Dated: July 27, 1999.

G.W. Sutton,

Captain U.S. Coast Guard, Commander, Seventh Coast Guard District Acting.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300880; FRL–6086–9]

RIN 2070–AB78

Azoxystrobin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of azoxystrobin or methyl (*E*)-2-[2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl]-3-methoxyacrylate) and its *Z* isomer in or on parsley. 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 parsley 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 December 30, 2000.

DATES: This regulation is effective August 4, 1999. Objections and requests for hearings must be received by EPA on or before October 4, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300880], 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–300880], 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–300880]. 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, gwaltney.jackie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for combined residues or residues of the fungicide azoxystrobin or methyl (*E*)-2-[2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl]-3-methoxyacrylate) and its *Z* isomer, in or on parsley at 20 parts per million (ppm) for fresh and at 100 ppm for dry. This tolerance will expire and is revoked on December 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) (Public Law 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 preamble 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 Parsley and FFDCA Tolerances

The State of California requested an exemption for the use of azoxystrobin (Quadris flowable fungicide) on 3,000 acres of parsley to control Septoria leaf blight disease caused by *Septoria petroselini*. After crop harvest the pathogen does not survive in the fields during the winter months and must therefore be reintroduced into parsley fields each season if disease is to reoccur. This is a seed borne-disease. When contaminated seeds are planted, the pathogen is reintroduced. The reintroduced pathogen spreads in the field through rain splash or sprinkler irrigation. During spring, the parsley growing areas have mild temperatures and high humidity favoring disease development. Disease severity is weather dependent and can vary from season to season. The most logical way of controlling this would be to eradicate this pathogen from the seeds. The spring seasons of 1995 and 1998 were wet and humid favoring disease development. In spite of using registered alternatives (copper fungicides and neem oil), California growers experienced significant losses due to high disease pressure. It is clearly documented that the registered alternatives are not effective in controlling the disease under high disease pressure. During 1999, the spring season was wet and conditions were favorable for the development of disease. It is expected that parsley growers in California will suffer significant losses during the 3rd and 4th parsley cutting without the use of azoxystrobin. EPA has authorized under FIFRA section 18 the use of azoxystrobin on parsley for control of septoria blight/septoria leaf spot in California. 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 parsley. 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 December 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 parsley 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 parsley 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 or methyl (*E*)-2-[2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl]-3-methoxyacrylate) and its *Z* isomer on parsley at fresh parsley at 20 ppm and dried parsley at 100 ppm 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 and the Agency's selection of toxicological endpoints upon which to assess risk caused by azoxystrobin are discussed below.

1. *Acute toxicity.* The Agency evaluated the existing toxicology data base for azoxystrobin and did not identify an acute dietary endpoint. Therefore, a risk assessment is not required.

2. *Short- and intermediate-term toxicity.* The Agency evaluated the existing toxicology data base for short- and intermediate-term dermal and inhalation exposure and determined that this risk assessment is not required. **Note:** From a 21-day dermal toxicity study the no observed adverse effect level (NOAEL) was 1,000 milligrams/kilograms/day (mg/kg/day) at the highest dose tested (HDT) (Acute inhalation toxicity category III).

3. *Chronic toxicity.* EPA has established the Reference Dose (RfD) for azoxystrobin at 0.18 mg/kg/day. This RfD is based on on a chronic toxicity study in rats with a NOAEL of 18.2 mg/kg/day. Reduced body weights and bile duct lesions were observed at the lowest effect level (LEL) 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.* The EPA has determined that azoxystrobin should be classified as ''Not Likely'' to be a human carcinogen according to the proposed revised Cancer Guidelines. This classification is based on the lack of evidence of carcinogenicity in long-term rat and mouse feeding studies.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.507(a)) for the combined residues of azoxystrobin and R230310 in or on a variety of raw agricultural commodities at levels ranging from 0.010 ppm in tree nuts to 20 ppm in rice hulls. Included in these tolerances are numerous ones for animal commodities which were established in conjunction with tolerances for rice and wheat

commodities. Time-limited tolerances range from 0.1 ppm in soybeans to 30 ppm in spinach.

2. *Acute risk*. No toxicological effects which could be attributed to a single dietary exposure were observed, including developmental and neurotoxic effects in the appropriate studies. Therefore, no acute endpoint has been assigned.

3. *Chronic risk*. In conducting this chronic dietary risk assessment, EPA has made very conservative assumptions: 100% of parsley 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 default ratio between grape juice and juice concentrate was retained. (Chronic RfD = 0.18 mg/kg/day)

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 tolerances result in a theoretical maximum residue contribution (TMRC) that is equivalent to the following percentages of the Chronic RfD. As the 10x safety factor was removed, the chronic RfD is equal to the PAD (population-adjusted dose). As a result, the exposure given as a percentage of the total allowable exposure is reported as %PAD.

TABLE 1.—SUMMARY: CHRONIC EXPOSURE ANALYSIS BY THE DEEM SYSTEM

Population Subgroup	Exposure (mg/kg/day)	Percent Reference Dose[1] (%Chronic PAD/RfD)
U.S. Population (total)	.012246	6.8%
All Infants (<1 year old)	0.014830	8.2%
Nursing Infants (<1 year old)	0.003917	2.2%
Non-Nursing Infants (<1 year old)	0.019422	10.8%
Children (1-6 years old)	0.022035	12.2%
Children (7-12 years old)	0.012990	7.2%
Non-Hispanic Blacks	0.016444	9.1%
Non-Hispanic/non-white/non-black	0.021015	11.7%
Females 20+ (not pregnant or nursing)	0.012325	6.8%
Females 13+ (nursing)	0.014238	7.9%
Seniors 55+	0.013489	7.5%

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

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

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

4. *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 has estimated the concentration of azoxystrobin in surface water based on GENEEC (Generic Estimated Environmental Concentration) modeling and in ground water based on Screening Concentration in Ground Water (SCI-GROW) modeling.

5. *Chronic 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 6, 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.

TABLE 2.—DRINKING WATER LEVELS OF COMPARISON FOR CHRONIC EXPOSURE[1]

Population Category[2]	Chronic RfD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure[3] (mg/kg/day)	DWLOC[4,5,6](µg/L)
U.S. Population (total)	0.18	0.012246	0.168	5,900
Females 13+ (nursing)	0.18	0.014238	0.166	5,000

TABLE 2.—DRINKING WATER LEVELS OF COMPARISON FOR CHRONIC EXPOSURE[1]—Continued

Population Category[2]	Chronic RfD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure[3] (mg/kg/day)	DWLOC[4,5,6](μg/L)
Non-nursing Infants	0.18	0.019422	0.161	1,600

[1] Values are expressed to 2 significant figures.
[2] Within each of these categories, the subgroup with the highest food exposure was selected.
[3] Maximum Water Exposure (Chronic) (mg/kg/day) = Chronic RfD (mg/kg/day) - Food Exposure (mg/kg/day).
[4] DWLOC(μg/L) = Max. water exposure (mg/kg/day) x body wt (kg) ÷ [(10^{-3} mg/μg) * water consumed daily (L/day)].
[5] 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.

6. *From non-dietary uses.* 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 (November 12, 1996) 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.

7. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. This risk assessment is not applicable since no indoor and outdoor residential exposure uses are currently registered for azoxystrobin.

C. Aggregate Cancer Risk for U.S. Population

1. *Short- and intermediate-term aggregate risk.* There are no applicable endpoints for short-term exposure (TES Committee, November 12, 1996); 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.

2. *Chronic aggregate risk.* Using the conservative TMRC 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 11.7% of the chronic PAD for the most highly exposed adult population subgroup (Non-Hispanic/non-white/non-black). The exposure to azoxystrobin from food for infants and children will utilize from 2.2% to 12.2% of the chronic PAD. EPA generally has no concern for exposures below 100% of the chronic PAD because the chronic PAD 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 PAD. 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.

D. 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 prenatal and postnatal 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 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. *Developmental toxicity studies*— a. *Rabbit.* In the developmental toxicity study in rabbits, developmental NOEL was 500 mg/kg/day, at the HDT. Because there were no treatment-related effects, the developmental LEL was ≧500 mg/kg/day. The maternal NOEL was 150 mg/kg/day. The maternal LEL of 500 mg/kg/day was based on decreased body weight gain during dosing.

b. *Rat.* In the developmental toxicity study in rats, the maternal (systemic) NOAEL was not established. The maternal LEL of 25 mg/kg/day at the lowest dose tested (LDT) was based on increased salivation. The developmental (fetal) NOAEL was 100 mg/kg/day (HDT).

iii. *Reproductive toxicity study*. In the reproductive toxicity study in rats, the parental (systemic) NOAEL was 32.3 mg/kg/day. The parental LEL of 165.4 mg/kg/day was based on decreased body weights in males and females, decreased food consumption and increased adjusted liver weights in females, and cholangitis. The reproductive NOAEL was 32.3 mg/kg/day. The reproductive LEL of 165.4 mg/kg/day was based on increased weanling liver weights and decreased body weights for pups of both generations.

iv. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicology data base for azoxystrobin is complete with respect to current toxicological data requirements. The results of these studies indicate that infants and children are not more sensitive to exposure, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation reproductive toxicity study in rats. The additional 10X safety factor to account for sensitivity of infants and children was removed by an ad hoc FQPA Safety Factor Committee.

v. *Conclusion*. Therefore, the tolerance is established for combined residues or residues of azoxystrobin or methyl (*E*)-2-[2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl]-3-methoxyacrylate) and its *Z* isomer in parsley at fresh parsley at 20 ppm and dried parsley at 100 ppm ppm. The results of these studies indicate that infants and children are not more sensitive to exposure, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation reproductive toxicity study in rats. The additional 10X safety factor to account for sensitivity of infants and children was removed by an ad hoc FQPA Safety Factor Committee.

3. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to azoxystrobin from food will utilize 2 to 5% 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. 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. EPA will translate these data to parsley for this section 18.

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

B. Analytical Enforcement Methodology

An adequate analytical method is available for enforcement of the proposed tolerances. Method RAM 243 (GC/NPD) can be used for parsley. The limit of quantitation for spinach was 0.01 ppm. This method has been validated by the Agency's Analytical Chemistry Laboratory and will be submitted to the Food and Drug Administration for inclusion in the Pesticide Analytical Manual II.

C. Magnitude of the Residues

1. *Plants*. IR-4 performed five field trials on spinach. In each trial, six applications were made at an application rate of 0.25 lb ai/A. The PHI was either 6 or 7 days. This use pattern is the same as that proposed for parsley.

2. *Animals*. There are no animal feed items associated with parsley; therefore, the magnitude of the residue in animals is not relevant to this petition.

D. Rotational Crop Restrictions

Rotational crop data were submitted in pesticide petition #6F4762. Based on this information, a 45-day plantback interval is appropriate for all crops other than those with azoxystrobin tolerances.

E. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits (MRL) for azoxystrobin on parsley. Thus, harmonization is not an issue for this section 18 request.

V. Conclusion

Therefore, the tolerance is established for combined residues or residues of azoxystrobin or methyl (*E*)-2-[2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl]-3-methoxyacrylate) and its *Z* isomer in fresh parsley at 20 ppm and dried parsley at 100 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 issued by EPA under new section 408(l)(6) 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 October 4, 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–300880] (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) (Public Law 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: July 22, 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, 321q and 371.

2. In § 180.507 (b), by revising two commodities in the table to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

* * * * *

(b)* * *

Commodity	Parts per million	Expiration/ revocation date
* *	* *	*
Parsley, dried	20.0	12/30/00
Parsley, fresh	100.0	12/30/00
* *	* *	*

* * * * *

[FR Doc. 99–19910 Filed 8–3–99; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 600 and 660

[Docket No. 981231333–8333–01; I.D. 072699C]

Fisheries off West Coast States and in the Western Pacific; Pacific Coast Groundfish Fishery; Trip Limit Adjustments

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Fishing restrictions; request for comments.

SUMMARY: NMFS announces changes to the trip limits in the Pacific Coast groundfish limited entry fisheries for *Sebastes* complex species north of Cape Mendocino, and for yellowtail rockfish and for rockfish other than yellowtail and canary rockfish within the *Sebastes* complex, north of Cape Mendocino. These actions, which are authorized by the Pacific Coast groundfish fishery management plan (FMP), are intended to help the fisheries achieve optimum yields (OYs).

DATES: Effective 0001 hours local time (l.t.) August 1, 1999. For vessels operating in the B platoon, effective 0001 hours l.t. August 16, 1999. These changes remain in effect, unless modified, superseded or rescinded, until the effective date of the 2000 annual specifications and management measures for the Pacific Coast groundfish fishery, which will be published in the **Federal Register**. Comments on this rule will be accepted through August 19, 1999.

ADDRESSES: Submit comments to William Stelle, Jr., Administrator, Northwest Region (Regional Administrator), NMFS, 7600 Sand Point Way N.E., BIN C15700, Bldg. 1, Seattle, WA 98115–0070; or Rodney McInnis, Acting Administrator, Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213.

FOR FURTHER INFORMATION CONTACT: Katherine King or Yvonne deReynier, Northwest Region, NMFS, 206–526–6140.

SUPPLEMENTARY INFORMATION: The following changes to current management measures were recommended by the Pacific Fishery Management Council (Council), in consultation with the States of Washington, Oregon, and California, at its June 22 through 25, 1999, meeting in Portland, OR. The adjusted trip limits are calculated to provide a year-long fishing opportunity. Pacific Coast groundfish landings will be monitored throughout the year, and further adjustments to the cumulative trip limits may be made as necessary.

Currently the limited entry cumulative landings limit for *Sebastes* complex species taken north of Cape Mendocino is 30,000 lb (13,608 kg) per 2-month period. Within that limit and also north of Cape Mendocino, the cumulative landings limit for yellowtail rockfish is 16,000 lb (7,257 kg) per 2-month period.

The best available information at the June Council meeting indicated that 1,107 mt of *Sebastes* complex species had been landed north of Cape Mendocino through May 31, 1999, which is 69 percent of the 1,613 mt expected *Sebastes* complex landings for the January 1 through May 31 period. Within those *Sebastes* complex landings, 630 mt of yellowtail rockfish had been landed north of Cape Mendocino through May 31, 1999, which is 76 percent of the 832 mt expected yellowtail rockfish landings for the January 1 through May 31 period. These relatively low landings rates may be due to several factors, including poor winter weather and unusual La Nina ocean conditions. If the fishery were to continue under current landings limits, the fleet would not harvest its allocations for these species by the end of the year and, therefore the fishery would not achieve OY. For this reason, the Council recommended that the 2-month cumulative trip limit for *Sebastes* complex species taken north of Cape Mendocino be increased to 35,000 lb (15,876 kg) for the period of August 1 through September 30. Within that limit, the Council recommended that the 2-month cumulative trip limit for yellowtail rockfish taken north of Cape Mendocino be increased to 20,000 lb (9,072 kg) for the period of August 1 through September 30. The Council further recommended adding a