the carbon monoxide national ambient air quality standard by December 31, 1995. This determination is based on air quality monitoring data from 1994 and 1995.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0238; FRL–7198–9]

Azoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of azoxystrobin and its z-isomer in or on caneberry subgroup at 5.0 part per million (ppm); cranberry at 0.50 ppm; hop, dried cones at 20.0 ppm; pistachio at 0.50 ppm; vegetable, legume, edible podded, subgroup, except soybean at 3.0 ppm; pea and bean, succulent shelled, subgroup, except cowpea at 0.50 ppm; and pea and bean, dried shelled, except soybean subgroup, except cowpea and field pea at 0.50. The Interregional Research Project #4 (IR-4) and Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective September 20, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0238, must be received on or before November 19, 2002.

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 ID number OPP–2002–0238 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–9368; e-mail address: jamerson.hoyt@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 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/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket ID number OPP–2002–0238. 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 May 1, 2002 (67 FR 21676) (FRL–6834–7) and August 22, 2001 (66 FR 44136) (FRL– 6794–6) , EPA issued notices pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170), announcing the filing of pesticide petitions (PP 2E6356, 2E6372, 2E6375, and 2E6376) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390 and 0F6218 by Syngenta Crop Protection, Inc., 410 Swing Road, P.O. Box 18300, Greensboro, NC 27409–8300. These notices included summaries of the petitions prepared by Syngenta Crop Protection, the registrant. There were no comments received in response to the notices of filing.

The petitions requested that 40 CFR 180.507 be amended by establishing tolerances for combined residues of the fungicide azoxystrobin, methyl(E)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate and the Z-isomer of azoxystrobin, methyl(Z)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxyphenyl)-3- methoxyacrylate, in or on food commodities as follows:

1. PP 2E6356 proposed a tolerance for the caneberry subgroup at 5.0 ppm.

2. PP 2E6372 proposed to increase the established tolerance for pistachio from 0.02 ppm to 1.0 ppm. The petition was subsequently revised to propose a tolerance for pistachio at 0.50 ppm.

3. PP 2E6376 proposed a tolerance for cranberry at 0.50 ppm.

4. PP 0F6218 proposed tolerances for the vegetable, legume, group at 3.0 ppm; hop, dried cones at 50 ppm. The petition was subsequently revised to propose tolerances for the vegetable, legume, edible podded subgroup, except soybean at 3.0 ppm; pea and bean, succulent shelled, subgroup, except cowpea at 0.50 ppm; pea and bean, dried shelled, except soybean subgroup, except cowpea and field pea at 0.50; and hop, dried cones at 20.0 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 combined residues of azoxystrobin and its Zisomer on caneberry subgroup at 5.0 ppm; cranberry at 0.50 ppm; hop, dried cones, at 20.0 ppm; pistachio at 0.50 ppm; vegetable, legume, edible podded, subgroup, except soybean at 3.0 ppm; pea and bean, succulent shelled, subgroup, except cowpea at 0.50 ppm; pea and bean, dried shelled, except soybean subgroup, except cowpea and field pea at 0.50. EPA's assessment of exposures and risks associated with establishing 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 is discussed in Unit III.A. of the **Federal Register** of September 29, 2000 (65 FR 58404) (FRL–6749–1).

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor 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). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{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 1:

TABLE 1.—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 = <200 mg/kg/day UF = 300 Acute RfD = 0.7 mg/kg/day	FQPA SF = 1X aPAD = acute RfD/FQPA SF = 0.67 mg/kg/day	Acute Neurotoxicity - Rat LOAEL = 200 mg/kg based on diarrhea at 2 hours post dose at all dose levels up to and including the LOAEL

TABLE 1.—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 mg//kg/day UF = 100 Chronic RfD = 0.18 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD/FQPA SF = 0.18 mg/kg/day	Combined Chronic Toxicity/Carcinogenicity Feeding study - Rat LOAEL in males/females = 34/117 mg/kg/day based on reduced body weights in both sexes and bile duct lesions in males
Short-term (1-7 days) Incidental Oral (Residential)	NOAEL= 25 mg//kg/day UF = 100	FQPA SF = 1X	Prenatal Developmental Oral Toxicity - Rat LOAEL = 100 mg/kg/day based on increased maternal diarrhea, urinary incontinence, and salivation
Intermediate-term (1 week to several months) incidental oral (Residential)	NOAEL= 21 mg//kg/day UF = 100	FQPA SF = 1X	90-Day Feeding - Rat LOAEL = 211/223 mg/kg/day in males/females based on decreased body weight gain in both sexes and clinical signs indicative of reduced nutrition
Short-term, intermediate-term, and long-term dermal (Residential)	None	No dermal or systemic toxicity was seen at the limit dose (1,000 mg/kg/day). This risk assessment was not performed.	21–Day Repeated Dose Dermal - Rat
Short-term (1-7 days) inhalation (Residential)	Oral NOAEL= 25 mg/kg/day Use route-to-route extrapolation (inhalation absorption rate = 100%).	LOC for MOE = 100 (Residential)	Prenatal Developmental Oral Toxicity - Rat LOAEL = 100 mg/kg/day based on increased maternal diarrhea, urinary incontinence, and salivation
Intermediate-term (1 week to several months) inhalation (Residential)	Oral NOAEL= 21 mg/kg/day Use route-to-route extrapolation (inhalation absorption rate = 100%).	LOC for MOE = 100 (Residential)	90–Day Feeding - Rat LOAEL = 211/223 mg/kg/day in males/females based on decreased body weight gain in both sexes and clinical signs indicative of reduced nutrition
Long-term (greater than 180 days) inhalation	NOAEL = N/A	This risk assessment is not applicable to the use scenario for azoxystrobin	

*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 and its Zisomer, in or on a variety of raw agricultural commodities at levels ranging from 0.01 ppm (pecans) to 55 ppm (soybean hay), and on meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep at levels ranging from 0.01 to 0.07 ppm, and on milk at 0.006 ppm. Time-limited tolerances (set to expire on December 31, 2003) are established at 30 ppm for the Brassica, head and stem subgroup; at 0.5 ppm for chick pea, seed; at 3.0 ppm for lychee; and at 2.0 ppm for pepper. 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 1 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: 100% of the crops with azoxystrobin tolerances (established and recommended) are treated and that all commodities contain tolerance level residues when consumed (with the exception of those with processing factors). DEEM™ default processing/concentration factors were used for all processed commodities.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment, the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: 100% of the crops with azoxystrobin tolerances (established and recommended) are treated and that all commodities contain

tolerance level residues when consumed (with the exception of those with processing factors). DEEM™ default processing/concentration factors were used for all processed commodities.

iii. *Cancer*. Azoxystrobin was classified by the Agency as not likely to be a human carcinogen. Therefore, a cancer dietary exposure 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 FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water, EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, 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 screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would 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.

Although moderately persistent in soils and stable to hydrolysis, the likelihood of azoxystrobin moving into ground water and surface water is low due to high soil/water partitioning coefficients and low single application rates. Three major degradates were detected and found to have greater potential to move through soil than the parent compound.

Based on the FIRST model, the estimated environmental concentrations (EECs) of azoxystrobin for acute and chronic exposures are estimated to be 170 parts per billion (ppb), and 33 ppb for surface water, respectively. Based on the SCI-GROW model the EECs of azoxystrobin for both acute and chronic exposures are estimated to be 3.1 ppb for ground water. These values were based on the highest use rate (turf use). These values represent upper-bound estimates of the concentrations that might be found in surface water and ground water which result from the use of azoxystrobin on turf.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Azoxystrobin is currently registered for use on the following residential non-dietary sites: turf and ornamentals. The risk assessment was conducted using the following residential exposure assumptions: Products containing azoxystrobin are registered for application to turf and ornamentals. They may be applied to turf at rates up to 0.95 lb active ingredient (ai) per acre (not to exceed 5 lb ai/acre/yr) and to ornamentals at rates up to 0.75 lb/ai/per acre every 7 to 14 days, but not to exceed 5 lb ai/acre/yr. The currently registered labels do not prohibit homeowners from mixing/loading/applying either the flowable concentrate or the water-dispersible granule formulations. This residential exposure and risk assessment was conducted using the application rate for turf because it is the highest single use rate.

Residential handlers may receive short-term dermal and inhalation exposure to azoxystrobin when mixing, loading, and applying the formulations. Adults and children may be exposed to azoxystrobin residues from dermal contact with foliage during post-application activities. Toddlers may receive short- and intermediate-term oral exposure from incidental ingestion during post-application activities.

As no dermal endpoint was selected by the Agency, a dermal exposure and risk assessment was not conducted for residential handlers or post-application activities.

Therefore, only the following exposure scenarios resulting from lawn treatment were assessed: (1) Toddlers' incidental ingestion of pesticide residues on lawns from hand-to-mouth transfer, (2) object-to-mouth transfer from mouthing of pesticide-treated turfgrass, and (3) incidental ingestion of soil from pesticide-treated residential areas, (4) short-term inhalation for residential handlers. Post-application exposures from various activities following lawn treatment are considered to be the most common and significant in residential settings. The exposure via incidental ingestion of other plant material may occur but is considered negligible.

The exposure and risk estimates for the post-application residential exposure scenarios are assessed for the day of application (day 0) because it is assumed that toddlers could contact the lawn immediately after application. Both short-term and intermediate-term exposure are expected. Risk from short-term and intermediate-term incidental ingestion by toddlers is assessed by comparing these exposures to the NOAELs of 25 milligrams/kilogram/day (mg/kg/day) and 21 mg/kg/day, respectively. Short-term adult handler risk is assessed by comparing exposure to the short-term inhalation NOAEL of 25 mg/kg/day.

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. *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.

2. *Prenatal and postnatal sensitivity*. The developmental and reproductive toxicity data, from a prenatal development study in rats, a prenatal development study in rabbits, and a two-generation reproductive toxicity study in rats, did not indicate increased susceptibility of young rats or rabbits to *in utero* and/or postnatal exposure.

3. *Conclusion*. There is a complete toxicity data base for azoxystrobin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because: (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.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 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 ground water 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 12% of the aPAD for the U.S. population, 12% of the aPAD for females (13-50 years old), 21% of the aPAD for children (1-6 years old), and 12% of the aPAD for seniors (55+ years). 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 water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO AZOXYSTROBIN

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.7	12	170	3.1	21,000
Children (1-6 years old)	0.7	21	170	3.1	5,300
Females (13-50 years old)	0.7	12	170	3.1	18,000
Seniors (55+ years)	0.7	12	170	3.1	21,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to azoxystrobin from food will utilize 13% of the cPAD for the U.S. population, 21% of the cPAD for children (1-6 years old), 12% of the cPAD for females (13-50 years old), and 14% of the cPAD for seniors (55+ years old). Based on the use pattern, chronic residential exposure to residues of azoxystrobin is not expected. In addition, there is potential for chronic dietary exposure to azoxystrobin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.— AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO AZOXYSTROBIN

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.18	13	33	3.1	5,500
Children (1-6 years old)	0.18	21	33	3.1	1,400
Females (13-50 years old)	0.18	12	33	3.1	4,800
Seniors (55+ years)	0.18	14	33	3.1	5,400

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). The short-term aggregate risk assessment estimates risks likely to result from 1- to 30-day exposure to azoxystrobin residues from food, drinking water, and residential pesticide uses. High-end estimates of residential exposure are used in the short-term assessment, while average values are used for food and drinking water exposure.

A short-term risk assessment is required for adults because there is a residential handler inhalation exposure scenario. In addition, a short-term risk assessment is required for infants and children because there is a residential post-application oral exposure scenario. As no short-term dermal endpoint was established, there is no dermal component to this aggregate risk assessment.

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

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,100 for adults and 450 for 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 of azoxystrobin in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water 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 4:

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

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. population	1,100	100	33	3.1	6,800
Children (1-6 years old)	450	100	33	3.1	1,900

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). The intermediate-term aggregate risk assessment estimates risks likely to result from 1-6 months of exposure to azoxystrobin residues from food, drinking water, and residential pesticide uses. High-end estimates of residential exposure are used in the intermediate-term assessment, while average values are used for food and drinking water exposure.

An intermediate-term risk assessment is not required for adults because residential handler scenarios are not expected to occur for longer than a short-term timeframe. However, an intermediate-term risk assessment is required for infants and children because there is a residential post-application oral exposure scenario. As no dermal endpoint was established, there is no dermal component to this aggregate risk assessment.

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

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 440 for 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 water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water 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 5:

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

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
Children (1-6 years old)	440	100	33	3.1	1,600

5. *Aggregate cancer risk for U.S. population*. Azoxystrobin was classified by EPA as not likely to be a human carcinogen. The Agency concludes that pesticides uses of azoxystrobin are not likely to pose a carcinogenic hazard to humans.

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 for azoxystrobin and its z-isomer on plants. An enforcement method for azoxystrobin in livestock commodities has been validated by the EPA analytical laboratory for the analysis of milk and livestock tissues.

The method may be requested from: Paul Golden, US EPA/OPP/BEAD/ACB, Environmental Science Center, 701 Mapes Road, Fort Meade, MD 20755–5350; telephone number: (410) 305–2960; Fax: (410) 305–3091; e-mail address: RAM Mailbox.

B. International Residue Limits

No Codex, Canadian, or Mexican maximum residue limits (MRLs) have been established for residues of azoxystrobin on caneberries, cranberries, pistachios, hops, or legumes.

V. Conclusion

Therefore, the tolerances are established for combined residues of azoxystrobin, methyl(E)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate and the z-isomer of azoxystrobin, methyl(Z)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxyphenyl)-3- methoxyacrylate, in or on caneberry subgroup at 5.0 ppm; cranberry at 0.50 ppm; hop, dried cones at 20.0 ppm; pistachio at 0.5 ppm; vegetable, legume, edible podded, subgroup, except soybean at 3.0 ppm; pea and bean, succulent shelled, subgroup, except cowpea at 0.50 ppm; and pea and bean, dried shelled, except soybean subgroup, except cowpea and field pea at 0.50.

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 ID number OPP–2002–0238 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 19, 2002.

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 ID number OPP–2002–0238, 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 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under 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). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. 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 13, 2002.

Richard P. Keigwin, Jr.,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

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

Authority: 21 U.S.C. 321(q), 346(a) and 374.

2. Section 180.507 is amended by revising the entry for pistachio and alphabetically adding the following

commodities to the table in paragraph (a) to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* *	* * *
Caneberry subgroup	5.0
Cranberry	0.50
* *	* * *
Hops, dried cones	20.0
* *	* * *
Pea and bean, dried shelled, except soybean, subgroup, except cowpea, and field pea	0.50
Pea and bean, succulent shelled, subgroup, except cowpea	0.50
Pistachio	0.50
* *	* * *
Vegetable, legume, edible podded, subgroup, except soybean	3.0
* *	* * *

* * * * *

[FR Doc. 02–23808 Filed 9–19–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0253; FRL–7273–7]

Diflubenzuron; Pesticide Tolerances for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of diflubenzuron in or on forage and hay of alfalfa. 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 alfalfa. This regulation establishes a maximum permissible level for residues of diflubenzuron in these feed commodities. The tolerances will expire and are revoked on June 30, 2004.

DATES: This regulation is effective September 20, 2002. Objections and requests for hearings, identified by docket control number OPP–2002–0253, must be received on or before November 19, 2002.

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–2002–0253 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Conrath, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9356; e-mail address: conrath.andrea@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/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–2002–0253. 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(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for residues of the insecticide diflubenzuron, [N-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide], in or on alfalfa, forage and alfalfa, hay at 6.0 parts per million (ppm). These tolerances will expire and are revoked on June 30, 2004. 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