

## IX. Statutory and Executive Order Reviews

This final rule establishes a temporary exemption from the tolerance requirement for *Bacillus pumilus* strain QST2808 under section 408(d) of the FFDCFA 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 the FFDCFA, such as the exemption 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 the FFDCFA. 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.

## X. 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: June 3, 2003.

**James Jones,**

*Director, Office of Pesticide Programs.*

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

## PART 180—[AMENDED]

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

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

■ 2. Section 180.1226 is added to subpart D to read as follows:

### § 180.1226 *Bacillus pumilus* strain QST2808; temporary exemption from the requirement of a tolerance.

A temporary exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Bacillus pumilus* strain QST2808 when used in or on all agricultural commodities when applied/used in accordance with label directions.

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-2003-0196; FRL-7311-2]

### Azoxystrobin; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of azoxystrobin, methyl (E)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-∞-(methoxymethylene)-benzeneacetate, and its Z isomer, methyl (Z)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-∞-(methoxymethylene)-benzeneacetate, in or on artichoke, globe, asparagus; brassica, head and stem, subgroup 5A; herb subgroup 19A, (dried) except chive; and herb subgroup 19A, (fresh) except chive. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCFA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective June 18, 2003. Objections and requests for hearings, identified by docket identification (ID) number OPP-2003-0196, must be received on or before August 18, 2003.

**ADDRESSES:** Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-3194; e-mail address: [brothers.shaja@epa.gov](mailto:brothers.shaja@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, and pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop Production (NAICS 111)
- Animal Production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 28522)

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 Get Copies of this Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP-2003-0196. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available

for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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.

2. *Electronic access.* 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 [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_00/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html), a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

##### **II. Background and Statutory Findings**

In the **Federal Register** of March 26, 2003 (68 FR 14622) (FRL-7299-3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of pesticide petitions (PP 2E6375, 2E6488, 2E6489, and 2E6495) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. That notice included a summary of the petitions prepared by Syngenta, the registrant.

The petitions requested that 40 CFR 180.507 be amended by establishing tolerances for combined residues of the fungicide azoxystrobin, methyl (*E*)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]- $\infty$ -(methoxymethylene) benzeneacetate and its *Z* isomer methyl (*Z*)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]- $\infty$ -(methoxymethylene) benzeneacetate, in or on artichoke, globe at 4.0 parts per million (ppm); asparagus at 0.02 ppm; brassica, head and stem, subgroup 5A at 3.0 ppm; herb subgroup 19A, dried, except chive at 260 ppm; and herb

subgroup 19A, fresh, except chive at 50 ppm.

Section 408(b)(2)(A)(i) of the 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 the 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 the 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 the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

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

Consistent with section 408(b)(2)(D) of the 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 the FFDCA, for tolerances for combined residues of azoxystrobin on artichoke, globe at 4.0 ppm; asparagus at 0.04 ppm; brassica, head and stem, subgroup 5A at 3.0 ppm; herb subgroup 19A, dried, except chive at 260 ppm; and herb subgroup 19A, fresh, except chive at 50 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follow.

###### *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. The nature of the toxic effects caused by azoxystrobin are discussed in Unit III.A of the Final Rule on Azoxystrobin Pesticide Tolerance published in the **Federal Register** on September 20, 2002 (67 FR 59169)(FRL-7198-9).

#### B. Toxicological Endpoints

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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology ( $Q^*$ ) is the primary method currently used by the Agency to quantify carcinogenic risk. The  $Q^*$  approach assumes that any amount of exposure will lead to some degree of cancer risk. A  $Q^*$  is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as  $1 \times 10^{-6}$  or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified

below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ( $MOE_{\text{cancer}} = \text{point of departure/exposures}$ ) is calculated. A summary of the toxicological endpoints for azoxystrobin used for human risk assessment is discussed in Unit III.B. of the Final Rule on Azoxystrobin Pesticide Tolerance published in the **Federal Register** on September 20, 2002 (67 FR 59169)(FRL-7198-9).

#### 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, in or on a variety of raw agricultural commodities. Tolerances have been established for residues of azoxystrobin in or on a variety of raw agricultural commodities at levels ranging from 0.01 ppm (pecans) to 55 ppm (soybean hay), and on meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep at levels ranging from 0.01 to 0.07 ppm, and on milk at 0.006 ppm. A time-limited tolerance (to expire on 12/31/2003) is currently established at 30 ppm for the head and stem Brassica vegetables, subgroup 5A. Risk assessments were conducted by EPA to assess dietary exposures from azoxystrobin in food as follows:

i. *Acute exposure.* Acute dietary 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 one day or single exposure. In conducting this acute risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) which incorporates food consumption data as reported by respondents in the 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 assumption was made for the acute exposure assessment: A Tier 1 acute dietary exposure analysis was performed for azoxystrobin.

ii. *Chronic exposure.* In conducting this chronic risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) which incorporates food consumption data as reported by respondents in the 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 chronic exposure assessments: The chronic dietary exposure analysis was performed for the general U.S. Population and all population subgroups using tolerance level residues (livestock) and total residues of concern (plants; parent and metabolites) and 100% crop treated data for the proposed commodities and all registered uses.

iii. *Cancer.* EPA's Cancer Assessment Review Committee (CARC) evaluated the carcinogenic potential of azoxystrobin and classified azoxystrobin as "not likely to be a human carcinogen" based on the revised Cancer Guidelines.

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.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in groundwater (SCI-GROW) model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. FIRST and PRZM/EXAMS incorporate an index reservoir environment, and a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to azoxystrobin they are further discussed in the aggregate risk section in Unit III.E.

Although moderately persistent in soils and stable to hydrolysis, the likelihood of azoxystrobin moving into ground and surface water is low due to high soil/water partitioning coefficients and low single application rates. However, with multiple applications and repeated usage, azoxystrobin and especially its degradate ("compound 2", (E)-2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]-3-methoxyacrylic acid) may eventually build up in environmental compartments and move into drinking water resources.

Based on the Tier I modeling results using the FQPA Index Reservoir Screening Tool (FIRST) model, azoxystrobin EECs in surface water are not likely to exceed 170 parts per billion (ppb) for the acute (peak) concentration or 33 ppb for the chronic (365-day) concentration. These values represent upper-bound estimates of the concentrations that might be found in surface water which result from the use of azoxystrobin on turf.

The SCI-GROW screening model developed in the Agency estimates potential ground water concentrations under hydrologically vulnerable conditions. Based on the highest use rate (turf use, nine applications per year, 10-day interval, and 0.55 lb ai/A/application), the upper-bound concentration of azoxystrobin was estimated at 3.1 ppb. This value was used for both acute and chronic risk assessments. This value represents upper-bound estimates of the concentrations that might be found in ground water which result from the use of azoxystrobin on turf.

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 residential non-dietary sites (turf and ornamentals). The risk assessment was conducted using the following residential exposure assumptions: There is a potential for short-term dermal and inhalation exposures to homeowners who apply products containing azoxystrobin; however, EPA did not identify dermal endpoints for azoxystrobin. Because no dermal endpoints could be identified, EPA expects no risk from dermal exposure to azoxystrobin. There is also potential for non-dietary, oral exposure following lawn treatment. Short- and intermediate-term non-dietary, oral exposure assessments were included for toddlers, since EPA selected toxicology endpoints for these exposures and there is a potential for hand-to-mouth and object-to mouth transfer of residues from treated turfgrass and incidental ingestion of soil from treated turfgrass.

Postapplication exposures from various activities following lawn treatment are considered to be the most common and significant in residential settings. The exposure via incidental ingestion of other plant material may occur but is considered negligible. The residential exposure and risk assessment was conducted using the application for turf because it is the highest single use rate. Azoxystrobin may be applied to turf at rates of up to 0.9516 active ingredient (a.i.) per acre five times per year (i.e., not to exceed 5 lb/ai/acre/year).

4. *Cumulative exposure to 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."

EPA does not have, at this time, available data to determine whether azoxystrobin has a common mechanism of toxicity with other substances. 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 the 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 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.

2. *Prenatal and postnatal sensitivity.* Azoxystrobin studies have indicated no increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to azoxystrobin.

3. *Conclusion.* There is a complete toxicity data base for azoxystrobin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10-fold safety factor for increased susceptibility of infants and children be removed (i.e., reduced to 1X). The FQPA factor is removed because:

- The toxicology data base is complete
- The developmental and reproductive toxicity data did not indicate increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure
- Unrefined chronic dietary exposure estimates (assuming all commodities contain tolerance level residues) will overestimate dietary exposure
- Modeling data are used for ground and surface source drinking water exposure assessments resulting in estimates considered to be upper-bound concentrations

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

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a

point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs 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. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult

female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a

pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to azoxystrobin will occupy 10% of the aPAD for the U.S. population, 17% of the aPAD for children 1–2 years old, 9% of the aPAD for females 13 years and older, and 10% of the aPAD for adults 50+ years old. In addition, there is potential for acute dietary exposure to azoxystrobin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 1 of this unit:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO AZOXYSTROBIN

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population .....	0.67	10	170	3.1	21,000
Children 1–2 years old .....	0.67	17	170	3.1	5,600
Females 13–49 years .....	0.67	9	170	3.1	18,000
Adults (50+ years) .....	0.67	10	170	3.1	21,000

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to azoxystrobin from food will utilize 12% of the cPAD for the U.S. population, 22% of the cPAD for children 1–2 years old, 11% of the

cPAD for females 13–49 years old, and 11% for adults 50+ years old. Based on the use pattern, chronic residential exposure to residues of azoxystrobin is not expected. In addition, there is potential for chronic dietary exposure to azoxystrobin in drinking water. After

calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO AZOXYSTROBIN

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population .....	0.18	12	33	3.1	5,500
Children 1–2 years .....	0.18	22	33	3.1	1,400
Females 13–49 years .....	0.18	11	33	3.1	4,800
Adults 50+ years .....	0.18	11	33	3.1	5,600

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 and water and short-term exposures for azoxystrobin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,200 for adults, and 430 for children 1–2 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared

to the EECs for chronic exposure of azoxystrobin in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO AZOXYSTROBIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. Population .....	1,200	100	33	3.1	8,000
Children 1–2 years old .....	430	100	33	3.1	1,900

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).

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

and water and intermediate-term exposures for azoxystrobin.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 420 for children 1–2 years old. These aggregate MOEs do not exceed the Agency’s level of concern for aggregate exposure to food and residential uses. In

addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of azoxystrobin in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency’s level of concern, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO AZOXYSTROBIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
Children 1–2 years old .....	420	100	33	3.1	1,600

5. *Aggregate cancer risk for U.S. population.* There is no evidence for mutagenicity or carcinogenicity. Azoxystrobin has been classified as “not likely to be carcinogenic in humans” by EPA; therefore, azoxystrobin is not expected to pose a carcinogenic 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*

No Codex, Canadian, or Mexican Maximum Residue Levels (MRLs) have been established for residues of azoxystrobin. Therefore, no tolerance discrepancies exist between countries for this chemical.

**V. Conclusion**

Therefore, the tolerances are established for combined residues of azoxystrobin, methyl (E)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-∞-(methoxymethylene)-benzeneacetate, and its Z isomer, methyl (Z)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-∞-(methoxymethylene)-benzeneacetate, in or on artichoke, globe at 4.0 ppm; asparagus at 0.04 ppm; brassica, head and stem, subgroup 5A at 3.0 ppm; herb subgroup 19A, dried, except chive at 260 ppm; and herb subgroup 19A, fresh, except chive at 50 ppm.

**VI. Objections and Hearing Requests**

Under section 408(g) of the FFDCA, as amended by the 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 the

FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the 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 the 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 OPP–2003–0196 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 August 18, 2003.

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 issues(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 objection 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 (1900C), 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 Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *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 Unit I.B.1. Mail your copies, identified by docket ID number OPP-2003-0196, to: Public Information and Records Integrity Branch, Information Resources and Services 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 Unit I.B.1. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov). Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

#### *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 issues(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 the FFDC 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 the FFDC, 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 the FFDC. 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: June 6, 2003.

**Debra Edwards,**

*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), 346(a) and 371.

■ 2. Section 180.507 is amended by adding alphabetically commodities to the table in paragraph (a)(1) to read as follows:

**§ 180.507 Azoxystrobin; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * *	*
Artichoke, globe .....	4.0
Asparagus .....	0.04
* * *	*
Brassica, head and stem, subgroup 5A .....	3.0
* * *	*
Herb subgroup 19A, dried, except chive .....	260
Herb subgroup 19A, fresh, except chive .....	50
* * *	*

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**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 257 and 258**

[FRL-7514-7]

**RIN 2050-AE86**

**Criteria for Classification of Solid Waste Disposal Facilities and Practices and Criteria for Municipal Solid Waste Landfills: Disposal of Residential Lead-Based Paint Waste**

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

**ACTION:** Final rule.

**SUMMARY:** To help accelerate the pace of lead-based paint removal from residences, and thereby reduce exposure to children and adults from the health risks associated with lead, EPA is promulgating a change to its definition of “municipal solid waste landfill unit” in both the Criteria for Classification of Solid Waste Disposal Facilities and Practices and the Criteria for Municipal Solid Waste Landfills. In addition, EPA is promulgating two new definitions for “construction and demolition (C&D) landfill” and “residential lead-based paint waste.” This final rule will expressly allow residential lead-based paint waste that is exempted from the hazardous waste management requirements as household waste to be disposed of in construction and

demolition landfills by stating that a construction and demolition landfill accepting residential lead-based paint waste, and no other household waste, is not a municipal solid waste landfill unit. Today’s action would not prevent a municipal solid waste landfill unit from continuing to receive residential lead-based paint waste.

**DATES:** This final rule will become effective on June 18, 2003. The Agency finds good cause to make this rule effective immediately because today’s final rule provides an additional disposal option for residential lead-based paint waste.

**ADDRESSES:** Copies of the documents relevant to this action (Docket No. RCRA-2001-0017) are available for public inspection during normal business hours from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays, at the RCRA Information Center (RIC), located at EPA West, Room B-102, 1301 Constitution Ave., NW, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** For general information, contact the RCRA Hotline at (800) 424-9346 or TDD (800) 553-7672 (hearing impaired). In the Washington, DC, metropolitan area, call (703) 412-9810 or TDD (703) 412-3323.

For information on specific aspects of this rule, contact Paul Cassidy, Municipal and Industrial Solid Waste Division, Office of Solid Waste (mail code 5306W), U.S. Environmental Protection Agency (EPA, HQ), 1200 Pennsylvania Avenue, NW, Washington, DC 20460; (703) 308-7281, [cassidy.paul@epa.gov](mailto:cassidy.paul@epa.gov). The index and some supporting materials are available on the Internet. You can find these materials at <http://www.epa.gov/epaoswer/non-hw/muncpl/landfill/pb-paint.htm>.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Regulated Entities*

Entities potentially covered by this regulation are public or private individuals or groups that generate residential lead-based paint (LBP) waste as a result of abatement, rehabilitation, renovation and remodeling in homes, residences, and other households. By “households,” we mean single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds, and day-use recreation areas. Affected categories and entities include: