section, the applicability shall be based on the utilization that occurred during the year preceding April 22, 1994.

(B) For chemical manufacturing process units that produce one or more of the chemicals listed in paragraph (b)(1)(ii) of this section and meet the criteria in paragraphs (b)(2) and (b)(3) of this section, the applicability shall be based on the utilization that occurred during the year preceding May 12, 1998.

* * * * *

(k) Except as provided in paragraphs (l), (m), and (p) of this section, sources subject to subparts F, G, or H of this part are required to achieve compliance on or before the dates specified in paragraphs (k)(1) through (k)(8) of this section.

* * * * *

(l)(1) * * *

(ii)(A) Such construction commenced after December 31, 1992 for chemical manufacturing process units that produce as a primary product one or more of the chemicals listed in table 1 of this subpart;

(B) Such construction commenced after August 22, 1997 for chemical manufacturing process units that produce as a primary product one or more of the chemicals listed in paragraph (b)(1)(ii) of this section; and

* * * * *

(2) * * *

(ii)(A) Such reconstruction commenced after December 31, 1992 for chemical manufacturing process units that produce as a primary product one or more of the chemicals listed in table 1 of this subpart; and

(B) Such construction commenced after August 22, 1997 for chemical manufacturing process units that produce as a primary product one or more of the chemicals listed in paragraph (b)(1)(ii) of this section.

* * * * *

(p) *Compliance dates for chemical manufacturing process units that produce crotonaldehyde or tetrahydrobenzaldehyde.* Notwithstanding the provisions of paragraph (k) of this section, chemical manufacturing process units that meet the criteria in paragraphs (b)(1)(ii), (b)(2), and (b)(3) of this section shall be in compliance with this subpart and subparts G and H of this part by the dates specified in paragraphs (p)(1) and (p)(2) of this section, as applicable.

(1) If the source consists only of chemical manufacturing process units that produce as a primary product one or more of the chemicals listed in paragraph (b)(1)(ii) of this section, new sources shall comply by the date specified in paragraph (p)(1)(i) of this section and existing sources shall comply by the dates specified in paragraphs (p)(1)(ii) and (p)(1)(iii) of this section.

(i) Upon initial start-up or May 12, 1998, whichever is later.

(ii) This subpart and subpart G of this part by May 14, 2001, unless an extension has been granted by the Administrator as provided in § 63.151(a)(6) or granted by the permitting authority as provided in § 63.6(i) of subpart A of this part. When April 22, 1994 is referred to in this subpart and subpart G of this part, May 12, 1998 shall be used as the applicable date for that provision. When December 31, 1992 is referred to in this subpart and subpart G of this part, August 22, 1997 shall be used as the applicable date for that provision.

(iii) Subpart H of this part by May 12, 1999, unless an extension has been granted by the Administrator as provided in § 63.151(a)(6) or granted by the permitting authority as provided in § 63.6(i) of subpart A of this part. When April 22, 1994 is referred to in subpart H of this part, May 12, 1998 shall be used as the applicable date for that provision. When December 31, 1992 is referred to in subpart H of this part, August 22, 1997 shall be used as the applicable date for that provision.

(2) If the source consists of a combination of chemical manufacturing process units that produce as a primary product one or more of the chemicals listed in paragraphs (b)(1)(i) and (b)(1)(ii) of this section, new chemical manufacturing process units that meet the criteria in paragraph (b)(1)(ii) of this section shall comply by the date specified in paragraph (p)(1)(i) of this section and existing chemical manufacturing process units producing crotonaldehyde and/or tetrahydrobenzaldehyde shall comply by the dates specified in paragraphs (p)(1)(ii) and (p)(1)(iii) of this section.

3. Section 63.103 is amended by adding paragraph (b)(6) to read as follows:

§ 63.103 General compliance, reporting, and recordkeeping provisions.

* * * * *

(b) * * *

(6) The owner or operator of a flexible operation unit shall conduct all required compliance demonstrations during production of the primary product. The owner or operator is not required to conduct compliance demonstrations for operating conditions during production of a product other than the primary product. Except as otherwise provided in this subpart or in subpart G or subpart H of this part, as applicable, the owner or operator shall operate each control device, recovery device, and/or recapture device that is required or used for compliance, and associated monitoring systems, without regard for whether the product that is being produced is the primary product or a different product. Except as otherwise provided in this subpart, subpart G and/or subpart H of this part, as applicable, operation of a control device, recapture device and/or recovery device required or used for compliance such that the daily average of monitored parameter values is outside the parameter range established pursuant to § 63.152(b)(2), or such that the monitoring data show operation inconsistent with the monitoring plan established pursuant to § 63.120(d)(2) or § 63.181(g)(1)(iv), shall constitute a violation of the required operating conditions.

* * * * *

Table 1 of Subpart F [Amended]

4. Table 1 of subpart F is amended by removing the entry for acetaldol and its associated CAS number and group number.

[FR Doc. 98–12579 Filed 5–11–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300648; FRL–5787–8]

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 cucurbits and watercress . This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on cucurbits and watercress in several states. 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 (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

The tolerance will expire and is revoked on June 30, 1999.

DATES: This regulation is effective May 12, 1998. Objections and requests for hearings must be received by EPA on or before July 13, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300648], 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–300648], 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, CM #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@epamail.epa.gov. Copies of 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 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300648]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Virginia Dietrich, 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: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9359, e-mail: dietrich.virginia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the FFDCA, 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for combined residues of the fungicide azoxystrobin and its Z isomer, in or on cucurbits and watercress at 1.0 and 1.0 part per million (ppm). This tolerance will expire and is revoked on June 30, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The FQPA (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the FFDCA, 21 U.S.C. 301 *et seq.*, and 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 below 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 tolerance 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 Cucurbits and Watercress and FFDCA Tolerances

For watercress, copper hydroxide is the only material registered for control of Cercospora leaf spot disease. Several applications of copper hydroxide are required per season for adequate control. Although copper hydroxide is still effective at controlling Cercospora leaf spot disease, due to the many required applications, levels of copper in soil and watercress plants have reached phytotoxic levels. As a consequence, in areas where watercress has been grown for several years, yield has been significantly reduced.

For cucurbits, azoxystrobin has been requested for the control of gummy stem blight and powdery mildew because unusually wet and cloudy weather conditions favor disease development. Similar weather conditions in 1997 resulted in estimated production losses of 68.4 and 36.2% in cantaloupe and honeydews. Registered alternatives are ineffective due to a combination of weather and resistance factors.

EPA has authorized under FIFRA section 18 the use of azoxystrobin on cucurbits and watercress for control of gummy stem blight on cucurbits and Cercospora leaf spot disease in watercress in several States. After having reviewed the submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of azoxystrobin in or on cucurbits and watercress. In doing so, EPA considered the new 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 new 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 June 30, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on cucurbits and watercress 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 cucurbits and watercress 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 the approved States to use this pesticide on this crop under section 18 of FIFRA without following all provisions of 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 above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated

considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (nonursing infants (<1 year old)) was not regionally based.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of azoxystrobin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of azoxystrobin and its Z isomer) on cucurbits and watercress at 1.0 and 1.0 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 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 database 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 database 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 NOEL was 1,000 mg/kg/day at the highest dose tested (Acute inhalation toxicity category III).

3. *Chronic toxicity*. EPA has established the RfD for azoxystrobin at 0.18 milligrams/kilogram/day (mg/kg/day). This RfD is based on a chronic toxicity study in rats with a NOEL 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 HED 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. 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.* 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 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.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Agency did not conduct an acute risk assessment because no toxicological endpoint of concern was identified during review of available data.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, HED has made very conservative assumptions -- 100% of cucurbits, watercress and all other commodities having azoxystrobin tolerances will contain azoxystrobin residues and those residues would be at the level of the tolerance -- which result in an overestimation of human dietary exposure. Thus, in making a safety determination for this tolerance, HED is taking into account this conservative exposure assessment.

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 RfD:

Population Sub-Group	TMRC (mg/kg/day)	% RFD
U.S. Population (48 States)	0.002	1%

Population Sub-Group	TMRC (mg/kg/day)	% RFD
Nursing Infants (<1 year old)	0.004	2%
Non-Nursing Infants (<1 year old)	0.009	5%
Children (1-6 years old)	0.005	3%
Children (7-12 years old)	0.003	2%
Hispanics	0.003	2%
Non-Hispanics Others	0.005	3%
U.S. Population (summer season)	0.003	2%
Females (13-19, not preg or nursing)	0.002	1%

The subgroups listed above are: (a) the U.S. population (48 states); (b) those for infants and children; (c) females (13-19 years old, not pregnant or nursing); and, (d) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

2. *From drinking water.* 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.

i. *Acute exposure and risk.* An assessment was not appropriate since no toxicological endpoint of concern was identified during review of the available data.

ii. *Chronic exposure and risk.* Based on the chronic dietary (food) exposure estimates, chronic drinking water levels of concern (DWLOC) for azoxystrobin were calculated and are summarized in Table 1. Estimated environmental concentrations (EECs) using GENEEC for azoxystrobin on bananas, grapes, peaches, peanuts, pecans, tomatoes, and wheat are listed in SWAT Team Second Interim Report (6/20/97). The highest EEC for azoxystrobin in surface water is from the application of azoxystrobin on grapes (39 µg/L) and is substantially lower than the DWLOCs calculated. Therefore, chronic exposure to azoxystrobin residues in drinking water do not exceed the Agency's level of concern.

Table 1. Drinking Water Levels of Concern

	RfD (mg/kg/day)	TMRC [Food Exposure] (mg/kg/day)	Max Water Exposure[1] (mg/kg/day)	DWLOC [2,3,4] (µg/L)
U.S. Population (48 States)	0.18	0.00231	0.178	6200
Females (13+ years old, not pregnant or nursing)	0.18	0.00176	0.178	5300
Non-nursing Infants (< 1 year old) ...	0.18	0.00879	0.171	1700

[1] Maximum Water Exposure (mg/kg/day) = RfD (mg/kg/day) - TMRC from DRES (mg/kg/day)
[2] DWLOC(µg/L) = Max water exposure (mg/kg/day) * body wt (kg) /[(10^{-3} mg/µg)*water consumed daily (L/day)]
[3] HED Default body wts for males, females, and children are 70 kg, 60 kg, and 10 kg respectively.
[4] HED Default Daily Drinking Rates are 2 L/Day for Adults and 1 L/Day for children

3. *From non-dietary exposure.* Azoxystrobin is not currently registered for use on residential non-food sites.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Azoxystrobin is related to the naturally occurring strobilurins. There are no other members of this class of fungicides registered with the Agency. 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.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

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.

C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Chronic risk.* Using the conservative TMRC exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, HED has estimated the exposure to azoxystrobin from food will utilize 1% of the RfD for the U.S. population. HED 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, HED does not expect the aggregate exposure to exceed 100% of the RfD. Under current HED guidelines, the registered non-dietary uses of azoxystrobin do not constitute a chronic exposure scenario. HED concludes that there is a reasonable certainty that no harm will result from chronic aggregate exposure to azoxystrobin residues. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to azoxystrobin residues.

2. *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.

D. Aggregate Risks and Determination of Safety for Infants and Children

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

2. *Developmental toxicity studies*—i. *Rabbit.* In the developmental toxicity study in rabbits, developmental NOEL was 500 mg/kg/day, at the highest dose tested (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.

ii. *Rat.* In the developmental toxicity study in rats, the maternal (systemic) NOEL 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) NOEL was 100 mg/kg/day (HDT).

3. *Reproductive toxicity study*— i. *Rat.* In the reproductive toxicity study (MRID #43678144) in rats, the parental (systemic) NOEL 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 NOEL 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.

ii. *Pre- and post-natal sensitivity.* The pre- and post-natal 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.

iii. *Conclusion.* 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.

4. *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.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in grapes is adequately understood. The residue of concern in grapes is parent azoxystrobin and its Z isomer. The qualitative nature of the residue in wheat is adequately understood. Again, the major residues are azoxystrobin and the Z isomer in wheat metabolism studies. These data are being translated for watercress for this emergency exemption.

The qualitative nature of the residue in animals is adequately understood for the purposes of this Section 18 request. A ruminant metabolism study has been submitted, however the animal metabolism data have not been reviewed by the Office of Pesticide Program's Metabolism Assessment Review Committee. The residues of concern in ruminants appears to be different from that of plants. Unidentified metabolite compounds, designated metabolites 2, 20, and 28, appear to be the major components of the residue in ruminant tissues. For the purposes of these time-limited tolerances for emergency exemptions only, the residues of concern in animal tissues are azoxystrobin and its Z-isomer.

B. Analytical Enforcement Methodology

A method (SOP RAM 243/03, GLC/NPD) to determine residues of azoxystrobin and its Z isomer in banana, peach, peanut, tomato, and wheat commodities has been submitted. This method has been independently validated as per PR Notice 88-5. An Agency validation of this method is pending. The Agency concludes this method is adequate for enforcement of the requested Section 18 tolerances on plant commodities.

GLC/NPD method RAM 255/01 is adequate for collection of residue data for azoxystrobin in animal commodities. Adequate independent method validation and concurrent method recovery data have been submitted. Method SOP RAM 255/01 has been submitted for Agency method validation. The Agency concludes this method is adequate for enforcement of the necessary Section 18 tolerances on livestock commodities.

C. Magnitude of Residues

Residues of azoxystrobin and its Z isomer are not expected to exceed 1.0 ppm in/on cucurbits or watercress as a result of this Section 18 use. Time-limited tolerances should be established at this level.

D. Rotational Crop Restrictions

Rotational crop data were previously submitted. Based on this information, a 45 day plantback interval is appropriate for all crops.

E. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits (MRL) for azoxystrobin on cucurbits or watercress. Thus, harmonization is not an issue for these section 18 requests.

VI. Conclusion

Therefore, the tolerance is established for combined residues of azoxystrobin and its Z isomer in cucurbits and watercress at 1.0 and 1.0 ppm.

VII. 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(e) and (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 July 13, 1998, 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 above (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). 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.

VIII. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300648] (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 Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above 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 rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified 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 these tolerances and exemptions that are established 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 has 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.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of 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: April 27, 1998.

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.

2. Section 180.507 is amended in paragraph (b) by alphabetically adding the following commodities to the table to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
* * *	* * *	*
Cucurbits	1.0	6/30/99
* * *	* * *	*
Watercress	1.0	6/30/99

* * * * *

[FR Doc. 98–12578 Filed 5–11–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300647; FRL–5787–7]

RIN 2070–AB78

Myclobutanil; Pesticide Tolerance.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for the fungicide myclobutanil [alpha-butyl-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile] and its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile (free and bound) in or on bananas (post-harvest). Rohm and Haas Company requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170).

DATES: This regulation is effective May 12, 1998. Objections and requests for hearings must be received by EPA on or before July 13, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300647], 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–300647], 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, CM #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@epamail.epa.gov. Copies of 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 or 6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300647]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Mary L. Waller, 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: Crystal Mall #2, Rm 247, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9354, e-mail: waller.mary@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 1, 1997 (62 FR 41379)(FRL–5732–4), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of pesticide petition (PP) 2E4141 for a tolerance by Rohm and Haas Company, 100 Independence Mall