamey at 0.6 ppm; and star apple at 0.6 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

#### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Pyraclostrobin has low to moderate acute toxicity. In repeated dose oral

toxicity studies, the main target organs for pyraclostrobin are the upper gastrointestinal tract (mainly the duodenum and stomach), the spleen/hematopoiesis, the immune system, and the liver. There was no evidence of increased quantitative or qualitative susceptibility of *in utero* rats or offspring following exposure to pyraclostrobin in the rat developmental or reproduction toxicity studies. There was evidence of increased qualitative susceptibility of *in utero* rabbits following exposure to pyraclostrobin in the rabbit developmental study. Increases in resorptions/litter and post-implantation losses occurred at doses that resulted in less severe maternal toxicity (decreases in body weight gain and food consumption). In both the acute and subchronic neurotoxicity studies, there were no indications of treatment-related neurotoxicity.

EPA has evaluated the carcinogenic potential of pyraclostrobin and concluded that, in accordance with the EPA's Final Guidelines for Carcinogen Risk Assessment (March 2005), pyraclostrobin should be classified into the category "Not Likely to be Carcinogenic to Humans." This determination is based on no treatment-related increase in tumors in either sex of rats and mice, which were tested at doses that were adequate to assess carcinogenicity, and the lack of evidence of mutagenicity.

Specific information on the studies received and the nature of the adverse effects caused by pyraclostrobin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document *Pyraclostrobin: Human Health Risk Assessment for Proposed Uses on Oats, Oilseed Group (Canola and Flax), Plus Seed Treatment on Oats, Canola, and Flax; Tropical Fruits (Avocado, Black Sapote, Canistel, Mamey Sapote, Mango; Papaya, Sapodilla, and Star Apple); Increased Tolerance on Barley; Adding Aerial Application to Turf and Ornamentals; and Adding In-Furrow Applications to Corn, Soybean, and Sugar Beets*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA-HQ-OPP-2007-0906-0003 in that docket.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed

(the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for pyraclostrobin used for human risk assessment can be found at <http://www.regulations.gov> in the document *Pyraclostrobin: Human Health Risk Assessment for Proposed Uses on Oats, Oilseed Group (Canola and Flax), Plus Seed Treatment on Oats, Canola, and Flax; Tropical Fruits (Avocado, Black Sapote, Canistel, Mamey Sapote, Mango; Papaya, Sapodilla, and Star Apple); Increased Tolerance on Barley; Adding Aerial Application to Turf and Ornamentals; and Adding In-Furrow Applications to Corn, Soybean, and Sugar Beets* at page 21 to 23 in docket ID number EPA-HQ-OPP-2007-0003.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyraclostrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing pyraclostrobin tolerances in 40 CFR 180.582. EPA assessed dietary

exposures from pyraclostrobin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. EPA identified such an effect for the general population (decreased body weight gain seen after a single oral dose in the rat acute neurotoxicity study) and for females 13 to 49 years old (increased resorptions/litter and increased total resorptions seen in the rabbit developmental toxicity study that are presumed to occur after a single exposure). The aPAD for the general population has been established at 3.0 milligrams/kilogram/day (mg/kg/day); whereas, the aPAD for females 13 to 49 years old is significantly lower (0.05 mg/kg/day), due to the more sensitive endpoint on which it is based.

In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed that residues are present at tolerance levels or for some commodities (amaranth, leafy; arugula; chrysanthemum; cress, garden; cress, upland; dandelion, leaves; fennel; parsley, leaves; radicchio; rhubarb; spinach; swiss chard; beans, dry; celery; lettuce, head; lettuce, leaf; and pea, dry) at the highest residue level found in residue field trials. One hundred percent crop treated (PCT) was assumed for all commodities in the assessment. Default processing factors were applied to all commodities except those for which experimentally-derived processing factors were available: apple juice, grape juice, citrus juices, cottonseed oil, tomato paste, tomato puree, wheat flour, and wheat germ.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed that residues are present at tolerance levels in all crops except apple, broccoli, celery, collard, grape, lettuce, citrus, pepper, mustard green and tomato. EPA relied on anticipated residues (average residues from field trials) for these crops. One hundred PCT was assumed for all commodities in the assessment. Default processing factors were applied to all commodities except those for which experimentally-derived processing factors were available: apple juice, grape juice, citrus juices, tomato

paste, tomato puree, wheat flour, and wheat germ.

iii. *Cancer.* Based on the results of carcinogenicity studies in rats and mice, EPA has concluded that pyraclostrobin is “not likely to be carcinogenic to humans.” Consequently, a quantitative cancer exposure and risk assessment is not appropriate for pyraclostrobin.

iv. *Anticipated residue information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA, must pursuant to section 408(f)(1) of FFDCA, 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. For the present action, EPA will issue such Data Call-Ins as are required by section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring 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 environmental fate characteristics of pyraclostrobin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of pyraclostrobin for acute exposures are estimated to be 35.6 parts per billion (ppb) for surface water and 0.02 ppb for ground water. The EECs for chronic exposures are estimated to be 2.3 ppb for surface water and 0.02 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 35.6 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration

value of 2.3 ppb was used to assess the contribution to drinking water.

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

Pyraclostrobin is currently registered for the following residential non-dietary sites: Residential and recreational turfgrass. EPA assessed residential exposure using the following assumptions: Residential and recreational turf applications are applied by professional pest control operators (PCOs) only, and, therefore, residential handler exposures do not occur. There is, however, a potential for short- and intermediate-term postapplication exposure of adults and children entering lawn and recreation areas previously treated with pyraclostrobin. Exposures from treated recreational sites are expected to be similar to, or in many cases lower than, those from treated residential turf sites; therefore, a separate exposure assessment for recreational turf sites was not conducted. EPA assessed exposures from the following residential turf postapplication scenarios:

i. Adult and toddler postapplication dermal exposure from contact with treated lawns,

ii. Toddlers’ incidental ingestion of pesticide residues on lawns from hand-to-mouth transfer,

iii. Toddlers’ object-to-mouth transfer from mouthing of pesticide-treated turfgrass, and

iv. Toddlers’ incidental ingestion of soil from pesticide-treated residential areas. The postapplication risk assessment was conducted in accordance with the Residential Standard Operating Procedures (SOPs) and recommended approaches of the Health Effects Division’s (HED’s) Science Advisory Council for Exposure (ExpoSAC).

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

and pyraclostrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pyraclostrobin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCFA provides that EPA shall apply an additional ("10X") tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. 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 FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology database for pyraclostrobin includes the rat and rabbit developmental toxicity studies and the 2-generation reproduction toxicity study in rats. There was no evidence of increased quantitative or qualitative susceptibility of *in utero* rats or offspring following exposure to pyraclostrobin in the rat developmental and reproduction studies. In the rabbit developmental study, there was evidence of increased qualitative susceptibility of *in utero* rabbits following exposure to pyraclostrobin (increases in resorptions/litter and post-implantation losses). However, the concern is low for the qualitative susceptibility in the rabbit developmental study because: The developmental effects were seen in the presence of maternal toxicity; there are clear NOAELs for maternal and developmental toxicities; and this endpoint is used in the acute dietary (reference dose) exposure assessment for females, 13 years and older, as well as for short- and intermediate-term dermal risk assessments.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce

the FQPA safety factor to 1X. This determination was exhaustively discussed in a prior order concerning pyraclostrobin, 72 FR 52108, 52118–52123 (September 12, 2007). In summary, the safety factor decision is based on the following findings:

- i. The toxicity database for pyraclostrobin is complete.
- ii. There is no indication that pyraclostrobin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that pyraclostrobin results in increased susceptibility in *in utero* rats in the prenatal developmental study or in young rats in the 2-generation reproduction study. Although there is qualitative evidence of increased susceptibility in the prenatal developmental study in rabbits, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of pyraclostrobin. The degree of concern for prenatal toxicity is low.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues or anticipated residues derived from reliable field trial data. Conservative ground and surface water modeling estimates were used. Similarly, conservative assumptions were used to assess post-application dermal exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by pyraclostrobin.

#### E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, EPA performed two different acute risk assessments – one focusing on females 13 to 49 years old and designed to protect against prenatal effects and the other focusing on acute

effects relevant to all other population groups. The more sensitive acute endpoint was seen as to prenatal effects rather than other acute effects. For females 13 to 49 years old, the acute dietary exposure from food and water will occupy 80% of the aPAD addressing prenatal effects. As to acute effects other than prenatal effects, the acute dietary exposure from food and water to pyraclostrobin will occupy 2.4% of the aPAD for children 1 to 2 years old, the population subgroup with the highest estimated acute dietary exposure to pyraclostrobin.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pyraclostrobin from food and water will utilize 48% of the cPAD for children 1 to 2 years old, the population subgroup with the highest estimated exposure and risk. Based on the use pattern, chronic residential exposure to residues of pyraclostrobin is not expected.

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 currently registered for uses 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 food, water, and residential exposures aggregated result in aggregate MOEs of 200 for adults and 100 for children, 1 to 2 years old. The aggregate MOE for adults is based on the residential turf scenario and includes combined food, drinking water and post-application dermal exposures. The aggregate MOE for children includes food, drinking water, post-application dermal and incidental oral exposures from entering turf areas previously treated with pyraclostrobin.

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 uses 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. Since the endpoints and points of departure (NOAELs) are identical for short- and intermediate-term exposures, the

aggregate MOEs for intermediate-term exposure are the same as those for short-term exposure (200 for adults and 100 for children, 1 to 2 years old).

5. *Aggregate cancer risk for U.S. population.* EPA has classified pyraclostrobin into the category "Not Likely to be Carcinogenic to Humans." Pyraclostrobin is not expected to pose a cancer risk.

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

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (a liquid chromatography/mass spectrometry (LC/MS/MS) method (BASF Method D9808), and a high performance liquid chromatography using ultraviolet detection (HPLC/UV) method (BASF Method D9904)) is 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](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for residues of pyraclostrobin, *per se*, at 0.5 ppm in or on oats and barley and at 0.05 ppm in or on papaya. The U.S. tolerance levels on these commodities are higher than the corresponding CODEX MRLs because the U.S. tolerances, unlike the Codex MRLs, include both pyraclostrobin and its desmethoxy metabolite.

##### C. Response to Comments

EPA received comments from a private citizen in response to the notice of filing of several pesticide petitions (including PP 6F7105; docket ID number EPA-HQ-OPP-2007-0214) which was published in the **Federal Register** on May 9, 2007 (72 FR 26372-26375) (FRL-8121-5). Although none of the comments specifically addressed pyraclostrobin, the commenter expressed concerns generally about the testing of pesticides, their toxicity (including potential carcinogenicity), residues in food and potential effects on bees. Comments received contained no scientific data or other substantive evidence to rebut the Agency's finding that there is a reasonable certainty that

no harm will result from aggregate exposure to pyraclostrobin from the establishment of these tolerances. The Agency has received these same or similar comments from this commenter on numerous previous occasions. Refer to the **Federal Register** of June 30, 2005 (70 FR 37686) (FRL-7718-3), January 7, 2005 (70 FR 1354) (FRL-7691-4), and October 29, 2004 (69 FR 63096-63098) (FRL-7681-9) for the Agency's previous responses to these objections. In response to the commenter's question about potential effects on bees, EPA would note that the environmental effects of a pesticide are considered in the registration process for pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*

##### D. Changes to Proposed Tolerances

Based upon review of the data supporting the petitions, EPA has modified the proposed tolerances as follows: (1) Revised the tolerance levels for oat, grain from 1.0 ppm to 1.2 ppm; oat, hay from 17 ppm to 18 ppm; and oat, straw from 17 ppm to 15 ppm; (2) decreased the tolerances for avocado, canistel, mango, papaya, sapodilla, sapote (black and mamey) and star apple from 0.7 ppm to 0.6 ppm; and (3) revised the barley, grain tolerance from 1.3 ppm to 1.4 ppm and determined that the existing tolerance of 6.0 ppm for barley, straw is adequate and should not be raised to 9.0 ppm, as proposed by IR-4. EPA made these changes based on analyses of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data.

#### V. Conclusion

Therefore, tolerances are established for combined residues of pyraclostrobin, carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester and its desmethoxy metabolite; methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenylcarbamate, in or on avocado at 0.6 ppm; barley, grain at 1.4 ppm; canistel at 0.6 ppm; mango at 0.6 ppm; oat, grain at 1.2 ppm; oat, hay at 18 ppm; oat, straw at 15 ppm; papaya at 0.6 ppm; sapodilla at 0.6 ppm; sapote, black at 0.6 ppm; sapote, mamey at 0.6 ppm; and star apple at 0.6 ppm.

#### VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to petitions 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, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology

Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 18, 2008.

**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 in the table in paragraph (a)(1) by revising the tolerances for "barley, grain", "mango" and "papaya"; removing the footnote; and alphabetically adding new commodities to read as follows:

**180.582 Pyraclostrobin; tolerances for residues.**

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

Commodity	Parts per million
Avocado .....	0.6
Barley, grain .....	1.4
Canistel .....	0.6
Mango .....	0.6
Oat, grain .....	1.2
Oat, hay .....	18

Commodity	Parts per million
Oat, straw .....	15
Papaya .....	0.6
Sapodilla .....	0.6
Sapote, black .....	0.6
Sapote, mamey .....	0.6
Star apple .....	0.6

\* \* \* \* \*

[FR Doc. E8-5893 Filed 3-21-08; 8:45 am]  
**BILLING CODE 6560-50-S**

**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Parts 15, 27, 54, 73, and 76**

[CS Docket No. 07-148; FCC 08-56]

**DTV Consumer Education Initiative**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document adopts rules requiring industry to participate in a coordinated, nationwide, consumer outreach campaign. Despite extensive consumer outreach efforts by the Commission and others, a large percentage of the public is not sufficiently informed about the DTV transition. The rules in this item will ensure that the full benefits of the transition are realized and experienced by consumers.

**DATES:** The rules in this document contain information collection requirements that have not been approved by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing the effective date of these rules.

**ADDRESSES:** Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554. In addition to filing comments with the Office of the Secretary, a copy of any comments on the Paperwork Reduction Act information collection requirements contained herein should be submitted to Cathy Williams, Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554, or via the Internet to [PRA@fcc.gov](mailto:PRA@fcc.gov).

**FOR FURTHER INFORMATION CONTACT:** For additional information on this proceeding, please contact Lyle Elder, [Lyle.Elder@fcc.gov](mailto:Lyle.Elder@fcc.gov), or Eloise Gore, [Eloise.Gore@fcc.gov](mailto:Eloise.Gore@fcc.gov), of the Media Bureau, Policy Division, (202) 418-

2120. For additional information concerning the Paperwork Reduction Act information collection requirements contained in this document, contact Cathy Williams on (202) 418-2918, or via the Internet at [PRA@fcc.gov](mailto:PRA@fcc.gov).

**SUPPLEMENTARY INFORMATION:** This is a summary of the Federal Communications Commission's Report and Order in MB Docket No. 07-148, FCC 08-56, adopted February 19, 2008 and released March 3, 2008. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street, SW., CY-A257, Washington, DC 20554. These documents will also be available via ECFs (<http://www.fcc.gov/cgb/ecfs/>). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) The complete text may be purchased from the Commission's copy contractor, 445 12th Street, SW., Room CY-B402, Washington, DC 20554. To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to [fcc504@fcc.gov](mailto:fcc504@fcc.gov) or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY).

**Paperwork Reduction Act of 1995 Analysis**

This document was analyzed with respect to the Paperwork Reduction Act of 1995 ("PRA"), Public Law 104-13 and contains new and modified information collection requirements, including the following: (1) Broadcasters must provide information to their viewers about the DTV transition, and must report those efforts to the Commission and the public; (2) MVPDs must provide monthly notices about the DTV transition in their customer billing statements; (3) manufacturers of television receivers and related devices must provide notice to consumers buying their devices of the transition's impact on that equipment; (4) DTV.gov Partners must provide the Commission with regular updates on their consumer education efforts; (5) ETCs that receive federal universal service funds must provide notice of the transition to their low income customers and potential customers; and (6) the winners of the 700 MHz spectrum auction will be required to report their consumer education efforts. The information collection requirements contained in this Report and Order will be submitted to the Office of