Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This action also is not subject to Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it approves a state rule implementing a Federal standard.

In reviewing state submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a state submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a state submission, to use VCS in place of a state submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 26, 2007. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: September 13, 2007.

John B. Askew,

Regional Administrator, Region 7.

■ Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart AA—Missouri

■ 2. In § 52.1320 the table in paragraph (c) is amended by revising the entry for 10–6.062 to read as follows:

§ 52.1320 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MISSOURI REGULATIONS

Missouri citation	Title	State effective date	EPA approval date	Explanation
Missouri Department of Natural Resources				
*	*	*	*	*
Chapter 6	**Air Quality Standards, Definitions, Sampling and Reference Methods, and Air Pollution Control Regulations for the State of Missouri**			
*	*	*	*	*
10–6.062	Construction Permits By Rule.	5/30/07	9/26/07 [insert FR page number where the document begins].	Section (3)(B)4 is not included in the SIP.
*	*	*	*	*

[FR Doc. E7–18792 Filed 9–25–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0522; FRL–8148–6]

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 berry, group 13; cotton, undelinted seed; and cotton, gin byproducts. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 26, 2007. Objections and requests for hearings must be received on or before November 26, 2007, 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–2006–0522. 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 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:

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to 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–2006–0522 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 November 26, 2007.

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–2006–0522, 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 July 5, 2006 (71 FR 38150–38151) (FRL–8074–2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F7002) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, 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]phenylcarbamate), expressed as parent compound, in or on berry, group 13 at 4.0 parts per million (ppm); cotton, undelinted seed at 0.4 ppm; and cotton, gin byproducts at 30 ppm. 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 modified the tolerance for cotton, undelinted seed from 0.4 ppm to 0.3 ppm. The reason for this change is explained in Unit V.

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 berry, group 13 at 4.0 ppm; cotton, undelinted seed at 0.3 pm; and cotton, gin byproducts at 30 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered 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. 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. In addition, reduced body weight/gain and feed intake/efficiency are also common findings. In the developmental toxicity study in rabbits, there was evidence of increased qualitative susceptibility of *in utero* rabbits following exposure to pyraclostrobin (increases in resorptions/litter and post-implantation losses), but only at doses that also resulted in maternal toxicity (decreases in body weight gain and food consumption). There was no evidence of increased quantitative or qualitative susceptibility of *in utero* rats or offspring following exposure to pyraclostrobin. In the 2–generation reproduction study, the highest dose tested did not cause maternal systemic toxicity, nor did it elicit reproductive or offspring toxicity. In both the acute and subchronic neurotoxicity studies, there were no indications of treatment-related neurotoxicity.

EPA has reevaluated the carcinogenic potential of pyraclostrobin in light of a new supplementary cancer study in female mice 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 human health risk assessment document in the docket established by this action, which is described under **ADDRESSES**. The referenced document is identified as EPA–HQ–OPP–2006–0522–0002 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 human health risk assessment document identified as document number 0002 in docket ID number EPA–HQ–OPP–2006–0522.

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/kilograms/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 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 grape, celery, spinach, tomato, pepper, citrus, apple, leaf lettuce and head lettuce. 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, cottonseed oil, tomato paste, tomato puree, wheat flour, and wheat germ.

iii. *Cancer*. EPA has classified pyraclostrobin as ''Not Likely to be Carcinogenic to Humans.'' Therefore, a cancer exposure assessment was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated 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 Groundwater (SCI-GROW) models, the estimated environmental concentrations (EECs) of pyraclostrobin for acute exposures are estimated to be 10.2 parts per billion (ppb) for surface water and 0.02 ppb for ground water. The EECs for chronic exposures are estimated to be 0.8 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 10.2 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.8 ppb was used to access 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 FFDCA 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), but only at doses that also resulted in maternal toxicity (decreases in body weight gain and food consumption).

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. That 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 and/or postnatal 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 Residential SOPs 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 78% 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 2.3% of the aPAD for children 1 to 2 years old, the population group 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 group 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 residential 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 170 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 residential 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 (170 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.'' Therefore, a cancer aggregate exposure assessment was not conducted. 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 (an LC/MS/MS method (BASF Method D9808), and an 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*.

B. International Residue Limits

There are no established or proposed Codex maximum residue limits (MRLs) for pyraclostrobin.

V. Conclusion

EPA determined that the proposed tolerance level for ''cotton, undelinted seed'' of 0.4 ppm should be revised to 0.3 ppm based on review of the supporting residue field trial data. As the majority of cottonseed samples had residues below the limit of quantitation (LOQ) of the method (0.04 ppm), the recommended tolerance for undelinted seed could not be determined using the Agency's Tolerance/MRL Harmonization Spreadsheet. Rather, the recommended tolerance of 0.3 ppm is based on the maximum combined residues of pyraclostrobin and its desmethoxy metabolite observed in seeds (0.17 ppm).

Therefore, the 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), expressed as parent compound, in or on berry, group 13 at 4.0 ppm; cotton, undelinted seed at 0.3 ppm; and cotton, gin byproducts at 30 ppm, respectively.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, 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 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 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: September 18, 2007.

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 amending paragraph (a)(1) in the table as follows:
■ i. By revising the entry for ''Berry group 13''; and
■ ii. By alphabetically adding ''Cotton, gin byproducts'' and ''Cotton, undelinted seed.''

The amendments read as follows:

§ 180.582 Pyraclostrobin; tolerances for residues.

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

Commodity	Parts per million
* * *	* *
Berry, group 13	4.0
* * *	* *
Cotton, gin byproducts ...	30
Cotton, undelinted seed	0.3
* * *	* *

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0206; FRL–8147–4]

Sulfosulfuron; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of sulfosulfuron in or on grass, forage, fodder, and hay group 17, forage, and grass, forage, fodder, and hay, group 17, hay. This regulation also increases tolerances for fat, meat, and meat by byproducts of cattle, goat, horse, and sheep, and milk. Monsanto Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 26, 2007. Objections and requests for hearings must be received on or before November 26, 2007, 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–2006–0206. 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 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