Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specficed by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established under section 408(l)(6) of FFDCA, 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

*B. Executive Order 12875*

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

*C. Executive Order 13084*

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

## IV. 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 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 the rule in the **Federal Register**. This 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: March 11, 1999.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

## PART 180—[AMENDED]

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

**Authority:** 21 U.S.C. 346a and 371.

### §180.472 [Amended]

2. In §180.472, by amending the table in paragraph (b) for the following commodity ''Vegetables, cucurbits'' by changing the date ''3/31/99'' to read ''3/31/00.''

[FR Doc. 99–6894 Filed 3–23–99; 8:45 am]

BILLING CODE 6560–50–F

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–300805; FRL–6066–4]**

**RIN 2070–AB78**

## Azoxystrobin; Pesticide Tolerances for Emergency Exemptions

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for combined residues of azoxystrobin in or on lettuce and spinach. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on lettuce grown in California. This regulation establishes a maximum permissible level for residues of azoxystrobin in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on September 30, 2000.

**DATES:** This regulation is effective March 24, 1999. Objections and requests for hearings must be received by EPA on or before May 24, 1999.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number [OPP–300805], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number [OPP–300805], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300805]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

**FOR FURTHER INFORMATION CONTACT:** By mail: Jacqueline E. Gwaltney, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 278, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6792, e-mail: gwaltney.jackie@epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA, on its own initiative, pursuant to sections 408 and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), is establishing a tolerance for combined residues of the fungicide, in or on lettuce, leaf at 20.0 part per million (ppm); lettuce, head at 6.0 ppm and spinach at 25 ppm. These tolerances will expire and be revoked on September 30, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

## I. Background and Statutory Findings

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described in this preeamble and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

New 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 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 FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

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.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

## II. Emergency Exemption for Azoxystrobin on Lettuce and FFDCA Tolerances

The California Department of Pesticide Regulation requested on December 30, 1998 a specific exemption for the use of azoxystrobin on lettuce to control anthracnose. This is the first year this use has been requested under section 18 of FIFRA. Anthracnose became a serious economic problem during the late winter-spring 1998, the lettuce growing season in California. This disease has not been reported in previous years, and it has never reached the infestation levels experienced in 1998. Under moderate to severe infestation conditions, anthracnose will cause reduction in yield and crop quality, with resultant economic losses to growers. The growers in the Salinas Valley estimate losses ranging from 20–60%, to a complete loss in some fields. EPA has authorized under FIFRA section 18 the use of azoxystrobin on lettuce for control of Anthracnose in California. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

The Maryland Department of Agriculture requested on February 19, 1999 a specific exemption for the use of azoxystrobin on spinach to control white rust. This is the first year this use has been requested under section 18 of FIFRA. White rust is one of the most serious constraints to increased spinach production, and disease control represents a large production investment in the mid-atlantic. The most severe disease of spinach whithin the region is white rust caused by *Albugo occidentalis*. When this disease is not controlled, losses in yield can be severe. White rust can cause dramatic quality reductions to the crop and can render a processing spinach crop unmarketable. EPA has authorized under FIFRA section 18 the use of azoxystrobin on spinach for control of white rust in Maryland. After having reviewed the submission, EPA concurs

that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of azoxystrobin in or on lettuce. 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 under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on September 30, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on lettuce 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 lettuce or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of azoxystrobin by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than California to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for azoxystrobin, contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

## III. 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 on lettuce, leaf at 20.0 ppm; lettuce, head at 6.0 ppm and spinach at 25.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance 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 are discussed in this unit.

### *B. Toxicological Endpoint*

1. *Acute toxicity*. The Agency did not identify an acute dietary endpoint and has determined that this risk assessment is not required.

2. *Short- and intermediate-term toxicity.* No toxic endpoints for these durations of exposure were identified in the toxicological data base.

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for azoxystrobin at 0.18 milligrams/kilogram/day (mg/kg/day). The RfD, based on a chronic toxicity study in rats with a no observed adverse effect level of 18.2 mg/kg/day, was established at 0.18 mg/kg/day. Reduced body weights and bile duct lesions were observed at the lowest obseved adverse effect level of 34 mg/kg/day. An Uncertainty Factor (UF) of 100 was used to account for both the interspecies extrapolation and the intraspecies variability.

4. *Carcinogenicity*. Azoxystrobin has been classified by the Agency's RfD Committee as ''Not Likely'' to be carcinogenic to humans via relevant routes of exposure. This decision was made according to the 1996 proposed guidelines. Therefore, cancer risk was not assessed.

### *C. Exposures and Risks*

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures to the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor and/or outdoor uses). In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.507) for the combined residues of azoxystrobin, in or on a variety of raw agricultural commodities. Permanent tolerances have been established (40 CFR 180.507(a)) for the combined residues of azoxystrobin and its Z isomer in or on a variety of raw agricultural commodities at levels ranging from 0.01 ppm in peanuts and pecans to 1.0 ppm in grapes. In addition, time-limited tolerances have been established (40 CFR 180.507(b)) at levels ranging from 0.006 ppm in milk to 20 ppm in rice hulls in conjunction with previous Section 18 requests. Risk assessments were conducted by EPA to assess dietary exposures and risks from azoxystrobin as follows:

i. *Acute exposure and risk*. No toxicological effects which could be attributed to a single dietary exposure were observed, including developmental and neurotoxic effects in the appropriate studies. 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.

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

(Dietary Exposure Evaluation Model) system was used for this chronic dietary exposure analysis. The analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1991. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure. The existing azoxystrobin tolerances (published, pending, and including the necessary Section 18 tolerance(s)) result in a theoretical maximum residue contribution (TMRC) that is equivalent to the following percentages of the Chronic RfD:

| Population Subgroup | Exposure (mg/kg/day) | Percent Reference Dose [1] (%Chronic RfD) |
|---|---|---|
| U.S. Population (48 States) | 0.0052 | 2.9 |
| All Infants (<1 year old) | 0.012 | 6.7 |
| Nursing Infants (<1 year old) | 0.0036 | 2.0 |
| Non-Nursing Infants (<1 year old) | 0.016 | 8.6 |
| Children (1–6 years old) | 0.010 | 5.6 |
| Children (7–12 years old) | 0.0068 | 3.8 |
| U.S. Population (Spring season) | 0.0060 | 3.3 |
| U.S. Population (Summer season) | 0.0056 | 3.1 |
| Northeast Region | 0.0058 | 3.2 |
| Western Region | 0.0055 | 3.0 |
| Pacific Region | 0.0057 | 3.2 |
| Hispanics | 0.0060 | 3.3 |
| Non-hispanic (other than black or white) | 0.0086 | 4.8 |
| Females (13+/nursing) | 0.0064 | 3.6 |

[1]Percentage reference dose (% Chronic RfD) = Exposure/Chronic RfD x 100%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the Chronic RfD occupied is greater than that occupied by the subgroup U.S. Population (48 states).

2. *From drinking water.* Azoxystrobin is persistent and mobile. There is no established Maximum Contaminant Level for residues of azoxystrobin in drinking water. No health advisory levels for azoxystrobin in drinking water have been established (EPA Safe Drinking Water Hotline, 1(800)426–4791, January 27, 1999). EPA has estimates for the concentration of azoxystrobin in surface water based on GENEEC (Generic Estimated Environmental Concentration) modeling.

*Chronic exposure and risk.* Estimated environmental concentrations (EECs) using GENEEC for azoxystrobin on bananas, grapes, peaches, peanuts, pecans, tomatoes, and wheat are listed in the SWAT Team Second Interim Report (June 20, 1997).

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

DRINKING WATER LEVELS OF COMPARISON FOR CHRONIC EXPOSURE [1]

| Population Category [2] | Chronic RfD (mg/kg/day) | Food Exposure (mg/kg/day) | Maximum Water Exposure [3] (mg/kg/day) | DWLOC [4,5,6] (µg/L) |
|---|---|---|---|---|
| U.S. Population (48 states) | 0.18 | 0.0052 | 0.17 | 6,100 |
| Females (13+ years, nursing) | 0.18 | 0.0064 | 0.17 | 5,200 |
| Non-nursing Infants (<1 year old) | 0.18 | 0.016 | 0.16 | 1,600 |

[1] Values are expressed to 2 significant figures.
[2] Within each of these categories, the subgroup with the highest food exposure was selected.
[3] Maximum Water Exposure (Chronic) (mg/kg/day) = Chronic RfD (mg/kg/day) - Food Exposure (mg/kg/day).
[4] DWLOC(µg/L) = Max. water exposure (mg/kg/day) x body wt (kg) ÷ [($10^{-3}$ mg/µg) * water consumed daily (L/day)].
[5] HED Default body weights are: General U.S. Population, 70 kg; Males (13+ years old), 70 kg; Females (13+ years old), 60 kg; Other Adult Populations, 70 kg; and, All Infants/Children, 10 kg.
[6] HED Default daily drinking rates are 2 L/day for adults and 1 L/day for children.

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

EPA bases this determination on a comparison of estimated average concentrations of azoxystrobin in surface and ground water to back-calculated DWLOCs for azoxystrobin in drinking water. These levels of comparison in drinking water were determined after EPA considered all other non-occupational human exposures for which it has reliable data, including all current uses, and the use considered in this action. The estimate of azoxystrobin in surface water is derived from a water quality model that uses conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of azoxystrobin in drinking water as a part

of the chronic (non-cancer) aggregate risk assessment process.

3. *From non-dietary exposure.* Azoxystrobin is currently registered for use on the following residential non-food sites: A search of References indicated that azoxystrobin (Heritage formulation) is registered for residential use on ornamental turf. Short-term exposure may occur for residential handlers and for postapplication activities. Because the TES Committee did not select applicable acute dietary or short-term dermal or inhalation endpoints, a short-term risk assessment is not required. No toxicity was observed at the limit dose (1,000 mg/kg body wt/day) in a 21–day dermal study and an acute inhalation study indicated low toxicity. Intermediate-term and chronic exposures are not expected for residential use.

4. *Cumulative exposure to substances with 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 more 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. Aggregate Risks and Determination of Safety for U.S. Population*

1. *Chronic risk.* Using the conservative Theoretical Maximum Residue Contribution exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, EPA has estimated the exposure to azoxystrobin from food will utilize 4.8% of the Chronic RfD for the most highly exposed adult population subgroup (Non-Hispanic (other than black or white)). The exposure to azoxystrobin from food for infants and children will utilize from 2.0% to 8.6% of the chronic RfD. EPA generally has no concern for exposures below 100% of the Chronic RfD (when the FQPA 10x safety factor is removed, as is the case with azoxystrobin) because the Chronic RfD represents the level at which daily aggregate oral exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to azoxystrobin in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the Chronic RfD. Chronic exposures are not expected for residential uses. EPA concludes that there is a reasonable certainty that no harm will result to adults, infants, or children from chronic aggregate exposure to azoxystrobin residues.

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

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

4. *Endocrine disrupter effects.* EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect....'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry, and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to azoxystrobin residues.

*E. Aggregate Risks and Determination of Safety for Infants and Children*

1. *Safety factor for infants and children*—i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of azoxystrobin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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 pre-and post-natal toxicity and the completeness of the data base 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. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Conclusion.* There is a complete toxicity data base for azoxystrobin and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk.* This is not applicable since no toxicological endpoints of concern were identified during review of the data.

3. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to azoxystrobin from food will utilize 2–8.6% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to azoxystrobin in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Determination of safety.* Based on these risk assessments, EPA concludes

that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to azoxystrobin residues.

## IV. Other Considerations

### *A. Metabolism In Plants and Animals*

1. *Plants.* The nature of the residue in plants is adequately understood. The HED Metabolism Assessment Review Committee (MARC) met on November 10, 1998 and determined that the residue of concern in plants is azoxystrobin and its Z isomer, R230310. The committee based this determination on the results of metabolism studies done on grapes, peanuts, and wheat. In all three studies the major residues were azoxystrobin and R230310. RAB2 will translate these data to lettuce for this Section 18.

2. *Animals.* As there are no animal feed items associated with lettuce, the nature of the residue in animal commodities is not of concern for this Section 18.

### *B. Analytical Enforcement Methodology*

Adequate methodology (RAM 243, GC/NPD, MRID No. 445951–05) is available for enforcement of the proposed tolerance in/on lettuce. This method will be submitted to FDA for inclusion in PAM. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

### *C. Magnitude of Residues*

Zeneca Ag Products has submitted field trial data for a variety of crops. The data from cherries were translated to lettuce for the purposes of this Section 18 only. The data were submitted in conjunction with a request for the establishment of a permanent tolerance on the stone fruit crop group. In choosing a crop to translate data from, the following criteria were considered: azoxystrobin application rate, PHI, and plant morphology. Several crops had similar application rates, but cherries had the most similar PHI.

### *D. International Residue Limits*

There are no CODEX, Canadian, or Mexican maximum residue limits for azoxystrobin on lettuce commodities. Thus, harmonization is not an issue for this Section 18 request.

### *E. Rotational Crop Restrictions*

Rotational crop data were previously submitted. Based on this information, a 45–day plantback interval is appropriate for all crops other than those with azoxystrobin tolerances.

## V. Conclusion

Therefore, the tolerance is established for combined residues of azoxystrobin in lettuce, leaf at 20.0 ppm; lettuce, head at 6.0 ppm; and spinach at 25.0 ppm.

## VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by May 24, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

## VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300805] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at: opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are

received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

## VIII. Regulatory Assessment Requirements

*A. Certain Acts and Executive Orders*

This final rule establishes a tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specficed by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

*B. Executive Order 12875*

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

*C. Executive Order 13084*

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do 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 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 the rule in the **Federal Register**. This 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: March 16, 1999.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

## PART 180—[AMENDED]

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

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

2. In § 180.507, paragraph (b), by adding an entry for ''lettuce, leaf'', ''lettuce, head'', and ''spinach'', to the table to read as follows:

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

* * * * *

(b) *Section 18 emergency exemptions.** * *

| Commodity | Parts per million | Expiration/ Revocation date |
|---|---|---|
| * * * | * | * |
| Lettuce, head | 6.0 | 9/30/00 |
| Lettuce, leaf | 20.0 | 9/30/00 |
| * * * | * | * |
| Spinach | 25.0 | 9/30/00 |

| Commodity | Parts per million | Expiration/ Revocation date |
|---|---|---|
| * * * | * | * |

[FR Doc. 99–7175 Filed 3–23–99; 8:45 am]

BILLING CODE 6560–50–F

## CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

### 45 CFR Parts 1207 and 2551

**RIN 3045–AA17**

### Senior Companion Program

**ACTION:** Final regulations.

**SUMMARY:** The Corporation for National and Community Service (hereinafter the ''Corporation''), amends the regulations governing the administration of the Senior Companion Program (SCP). This final rule implements changes to the Domestic Volunteer Service Act of 1973, as amended, and establishes minimum program requirements with greater clarity. It updates program operations, consolidates requirements from outdated sources into one user friendly document; and incorporates new concepts of programming to highlight the accomplishments and impact of senior service. This amendment supersedes the old ACTION Senior Companion Program regulations and provisions of the SCP Operations Handbook.

**DATES:** These regulations take effect April 23, 1999.

**FOR FURTHER INFORMATION CONTACT:** Rey Tejada at 202–606–5000 ext. 197.

**SUPPLEMENTARY INFORMATION:** The Corporation published a notice of proposed rulemaking (NPRM) for the Senior Companion Program 45 CFR Parts 1207 and 2551 in the **Federal Register** at 63 FR 46954, September 3, 1998.

### Summary of Main Comments and Changes

In response to the Corporation's invitation in the NPRM, the Corporation received 223 letters. A significant number (80 percent) of the letters came from one state. A summary of the main comments received and the Corporation's responses are provided in this final rule. Comments that are general or editorial in nature, or those requesting clarification of program requirements are not addressed in this final rule. The significant comments and the Corporation's responses are summarized by section as follows:

*Section 2551.11 What is the Senior Companion Program?*

*Comments*: Expressed concern that the language proposed for § 2551.11 puts too much emphasis on service, less on the volunteers, and disregards the dual purpose of the program.

*Response*: The Corporation understands the concerns expressed and has modified the section to emphasize the dual purpose of the program. The first sentence of § 2551.11 was revised by adding ''for the dual purpose of engaging'' after ''organizations'', and ''and to provide a high quality experience that will enrich the lives of the volunteers'' after ''needs.''

*Section 2551.12(d) Annual Income*

*Comments*: Expressed some confusion as to whether it is mandatory to count the value of food and shelter given the use of the word ''may'' in this section, and the word ''should'' in the second sentence of § 2551.42(b).

*Response*: In determining income eligibility, it is the Corporation's intent to count the value of food and shelter provided at no cost to a volunteer. This is to ensure that volunteer applicants receiving such assistance do not have an undue advantage over those who do not. To make this point clear, the Corporation has amended the second sentence of this section by using the word ''shall'' instead of ''may'', and has also inserted the word ''in-kind'' after ''cash'' in the first sentence.

*Section 2551.12(l) National Senior Service Corps*

*Comments*: Object to the use of the name National Senior Service Corps (NSSC) because it is not the name used in the DVSA.

*Response*: This name has been in use for the last several years and the Corporation has used significant resources for the development and design of a number of promotional program materials that are now in wide use by projects across the country.

*Section 2551.22 General Responsibilities of Sponsor*

*Comments:* Suggested adding language that would prohibit a sponsor from delegating its responsibilities to its own subsidiary.

*Response:* The Corporation gives the sponsor primary responsibility for fulfilling all project management requirements. It would be inconsistent with its obligations under the grant, if the sponsor were to be prohibited from delegating part of its responsibilities to any subsidiary under its control.

*Section 2551.23(f) Volunteer Orientation*

*Comments:* Indicated that 40 hours of pre-service orientation is difficult for staff to deliver; others thought that the four hours of monthly in-service training is excessive.

*Response:* The Corporations understands the concerns expressed. To increase flexibility and training options, the Corporation amended the provision to provide 40 hours of orientation, of which 20 hours must be pre-service. The Corporation believes four hours of monthly in-service training is essential.

*Section 2551.23(i) Strategic Plan*

*Comments:* Expressed concern that to require the development of a strategic plan would be a significant paperwork burden on projects.

*Response:* The Corporation understands the concerns expressed regarding the requirement and the potential burden it may produce. For this reason, the provision has been withdrawn from the final rule.

*Section 2551.23(k) Assessment of Accomplishments and Impact*

*Comments:* Expressed concern about administrative demands the requirement for assessing impact would entail.

*Response:* The Corporation appreciates the concern expressed. However, the provision is essential for the Corporation to meet its obligations under The Government Performance and Results Act.

*Section 2551.24 Securing Community Participation*

*Comments:* The comments were mixed. Some oppose any changes in the structure, role and operation of the Advisory Council as they were specified in previous regulations. Others support the flexibility provided by the new rule.

*Response:* The new provision gives local program sponsors maximum flexibility for securing community participation. It gives them discretion to use an Advisory Council or another organizational structure to meet the requirement. The Corporation believes that the new rule gives local sponsors the ability to choose whatever method works best for them to involve the community in program operations.

*Section 2551.25(b) Delegation of Authority*

*Comments:* Expressed concern about the potential increase in workload for project directors to meet this