

Par. 5. In § 602.101, paragraph (b) is amended by removing the entry for “1.6695–2T” and adding the following entry in numerical order to the table to read as follows:

§ 602.101 OMB Control numbers.

* * * *				
(b) * * *				
CFR part or section where identified and described				Current OMB control No.
* * * *				*
1.6695–2			1545–1570
* * * *				*

Approved: October 6, 2000.

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Jonathan Talisman,

Acting Assistant Secretary of the Treasury.

[FR Doc. 00–26521 Filed 10–16–00; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 56, 57, 62, 70 and 71

RIN 1219–AA53

Health Standards for Occupational Noise Exposure; Correction

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Final rule; corrections.

SUMMARY: This document contains corrections to preamble to the final rule which were published in the **Federal Register** of Monday, September 13, 1999 (64 FR 49548). The rule related to the health standards for occupational noise exposure.

DATES: Effective October 17, 2000.

FOR FURTHER INFORMATION CONTACT:

Carol J. Jones, Director, Office of Standards, Regulations, and Variances, MSHA, (703) 235–1910 (not a toll-free call).

SUPPLEMENTARY INFORMATION: As published, the preamble contains errors which may prove to be misleading and which need to be corrected.

Accordingly, the preamble is corrected as follows:

1. On page 49551, in “Chart 1: General Requirements” under the heading Noise level, the phrase “At or above 105 dBA (dual hearing protection level)” should read “Above 105 dBA (dual hearing protection level).”

2. On page 49551, in “Comparison Chart 2: General Features” under the heading Final rule, the third entry should read “80 dBA for action level and 90 dBA for PEL.”

3. On page 49558, in the second column, in the last sentence, the word “tone” should be deleted to make the sentence read “Most definitions of hearing impairment are based solely on pure audiometry, in which an audiometer is used to measure an individual’s threshold hearing level—the lowest level of discrete frequency tones that he or she can hear.”

4. On page 49590, in the second column, in the first paragraph, in the last sentence, the word “regulations” should be changed to “standards” to make the sentence read “Accordingly, MSHA has concluded that noise falls within the scope of section 103(c) of the Mine Act, and that MSHA has the authority to establish standards that provide miners and their representatives access to noise exposure monitoring conducted by mine operators.”

5. On page 49607, in the third column, in the first full paragraph, in the first full sentence, the words “equals or” should be inserted so that the sentence reads “The final rule, like the proposal, requires mine operators to offer miners whose noise exposure equals or exceeds the action level the opportunity for audiometric . . .”

6. On page 49608, in the second column, in the first full paragraph, in the first sentence, the words “equals or” should be inserted so that the sentence reads “Under § 62.120 of the final rule, mine operators must enroll miners whose exposure to noise equals or exceeds the action level in a hearing conservation program . . .”

7. On page 49627, in the first column, in the first full paragraph, in the fourth sentence, the term “Paragraph (c)” should be changed to “Paragraph (b).” In the second full paragraph, in the first sentence, the term “Paragraph (a)(3)” should be changed to “Paragraph (b).” In the third full paragraph, in the first sentence, the term “Paragraph (b)(1)” should be changed to “Paragraph (c)(1).” In the last paragraph, in the last sentence, the term “Paragraph (b)(1)” should be changed to “Paragraph (c)(1).” In the second column, in the first full paragraph, in the first sentence, the term “Paragraph (b)(2)” should be changed to “Paragraph (c)(2),” and in the last sentence the term “Paragraph (b)(2)” should be changed to “Paragraph (c)(2).”

Dated: September 28, 2000.

J. Davitt McAteer,

Assistant Secretary for Mine Safety and Health.

[FR Doc. 00–26620 Filed 10–16–00; 8:45 am]

BILLING CODE 4510–43–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301049; FRL–6742–9]

RIN 2070–AB78

Azoxystrobin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of azoxystrobin or methyl (E)-2-2-[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy]phenyl-3-methoxyacrylate) and its Z isomer in or on brassica leafy vegetable. This action is in response to EPA’s granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on brassica leafy vegetable. This regulation establishes a maximum permissible level for residues of azoxystrobin in this food commodity. The tolerance will expire and is revoked on December 31, 2001.

DATES: This regulation is effective October 17, 2000. Objections and requests for hearings, identified by docket control number OPP–301049, must be received by EPA on or before December 18, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301049 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Jacqueline E. Gwaltney, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703 305–6792; and e-mail address: gwaltney.jackie@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 categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301049. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record

does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the fungicide azoxystrobin or methyl (E)-2-[6-(2-cyanophenoxy)pyrimidin-4-yl]oxyphenyl-3-methoxyacrylate and its Z isomer, in or on brassica leafy vegetable at 25.0 parts per million (ppm). This tolerance will expire and is revoked on December 31, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

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) 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) 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. . . ."

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Azoxystrobin on Brassica Leafy Vegetable and FFDCA Tolerances

Georgia has also requested the use of azoxystrobin to control leaf spots of leafy greens caused by *Cercospora brassicicola* and *cercospora brassica*. Losses due to these fungal pathogens have increased in recent year and, in some cases, entire fields are destroyed because leaves of greens are unmarketable due to spotting.

EPA has authorized under FIFRA section 18 the use of azoxystrobin on brassica leafy vegetable. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of azoxystrobin in or on brassica leafy vegetable. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on brassica leafy vegetable after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this

pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether azoxystrobin meets EPA's registration requirements for use on brassica leafy vegetable or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of azoxystrobin by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for azoxystrobin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT.**

IV. Aggregate Risk Assessment and Determination of Safety

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 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).

Consistent with section 408(b)(2)(D), 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 azoxystrobin and to make a

determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerances for residues of azoxystrobin in or on brassica leafy vegetable at 25.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. 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 endpoint. 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 intra species differences. Discuss any additional uncertainty factors (other than the FQPA SF) used in the assessment.

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 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 Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (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 1×10^{-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 ($\text{MOE}_{\text{cancer}} = \text{point of departure} / \text{exposures}$) is calculated. A summary of the toxicological endpoints for azoxystrobin used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR AZOXYSTROBIN FOR USE IN HUMAN RISK ASSESSMENT

Endpoint	Dose (mg/kg/day)	TES/RfD/FQPA Committee Determinations	Conclusion
Acute Dietary		No appropriate endpoint was identified for this exposure scenario. No developmental toxicity was observed in the rabbit and rat studies reviewed. Effects seen in the acute neurotoxicity study were due to abdominal discomfort, not primary neurotoxicity (TES Committee, 12/10/96).	This risk assessment is not required.
Chronic Dietary	NOAEL = 18.2 UF = 100	The RfD was established based on a chronic toxicity study (MRID 43678139) in rats with a NOAEL of 18.2 mg/kg/day. Reduced body weights and bile duct lesions were observed at the LOAEL of 34 mg/kg/day. An uncertainty factor of 100 was used to account for both the inter-species extrapolation and the intra-species variability (see Memo, RfD Committee, 11/7/96).	This risk assessment is required. Chronic RfD = 0.18 mg/kg/day.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR AZOXYSTROBIN FOR USE IN HUMAN RISK ASSESSMENT—Continued

Endpoint	Dose (mg/kg/day)	TES/RfD/FQPA Committee Determinations	Conclusion
FQPA Safety Factor		The FQPA Safety Factor Committee recommended that the 10x Safety Factor be removed for the following reasons: 1) the toxicology data base is complete; 2) the developmental and reproductive toxicity data did not indicate increased susceptibility of rats or rabbits to in utero and/or postnatal exposure; 3) unrefined chronic dietary exposure estimates (assuming all commodities contain tolerance level residues) will overestimate dietary exposure; 4) modeling data are used for ground and surface source drinking water exposure assessments resulting in estimates considered to be upper-bound concentrations; and 5) there are currently no registered residential uses for Azoxystrobin (FQPA document, 9/3/98).	10x Safety Factor was removed. The chronic population adjusted dose is equivalent to the chronic RfD (cPAD = cRfD).
Carcinogenicity		The HED RfD/Peer Review Committee determined that azoxystrobin should be classified as "Not Likely" to be a human carcinogen according to the proposed revised Cancer Guidelines (See TES Document, 12/10/96).	A cancer risk assessment is not required.

B. Residue Information

Tolerances for azoxystrobin (including time-limited tolerances) are published in 40 CFR 180.507. The tree nuts tolerance of 0.01 ppm which is listed in the 40 CFR was amended to 0.02 ppm.

For this analysis, tolerance level residues and 100 percent crop treated assumptions were made for all commodities. Processing studies show that residues do not concentrate in the following foods: citrus juice, grapes-raisins, plums-prunes (dried), potatoes-white (dry), grape juice, tomato juice, and tomatoes-puree. As a result, DEEM default processing factors (adjustment factors #1) were set to 1.0 for these commodities. The concentration factors for the following juice concentrates were changed to preserve the concentration ratio from juice to concentrate: grapes (3.6 to 3.0), grapefruit (8.3 to 3.9), lemons (11.4 to 5.7), limes (6 to 3), oranges (6.7 to 3.7), and tangerines (7.4 to 3.2).^{*} The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.507) for the residues of azoxystrobin, in or on a variety of raw agricultural commodities at levels ranging from 0.010 ppm in tree nuts to 20 ppm in rice hulls. Included in these tolerances are numerous ones

for animal commodities which were established in conjunction with tolerances for rice and wheat commodities. Risk assessments were conducted by EPA to assess dietary exposures from azoxystrobin in food as follows:

i. *Acute risk.* No toxicological effects which could be attributed to a single dietary exposure were observed, including developmental and neurotoxic effects in the appropriate studies. The Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 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:

ii. *Chronic risk.* (Chronic RfD = 0.18 mg/kg/day) In conducting this chronic dietary risk assessment, HED has made very conservative assumptions: 100% of Brassica vegetables and turnip tops and all other commodities having azoxystrobin tolerances will contain azoxystrobin residues, and those residues will be at the level of the tolerance. Default concentration factors have been removed (i.e., set to 1) for the following commodities: grapes-juice, grapes-raisins, tomatoes-juice, tomatoes-puree, and potatoes-white (dry). Concentration factors were removed because data which were previously submitted show no concentration of

residues into raisins, tomato juice and puree or potatoes. The default ratio between grape juice and juice concentrate was retained.

The Novigen DEEM (Dietary Exposure Evaluation Model) system was used for this chronic dietary exposure analysis. The analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1991. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure.

The existing azoxystrobin tolerances (published, pending, and including the necessary Section 18 tolerance(s)) result in a theoretical maximum residue contribution (TMRC) that is equivalent to the following percentages of the Chronic RfD. As the 10x safety factor was removed, the chronic RfD is equal to the PAD (population-adjusted dose). As a result, the exposure given as a percentage of the total allowable exposure is reported as %PAD, as shown in the following Table 2:

TABLE 2.—SUMMARY: CHRONIC EXPOSURE ANALYSIS BY THE DEEM SYSTEMS

Population Subgroup	Exposure (mg/kg/day)	Percent Reference Dose ¹ (%Chronic PAD/RfD)
U.S. Population (total)	0.012207	7.4%
All Infants (less than 1 year old)	0.014855	11.5%
Nursing Infants (less than 1 year old)	0.003915	3.1%
Non-Nursing Infants (less than 1 year old)	0.019460	14.0%
Children (1-6 years old)	0.021949	12.1%
Children (7-12 years old)	0.012950	7.7%
Non-Hispanic Blacks	0.016431	9.1%
Non-Hispanic/ non-white/ non-black	0.020967	14.8%
Females (13+ nursing)	0.014210	8.8%
Seniors 55+	0.013462	7.5%

¹ Percentage reference dose (% Chronic PAD) = Exposure/Chronic PAD x 100% (as RfD=PAD in this case)

The subgroups listed above are: (1) the U.S. Population (total); (2) those for infants and children; and, (3) the other subgroups (except regions and seasons) for which the percentage of the Chronic PAD occupied is greater than that

occupied by the subgroup U.S. Population (total).

iii. *Anticipated residue and percent crop treated information.* The Agency used percent crop treated (PCT) information as follows:

A routine chronic dietary exposure analysis for the wheat hybridizing agent X was based on 0.1% of wheat crop treated, and 0.1% of the cereal grains group (except rice, wild rice, sweet corn, and wheat) and soybeans as rotated crops in fields previously containing wheat treated with chemical X. PCT of 0.1% was based on the petitioner's expectations that up to 35,000 acres of wheat grown for seed will be treated annually, which amounts to 0.05% of the 70,000,000 acres of wheat grown in the United States. The reason for using 0.1% instead of 0.05% is to allow expansion of use if other conditions of registration are satisfied. Before expansion beyond 0.1% is allowed, reevaluation of the dietary exposure may be performed using all available information.

The Agency believes that the three conditions previously discussed have been met. With respect to Condition 1, EPA finds that the PCT information described above for chemical X used on wheat grown for seed is reliable and has a valid basis. Chemical X is a hybridizing agent specific for sterilizing the male organ of the wheat plant in seed production. The majority of seed will be used planting purposes, and not directly as food or feed. Before the petitioner can increase production of product for treatment of greater than 35,000 acres per year, permission from the Agency must be obtained. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk

assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which pesticide X may be applied in a particular area.

2. *Dietary exposure from drinking water.* Azoxystrobin is persistent and mobile. There is no established Maximum Contaminant Level for residues of azoxystrobin in drinking water. No health advisory levels for azoxystrobin in drinking water have been established (EPA Safe Drinking Water Hotline, 1 (800) 426-4791, 4/15/99). EFED has supplied RAB2 with estimates for the concentration of azoxystrobin in surface water based on GENECC (Generic Estimated Environmental Concentration) modeling and in ground water based on SCIGROW modeling.

Chronic risk. Estimated environmental concentrations (EECs) using GENECC for azoxystrobin on bananas, grapes, peaches, peanuts, pecans, tomatoes, and wheat are listed in the SWAT Team Second Interim Report (6/20/97).

The highest EEC for azoxystrobin in surface water (39 µg/L) is from the application of azoxystrobin to grapes. The EEC for ground water is 0.064 µg/L resulting from use on turf. For purposes of risk assessment, the maximum EEC for azoxystrobin in drinking water (39 µg/L) should be used for comparison to the back-calculated human health drinking water levels of comparison (DWLOC) for the chronic (non-cancer) endpoint. These DWLOCs for various population categories are summarized in the following Table 3:

TABLE 3.—DRINKING WATER LEVELS OF COMPARISON FOR CHRONIC EXPOSURE¹

Population Category ²	Chronic RfD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure ³ (mg/kg/day)	DWLOC ^{4,5,6} (µg/L)
U.S. Population (total)	0.18	0.0122 07	0.168	5,900
Females (13+ years, nursing)	0.18	0.0142 10	0.166	5,000
Non-nursing Infants (less than 1 year old)	0.18	0.0194 60	0.161	1,600

¹ Values are expressed to 2 significant figures.

² Within each of these categories, the subgroup with the highest food exposure was selected.

³ Maximum Water Exposure (Chronic) (mg/kg/day) = Chronic RfD (mg/kg/day) - Food Exposure (mg/kg/day).

⁴ DWLOC(µg/L) = Max. water exposure (mg/kg/day) x body wt (kg) ÷ (10⁻³ mg/µg) * water consumed daily (L/day).

⁵ Default body weights are: General U.S. Population, 70 kg; Males (13+ years old), 70 kg; Females (13+ years old), 60 kg; Other Adult Populations, 70 kg; and, All Infants/Children, 10 kg.

⁶ Default daily drinking rates are 2 L/day for adults and 1 L/day for children.

The estimated maximum concentrations of azoxystrobin in surface water and ground water are less than EPA's levels of comparison for azoxystrobin in drinking water as a contribution to chronic aggregate exposure. Therefore, taking into account the present uses and uses proposed in this Section 18 and the fact that GENEEC can substantially overestimate (by up to 3x) true pesticide concentrations in drinking water, EPA concludes with reasonable certainty that residues of azoxystrobin in drinking water (when considered along with other sources of chronic exposure for which EPA has reliable data) would not result in an unacceptable estimate of chronic (non-cancer) aggregate human health risk at this time.

EPA bases this determination on a comparison of estimated average concentrations of azoxystrobin in surface and ground water to back-calculated DWLOCs for azoxystrobin in drinking water. These levels of comparison in drinking water were determined after HED considered all other non-occupational human exposures for which it has reliable data, including all current uses, and the use considered in this action. The estimate of azoxystrobin in surface water is derived from a water quality model that uses conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water. 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 azoxystrobin in drinking water as a part of the chronic (non-cancer) aggregate risk assessment process.

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 Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCIGROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1

model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes 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 sections below.

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: ornamental turf. The risk assessment was conducted using the following exposure assumptions: Short-term exposure may occur for residential handlers and for postapplication activities. Because the TES Committee (11/12/96) did not select applicable acute dietary or short-term dermal or inhalation endpoints, a short-term risk assessment is not required. No toxicity was observed at the limit dose (1,000 mg/kg body wt/day) in a 21-day dermal

study and an acute inhalation study indicated low toxicity. Intermediate-term and chronic exposures are not expected for residential use.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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 or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

Safety factor for infants and children—In general. FFDCA section 408 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

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 + chronic non-dietary, non-occupational 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: 2L/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 azoxystrobin 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 azoxystrobin on drinking water as a part of the aggregate risk assessment process.

1. *Chronic risk.* Using the conservative TMRC exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to azoxystrobin from food will utilize 11.6% of the cPAD for the U.S. population, 2.2% of the cPAD for infant subpopulations at greatest exposure and 12.2% of the cPAD for children subpopulation at greatest exposure. Based on the use pattern, chronic residential exposure to residues of the azoxystrobin is not expected. In addition, despite the potential for chronic dietary exposure to azoxystrobin in drinking water, after calculating the DWLOCs and comparing

them to conservative model estimated environmental concentrations of azoxystrobin in surface and ground water. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

2. *Short-term risk.* There are no applicable endpoints for short-term exposure; therefore, a short-term aggregate risk assessment is not required. Intermediate-term exposure is not expected for registered residential uses; therefore, an intermediate-term risk assessment is not required.

Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Though residential exposure could occur with the use of azoxystrobin, the potential short-term exposures were not aggregated with chronic dietary food and water exposures because the toxic effects are different. Therefore, based on the best available data and current policies, potential risks do not exceed the Agency's level of concern.

3. *Aggregate cancer risk for U.S. population.* The EPA RfD/Peer Review Committee (November 7, 1996) determined that azoxystrobin should be classified as "Not Likely" to be a human carcinogen according to the proposed revised Cancer Guidelines. Therefore, a cancer risk assessment is not required.

4. *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.

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate analytical method is available for enforcement of the proposed tolerances. Method RAM 243 (GC/NPD) can be used for the commodities in crop groups 2 and 5. The limit of quantitation for spinach and leaf lettuce was 0.01 ppm and the LOQ for head lettuce was either 0.02 ppm or 0.05 ppm (depending on laboratory). This method has been validated by the Agency's Analytical Chemistry Laboratory and will be submitted to FDA for inclusion in PAM II.

The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits (MRL) for azoxystrobin.

C. Conditions

No special conditions, other than this tolerance are in conjunction with a Section 18 specific exemption.

VI. Conclusion

Therefore, the tolerance is established for residues of azoxystrobin in or on brassica leafy vegetable at 25.0 ppm ppm.

VII. 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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP-301049 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 December 18, 2000, Federal Register].

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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) 260-4865.

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, 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.

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.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.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.2. Mail your copies, identified by the docket control number OPP-301049, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: 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 file format 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).

VIII. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408. 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). 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require 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 FIFRA section 18 petition under FFDCA section 408, such as the tolerance/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 FFDCA section 408(n)(4).

IX. Submission to Congress and the Comptroller General

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: September 28, 2000.

James Jones,

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 alphabetically adding commodities to the table in paragraph (b) to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

* * * * *

(b)* * *

Commodity	Parts per million	Expiration/Revocation Date
Brassica leafy vegetable	25.0	12/31/01

* * * * *

[FR Doc. 00-26638 Filed 10-16-00; 8:45 am]

BILLING CODE 6560-50-S

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA-7736]

List of Communities Eligible for the Sale of Flood Insurance

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: This rule identifies communities participating in the National Flood Insurance Program (NFIP). These communities have applied to the program and have agreed to enact certain floodplain management measures. The communities' participation in the program authorizes the sale of flood insurance to owners of property located in the communities listed.

EFFECTIVE DATES: The dates listed in the third column of the table.

ADDRESSES: Flood insurance policies for property located in the communities listed can be obtained from any licensed property insurance agent or broker serving the eligible community, or from the NFIP at: Post Office Box 6464, Rockville, MD 20849, (800) 638-6620.

FOR FURTHER INFORMATION CONTACT: Donna M. Dannels, Branch Chief, Policy, Assessment and Outreach Division, Mitigation Directorate, 500 C Street SW., room 411, Washington, DC 20472, (202) 646-3098.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase

flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Since the communities on the attached list have recently entered the NFIP, subsidized flood insurance is now available for property in the community.

In addition, the Associate Director of the Federal Emergency Management Agency has identified the special flood hazard areas in some of these communities by publishing a Flood Hazard Boundary Map (FHBM) or Flood Insurance Rate Map (FIRM). The date of the flood map, if one has been published, is indicated in the fourth column of the table. In the communities listed where a flood map has been published, Section 102 of the Flood Disaster Protection Act of 1973, as amended, 42 U.S.C. 4012(a), requires the purchase of flood insurance as a condition of Federal or federally related financial assistance for acquisition or construction of buildings in the special flood hazard areas shown on the map.

The Associate Director finds that the delayed effective dates would be contrary to the public interest. The Associate Director also finds that notice and public procedure under 5 U.S.C. 553(b) are impracticable and unnecessary.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Associate Director certifies that this rule will not have a significant economic impact on a substantial number of small entities in accordance with the

Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, because the rule creates no additional burden, but lists those communities eligible for the sale of flood insurance.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, October 26, 1987, 3 CFR, 1987 Comp., p. 252.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778, October 25, 1991, 56 FR 55195, 3 CFR, 1991 Comp., p. 309.

List of Subjects in 44 CFR Part 64.

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*, Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 64.6 [Amended]

2. The tables published under the authority of § 64.6 are amended as follows: