### VIII. Congressional Review Act

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

### List of Subjects in 40 CFR Part 180

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

Dated: April 24, 2006.

**Lois Rossi,**

*Acting 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 180.589 is amended in the table to paragraph (a)(1) by revising the entry for strawberry, and in the table to paragraph (d) by revising the entries for; beet, garden, roots; beet, sugar, roots; radish, roots; turnip, roots and vegetables, root and tuber, leaves, group 2 in the table in paragraph (d):

**§ 180.589 Boscalid; tolerance for residues.**

(a) * * *

| Commodity | Parts per million |
|---|---|
| * * * * | * |
| Strawberry | 4.5 |
| * * * * | * |

* * * * * *

(d) * * *

| Commodity | Parts per million |
|---|---|
| * * * * | * |
| Beet, garden, roots | 0.1 |
| Beet, sugar, roots | 0.1 |
| Radish, roots | 0.1 |
| * * * * | * |
| Turnip, roots | 0.1 |
| * * * * | * |
| Vegetable, root and tuber, leaves, Group 2 | 0.1 |

[FR Doc. 06–4158 Filed 5–2–06; 8:45 am]

**BILLING CODE 6560–50–S**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2005–0540; FRL–8063–2]**

### Azoxystrobin; Pesticide Tolerance

**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-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 Herb Subgroup 19A, fresh leaves; Herb Subgroup 19A, dried leaves; Spice Subgroup 19B, except black pepper; Rapeseed, seed; Rapeseed, Indian; Mustard, Indian, seed; Mustard, field, seed; Mustard, seed; Flax, seed; Sunflower, seed; Safflower, seed; Crambe, seed. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective May 3, 2006. Objections and requests for hearings must be received on or before July 3, 2006.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number EPA–HQ–OPP–2005–0540. All documents in the docket are listed on the *regulations.gov* Web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov*. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

• **Important Note:** OPP will be moving to a new location the first week of May 2006. As a result, from Friday, April 28 to Friday, May 5, 2006, the OPP Regulatory Public Docket will NOT be accepting any deliveries at the Crystal Mall #2 address and this facility will be closed to the public. Beginning on May 8, 2006, the OPP Regulatory Public Docket will reopen at 8:30 a.m. and deliveries will be accepted in Rm. S–4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202. The mail code for the mailing address will change to (7502P), but will otherwise remain the same. The OPP Regulatory Public Docket telephone number and hours of operation will remain the same after the move.

**FOR FURTHER INFORMATION CONTACT:** Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

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

• Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.

• Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.

• Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.

• Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

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

In addition to using EDOCKET *(http://www.epa.gov/edocket)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*.

## II. Background and Statutory Findings

In the **Federal Register** of March 8, 2006 (71 FR 11624) (FRL–7765–5), 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 petitions (PP 3E6637, 3E6749, and 4E6823) by Interregional Research Project #4 (IR–4), 681 US Highway #1 South, North Brunswick, NJ 08902–3390. The petitions requested that 40 CFR 180.507 be amended by establishing a tolerance 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 Herb Subgroup 19A, fresh leaves at 50 parts per million (ppm) (PP 4E6823); Herb Subgroup 19A, dried leaves at 260 ppm (PP 4E6823); Spice Subgroup 19B, except black pepper at 38 ppm (PP 3E6637); Rapeseed, seed at 0.5 ppm (PP 3E6749); Rapeseed, Indian at 0.5 ppm (PP 3E6749); Mustard, Indian, seed at 0.5 ppm (PP 3E6749); Mustard, field, seed at 0.5 ppm (PP 3E6749); Mustard, seed at 0.5 ppm (PP 3E6749); Flax, seed at 0.5 ppm (PP 3E6749); Sunflower, seed at 0.5 ppm (PP 3E6749); Safflower, seed at 0.5 ppm (PP 3E6749); and Crambe, seed at 0.5 ppm (PP 3E6749). That notice included a summary of the petition prepared by Syngenta, the registrant on behalf of the Interregional Research Project Number 4 (IR–4). One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

EPA is also deleting the tolerance established for coriander, leaves in § 180.507(a), since it is being replaced by establishing the Herb Subgroup 19A and Spice Subgroup 19B.

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....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for 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] on Herb Subgroup 19A, fresh leaves at 50 ppm; Herb Subgroup 19A, dried leaves at 260 ppm; Spice Subgroup 19B, except black pepper at 38 ppm; rapeseed, seed at 0.5 ppm; Rapeseed, Indian at 0.5 ppm; Mustard, Indian, seed at 0.5 ppm; Mustard, field, seed at 0.5 ppm; Mustard, seed at 0.5 ppm; Flax, seed at 0.5 ppm; Sunflower, seed at 0.5 ppm; Safflower, seed at 0.5 ppm; and Crambe, seed at 0.5 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

*A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic 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 can be found at *http://www.epa.gov/fedrgstr/EPA-PEST/2000/September/Day-29/p25051.htm*

*B. Toxicological Endpoints*

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.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 (65 FR 58404) (FRL–6749–1).

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.507) for the 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 a variety of raw agricultural commodities. In addition, tolerances for livestock commodities have been established for the residues of azoxystrobin (methyl(E)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) in or on milk; meat, fat, and meat byproducts (mbyp) of cattle, goat, hog, horse, and sheep. Risk assessments were conducted by EPA to assess 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 conducting the acute dietary exposure assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: One hundred percent of proposed and registered crops are treated with azoxystrobin (100% CT) and tolerance-level residues for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the DEEM-FCID™, Version 2.03, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: One hundred percent of proposed and registered crops are treated with azoxystrobin (100% CT) and tolerance-level residues for all commodities.

iii. *Cancer.* Azoxystrobin is classified as ''not likely to be a human carcinogen.'' Therefore, a cancer dietary exposure assessment was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for azoxystrobin 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 physical 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 FQPA Index Reservoir Screening Tool (FIRST) and screening concentration in ground water (SCI-GROW) models, the estimated environmental concentrations (EECs) of azoxystrobin for acute exposures are estimated to be 170 parts per billion (ppb) for surface water and 3.1 ppb for ground water. The EECs for chronic exposures are estimated to be 33 ppb for surface water and 3.1 ppb for ground water.

The drinking water estimates are based upon the crop with the highest application rate (turf). The use of azoxystrobin on turf has the highest single and yearly application rate at 0.55 pound/active ingredient/Acre (lb ai/A) and 5 lb ai/A/year, respectively, this application rate was used in the FIRST and SCI-GROW models to estimate the concentrations of this chemical in surface water and ground water, respectively.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID™). For acute dietary risk assessment, the peak water concentration value of 107 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the annual average concentration of 33 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).

Azoxystrobin is currently registered for use on the following residential non-dietary sites: Residential turfgrass and ornamentals, as well as indoor surfaces. The risk assessment was conducted using the following residential exposure 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 post-application activities. Toddlers may receive short- and intermediate-term oral exposure from incidental ingestion during post-application activities.

Inhalation daily doses for residential handlers were calculated for the WDG formulation using data for mixing, loading and applying a liquid. Based on PHED, unit exposure values from other handler scenarios with these formulation types, the exposure from a WDG is expected to be less than that of handling a liquid. The open mixing, loading, and applying liquid using a low pressure handwand (PHED) handler scenario was evaluated. The residential exposure and risk assessment for turf and ornamentals was conducted using the application rate for turf because it is the highest use rate.

Exposures were estimated for residential handler activities including: Mix, load and spot application of liquid formulation (low-pressure hand sprayer), and mix, load and broadcast application of liquid formulation (garden hose-end sprayer). In addition, short-term exposures were estimated for infants and children for post-application exposure scenarios resulting from indoor surface treatment including: Toddlers' incidental ingestion of pesticide residues on hard indoor surfaces from hand-to-mouth transfer, and toddlers' incidental ingestion of pesticide residues on carpet/textile indoor surfaces from hand-to-mouth transfer. Intermediate-term exposures were also estimated for infants and children for residential post-application oral exposures.

The exposure estimates are based on some upper-percentile (i.e., maximum application rate, initial amount of transferrable residue and duration of exposure) and some central tendency (i.e., surface area, hand-to-mouth activity, and body weight) assumptions and are considered to be representative of high-end exposures. The uncertainties associated with this assessment stem from the use of an assumed amount of pesticide available from turf, and assumptions regarding

transfer of chemical residues and hand-to mouth activity. The estimated exposures are believed to be reasonable high-end estimates.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the 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 azoxystrobin and 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 not assumed that azoxystrobin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

*D. Safety Factor for Infants and Children*

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

2. *Prenatal and postnatal sensitivity*. The developmental and reproductive toxicity data, from a Prenatal Development Study in Rats, a Prenatal Development Study in Rabbits, and a 2–Generation Reproductive Toxicity Study in Rats, did not indicate increased susceptibility of young rats or rabbits to *in utero* and/or postnatal exposure.

3. *Conclusion*. There is a complete toxicity database for azoxystrobin and exposure data are complete or are estimated based on data that reasonably account for potential exposures. The Agency has determined that the 10X FQPA safety factor to protect infants and children should be removed (that is, set to 1) because, in addition to the completeness of the toxicological database and the lack of increased susceptibility of young rats and rabbits to pre- and postnatal exposure to azoxystrobin, the unrefined acute and chronic dietary exposure estimates will overestimate dietary exposure from food, and ground water and surface water modeling data produce upper-bound concentration estimates. The residential post-application assessment is based upon the residential standard operational procedures (SOPs). 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*

The Agency currently has two ways to estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses. First, a screening assessment can be used, in which the Agency calculates drinking water levels of comparison (DWLOCs) which are used as a point of comparison against estimated drinking water concentrations (EDWCs). The DWLOC values are not regulatory standards for drinking water, but are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. More information on the use of DWLOCs in dietary aggregate risk assessments can be found at *http://www.epa.gov/oppfead1/trac/science/screeningsop.pdf*.

More recently the Agency has used another approach to estimate aggregate exposure through food, residential and drinking water pathways. In this approach, modeled surface water and ground water EDWCs are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual body weights and water consumption from the CSFII are used. The combined food and water exposures are then added to estimated exposure from residential sources to calculate aggregate risks. The resulting exposure and risk estimates are still considered to be high end, due to the assumptions used in developing drinking water modeling inputs.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to azoxystrobin will occupy 27% of the aPAD for the U.S. population, 24% of the aPAD for females 13 years and older, 23% of the aPAD for infants (<1 year old), and 74% of the aPAD for children 1–2 years old, the subpopulation at greatest exposure. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to azoxystrobin from food and water will utilize 28% of the cPAD for the U.S. population, 19% of the cPAD for All infants (<1 year old), and 70% of the cPAD for children 1–2 years old, the subpopulation at greatest exposure. Based on the use pattern, chronic residential exposure to residues of azoxystrobin is not expected. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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). Azoxystrobin is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food, water and short-term exposures for azoxystrobin.

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 500 for the U.S. population, 550 for youth 13–19 years old, 200 for all infants less than 1 year old, 120 for children 1 to 2 years old and 580 for females 13–49 years old. These aggregate MOEs do not exceed the Agency's level of concern, a MOE of 100, for aggregate exposure to food, water and residential uses.

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) of the risk from food and water, which do not exceed the Agency's level of concern. Azoxystrobin is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food, water and intermediate-term exposures for azoxystrobin.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food, water and residential exposures aggregated result in aggregate MOEs of 120 for children 1 to 2 years old. These aggregate MOEs do not exceed the Agency's level of concern, a MOE of 100, for aggregate exposure to food, water and residential uses.

5. *Aggregate cancer risk for U.S. population*. Azoxystrobin has been classified as not likely to be carcinogenic to humans. Therefore, azoxystrobin is expected to pose at most a negligible 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, and to infants and children from aggregate exposure to azoxystrobin residues.

## IV. Other Considerations

### *A. Analytical Enforcement Methodology*

Adequate methodology is available for enforcement of these tolerances. The gas chromatography/nitrogen phosphorous detector (GC/NPD) method (RAM 243/04) has undergone a method validation by the EPA analytical laboratory. EPA comments have been incorporated and the revised method (designated RAM 243) will be submitted to FDA for inclusion in PAM, Volume II as an enforcement method. 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*

There are no Codex, Canadian, or Mexican MRLs for azoxystrobin in or on the proposed commodities. Therefore, harmonization of tolerances is not an issue.

### *C. Response to Comments*

One comment was received from a private citizen who opposed the manufacturing and selling of this product due to potential effects on the environment. This comment is considered irrelevant because the safety standard for approving tolerances under section 408 of the FFDCA focuses on potential harms to human health and does not permit consideration of effects on the environment.

## 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] on Herb Subgroup 19A, fresh leaves at 50 ppm; Herb Subgroup 19A, dried leaves at 260 ppm; Spice Subgroup 19B, except black pepper at 38 ppm; Rapeseed, seed at 0.5 ppm; Rapeseed, Indian at 0.5 ppm; Mustard, Indian, seed at 0.5 ppm; Mustard, field, seed at 0.5 ppm; Mustard, seed at 0.5 ppm; Flax, seed at 0.5 ppm; Sunflower, seed at 0.5 ppm; Safflower, seed at 0.5 ppm; and Crambe, seed at 0.5 ppm.

## VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

### *A. What Do I Need to Do to File an Objection or Request a Hearing?*

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2005–0540 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before July 3, 2006.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objetion or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number EPA–HQ–OPP–2005–0540, to: Public Information and Records Integrity Branch, Information Technology and Resource Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**.

### *B. When Will the Agency Grant a Request for a Hearing?*

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the

requestor would be adequate to justify the action requested (40 CFR 178.32).

### VII. 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 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

### VIII. Congressional Review Act

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

### List of Subjects in 40 CFR Part 180

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

Dated: April 25, 2006.

**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 deleting the entries for ''Herb subgroup 19A, dried, except chive,'' and ''Herb subgroup 19A, fresh, except chive,'' and by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

**§ 180.507 Azoxystrobin.**

(a) * * *

| Commodity | Parts per million |
|---|---|
| * * * * * | |
| Crambe, seed | 0.5 |
| * * * * * | |
| Flax, seed | 0.5 |
| * * * * * | |
| Herb Subgroup 19A, dried leaves | 260 |
| Herb Subgroup 19A, fresh leaves | 50 |
| * * * * * | |
| Mustard, field, seed | 0.5 |
| Mustard, Indian, seed | 0.5 |
| Mustard, seed | 0.5 |
| * * * * * | |
| Rapeseed, Indian | 0.5 |
| Rapeseed, seed | 0.5 |
| * * * * * | |
| Safflower, seed | 0.5 |
| * * * * * | |
| Spice Subgroup 19B, except black pepper | 38 |
| * * * * * | |
| Sunflower, seed | 0.5 |
| * * * * * | |

* * * * *

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