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 25, 2009.

Lois Rossi,

Acting Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.463 is amended by revising paragraph (b) to read as follows:

§ 180.463 Quinclorac; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of quinclorac, 3,7-dichloro-8-quinolinecarboxylic acid in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

Commodity	Parts per million	Expiration/ revocation date
Cranberry	15.0	12/31/12

* * * * *

[FR Doc. E9–24188 Filed 10–06–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0713; FRL–8793–2]

Pyraclostrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of pyraclostrobin and its desmethoxy metabolite, expressed as parent compound, in or on coffee, bean, green at 0.3 parts per million (ppm; this is a new import tolerance); fruit, stone, group 12 at 2.5 ppm (this is an increase in the existing domestic tolerance); sorghum, grain, forage at 5.0 ppm; sorghum, grain, grain at 0.60 ppm; and sorghum, grain, stover at 0.80 ppm (the sorghum tolerances are new domestic tolerances). BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 7, 2009. Objections and requests for hearings must be received on or before December 7, 2009, 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–2008–0713. All documents in the docket are listed in the docket index available at *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: John Bazuin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7381; e-mail address: *bazuin.john@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may potentially be 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).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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 electronically available documents 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 e-CFR site 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.gov/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, 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–2008–0713 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 December 7, 2009.

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–2008–0713, 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 Facility'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 December 3, 2008 (73 FR 73644) (FRL–8386–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 8F7385, 8F7390, and 8E7394) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.582 be amended by establishing tolerances for combined residues of the fungicide pyraclostrobin, carbamic acid, [2-[[[1-(4-chlorophenyl)-1H- pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl carbamate, expressed as parent compound, in or on coffee, bean, green at 0.5 ppm (PP#8E7394; a new import tolerance); fruit, stone, group 12 at 2.5 ppm (8F7390; an increase in the existing domestic tolerance); sorghum, grain at 0.5 ppm (PP#8F7385; a new domestic tolerance); sorghum, forage at 5.0 ppm (PP#8F7385; a new domestic tolerance); and sorghum, stover at 0.8 ppm (PP#8F7385; a new domestic tolerance). That notice referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has reduced the proposed pyraclostrobin tolerance for coffee, bean, green from 0.5 ppm to 0.3 ppm and has increased the proposed tolerance for sorghum, grain, grain (termed sorghum, grain in PP#8F7385) from 0.5 ppm to 0.60 ppm. The reasons for these changes are 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....''

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 to the petitioned-for tolerances for combined residues of pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H- pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl carbamate), expressed as parent compound, in or on coffee, bean, green at 0.3 ppm; fruit, stone, group 12 at 2.5 ppm; sorghum, grain, forage at 5.0 ppm; sorghum, grain, grain at 0.60 ppm; and sorghum, grain, stover at 0.80 ppm. EPA's assessment of exposures and risks associated with establishing 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. Pyraclostrobin has a low to moderate acute toxicity via the oral, dermal, and inhalation routes of exposure. Pyraclostrobin produces moderate eye irritation, is a moderate dermal irritant, and is not a dermal sensitizer. The main target organs for pyraclostrobin are the upper gastrointestinal tract (mainly the duodenum and stomach), the spleen/hematopoiesis, and the liver. In the 90–day mouse oral toxicity study, thymus atrophy was seen at doses of 30 milligrams\kil0gram (mg/kg) or above, but similar effect was not found in the mouse carcinogenicity study at doses as high as 33 mg/kg. In reproductive and developmental studies, there was evidence of increased qualitative susceptibility following *in utero* exposure in the rabbit, but not in rats. In both the acute and subchronic neurotoxicity studies, there were no indications of treatment-related neurotoxicity. EPA classified pyraclostrobin as ''Not Likely to be Carcinogenic to Humans'' based on no treatment-related increase in tumors in both sexes 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 *Revised Pyraclostrobin: Human Health Risk Assessment for Proposed Uses on Cotton and Belgian Endive*, page 15 in docket ID number EPA–HQ–OPP–2006–0522–004.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as 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) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction

with the POD 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 dietary risks by comparing aggregate food and water 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 POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. 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 document *Pyraclostrobin: Human Health Risk Assessment for Proposed Uses on Grain Sorghum (PP#8F7385); Increase of Tolerance for the Stone Fruit Crop Group 12 to Satisfy European Union (EU) Import Requirement (PP#8F7390); and Establishment of a Permanent Import Tolerance for Coffee (PP#8E7394)*, page 17 in docket ID number EPA–HQ–OPP–2008–0713.

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.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA performed a slightly refined acute dietary exposure assessment for pyraclostrobin. EPA assumed that 100 percent of crops covered by existing or proposed tolerances were treated with pyraclostrobin and that these crops either had tolerance-level residues or residues at the highest level found in field trials. Experimentally derived processing factors were used for fruit juices, tomato, and wheat commodities but for all other processed commodities Dietary Exposure Evaluation Model (DEEM) default processing factors were assumed.

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 performed a refined chronic dietary exposure assessment for pyraclostrobin. EPA used data on average percent crop treated (PCT) (when available) and either tolerance-level residues or average field trial residues. Experimentally derived processing factors were used for fruit juices, tomato, and wheat commodities, but for all other processed commodities DEEM™ default processing factors were assumed.

iii. *Cancer*. EPA classified pyraclostrobin as ''Not Likely to be Carcinogenic to Humans'' based on no treatment-related increase in tumors in both sexes of rats and mice, which were tested at doses that were adequate to assess carcinogenicity, and the lack of evidence of mutagenicity. Accordingly, an exposure assessment to evaluate cancer risk is unnecessary.

iv. *Anticipated residue and PCT 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 require pursuant to FFDCA section 408(f)(1) 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 FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition A: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition B: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition C: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Commodity	PCT
Almond	35
Apple	10
Apricot	10
Barley	1
Black bean seed	5
Broad bean (succulent)	2.5
Broad bean seed	5
Cowpea (succulent)	2.5
Cowpea seed	5
Great northern bean seed	5
Kidney bean seed	5
Lima bean (succulent)	2.5
Lima bean seed	5
Mung bean seed	5
Navy bean seed	5
Pink bean seed	5
Pinto bean seed	5
Snap bean (succulent)	2.5
Sugar beet	35

Commodity	PCT
Blackberry	20
Blueberry	20
Broccoli	5
Cabbage	10
Napa cabbage	10
Chinese mustard cabbage	10
Cantaloupe	15
Carrot	25
Celery	2.5
Cherry	30
Field corn	5
Pop corn	5
Sweet corn	5
Cucumber	5
Currant	5
Filbert	10
Garlic	10
Grape	25
Grapefruit	25
Head lettuce	5
Leaf lettuce	5
Nectarine	15
Dry bulb onion	15
Green onion	15
Orange	5
Succulent pea	5
Pigeon pea (succulent)	5
Peach	15
Peanut	25
Pear	10
Pecan	2.5
Bell pepper	10
Non-bell pepper	10
Pistachio	25
Plum	5
Potato	10
Pumpkin	20
Raspberry	35
Soybean	5
Spinach	10
Summer squash	10
Winter squash	10
Strawberry	50
Tangerine	15
Tomato	20
Watermelon	30
Wheat	5

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition A, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions B and C, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which pyralostrobin may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pyraclostrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport 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 drinking water concentrations (EDWCs) 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 and for chronic exposures for non-cancer assessments 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 of value 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 uses that could result in residential exposures: Residential turf grass and recreational sites. 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 post-application 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 so a separate exposure assessment for recreational turf sites was not conducted. EPA assessed exposures from the following residential turf post-application scenarios:

i. Short-/intermediate-term adult and toddler post-application dermal exposure from contact with treated lawns,

ii. Short-/intermediate-term toddlers' incidental ingestion of pesticide residues on lawns from hand-to-mouth transfer,

iii. Short-/intermediate-term toddlers' object-to-mouth transfer from mouthing of pesticide-treated turfgrass, and

iv. Short-/intermediate-term toddlers' incidental ingestion of soil from pesticide-treated residential areas. The post-application risk assessment was conducted in accordance with the Residential Standard Operating Procedures and recommended approaches of the Health Effects Division's Science Advisory Council for Exposure.

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

EPA has not found pyraclostrobin to share a common mechanism of toxicity with 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 assumed that pyraclostrobin does not have 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(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

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. In reproductive and developmental studies there was evidence of increased qualitative susceptibility following *in utero* exposure in the rabbits, but not in rats. In the 2–generation reproduction study, the highest dose tested did not cause maternal systemic toxicity, nor did it elicit reproductive or offspring toxicity. There is low concern for prenatal developmental effects seen in the rabbit because there are clear NOAELs for maternal and developmental effects, this toxicity endpoint is used to establish the acute dietary RfD, and the developmental effect was seen at the same dose level as that produced for the maternal effect.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for pyraclostrobin is considered adequate to support toxicity endpoint selection for risk assessment and FQPA evaluation. However, under the current 40 CFR 158.500 data requirement guidelines, the immunotoxicity data (OPPTS 780.7800) is required as a condition of approval. In the absence of specific immunotoxicity studies, EPA has evaluated the available pyraclostrobin toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. For pyraclostrobin a complete battery of subchronic, chronic, carcinogenicity, developmental and reproductive studies, and acute and subchronic neurotoxicity screening studies are available for consideration. The immunotoxic potential of pyraclostrobin has been well characterized in relationship to other adverse effects seen in the submitted toxicity studies. Under the conditions of the studies the results do not indicate the immune system to be the primary target and, other than the high-dose thymus effects seen in the 90–day mouse study, no significant evidence of pyraclostrobin-induced immunotoxicity was demonstrated in the studies conducted either in adult animals or in the offspring following prenatal and postnatal exposures. Increased spleen weights observed in 28–day rat studies were accompanied by mild hemolytic anemia (a hematopoi-response) indicating these effects are unrelated to an immunotoxic response. Currently, the point of departure in establishing the chronic RfD is 3.4 mg/kg/day. The Agency does not believe that conducting a special series 870.7800 immunotoxicity study will result in a NOAEL less than 3.4 mg/kg/day. A similar conclusion was reached in an earlier action on pyraclostrobin. (See 72 FR 52108, September 12, 2007). In light of these conclusions, EPA does not believe an additional uncertainty or safety factor is needed to address the lack of the required immunotoxicity study.

ii. There is no indication that pyraclostrobin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional safety factors to account for neurotoxicity.

iii. There is no evidence that pyraclostrobin results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study. Although there is qualitative evidence of increased susceptibility in the prenatal development 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 and/or postnatal toxicity is low.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessments were performed using tolerance-level or highest field trial residues and 100 PCT. The chronic dietary food exposure assessments were performed using tolerance-level or average field trial residues and 100 PCT or average PCT. Average PCT is conservatively derived from multiple data sources and is averaged by year and then across all years. The field trials represent maximum application rates and minimum PHIs. A limited number of experimentally derived processing factors from pyraclostrobin processing studies were also used to refine the analysis. The results of the refined chronic dietary analysis are based on reliable data and will not underestimate the exposure and risk. Conservative surface water modeling estimates were used. Similarly, residential standard operating procedures were used to assess post-application dermal exposure

of children as well as incidental oral exposure of toddlers. EPA used similarly conservative assumptions to assess post-application 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

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD 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, the acute dietary exposure from food and water to pyraclostrobin will occupy 81% of the aPAD for females 13–49 years old, and 2.5% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyraclostrobin from food and water will utilize 24% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of pyraclostrobin is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term 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 exposure through food and water with short- and intermediate-term residential exposures to pyraclostrobin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs of 230 for adults and 120 for children 1–2 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, and post-application dermal and incidental oral exposures from entering turf areas previously treated with pyraclostrobin. MOEs above 100 are considered to be of no concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term 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 exposure to pyraclostrobin through food and water with intermediate-term exposures for pyraclostrobin.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures aggregated result in aggregate MOEs of 230 for adults and 120 for children 1–2 years old. The endpoints and points of departure (NOAELs) are identical for short- and intermediate-term exposures, so the aggregate MOEs for intermediate-term exposure are the same as those for short-term exposure.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Two adequate methods were proposed for enforcing the tolerances for residues of pyraclostrobin and its desmethoxy metabolite in/on plant commodities: A liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) method (BASF Method D9908), and a high pressure liquid chromatography/ultraviolet (HPLC/UV) method (BASF Method D9904). The validated method level of quantitation (LOQ) for both pyraclostrobin and its desmethoxy metabolite is 0.02 ppm in all tested plant matrices, for a combined LOQ of 0.04 ppm. Adequate independent method validation and radiovalidation data were submitted for both methods. Following the standard operating procedure for reviewing tolerance methods, EPA has determined that Method D9904 is suitable as an enforcement method.

Adequate enforcement methodology is available to enforce the tolerance expression. The method (D9904) 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

The Codex Alimentarius Commission (CAC) has established maximum residue limits (MRLs) for residues of pyraclostrobin on stone fruit and coffee beans. However, the residue definitions for pyraclostrobin differ in the CAC MRLs and United States tolerances. The CAC definition contains parent only, whereas the United States residue definition includes a metabolite. EPA is unwilling to modify the residue definition for the United States tolerance because both parent and its metabolite are major residues in crop matrices and are measured by the enforcement method. Additionally, the CAC MRL and United States tolerance values differ for stone fruit. They are the same for coffee beans. The CAC value for stone fruits of 1 ppm is based on evaluation of United States residue data for cherries, where the highest residue was 0.63 ppm. This action sets a United States tolerance of 2.5 ppm based on results from new trials conducted in 2007 on cherries, peaches, and plums using a water dispersible granule formulation containing pyraclostrobin and boscalid. Use of this particular formulation requires an increase in the United States tolerance from its present value of 0.9 ppm (40 CFR 180.582) because measured residues were as high as 1.9 ppm. For this reason the United States tolerance value cannot be harmonized with the CAC MRL. Canada has established tolerances for various stone fruits at 0.7 ppm. The United States and Canadian residue definitions are the same; however, the United States tolerance for stone fruits being set in this action is higher than the Canadian tolerances for individual stone fruit commodities because of the new formulation uses of pyraclostrobin in the United States that result in higher residues in stone fruits.

C. Revisions to Petitioned-For Tolerances

EPA reduced the pyraclostrobin tolerance for coffee, bean, green from 0.5 ppm, as proposed by BASF Corporation,

to 0.3 ppm because the Agency's tolerance spreadsheet determined that the lower value was more appropriate based on the field trial data. EPA increased the tolerance for sorghum, grain, grain (termed sorghum, grain in PP#8F7385) from 0.5 ppm to 0.60 ppm because the Agency's tolerance spreadsheet determined that the higher value was more appropriate based on the 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]phenyl carbamate), expressed as parent compound, in or on coffee, bean, green at 0.3 ppm; fruit, stone, group 12 at 2.5 ppm; sorghum, grain, forage at 5.0 ppm; sorghum, grain, grain at 0.60 ppm; and sorghum, grain, stover at 0.80 ppm

VI. 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *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 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.

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 9, 2000) do not apply to this final rule. In addition, this final 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: September 25, 2009.

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 by alphabetically adding the following commodities to the table and by revising fruit, stone, group 12 in the table in paragraph (a)(1) read as follows:

180.582 Pyraclostrobin; tolerances for residues.

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

Commodity	Parts per million
* * * * *	
Coffee, bean, green	0.3[1]
* * * * *	
Fruit, stone, group 12	2.5
* * * * *	
Sorghum, grain, forage	5.0
Sorghum, grain, grain	0.60
Sorghum, grain, stover	0.80
* * * * *	

[1] There is no U.S. registration on coffee, bean, green as of September 30, 2009.

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[FR Doc. E9–24058 Filed 10–06–09; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 415, 485, and 489

[CMS–1406–CN]

RINs 0938–AP33; 0938–AP39; 0938–AP76

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2010 Rates and to the Long-Term Care Hospital Prospective Payment System and Rate Year 2010 Rates; Corrections

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Correction of final rules and interim final rule with comment period.

SUMMARY: This document corrects technical errors and typographical errors that appeared in the final rules and interim final rule with comment