Inert ingredients	Limits	Uses
* * * * * * *		
Dimethyl silicone polymer with silica, Minimum number average molecular weight (in amu) 1,100,000 daltons, CAS Reg. No. 67762–90–7	.....	Moisture barrier, anti-caking agent, anti-settling agent, thickening agent
* * * * * * *		
Hexamethyldisilizane, reaction product with silica, Minimum number average molecular weight (in amu) 645,000 daltons, CAS Reg. No. 68909–20–6	.....	Moisture barrier, anti-caking agent, anti-settling agent, thickening agent
* * * * * * *		
Silane, dichloromethyl-, reaction product with silica, Minimum number average molecular weight (in amu) 3,340,000 daltons, CAS Reg. No. 68611–44–9	.....	Moisture barrier, anti-caking agent, anti-settling agent, thickening agent
* * * * * * *		

[FR Doc. 00–25050 Filed 9–28–00]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301069; FRL–6749–1]

RIN 2070–AB78

Azoxystrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for the combined residues of azoxystrobin (methyl (E)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and its Z isomer (methyl (Z)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) in or on barley, bran at 0.2 parts per million (ppm); barley, grain at 0.1 ppm; barley, hay at 15.0 ppm; barley, straw at 4.0 ppm; citrus, dried pulp at 2.0 ppm; citrus, oil at 4.0 ppm; coriander, leaves at 30.0 ppm; corn, field, forage at 12.0 ppm; corn, field, grain at 0.05 ppm; corn, field, refined oil at 0.3 ppm; corn, field, stover at 25.0 ppm; corn, pop, grain at 0.05 ppm; corn, pop, stover at 25.0 ppm; corn, sweet, forage at 12.0 ppm; corn, sweet (kernels plus cob with husks removed) at 0.05 ppm; corn, sweet, stover at 25.0 ppm; cotton, gin byproducts at 0.02 ppm; cotton, undelinted seed at 0.02 ppm; fruit, citrus, group at 1.0 ppm; grain, aspirated grain fractions at 30.0 ppm; onion, dry bulb at 1.0 ppm; onion, green at 7.5 ppm; peanut at 0.2 ppm; peanut, refined oil at 0.6 ppm; peanut, hay at 15.0 ppm; soybean, forage at 25.0 ppm; soybean, hay at 55.0 ppm; soybean, hulls at 1.0 ppm; soybean, seed at 0.5 ppm; vegetable, leafy, except Brassica, group at 30.0 ppm; vegetable, leaves of root and tuber, group at 50.0 ppm; vegetable, root, subgroup at 0.5 ppm; and vegetable, tuberous and corm, subgroup at 0.03 ppm; and increases the tolerance for azoxystrobin (only) in or on cattle, fat to 0.03 ppm; cattle, meat byproducts to 0.07 ppm; goat, fat to 0.03 ppm; goat, meat byproducts to 0.07 ppm; horse, fat to 0.03 ppm; horse, meat byproducts to 0.07 ppm; sheep, fat to 0.03 ppm; and sheep, meat byproducts to 0.07 ppm. Zeneca Ag Products requested these tolerances in pesticide petition number (PP#) 9F6058 under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 29, 2000. Objections and requests for hearings, identified by docket control number OPP–301069, must be received by EPA on or before November 28, 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 VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301069 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT By mail: Dan Kenny, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703)305–7546; and e-mail address: kenny.dan@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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	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/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly

to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301069. 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, Crystal 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

In the **Federal Register** of August 2, 2000 (65 FR 47498) (FRL–6592–1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP) for tolerance by Zeneca Ag Products, 1800 Concord Pike, P.O. Box 15458, Wilmington, DE 19850–-5458. This notice included a summary of the petition prepared by Zeneca Ag Products, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.507 be amended by establishing a tolerance for combined residues of the fungicide azoxystrobin (methyl (E)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and its Z isomer (methyl (Z)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate), in or on barley, bran at 0.2 ppm; barley, grain at 0.1 ppm; barley, hay at 15 ppm; barley, straw at 4 ppm; citrus, dried pulp at 2.0 ppm; citrus, oil at 4.0 ppm; coriander, leaves at 30 ppm; corn, field, forage at 12 ppm; corn, field, grain at 0.05 ppm; corn, field, refined oil at 0.3 ppm; corn, field, stover at 25 ppm; corn, pop, grain at 0.05 ppm; corn, pop, stover at 25 ppm; corn, sweet, forage at 12 ppm; corn, sweet, kernel plus cob with husks removed at 0.05 ppm; corn, sweet, stover at 25 ppm; cotton, gin byproducts at 0.02 ppm; cotton, undelinted seed at 0.02 ppm; fruit, citrus, group at 1.0 ppm; onion, dry bulb at 1.0 ppm; onion, green at 7.5 ppm; peanut at 0.2 ppm; peanut, hay at 15.0 ppm; peanut, refined oil at 0.6 ppm; soybean, forage at 25 ppm; soybean, hay at 55 ppm; soybean, hulls at 1.0 ppm; soybean, seed at 0.5 ppm; vegetable, leafy, except Brassica, group at 30 ppm; vegetable, leaves of root and tuber, group at 50 ppm; and vegetable, root, subgroup at 0.5 ppm; and vegetable, tuberous and corm, subgroup at 0.03 ppm; and increase the tolerances for residues of azoxystrobin (only) in or on cattle, fat to 0.03 ppm; cattle, meat byproducts to 0.07 ppm; goat, fat to 0.03 ppm; goat, meat byproducts to 0.07 ppm; horse, fat to 0.03 ppm; horse, meat byproducts to 0.07 ppm; sheep, fat to 0.03 ppm; and sheep, meat byproducts to 0.07 (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) 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....''

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).

III. Aggregate Risk Assessment and Determination of Safety

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 and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for the combined residues of azoxystrobin (methyl (E)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and its Z isomer (methyl (Z)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) on barley, bran at 0.2 ppm; barley, grain at 0.1 ppm; barley, hay at 15.0 ppm; barley, straw at 4.0 ppm; citrus, dried pulp at 2.0 ppm; citrus, oil at 4.0 ppm; coriander, leaves at 30.0 ppm; corn, field, forage at 12.0 ppm; corn, field, grain at 0.05 ppm; corn, field, refined oil at 0.3 ppm; corn, field, stover at 25.0 ppm; corn, pop, grain at 0.05 ppm; corn, pop, stover at 25.0 ppm; corn, sweet, forage at 12.0 ppm; corn, sweet (kernels plus cob with husks removed) at 0.05 ppm; corn, sweet, stover at 25.0 ppm; cotton, gin byproducts at 0.02 ppm; cotton, undelinted seed at 0.02 ppm; fruit, citrus, group at 1.0 ppm; grain, aspirated grain fractions at 30.0 ppm; onion, dry bulb at 1.0 ppm; onion, green at 7.5 ppm; peanut at 0.2 ppm; peanut, refined oil at 0.6 ppm; peanut, hay at 15.0 ppm; soybean, forage at 25.0 ppm; soybean, hay at 55.0 ppm; soybean, hulls at 1.0 ppm; soybean, seed at 0.5 ppm; vegetable, leafy, except Brassica, group at 30.0 ppm; vegetable, leaves of root and tuber, group at 50.0 ppm; vegetable, root, subgroup at 0.5 ppm; and vegetable, tuberous and corm, subgroup at 0.03 ppm; and to increase the tolerances for residues of azoxystrobin (only) in or on cattle, fat to 0.03 ppm; cattle, meat byproducts to 0.07 ppm; goat, fat to 0.03 ppm; goat, meat byproducts to 0.07 ppm; horse, fat to 0.03 ppm; horse, meat byproducts to 0.07 ppm; sheep, fat to 0.03 ppm; and sheep, meat byproducts to 0.07 ppm. EPA's assessment of exposures and risks associated with establishing or increasing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by azoxystrobin, as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed, are discussed in the following Table 1.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity in rodents	NOAEL = 20.4 mg/kg/day for both males and females LOAEL = 211.0 mg/kg/day based on decreased body weight gain in both sexes, clinical observations of distended abdomens, reduced body size, and clinical pathology findings atributable to reduced nutritional status.
870.3150	90-Day oral toxicity in nonrodents	NOAEL = 50 mg/kg/day LOAEL = 250 mg/kg/day based on treatment-related clinical observations and clinical chemistry alterations .
870.3250	21-Day dermal toxicity	NOAEL = greater than or equal to 1,000 mg/kg/day (the highest dosing regimen) LOAEL = was not determined.
870.3700a	Prenatal developmental in rodents	Maternal NOAEL = not established Maternal LOAEL = 25 mg/kg/day based on increased salivation. Developmental NOAEL = greater than or equal to 100 mg/kg/day Developmental LOAEL = greater than 100 mg/kg/day because no adverse effects were observed.
870.3700b	Prenatal developmental in non-rodents	Maternal NOAEL = 150 mg/kg/day Maternal LOAEL = 500 mg/kg/day based on decreased body weightgain. Developmental NOAEL = 500 mg/kg/day Developmental LOAEL = greater than 500 mg/kg/day because no treatment-related adverse effects on development were seen.
870.3800	Reproduction and fertility effects	Reproductive NOAEL = 32.2 mg/kg/day Reproductive LOAEL = 165.4 mg/kg/day based on treatment-related reductions in adjusted pup body weights that were observed in the F1a and F2a pups.
870.4100a	Chronic toxicity rodents	NOAEL = 18.2 mg/kg/day for males and 22.3 mg/kg/day for females LOAEL = 34 mg/kg/day for males based on reduced body weights, food consumption and food efficiency, and bile duct lesions and 117.1 mg/kg/day for females based on reduced body weights.
870.4100b	Chronic toxicity dogs	NOAEL = 25 mg/kg/day LOAEL = 200 mg/kg/day based on clinical observations, clinical chemistry changes, and liver weight increases in both sexes.
870.4200	Carcinogenicity in rats	Systemic toxicity NOAEL = 18.2 mg/kg/day for males and 22.3 mg/kg/day for females Systemic toxicity LOAEL = 34 mg/kg/day for males based on reduced body weights, food consumption and food efficiency, and bile duct lesions and 117.1 mg/kg/day for females based on reduced body weights. There was no evidence of carcinogenicity.
870.4300	Carcinogenicity in mice	Systemic toxicity NOAEL = 37.5 mg/kg/day Systemic toxicity LOAEL = 272.4 mg/kg/day based on reduced body weights in both males and females. There was no evidence of carcinogenicity.
870.5100	Gene Mutation	Azoxystrobin was positive for forward gene mutation in mouse lymphoma cells, but was not mutagenic in the salmonella/mammalian activation gene mutation assay, showed some evidence of concentration-related induction of chromosomal aberrations over background in the presence of moderate to severe toxicity in the *in vitro* mammalian cytogenetics assay in human lymphocytes, caused no increase in the induction of micronuclei in the mouse bone marrow micronucleus assay, and did not increase the incidence of unscheduled DNA synthesis in rat hepatocytes/mammalian cells.
870.6200a	Acute neurotoxicity screening battery	Systemic toxicity NOAEL = less than 200 mg/kg/day Systemic toxicity Systemic toxicity LOAEL = 200 mg/kg/day based on transient diarrhea in both sexes. There was no indication of neurotoxicity at the doses tested.
870.6200b	Subchronic neurotoxicity screening battery	Systemic toxicity NOAEL = 38.5 mg/kg/day Systemic toxicity LOAEL = 161 mg/kg/day based on decreased body weight and weight gain in both sexes. There were no consistent indications of treatment-related neurotoxicity.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.7485	Metabolism and pharma-cokinetics	Metabolism studies were conducted with azoxystrobin that was either unlabeled or was labeled on the pyrimidinyl, phenylacrylate, or cyanophenyl part of the molecule. Dosing was single or for a period of 14 days. Overall recovery of label was 92–104%. Absorption was widely distributed but less than 0.5% of the dose was detected in the tissues and carcass up to 7 days postdosing. Most absorbed azoxystrobin was in excretion-related organs, especially the liver and kidneys. There was no evidence of potential for bioaccumulation. Excretion via expired air was minimal. Most excretion, in both sexes, was via the feces (73–89%) and urine (9–18%). Absorbed azoxystrobin seemed to be metabolized. Except for metabolite V (a glucuronide conjugate), which represented 27.4–29.3% of the administered dose, individual biliary metabolites represented less than 10% of the administered dose. A metabolic pathway was proposed showing hydrolysis and subsequent glucuronide conjugation as the major biotransformation process. This study was considered supplementary but can be upgraded upon acceptable additional explanations of fecal excretion data and how they pertain to assessing absorption in the two low-dose studies.
870.7600	Dermal penetration	Doses of 0.01 to 13.3 mg/kg were used. No animals died as a result of the treatment. Percutaneous absorption was minimal and did not appear to exhibit a dose-response relationship. Limited absorption precluded accurate assessment of distribution and metabolite characterization. Both fecal and urinary excretion were quantified, the former representing ca. 6% or less of total absorption and the latter accounting for less than 0.1% of the absorbed dose over a 24-hour period.

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. No additional uncertainty factors were used in this 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 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). In certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment instead. 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_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for azoxystrobin used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR AZOXYSTROBIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary general population including infants and children	NOAEL = less than 200 mg/kg/day; UF = 300; Acute RfD = 0.67 mg/kg/day	FQPA SF = 1; aPAD = acute RfD FQPA SF = 0.67 mg/kg/day	Acute Neurotoxicity in the Rat LOAEL = 200 mg/kg/day based on transient diarrhea in both sexes

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR AZOXYSTROBIN FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Chronic Dietary all populations	NOAEL = 18.2 mg/kg/day; UF = 100; Chronic RfD = 0.18 mg/kg/day	FQPA SF = 1; cPAD = 0.18 mg/kg/day chronic RfD x FQPA SF = 0.18 mg/kg/day	Chronic/Carcinogenicity Feeding Study in Rats LOAEL = 34 mg/kg/day for males based on reduced body weights, reduced food consumption and food efficiency, and bile duct lesions and 117.1 mg/kg/day for females based on reduced body weights
Short-Term Incidental Oral	NOAEL = 25 mg/kg/day; UF = 100	FQPA SF = 1	Prenatal Developmental Oral Toxicity in the Rat LOAEL = 100 mg/kg/day based on increased maternal diarrhea, urinary incontinence, and salivation
Intermediate-Term Incidental Oral	NOAEL = 20 mg/kg/day; UF = 100	FQPA SF = 1	90-Day Feeding Study in the Rat LOAEL = 211 mg/kg/day based on decreased body weight gain and clinical signs indicative of malnutrition in both sexes
Short-Term Dermal	NOAEL= not applicable	.....	21-Day Repeated-Dose Dermal in the Rat LOAEL = not applicable based on no dermal or systemic effects seen at the limit dermal dose of 1000 mg/kg/day. This risk assessment is thus not required.
Intermediate-Term Dermal	NOAEL = not applicable	.....	21-Day Repeated Dose Dermal in the Rat LOAEL = not applicable based on no dermal or systemic effects seen at the limit dermal dose of 1000 mg/kg/day.This risk assessment is thus not required.
Long-Term Dermal	NOAEL = not applicable	.....	This risk assessment is not required, based on the use pattern.
Short-Term Inhalation	NOAEL = 25 mg/kg/day (route-to-route extrapolation and 100% absorption rate (default value) used)	LOC for MOE = 100	Prenatal Development Oral Toxicity in the Rat LOAEL = 100 mg/kg/day based on increased maternal diarrhea, urinary incontinence, and salivation
Intermediate-Term Inhalation	NOAEL = 20 mg/kg/day (route-to-route extrapolation and 100% absorption rate (default value) used)	LOC for MOE = 100	90-Day Feeding Study in the Rat LOAEL = 211 mg/kg/day based on decreased body weight gain and clinical signs indicative of reduced nutrition in both sexes
Long-Term Inhalation	NOAEL = not applicable	.....	This risk assessment is not applicable to the use scenario of azoxystrobin.
Cancer	....	....	Chronic/Carcinogenicity Feeding Study in Rats; Carcinogenicity Feeding Study in Mice. There was no evidence of carcinogenic activity in either study. This assessment is thus not applicable and azoxystrobin is considered not likely to be a human carcinogen.

* 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 combined residues of azoxystrobin (methyl (E)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and its Z isomer (methyl (Z)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate), in or on a variety of raw agricultural commodities. Tolerances for azoxystrobin (only) have also been established for the animal commodities fat (0.010 ppm), meat byproducts (0.010 ppm), and meat (0.01 ppm) of cattle, goats, hogs, horses, and sheep; and for milk (0.006 ppm). Time-limited, emergency exemption tolerances have been established for azoxystrobin in/on several raw agriculutural commodities and animal commodities. Additional time-limited, emergency exemption azoxystrobin tolerances have also recently been recommended for carrots, roots (0.50 ppm); fruit, citrus, group (3.0 ppm); cotton, seed (0.10 ppm); beets, garden, roots (0.50 ppm); beets, garden, tops (50 ppm); and ginseng (0.50 ppm). Several of the time-limited tolerances will be replaced with permanent tolerances by this rule. Where both a time-limited and a permanent tolerance are proposed or established and where the tolerance values are not the same, the higher of the values was used in the dietary risk analysis. For the animal commodities whose azoxystrobin tolerances are proposed to be increased in PP#9F6058, the increased tolerance value was used in the dietary risk analysis. 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. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 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: tolerance level residues were assumed and it was also assumed that 100% of the crops and other commodities with proposed or established azoxystrobin tolerances contained those residues. Anticipated residues, and percent crop treated (PCT) values of less than 100%, were not used.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 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: tolerance level residues were assumed and it was also assumed that 100% of the crops and other commodities with proposed or established azoxystrobin tolerances contained those residues. Anticipated residues, and percent crop treated (PCT) values of less than 100%, were not used.

iii. *Cancer.* Since carcinogenicity studies produced no evidence that azoxystrobin is a carcinogen, the Agency concluded that azoxystrobin is unlikely to be a human carcinogen. There is also, as a consequence, no carcinogenicity endpoint, and this analysis was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for azoxystrobin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of azoxystrobin.

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 Screening Concentration in Ground Water (SCI-GROW) to predict pesticide concentrations in ground water. 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 incorporates 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 of the processing (mixing, dilution, or treatment) of raw water for distribution that 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.

Based on the GENEEC and SCI-GROW models the estimated environmental concentrations (EECs) of azoxystrobin for acute exposures are estimated to be 141 parts per billion (ppb) for surface water and 0.064 ppb for ground water. The EECs for chronic exposures are estimated to be 0.064 ppb for surface water and 127 ppb for ground water. Agency policy allows the estimated chronic surface water concentrations to be divided by 3 to obtain the value that is used in chronic risk assessment calculations. Therefore, the value that will be used in this type of assessment for azoxystrobin is 42 ppb.

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: turf and ornamentals. The risk assessment was conducted using the following residential exposure assumptions:

Products containing azoxystrobin may be applied 1–5 times per year at rates up to 0.95 lb. of active ingredient per acre. The current registered labels permit homeowners to mix/load/apply both flowable (i.e., liquid) and water-dispersable granule formulations. Residential handlers may be exposed to azoxystrobin for both short-term and

intermediate-term durations. Toddlers may also receive short-term and intermediate-term oral exposure from hand-to-mouth ingestion during post-application activities. The Agency's Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments were used as the basis for all residential handler exposure calculations. The post-application risk assessment is based on generic assumptions as specified by the newly proposed Residential SOPs and recommended approaches by the Agency's Exposure Science Advisory Committee. Changes to the Residential SOPs have been proposed that alter the residential post-application scenario assumptions. The proposed assumptions are expected to better represent residential exposure and are still considered to be high-end, screening level assumptions. Agency management has authorized the use of the revised residential SOPs that were presented to the FIFRA Science Advisory Panel in September 1999. Therefore, the current Residential SOP assumptions have been deviated from and the proposed assumptions have been used to calculate exposure estimates.

The short-term and intermediate-term NOAELs of 25 mg/kg/day and 20 mg/kg/day, derived from the Short-Term Inhalation and Intermediate-Term Inhalation scenarios (see above), respectively, were used in the inhalation and hand-to-mouth risk assessment of residential exposure. As no dermal endpoint was selected, a dermal risk assessment was not required for residential exposure. For residential inhalation and oral risk assessments, the target margin of exposure (MOE) was 100, which incorporates the FQPA Safety Factor of 1x.

MOEs calculated for residential handlers' inhalation exposure and children's oral exposure were well above the target of 100.

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

1. *Safety factor for infants and children*—i. *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.

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

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

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 value, drinking water consumption, and body weights. The following default body weights and consumption values are used by the U.S. EPA Office of Water 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, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP 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 11% of the aPAD for the U.S. population, 12% of the aPAD for females 13 years old and older and 19%

of the aPAD for infants and children. 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 the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO AZOXYSTROBIN

Population Subgroup	a PAD (mg/kg)	% aPAD (Food)	Surface Water EEC (µg/L)	Ground Water EEC (µg/L)	Acute DWLOC (µg/L)
U.S. population (total)	0.67	11	141	0.064	21,000
Infants/children	0.67	19	141	0.064	5,400
Females 13+	0.67	12	141	0.064	18,000

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, 12% of the cPAD for females 13 years old and older, and 18% of the cPAD for children 1–6 years old. Based 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 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO AZOXYSTROBIN

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (µg/L)	Ground Water EEC (µg/L)	Chronic DWLOC (µg/L)
U.S. Population (total)	0.18	12	42	0.064	5,600
Infants/children	0.18	18	42	0.064	1,500
Females 13+	0.18	12	42	0.064	4,800

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 uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term 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 the U.S. population and 520 for the subgroup children 1–6 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 to 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 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO AZOXYSTROBIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (µg/L)	Ground Water EEC (µg/L)	Short-Term DWLOC (µg/L)
U.S. population	1,200	100	42	0.064	6,900
Children 1–6 years old	520	100	42	0.064	2,000

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 uses that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term 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 an aggregate MOE of 420 for the subgroup children 1–6 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 6:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO AZOXYSTROBIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (µg/L)	Ground Water EEC (µg/L)	Intermediate-Term DWLOC (µg/L)
Children 1–6 years old	420	100	42	0.064	1,500

5. *Aggregate cancer risk for U.S. population*. Because of the lack of evidence of any carcinogenic potential of azoxystrobin in long-term rat and mouse feeding studies, the Agency has classified it as not likely to be a human carcinogen and there are no endpoints or other values against which to assess carcinogenic risk. Therefore, this risk analysis is not applicable.

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 the proposed tolerances. The registrant has previously submitted three analytical methods for the analysis of commodities for which azoxystrobin tolerances exist.

1. The first method, RAM 243, is a gas chromatography with nitrogen-phosphorus detection (GC/NDP) method previously submitted by the registrant which can be used for the analysis of the tolerances in or on non-oily commodities such as barley, bran; barley, grain; barley, hay; barley, straw; citrus, dried pulp; coriander, leaves; corn, field, forage; corn, field, grain; corn, field, refined oil; corn, field, stover; corn, pop, grain; corn, pop, stover; corn, sweet, forage; corn, sweet (kernels plus cob with husks removed); corn, sweet, stover; fruit, citrus, group; onion, dry bulb; onion, green; peanut, hay; vegetable, leafy, except Brassica, group; vegetable, leaves of root and tuber, group; vegetable, root, subgroup; vegetable, tuberous and corm, subgroup; and non-oily processed commodities. This method has been reviewed and validated by the Agency, and will be submitted to the Food and Drug Administration (FDA) for inclusion in Pesticide Analytical Manual (PAM) II.

2. The second method, RAM 260, is a GC/NPD method previously submitted by the registrant for the analysis of azoxystrobin and its Z isomer in or on crops of high lipid content. It is adequate for the enforcement of tolerances such as cotton, undelinted seed; peanut; soybean, seed; and oily processed commodities. This method has also been validated by the Agency and will be submitted to FDA for inclusion in PAM II.

3. The third method, RAM 255/01, also previously submitted by the registrant, uses gas chromatography with thermionic protection, nitrogen mode, for analysis of animal commodities, including the fat and meat byproducts of cattle, goat, horse, and sheep. This method, as well, has been validated by the Agency for analysis of milk and animal tissues. This method, which will be accompanied by a written laboratory report and an Agency addendum, are to be submitted to FDA for inclusion in PAM II.

The above methods 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

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

C. Conditions

As conditions of registration of the use of azoxystrobin on the sites for which tolerances are being established in this rule, the registrant must submit the following:

(1) In order to retain the use of the flowable concentrate formulation for late season uses the registrant must either submit separate crop field trials for the flowable concentrate or bridging data (side-by-side field trials) on representative crops for both the flowable concentrate and the water dispersible granule formulations of azoxystrobin.

(2) The registrant must submit additional data on the frozen storage stability of azoxystrobin and its Z isomer in or on one representative crop each in the leafy vegetable group, the root and tuber vegetable group, and the processed commodities of a root and tuber vegetable group member.

(3) Two additional spinach field trial studies that reflect the maximum proposed seasonal use pattern in each of two Regions must be submitted.

(4) Additional rotational field crop studies using a higher application rate must also be submitted.

V. Conclusion

Therefore, tolerances are established for the combined residues of azoxystrobin (methyl (E)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and its Z isomer (methyl (Z)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate), , in or on barley, bran at 0.2 ppm; barley, grain at 0.1 ppm; barley, hay at 15.0 ppm; barley, straw at 4.0 ppm; citrus, dried pulp at 2.0 ppm; citrus, oil at 4.0 ppm; coriander, leaves at 30.0 ppm; corn, field, forage at 12.0 ppm; corn, field, grain at 0.05 ppm; corn, field, refined oil at 0.3 ppm; corn, field, stover at 25.0 ppm; corn, pop, grain at 0.05 ppm; corn, pop, stover at 25.0 ppm; corn, sweet, forage at 12.0 ppm; corn, sweet (kernels plus cob with husks removed) at 0.05 ppm; corn, sweet, stover at 25.0 ppm; cotton, gin byproducts at 0.02 ppm; cotton, undelinted seed at 0.02 ppm; fruit, citrus, group at 1.0 ppm; grain, aspirated grain fractions at 30.0 ppm; onion, dry bulb at 1.0 ppm; onion, green at 7.5 ppm; peanut at 0.2 ppm; peanut, refined oil at 0.6 ppm; peanut, hay at 15.0 ppm; soybean, forage at 25.0 ppm; soybean, hay at 55.0 ppm; soybean, hulls at 1.0 ppm; soybean, seed at 0.5 ppm; vegetable, leafy, except Brassica, group at 30.0 ppm; vegetable; leaves of root and tuber, group at 50.0 ppm; vegetable, root, subgroup at 0.5 ppm; and vegetable, tuberous and corm, subgroup at 0.03 ppm; and tolerances are increased for residues of azoxystrobin

(only) in or on cattle, fat to 0.03 ppm; cattle, meat byproducts to 0.07 ppm; goat, fat to 0.03 ppm; goat, meat byproducts to 0.07 ppm; horse, fat to 0.03 ppm; horse, meat byproducts to 0.07 ppm; sheep, fat to 0.03 ppm; and sheep, meat byproducts to 0.07 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 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–301069 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 November 28, 2000.

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 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.2. Mail your copies, identified by docket control number OPP–301069, 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).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) 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). 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 petition under FFDCA section 408(d), 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 FFDCA section 408(n)(4).

VIII. 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 21, 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. In Section 180.507, the table to paragraph (a)(1) is amended by revising the entries for ''peanut, hay'', and ''peanuts'', by adding new entries to read as set forth below, and by removing the entry for ''peanut oil''; the table in paragraph (a)(2) is amended by revising the entries for ''cattle, fat''; ''cattle, meat byproducts''; ''goat, fat''; ''goat, meat byproducts''; ''horse, fat''; ''horse, meat byproducts''; ''sheep, fat''; and ''sheep, meat byproducts'', and in the table to paragraph (b) the entries for ''soybean hay''; ''soybean forage''; ''soybean hulls''; and ''soybean seed'' are removed.

§ 180.507 Azoxystrobin; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Barley, bran	0.2
Barley, grain	0.1
Barley, hay	15.0
Barley, straw	4.0
* * * * *	
Citrus, dried pulp	2.0
Citrus, oil	4.0
Coriander, leaves	30.0
Corn, field, forage	12.0
Corn, field, grain	0.05
Corn, field, refined oil	0.3
Corn, field, stover	25.0
Corn, pop, grain	0.05
Corn, pop, stover	25.0
Corn, sweet, forage	12.0
Corn, sweet (K+CWHR)	0.05
Corn, sweet, stover	25.0
Cotton, gin byproducts	0.02
Cotton, undelinted seed	0.02
* * * * *	
Fruit, citrus, group	1.0
Grain, aspirated grain fractions	30.0
* * * * *	
Onion, dry bulb	1.0
Onion, green	7.5
Peanut	0.2
Peanut, refined oil	0.6
Peanut, hay	15.0
* * * * *	
Soybean, forage	25.0
Soybean, hay	55.0
Soybean, hulls	1.0
Soybean, seed	0.5
* * * * *	
Vegetable, leafy, except Brassica, group	30.0
Vegetable, leaves of root and tuber, group	50.0
Vegetable, root, subgroup	0.5
Vegetable, tuberous and corm, subgroup	0.03
* * * * *	

(2) * * *

Commodity	Parts per million
Cattle, fat	0.03
* * * *	
Cattle, meat byproducts	0.07
Goat, fat	0.03
* * * * *	
Goat, meat byproducts	0.07
Horse, fat	0.03
* * * * *	
Horse, meat byproducts	0.07
* * * * *	
Sheep, fat	0.03
* * * * *	
Sheep, meat byproducts	0.07

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[FR Doc. 00–25051 Filed 9–28–00; 8:45 am]

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