

States Court of Appeals for the appropriate circuit by September 8, 2008. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action 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, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: April 16, 2008.

Laura Yoshii,

Acting Regional Administrator, Region IX.

Part 52, 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 F—California

2. Section 52.220 is amended by adding paragraphs (b)(7)(iii), (c)(26)(ix)(D), (c)(27)(vii)(F), (c)(93)(iii)(E), (c)(93)(iv)(F), (c)(246)(i)(A)(4) and (5) to read as follows:

§ 52.220 Identification of plan.

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(b) * * *
(7) * * *

(iii) Previously approved on May 31, 1972 in paragraph (b) of this section and now deleted without replacement Rules 11 and 51.

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(c) * * *
(26) * * *
(ix) * * *

(D) Previously approved on August 22, 1977 in paragraph (c)(26)(ix)(A) of this section and now deleted without replacement Rules 201 and 205.

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(27) * * *
(vii) * * *

(F) Previously approved on June 14, 1978 in paragraph (c)(27)(vii)(A) of this section and now deleted without replacement Rules 106, 107, 201, 215, 401, and 403.

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(93) * * *

(iii) * * *

(E) Previously approved on June 18, 1982 in paragraph (c)(93)(iii)(B) of this section and now deleted without replacement Rules 507 and 508.

(iv) * * *

(F) Previously approved on June 18, 1982 in paragraph (c)(93)(iv)(B) of this section and now deleted without replacement Rules 507 and 508.

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(246) * * *

(i) * * *

(A) * * *

(4) Rule 505, "Conditional Approval," Rule 510, "Separation of Emissions," Rule 511, "Combination of Emissions," Rule 512, "Circumvention," Rule 515, "Provision of Sampling and Testing Facilities," and Rule 517, "Transfer," adopted on September 11, 1991.

(5) Rule 501, "Permit Required" and Rule 513, "Source Recordkeeping," amended on May 11, 1994.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-0416; FRL-8371-9]

Azoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of azoxystrobin (methyl (E)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-ylloxy)phenyl)-3-methoxyacrylate) and its Z isomer (methyl (Z)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-ylloxy)phenyl)-3-methoxyacrylate) in or on animal feed, nongrass, forage, group 18 at 45 parts per million (ppm); animal feed, nongrass, hay, group 18 at 120 ppm; barley, forage at 25 ppm; cotton, gin byproducts at 45 ppm; cotton, undelinted seed at 0.6 ppm; grain, aspirated fractions at 420 ppm; rice, wild, grain at 5.0 ppm; sorghum, forage at 25 ppm; sorghum, grain at 11 ppm; sorghum, stover at 40 ppm; and wheat, forage at 25 ppm. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA is also deleting certain azoxystrobin tolerances that are no longer needed as a result of this action.

DATES: This regulation is effective July 9, 2008. Objections and requests for

hearings must be received on or before September 8, 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-2007-0416. To access the electronic docket, go to http://www.regulations.gov, and search for the docket number. 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: 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 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).
• 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 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-2007-0416 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 September 8, 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-2007-0416, 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 September 28, 2007 (72 FR 55204) (FRL-8147-1), 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 6F7106 and 7F7198) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27409. Petition PP 6F7106 requested that 40 CFR 180.507(a)(1) be amended by establishing tolerances for combined residues of the fungicide azoxystrobin (methyl (E)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and the Z isomer of azoxystrobin (methyl (Z)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) in or on barley, forage at 30 ppm; non-grass animal feeds, forage at 35 ppm; non-grass animal feeds, hay at 100 ppm; sorghum, forage at 25 ppm; sorghum, grain at 9 ppm; sorghum, stover at 40 ppm; and wheat, forage at 30 ppm. Petition PP 6F7106 also requested that 40 CFR 180.507(a)(2) be amended by establishing tolerances for residues of the fungicide azoxystrobin in or on cattle, kidney at 1.00 ppm; cattle, liver at 5.10 ppm; cattle, meat byproducts (except liver and kidney) at 0.07 ppm; goat, kidney at 1.00 ppm; goat, liver at 5.10 ppm; goat, meat byproducts (except liver and kidney) at 0.07 ppm; egg, white at 0.01 ppm; egg, yolk at 0.15 ppm; hog, kidney at 0.03 ppm; hog, liver at 0.23 ppm; hog, meat byproducts (except liver and kidney) at 0.01 ppm; horse, kidney at 1.00 ppm; horse, liver at 5.10 ppm; poultry, fat at 0.01 ppm; poultry, liver at 0.12 ppm; poultry, meat at 0.02 ppm; sheep, kidney at 1.00 ppm; sheep, liver at 5.10 ppm; sheep, meat byproducts (except liver and kidney) at 0.07 ppm. Petition PP 6F7106 additionally requested that 40 CFR 180.507(a)(1) be amended by increasing the tolerance for the combined residues of the fungicide azoxystrobin and the Z isomer of azoxystrobin in or on aspirated grain fractions to 112 ppm; increasing the tolerances for the residues of the fungicide azoxystrobin in or on cattle, fat to 0.13 ppm; cattle, meat to 0.07 ppm; goat, fat to 0.13 ppm; goat, meat to 0.07 ppm; hog, fat to 1.10 ppm; horse, meat to 0.07 ppm; milk to

0.05 ppm; sheep, fat to 0.13 ppm; and sheep, meat to 0.07 ppm; and leaving the tolerance for the residues of the fungicide azoxystrobin and the Z isomer of azoxystrobin in or on hog, meat unchanged at 0.01 ppm. Petition PP 7F7198 requested that 40 CFR 180.507(a)(1) be amended by establishing a permanent tolerance for combined residues of the fungicide azoxystrobin and the Z isomer of azoxystrobin in or on rice, wild at 5.0 ppm and by changing the tolerances for combined residues of the fungicide azoxystrobin and the Z isomer of azoxystrobin in or on cotton, gin byproducts to 35 ppm and cotton, undelinted seed to 0.7 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., 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 is not modifying the tolerances for ruminant and swine raw agricultural commodities (RACs) or establishing tolerances for poultry RACs. EPA is, however, increasing the proposed tolerance for sorghum grain from 9 ppm to 11 ppm, increasing the proposed tolerance for aspirated grain fractions from 112 ppm to 420 ppm, reducing the proposed tolerances of 30 ppm for both wheat forage and barley forage to 25 ppm, reducing the proposed tolerance for undelinted cotton seed from 0.7 to 0.6 ppm, increasing the proposed tolerance for cotton gin byproducts from 35 to 45 ppm, increasing the proposed tolerance for non-grass animal feeds, forage from 35 to 45 ppm, and increasing the proposed tolerance for non-grass animal feeds, hay from 100 to 120 ppm. EPA is also revoking the two expired time-limited tolerances for safflower, seed at 1.0 ppm; and for Brassica, head and stem, subgroup 5A of 30 ppm in 40 CFR 180.507(b). The rice, wild tolerance in 40 CFR 180.507(b) is also being revoked. The reasons for these changes are explained in Unit IV.C.

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 for the petitioned-for tolerances for combined residues of azoxystrobin (methyl (E)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and the Z isomer of azoxystrobin (methyl (Z)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) in or on animal feed, nongrass, forage, group 18 at 45 ppm; animal feed, nongrass, hay, group 18 at 120 ppm; barley, forage at 25 ppm; cotton, gin byproducts at 45 ppm; cotton, undelinted seed at 0.6 ppm; grain, aspirated fractions at 420 ppm; rice, wild, grain at 5.0 ppm; sorghum, forage at 25 ppm; sorghum, grain at 11 ppm; sorghum, stover at 40 ppm; and wheat, forage at 25 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

Azoxystrobin has low acute toxicity via the oral, dermal and inhalation routes of exposure. Azoxystrobin is not an eye or skin irritant and is not a skin sensitizer. The most common toxicity findings from administration of azoxystrobin to rats, via the oral route, were decreased body weight, decreased food intake/utilization, increased diarrhea, and other clinical toxicity observations such as, increased urinary incontinence, hunched postures and distended abdomens. There were no developmental effects in the rat and

rabbit developmental studies. In the reproduction study, decreased body weights and increased adjusted liver weights were observed at the same dose in both offspring and parental animals. In both the acute and subchronic neurotoxicity studies, there were no consistent indications of treatment-related neurotoxicity. There was no evidence of carcinogenicity in rats and mice at acceptable dose levels. Azoxystrobin induced a weak mutagenic response in the mouse lymphoma assay, but the activity expressed *in vitro* is not expected to be expressed in whole animals.

Specific information on the studies received and the nature of the adverse effects caused by azoxystrobin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of September 29, 2000 (65 FR 58404) (FRL-6749-1).

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 azoxystrobin used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of September 29, 2000.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to azoxystrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing azoxystrobin tolerances in (40 CFR 180.507). EPA assessed dietary exposures from azoxystrobin 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 used tolerance level residues, a 100% crop treated assumption, and default processing factors for all existing and proposed uses.

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 used tolerance level residues and default processing factors for all existing and proposed uses. As to percent crop treated, EPA used data on the actual percentage of crop treated for some existing uses and assumed 100% crop treated for all proposed uses, and all other existing uses.

iii. *Cancer.* The Agency has determined that azoxystrobin is not likely to be a human carcinogen, so an exposure assessment to estimate cancer risk is unnecessary.

iv. *Percent crop treated (PCT) information.* EPA did not use anticipated residue information in the dietary assessment for azoxystrobin.

Tolerance level residues were assumed for all food commodities.

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: Acerola – 100%; almond – 20%; amaranth, leafy – 100%; apricot – 15%; arrowroot – 100%; artichoke, globe – 100%; artichoke, Jerusalem – 100%; arugula – 100%; asparagus – 1%; avocado – 100%; balsam pear – 100%; banana – 100%; barley – 100%; basil – 100%; bean, black – 1%; bean, broad – 1%; bean, cowpea – 1%; bean, great northern – 1%; bean, kidney – 1%; bean, lima – 1%; bean, mung – 1%; bean, navy – 1%; bean, pink – 1%; bean, pinto – 1%; bean, snap – 25%; beet, garden – 15%; beet, sugar – 1%; blackberry – 100%; blueberry – 15%; boysenberry – 100%; Brazil nut – 100%; broccoli – 100%; Brussels sprouts – 100%; burdock – 100%; butternut – 100%; cabbage – 5%; canistel – 100%; cantaloupe – 10%; cardoon – 100%; carrot – 10%; casaba – 100%; cashew – 100%; cassava – 100%; cattle fat, kidney, liver, meat, and meat byproducts – 100%; cauliflower – 100%; celeriac – 100%; celery – 10%; celtuce – 100%; chayote – 100%; cherimoya – 100%; cherry – 5%; chestnut – 100%; chickpea – 1%; chicory – 100%; Chinese waxgourd – 100%; chive – 100%; chrysanthemum, garland – 100%; cinnamon – 100%; citrus citron – 100%; citrus hybrids – 100%; citrus, oil – 100%; collards – 100%; coriander – 100%; corn, field – 100%; corn, pop – 100%; corn, sweet – 10%; cottonseed, oil – 1%; cranberry – 100%; cress, garden – 100%; cress, upland – 100%; cucumber – 15%; currant – 100%; dandelion, leaves – 100%; dasheen, corm – 100%; dasheen, leaves – 100%; dewberry – 100%; dill, seed – 100%; dillweed – 100%; eggplant – 100%;

elderberry – 100%; endive – 100%; feijoa – 100%; fennel, Florence – 100%; filbert – 5%; flaxseed, oil – 5%; garlic – 50%; ginger – 100%; ginseng – 100%; goat fat, kidney, liver, meat, and meat byproducts – 100%; gooseberry – 100%; grape – 10%; grapefruit – 20%; guar, seed – 1%; guava – 100%; herbs, other – 100%; hickory nut – 100%; honeydew melon – 5%; hop – 100%; horse, meat – 100%; horseradish – 100%; huckleberry – 100%; jaboticaba – 100%; jackfruit – 100%; kale – 100%; kohlrabi – 100%; kumquat – 100%; leek – 100%; lemon – 100%; lemongrass – 100%; lentil, seed – 1%; lettuce, head – 1%; lettuce, leaf – 1%; lime – 100%; loganberry – 100%; longan – 100%; loquat – 100%; lychee – 100%; macadamia nut – 100%; mango – 100%; marjoram – 100%; milk – 100%; mustard greens – 15%; nectarine – 100%; okra – 100%; onion, dry bulb – 10%; onion, green – 10%; orange – 17%; papaya – 100%; parsley – 30%; parsley, turnip-rooted – 100%; passionfruit – 100%; pawpaw – 100%; pea, succulent – 1%; pea, dry – 1%; pea, edible podded – 25%; pea, pigeon – 1%; peach – 5%; peanut – 10%; pecan – 1%; pepper, bell – 10%; pepper, non-bell – 10%; peppermint – 100%; persimmon – 100%; pistachio – 30%; plantain – 100%; plum – 1%; pork fat, kidney, liver, meat, meat byproducts, and skin – 100%; potato – 25%; pummelo – 100%; pumpkin – 20%; radicchio – 100%; radish – 100%; radish, Oriental – 100%; rape greens – 100%; rapeseed, oil – 5%; raspberry – 100%; rhubarb – 100%; rice – 25%; rutabaga – 100%; safflower – 5%; salsify, roots – 100%; salsify, tops – 100%; sapote, Mamey – 100%; savory – 100%; shallot – 100%; sheep fat, kidney, liver, meat, and meat byproducts – 100%; sorghum – 100%; soursop – 100%; soybean – 1%; Spanish lime – 100%; spearmint – 100%; spices, other – 100%; spinach – 10%; squash, summer – 15%; squash, winter – 15%; starfruit – 100%; strawberry – 20%; sugar apple – 100%; sunflower – 5%; sweet potato – 100%; Swiss chard – 100%; tamarind – 100%; tangerine – 20%; tanier – 100%; tomatillo – 100%; tomato – 20%; turmeric – 100%; turnip, roots – 100%; turnip, greens – 15%; walnut – 1%; watercress – 100%; watermelon – 25%; wheat – 1%; wild rice – 100%; yam, true – 100%; and yam bean – 100%.

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 azoxystrobin 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 azoxystrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of azoxystrobin. 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 First Index Reservoir Screening Tool (FIRST) model for surface water and the Screening Concentration in Ground Water (SCI-GROW) model for ground water, the

estimated drinking water concentrations (EDWCs) of azoxystrobin for acute exposures are estimated to be 173 parts per billion (ppb) for surface water and 3.1 ppb for ground water and for chronic exposures for non-cancer assessments are estimated to be 33 ppb for surface water and 3.1 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 173 ppb for surface water was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 33 ppb for surface water 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).

Azoxystrobin is currently registered for the following uses that could result in residential exposures: residential turf grass and ornamentals, as well as indoor surfaces. EPA assessed residential exposure using the following assumptions. Residential handlers may receive short-term dermal and inhalation exposure to azoxystrobin when mixing, loading and applying the formulations. Adults and children may be exposed to azoxystrobin residues from dermal contact with foliage/surfaces during postapplication activities. Toddlers may receive short- and intermediate-term oral exposure from incidental ingestion during postapplication activities.

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 azoxystrobin to share a common mechanism of toxicity with any other substances, and azoxystrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that azoxystrobin 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 (Food Quality Protection Act) safety factor (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 available studies do not indicate any evidence of increased susceptibility and there are no residual uncertainties with regard to prenatal toxicity in rats or rabbits following *in utero* and/or postnatal exposure to azoxystrobin. In the prenatal developmental toxicity studies in rats and rabbits and the 2-generation reproduction study in rats, any observed toxicity to the offspring occurred at equivalent or higher doses than it did to parental animals.

3. *Conclusion.* The Agency has retained the FQPA SF at 3X, for the following reasons:

- i. The toxicology data base is complete.
- ii. The developmental and reproductive toxicity data do not indicate increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.
- iii. Although a NOAEL was not identified in the study used to derive the aPAD, a 3X (as opposed to a 10X) is adequate to extrapolate a NOAEL due to the low concern for the effect seen taking into account the nature of the effect seen (transient diarrhea) and the overall toxicity of this chemical;
- iv. The acute dietary food exposure assessment utilizes existing and proposed tolerance level residues and 100 PCT information for all commodities;
- v. The chronic dietary exposure analysis for azoxystrobin is a somewhat refined assessment using less than 100% of the crop treated data for selected existing crops (but a 100 PCT value for all new crops);

vi. The exposure assessments will not underestimate the potential dietary (food and drinking water) or non-dietary

exposures for infants and children from the use of azoxystrobin;

vii. The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which are not likely to be exceeded; and

viii. The residential postapplication assessment is based upon the residential standard operating procedures. The assessment is based upon surrogate study data. These data are reliable and are not expected to underestimate risk to adults or children. The residential SOPs are based upon reasonable "worst-case" assumptions and are not expected to underestimate risk.

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.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water, and does not include dermal, inhalation, or incidental oral exposure. Using these exposure assumptions, EPA has concluded that acute exposure to azoxystrobin will occupy 70% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure, and 25% of the aPAD for the U.S. population as a whole.

2. *Chronic risk.* The chronic aggregate risk assessment takes into account average estimates of exposure to azoxystrobin from consumption in food and drinking water. Using these exposure assumptions, EPA has concluded that chronic exposure to azoxystrobin will utilize 15% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure, and 6% of the cPAD for the U.S. population as a whole.

3. *Short-term risk.* Short-term aggregate exposure takes into account

short-term (1-30 day) residential exposure plus chronic exposure to food and drinking water (considered to be a background exposure level).

Azoxystrobin is currently registered for uses that could result in short-term residential exposure both for adults (because there is a residential handler inhalation exposure scenario) and for toddlers and children (because there is a residual post-application oral exposure scenario). Dermal studies with azoxystrobin identified no toxic endpoints so dermal exposure to azoxystrobin is not expected to pose a short-term risk. The Agency has determined that it is appropriate to aggregate chronic exposure through food and drinking water with short-term residential exposures to azoxystrobin in performing this assessment. High-end estimates of residential exposure are used in the short-term assessment but average (i.e., chronic) exposure values are used for food and drinking water exposure. Toddlers' incidental oral exposure is assumed to include hand-to-mouth exposure, object-to-mouth exposure, and exposure via incidental ingestion of soil.

Using the exposure assumptions described in this unit for short-term exposures, EPA has calculated the following aggregated short-term food, water, and residential exposures and resulting MOEs. For the U.S. population and all assessed subgroups the NOAEL used was 25 milligrams/kilograms/day (mg/kg/day). For the U.S. population the estimated food and drinking water exposure was 0.009878 mg/kg/day, the residential exposure estimate was 0.00011 mg/kg/day, and the aggregate MOE was 2503. For the subgroup children (1-2 years) the estimated food and drinking water exposure was 0.026629 mg/kg/day, the residential exposure estimate was 0.089 mg/kg/day, and the aggregate MOE was 216. For the subgroup youth (13-19 years) the estimated food and drinking water exposure was 0.009499 mg/kg/day, the residential exposure estimate was 0.00011 mg/kg/day, and the aggregate MOE was 2602. For the subgroup females (13-49 years old) the estimated food and drinking water exposure was 0.008081 mg/kg/day, the residential exposure estimate was 0.00011 mg/kg/day, and the aggregate MOE was 3052. None of these MOEs exceeds the Agency's level of concern for azoxystrobin. The level of concern for azoxystrobin is for MOEs below 100.

4. Intermediate-term risk.

Intermediate-term aggregate exposure takes into account intermediate-term (1 to 6 months) residential exposure plus chronic exposure to food and water

(considered to be a background exposure level).

Azoxystrobin is currently registered for uses that could result in intermediate-term residential oral exposure for toddlers and children, so an exposure assessment was conducted for that scenario. No endpoint has been selected for intermediate-term dermal exposure to azoxystrobin so no dermal assessment was performed. Intermediate-term residential handler scenarios are not expected to occur, so this risk assessment was not conducted for adults. The Agency has determined that it is appropriate to aggregate chronic exposure to azoxystrobin through food and drinking water with intermediate-term residential exposures to azoxystrobin in doing this assessment. High-end estimates of residential exposure are used in the intermediate-term assessment but average (i.e., chronic) exposure values are used for food and drinking water exposure.

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 an aggregate MOE for the population subgroup children 1-2 years old of 291, which does not exceed the Agency's level of concern. This value and MOE are derived from a NOAEL for this subgroup of 20 mg/kg/day, an LOC MOE of 100, an estimated average food and drinking water exposure of 0.026629 mg/kg/day, and an estimated oral residential exposure of 0.042 mg/kg/day.

5. *Aggregate cancer risk for U.S. population.* The Agency has determined that azoxystrobin is not likely to be a human carcinogen, and thus azoxystrobin 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 azoxystrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

For analysis of plant commodities for residues of azoxystrobin and the Z isomer of azoxystrobin a gas chromatography with nitrogen phosphorus detector (GC/NPD) method (RAM 243/04) has been validated by the Agency, revised, and sent to the Food and Drug Administration (FDA) for inclusion in the Pesticide Analytical Manual (PAM), Volume II. This method

is adequate for enforcement of the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

No CODEX maximum residue levels (MRLs) have been established for azoxystrobin. No Canadian or Mexican MRLs have been established for azoxystrobin in or on the crops for which tolerances are being established in this document.

C. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA is not modifying the existing tolerances for ruminant and swine raw agricultural commodities (RACs) because a recalculation of the dietary burdens of ruminants and swine indicates that no such changes are necessary, while the proposed kidney and liver tolerances are covered by existing meat byproducts tolerances. EPA is not establishing tolerances for poultry RACs because a recalculation of dietary burdens for poultry continues to indicate that there is no reasonable expectation of finite residues in poultry commodities. EPA is raising the proposed tolerance for sorghum grain from 9 ppm to 11 ppm based on a review of the residue field trial data and EPA's statistical examination of the residue data. The proposed tolerance of 112 ppm in or on aspirated grain fractions is being raised to 420 ppm based on a residue for sorghum grain of 8.46 ppm and a processing factor of 49.4x. EPA is reducing the proposed tolerance of 30 ppm in or on wheat forage to 25 ppm based on a review of the wheat forage field trial data and EPA's statistical examination of the residue data; these data have also been translated to barley, forage with the result that this proposed tolerance is also being reduced from 30 to 25 ppm. A review of the residue data from use on cotton leads EPA to reduce the proposed tolerance for undelinted cotton seed from 0.7 to 0.6 ppm and to increase the proposed tolerance for cotton gin byproducts from 35 to 45 ppm. EPA is also raising the proposed tolerance for non-grass animal feeds, forage from 35 to 45 ppm and the proposed tolerance for non-grass animal feeds, hay from 100 to 120 ppm based on a review of the field trial data for use on alfalfa and clover forage and hay and EPA's statistical examination of the residue data. EPA is also revoking the

time-limited tolerance for Brassica, head and stem, subgroup 5A of 30 ppm, and for safflower, seed at 1.0 ppm, both in 40 CFR 180.507(b), because they expired on December 31, 2006, and June 30, 2008, respectively. Furthermore, Brassica, head and stem, subgroup 5A and safflower, seed have existing tolerances under 40 CFR 180.507(a)(1). The rice, wild time-limited tolerance in 40 CFR 180.507(b) is also being revoked because it is being superceded by a permanent tolerance for rice, wild, grain.

V. Conclusion

Therefore, tolerances are established for combined residues of azoxystrobin (methyl (E)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and the Z isomer of azoxystrobin (methyl (Z)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) in or on animal feed, nongrass, forage, group 18 at 45 ppm; animal feed, nongrass, hay, group 18 at 120 ppm; barley, forage at 25 ppm; cotton, gin byproducts at 45 ppm; cotton, undelinted seed at 0.6 ppm; grain, aspirated fractions at 420 ppm; rice, wild, grain at 5.0 ppm; sorghum, forage at 25 ppm; sorghum, grain at 11 ppm; sorghum, stover at 40 ppm; and wheat, forage at 25 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, *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: June 30, 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 180.507 is amended by:

- i. Removing the first entry for "grain, aspirated fractions" at 10 ppm in paragraph (a)(1).
- ii. Revising the entries "cotton, gin byproducts"; "cotton, undelinted seed"; and "grain, aspirated fractions."
- iii. Alphabetically adding entries to the table in paragraph (a)(1).
- iv. Removing the text of paragraph (b) and reserving the paragraph designation and heading.

§ 180.507 Azoxystrobin; tolerances for residues.

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

Commodity	Parts per million
Animal feed, nongrass, forage, group 18	45
Animal feed, nongrass, hay, group 18	120
Barley, forage	25
Cotton, gin byproducts	45
Cotton, undelinted seed	0.6
Grain, aspirated fractions	420

Commodity	Parts per million
Rice, wild, grain	5.0
Sorghum, forage	25
Sorghum, grain	11
Sorghum, stover	40
Wheat, forage	25

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(b) Section 18 emergency exemption.

[Reserved]

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[FR Doc. E8-15517 Filed 7-8-08; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-0871; FRL-8370-2]

Flumioxazin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flumioxazin in or on corn, field grain; corn, field forage; and corn, field stover. Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 9, 2008. Objections and requests for hearings must be received on or before September 8, 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-2007-0871. 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:

Joanne I. Miller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6224; e-mail address: miller.joanne@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).
- 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 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-2007-0871 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 September 8, 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-2007-0871, 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.