process tanks, unit operations such as reactions and blending are conducted. Other process tanks, such as surge control vessels and bottom receivers, however, may not involve unit operations.

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[FR Doc. 01–29098 Filed 11–20–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[VA–T5–2001–01a; FRL–7106–3]

Clean Air Act Full Approval of Operating Permit Program; Virginia; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to an adverse comment, EPA is withdrawing the direct final rule fully approving the operating permit program of the Commonwealth of Virginia. In the direct final rule published on October 10, 2001 (66 FR 51581), we stated that if we received adverse comment by November 9, 2001, the rule would be withdrawn and not take effect. EPA subsequently received adverse comment. EPA will address the comments received in a subsequent final action based upon the proposed action also published on October 10, 2001 (66 FR 51620). EPA will not institute a second comment period on this action.

EFFECTIVE DATE: The Direct final rule is withdrawn as of November 21, 2001.

FOR FURTHER INFORMATION CONTACT: David Campbell, Permits and Technical Assessment Branch at (215) 814–2196 or by e-mail at campbell.dave@.epa.gov.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Environmental protection, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Dated: November 13, 2001.

James W. Newsom,

Regional Administrator, Region III.

Accordingly, the addition of 40 CFR part 70, Appendix A, ''Virginia'', paragraph (b) is withdrawn as of November 21, 2001.

[FR Doc. 01–29102 Filed 11–20–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301190; FRL–6809–3]

RIN 2070–AB78

Azoxystrobin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation revises a time-limited tolerance for combined residues of azoxystrobin in or on the crop group Brassica leafy vegetables by limiting the listing to Head and Stem (Brassica) subgroup (subgroup 5A) and raising the residue level from 25 parts per million (ppm) to 30 ppm. 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 cabbage. This regulation establishes a maximum permissible level for residues of azoxystrobin in this food commodity. The tolerance will expire and is revoked on December 31, 2003.

DATES: This regulation is effective November 21, 2001. Objections and requests for hearings, identified by docket control number OPP–301190, must be received by EPA on or before January 22, 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–301190 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9364; and e-mail address: pemberton.libby@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_180/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 control number OPP–301190. 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 a tolerance for combined residues of the fungicide azoxystrobin, [methyl(E)-2-(2-(6-(2-cyanophenoxt)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] and the Z-isomer of azoxystrobin, [methyl(Z)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3 methoxyacrylate], in or on Head and Stem (Brassica) subgroup at 30 ppm and removing the listing for Brassica vegetables at 25 ppm. This tolerance will expire and is revoked on December 31, 2003. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

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

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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

III. Emergency Exemption for Azoxystrobin on Cabbage and FFDCA Tolerances

Alternaria Leafspot and Cercospora Leafspot are highly destructive fungi that can ruin fields of cabbage. Several rainstorms occurred in the affected area during the month of August with total rainfall exceeding 10 inches. It was feared that more warm wet weather could allow bacterial soft rot to invade damaged tissue and reduce both yields and quality during shipment. Texas issued a crisis exemption for the use of azoxystrobin to control Alternaria Leafspot (*Alternaria brassicae*) and Cercospora Leafspot (*Cercospora Carotae*) on cabbage.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of azoxystrobin in or on Head and Stem (Brassica) subgroup (subgroup 5A). In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 2003, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on cabbage after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

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

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of azoxystrobin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of azoxystrobin and its Z-isomer in or on Head and Stem (Brassica) subgroup at 30 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent

in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for 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 level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 X 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 AZOXYSTOBIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary general population including infants and children	NOAEL < 200 mg/kg/day UF = 300 Acute RfD = 0.67 mg/kg/day	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 0.67 mg/kg/day	Acute Neurotoxicity - Rat (MRID 43678134, 44182013, 44182015) LOAEL = 200 mg/kg based on diarrhea at two-hours post dose at all dose levels up to and including the LOAEL.
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 (MRID 43678139) 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 (MRID 43678142) 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= 20 mg/kg/day UF = 100	FQPA SF = 1X	90–Day Feeding - Rat (MRID 43678135) 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-, Intermediate-, and Long-Term Dermal (Occupational/Residential)	none	No dermal or systemic toxicity was seen at the limit dose (1,000 mg/kg/day). This risk assessment is not required.	21–Day Repeated Dose Dermal - Rat (MRID 43678137)
Short-Term (1–7 days) Inhalation (Occupational/Residential)	Oral NOAEL= 25 mg/kg/day Use route-to-route extrapolation (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational/Residential)	Prenatal Developmental Oral Toxicity - Rat (MRID 43678142) LOAEL = 100 mg/kg/day based on increased maternal diarrhea, urinary incontinence, and salivation.
Intermediate-Term (1 week to several months) Inhalation (Occupational/Residential)	Oral NOAEL= 20 mg/kg/day Use route-to-route extrapolation (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational/Residential)	90–Day Feeding - Rat (MRID 43678135) 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.

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and LOC for Risk Assessment	Study and Toxicological Effects
Long-Term (> 180 days) Inhalation	NOAEL = N/A	This risk assessment is not applicable to the use scenario of azoxystrobin.	
Cancer (oral, dermal, inhalation)	None	None	Azoxystrobin is classified as ''not likely to be carcinogenic in humans''

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

B. 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 Z-isomer, in or on a variety of raw agricultural commodities. Tolerances are established on agricultural commodities at levels ranging from 0.01 ppm to 55.0 ppm; on meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep at levels ranging from 0.01 ppm to 0.07 ppm; and on milk at 0.006 ppm. Tolerances were recently established on Brassica, leafy greens, subgroup. Time limited tolerances in connection with use under section 18 emergency exemptions on Brassica leafy vegetables are currently in effect at 25 ppm. 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: In conducting this acute dietary exposure analysis, EPA has made very conservative assumptions: all commodities having established or proposed azoxystrobin tolerances will contain azoxystrobin residues (i.e., 100% crop treated), and those residues will be at the level of the tolerance.

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 CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: In conducting this chronic dietary exposure analysis, EPA has made very conservative assumptions: all commodities having established or proposed azoxystrobin tolerances will contain azoxystrobin residues (i.e., 100% crop treated), and those residues will be at the level of the tolerance.

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 First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentration in Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will generally 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 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 FIRST and SCI-GROW models the EECs of azoxystrobin for acute exposures are estimated to be 170 parts per billion (ppb) for surface water and 0.06 ppb for ground water. The EECs for chronic exposures are estimated to be 33 ppb for surface water and 0.06 ppb for ground water.

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

Azoxystrobin is currently registered for use on the following residential non-dietary sites: turf and ornamentals. The risk assessment was conducted using the following exposure assumptions: Products containing azoxystrobin may

be applied to turf 1 to 5 times per year at rates up to 0.95 lb active ingredient (ai) per acre (i.e., not to exceed 5 lb ai per acre per year) 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 per acre per year. 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 use rate.

Residential handlers may be exposed to azoxystrobin for both 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, a dermal exposure and risk assessment was not conducted for residential handlers or post-application activities. NOAELs of 25 mg/kg/day and 20 mg/kg/day were selected for assessing the risk from short- and intermediate-term incidental oral exposures, respectively. These same NOAELs were selected for assessing the risks from short- and intermediate-term inhalation exposures. The LOC for risk assessment purposes is 100.

No chemical-specific exposure or residue dissipation data for handler or post-application activities were submitted in support of the registered lawn uses. EPA's Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments, and Recommended Revisions, were used as the basis for all residential handler exposure calculations. Some of the handler exposure data used in this assessment are from the Outdoor Residential Exposure Task Force (ORETF). The task force recently submitted proprietary data to the Agency on hose-end sprayers, push-type granular spreaders, and handgun sprayers. The ORETF data were used in this assessment in place of PHED data for the garden hose-end sprayer scenario. The ORETF data were designed to replace the present Pesticide Handler Exposure Database (PHED) data with higher-confidence, higher quality data that contains more replicates than the PHED data for those scenarios.

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).

C. 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 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.* Prenatal development studies in rats and rabbits, and a 2–generation reproductive toxicity study in rats did not indicate increased susceptibility of young rats or rabbits to *in utero* and/or postnatal exposure.

3. *Conclusion.* There is a complete toxicity data base for azoxystrobin and exposure data are complete or are estimated based on data that reasonably accounts 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 data base and the lack of increased susceptibility of young rats and rabbits to prenatal 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.

D. Aggregate Risks and Determination of Safety

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

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to azoxystrobin in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of azoxystrobin on drinking

water as a part of the aggregate risk assessment process.

1. *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, 11% of the aPAD for females 13 years and older, 20% of the aPAD for children 1 to 6 years, the subpopulation at greatest exposure. In addition, despite the potential for acute dietary exposure to azoxystrobin in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of azoxystrobin in surface 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	0.67	11	170	0.06	21,000
Females 13 to 50 years	0.67	11	170	0.06	18,000
Children 1 to 6 years	0.67	20	170	0.06	5,400

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, 11% of the cPAD for females 13 to 50 years and 18% of the cPAD for children 1 to 6, the subpopulation at greatest exposure. Based on the use pattern, chronic residential exposure to residues of azoxystrobin is not expected. In addition, despite the potential for chronic dietary exposure to azoxystrobin in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of azoxystrobin in 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	12	33	0.06	5,600
Females 13 to 50 years	0.18	11	33	0.06	4,800
Children 1 to 6 years	0.18	18	33	0.06	1,500
Seniors 55+ years	0.18	12	33	0.06	5,600

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Azoxystrobin is currently registered for use(s) 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 1,183 for adults and 490 for children 1 to 6 years. These aggregate MOEs do not exceed the Agency's LOC 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 and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's LOC, 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 LOC	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. population	1,183	100	33	0.06	8,050
Children 1 to 6 years	490	100	33	0.06	2,000

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level).

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

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 580 for children 1 to 6 years. These aggregate MOEs do not exceed the Agency's LOC 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 and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's LOC, as shown in the following Table 5:

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

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate LOC	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
Children 1 to 6 years old	580	100	33	0.06	2,100

5. *Aggregate cancer risk for U.S. population.* Azoxystrobin is classified as ''not likely to be carcinogenic in humans'' based on the results of carcinogenicity studies in mice and rats. Therefore, azoxystrobin is not expected to pose a cancer risk 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.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate methodology is available for enforcement of the proposed tolerances. 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. 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. The method may be requested from: Calvin Furlow, PRRIB, 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 in or on the these commodities. Therefore, no tolerance discrepancies exist between countries for this chemical.

VI. Conclusion

Therefore, the tolerance is revised for 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 Head and Stem (Brassica) subgroup at 30 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301190 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 January 22, 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 VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP–301190, 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).

VIII. Regulatory Assessment Requirements

This final rule establishes a time limited tolerance under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 FIFRA section 18 exemption under FFDCA section 408, 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.

IX. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: November 8, 2001.

Peter Caulkins,

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 371.

2. In § 180.507, paragraph (b) is amended by revising the introductory text, and the entry for ''Brassica leafy vegetable'' in the table to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of the fungicide, azoxystrobin, [methyl (E)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and the Z isomer of azoxystrobin, [methyl (Z)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances are specified in the following table. The tolerances expire and will be revoked by EPA on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
* * * * *		
Head and Stem (Brassica) subgroup	30	12/31/03
* * * * *		

* * * * *

[FR Doc. 01–28971 Filed 11–20–01; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–2626; MM Docket No. 01–170; RM–10190]

Radio Broadcasting Services; Pittsburg, NH

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allots Channel 246A to Pittsburg, New Hampshire, as that community's first local aural transmission service, in response to a petition for rule making filed on behalf of Pittsburg Broadcasting Company. See 66 FR 41490, August 8, 2001. Coordinates used for Channel 246A at Pittsburg, New Hampshire, are 45–02–25 NL and 71–21–17 WL. As Pittsburg is located within 320 kilometers of the U.S.-Canada border, concurrence of the Canadian government has been requested for Channel 246A at Pittsburg, but has not been received. Therefore, if a construction permit is granted for Channel 246A at Pittsburg, New Hampshire, prior to receipt of final notification by the Canadian government, the construction permit will include the following condition: ''Operation with the facilities specified herein is subject to modification, suspension or termination without right to a hearing if found by the Commission to be necessary in order to conform to the Canada-USA FM Broadcast Agreement, or if specifically objected to by Industry Canada.'' With this action, this docketed proceeding is terminated.

DATES: Effective December 24, 2001. A filing window for Channel 246A at Pittsburg, New Hampshire, will not be opened at this time. Instead, the issue of opening the allotment for auction will be addressed by the Commission in a subsequent Order.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180. Questions related to the application filing process for Channel 246A at Pittsburg, New Hampshire, should be addressed to the Audio Services Division, (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 01–170, adopted October 31, 2001, and released November 9, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room CY–A257), 445 Twelfth Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Qualtex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone (202) 863–2893.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under New Hampshire, is amended by adding Pittsburg, Channel 246A.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 01–29083 Filed 11–20–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–2629; MM Docket No. 01–141; RM–10146]

Radio Broadcasting Services; Las Vegas and Pecos, NM

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In response to a proposal filed on behalf of Meadows Media, LLC, permittee of Station KTRL(FM), Channel 275C2, Las Vegas, New Mexico, the Allocations Branch substitutes Channel 275C3 for Channel 275C2 at Las Vegas, reallots Channel 275C3 to Pecos, New Mexico, as that community's second local FM service, and modifies the authorization for Station KTRL(FM), accordingly. This document also allots Channel 283C2 to Las Vegas, New Mexico, as that community's fifth local FM service, as requested by Meadows Media, LLC. *See* 66 FR 35925, July 10, 2001. Coordinates used for Channel 275C3 at Pecos, New Mexico, are those of the petitioner's intended transmitter site at 35–40–15 NL and 105–33–06 WL. Coordinates used for Channel 283C2 at Las Vegas, New Mexico are those at the currently authorized site of Station KTRL(FM) at 35–35–57 NL and 105–12–12 WL. With this action, this docketed proceeding is terminated.

DATES: Effective December 24, 2001. A filing window for Channel 283C2 at Pecos, New Mexico, will not be opened at this time. Instead, the issue of