the Storrow Drive Connector Bridge, which will be located on the south side of the Charles River between the Gridley Lock and Dam and the Amtrak Railroad Bridge, is presently under construction. Six bridge spans need to be erected during the construction of Section 1. These bridge spans will be transported to Boston on board barges. The barges will be towed into Boston Harbor with a single bridge span on each barge. This will occur on six separate occasions over the next several months. The spans will then be transported through the Gridley Lock, put into place using a crane on a barge and secured. The crane and barge cannot be shifted by vessel wakes during the securing process. Therefore, a safety zone is necessary to allow the safe erection of the six spans and to protect vessel traffic.

This regulation establishes a safety zone in all waters of the Charles River between the Gridley Lock and Dam and the western side of the Amtrak Railroad Bridge. This safety zone prevents entry into or movement within this portion of the Charles River. Upon notification from the primary contractor on the project, the Coast Guard will make Marine Safety Information Broadcasts informing mariners of the activation of this safety zone. The expected duration of the safety zone will vary between eight and forty-eight hours depending upon construction requirements. The safety zone will be activated primarily on nights and/or weekends as construction on the Storrow Drive Connector Bridge is restricted by weekday commuter rail traffic on the Amtrak Railroad Bridge.

Regulatory Evaluation

This final rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory polices and procedures of DOT is unnecessary. There is expected to be minimal recreational and commercial traffic in this area, in part due to the seasonal end of the recreational and tourist boating season. Commercial tour operators have received advance notification of the project and can make alternate arrangements. Due to the limited number and duration of the arrivals, departures and transits, the Coast Guard expects the economic impact of this regulation to be minimal.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this rule would have a significant economic impact on a substantial number of small entities. ''Small entities'' may include (1) small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and (2) governmental jurisdictions with populations of less than 50,000.

For the reasons discussed in the Regulatory Evaluation above, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), that this rule will not have a significant impact on a substantial number of small entities.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612, and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard has considered the environmental impact of this final rule and concluded that, under Figure 2–1, paragraph 34(g), of Commandant Instruction M16475.1C, this final rule is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

Regulation

For reasons set out in the preamble, the Coast Guard amends 33 CFR Part 165 as follows:

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. Add temporary § 165.T01–140 to read as follows:

§ 165.T01–140 Safety Zone: Storrow Drive Connector Bridge (Central Artery Tunnel Project), Charles River, Boston, MA.

(a) *Location.* The following area is a safety zone: All waters of the Charles River between the Gridley Lock and Dam and the western side of the AMTRAK Railroad Bridge.

(b) *Effective Date.* This section is effective from September 30, 1998 to December 31, 1998.

(c) *Notification.* Upon notification from the primary contractor on the Storrow Drive Connector Bridge construction project that a span is ready to be erected, the Coast Guard will make Marine Safety Information Broadcasts informing mariners of the activation of this safety zone. The expected duration of the safety zone will vary between eight and forty-eight hours depending upon construction requirements. The safety zone will be activated primarily on nights and/or weekends.

(d) *Regulations.* (1) Entry into or movement within this zone is prohibited unless authorized by the COTP Boston.

(2) All persons and vessels shall comply with the instructions of the COTP or the designated on-scene U.S. Coast Guard patrol personnel. U.S. Coast Guard patrol personnel include commissioned, warrant, and petty officers of the U.S. Coast Guard.

(3) The general regulations covering safety zones in section 165.23 of this part apply.

Dated: September 18, 1998.

J.L. Grenier,

Captain, U.S. Coast Guard, Captain of the Port, Boston, Massachusetts.

[FR Doc. 98–27872 Filed 10–15–98; 8:45 am]

BILLING CODE 4910–15–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300744; FRL–6037–8]

RIN 2070–AB78

Azoxystrobin; Time-limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for the combined residues of azoxystrobin [methyl(E)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] and

its *Z* isomer in or on potatoes. This action is in response to the combined efforts of Wisconsin potato growers, University extension specialists, Zeneca Ag Products, and EPA to generate the information necessary for registration of the reduced risk fungicide, azoxystrobin, for use against the pests late blight and early blight of potatoes. This regulation establishes a maximum permissible level of 0.03 parts per million (ppm) for residues of azoxystrobin and its *Z* isomer 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 October 18, 1999.

DATES: This regulation is effective October 16, 1998. Objections and requests for hearings must be received by EPA on or before December 15, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300744], 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–300744], 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@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 5.1/6.1 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–300744]. 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: John Bazuin, Jr., 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) 305–7381, e-mail: bazuin.john@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, in cooperation with Wisconsin potato growers, University extension specialists, and Zeneca Ag Products, Inc., pursuant to sections 408(e) and (r) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (r), is establishing a tolerance for combined residues of the fungicide azoxystrobin and its *Z* isomer, in or on potatoes at 0.03 part per million (ppm). This tolerance will expire and is revoked on October 18, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations. The only comments received concerning the proposed rule were from the United States Department of Agriculture, which requested some modifications to the summary (these changes were made) and indicated their feeling that the comment period of 15 days was very short (the reasons behind the use of such a short comment period were explained in the proposed rule)(63 FR 48664, September 11, 1998)(FRL–6026–8)).

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described 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 5 of FIFRA authorizes EPA to issue an experimental use permit for a pesticide. This provision was not amended by FQPA. EPA has established regulations governing such experimental use permits in 40 CFR part 172. Section 408(r) of FFDCA authorizes EPA to issue time-limited tolerances for pesticide residues resulting from FIFRA experimental use permits.

II. 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. The Agency has determined that azoxystrobin is a reduced risk pesticide for use on potatoes.

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 potatoes at 0.03 ppm. EPA's assessment of the dietary and other exposures and risks associated with establishing the tolerance follows.

A. Toxicity

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by azoxystrobin are discussed below.

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 adverse effects (the ''no-observed adverse effect level'' or ''NOAEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOAEL from the study with the lowest NOAEL 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 NOAEL 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 NOAEL) 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/NOAEL 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 (non-nursing infants (<1 year old)) was not regionally based.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of azoxystrobin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for 12 months for combined residues of azoxystrobin and its *Z* isomer on potatoes at 0.03 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.

Both permanent and time-limited tolerances have been established (40 CFR 180.507) for the combined residues of azoxystrobin and its *Z* isomer, in or on a variety of raw agricultural commodities. Permanent tolerances have been established for bananas, grapes, peaches, peanuts, pecans, and tomatoes. Time-limited tolerances have been established for the fat, liver, and meat of cattle, goats, hogs, horses, poultry, and sheep; kidney of cattle; eggs; milk; cucurbits; parsley; rice; and watercress. The time-limited tolerances stem from the issuance of several FIFRA section 18 emergency exemptions for the use of azoxystrobin. The risk assessments were conducted by EPA to assess dietary exposures and risks from azoxystrobin as follows:

1. *Acute toxicity.* The Agency evaluated the existing toxicology database for azoxystrobin. No acute dietary endpoint was identified, no developmental toxicity was observed in the rabbit and rat studies reviewed, and no primary neurotoxicity was seen in the acute neurotoxicity study. Therefore, no risk has been identified for this scenario and a risk assessment is not needed.

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 also not required. In a 21-day dermal toxicity study the NOAEL 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 on a chronic toxicity study in rats with a NOAEL of 18.2 mg/kg/day. The endpoint effects were reduced body weights and bile duct lesions 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.* Carcinogenicity testing of azoxystrobin in two appropriate species of mammals revealed no evidence that this fungicide is carcinogenic. Therefore, EPA classifies azoxystrobin as ''not likely'' to be a human carcinogen in line with the proposed revised Cancer Guidelines.

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 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 1 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. *Short- and intermediate-term exposure and risk.* Short- and intermediate-term risk assessments are performed for a food-use pesticide if a toxicology study has indicated the possibility of an effect of concern as a result of an exposure of 1 day to several months. The Agency did conduct such an assessment because no toxicological endpoint of concern was identified.

iii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, the Agency has made very conservative assumptions -- 100% of potatoes 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)	Percent RFD
U.S. Population (48 States)	0.003	1.8
Nursing Infants (<1 year old) ..	0.004	2
Non-Nursing Infants (<1 year old)	0.011	8
Children (1-6 years old)	0.007	4
Children (7-12 years old)	0.004	2
Hispanics	0.004	2
Non-Hispanics Others	0.005	3
U.S. Population (summer season)	0.003	2
U.S. Population (Northeast region)	0.003	2
U.S. Population (Western region)	0.003	2
U.S. Population (Pacific region)	0.003	2
Females (13+, nursing)	0.003	2
Females (13-19, not pregnant or nursing)	0.002	1

Neither the U.S. population as a whole nor any of the subgroups whose food consumption patterns were analyzed for dietary exposure and risk to azoxystrobin reached even one-twelfth of the RfD under these assumed theoretical maximum exposures to azoxystrobin for all published, pending, and proposed tolerances. Moreover, real-world exposure is likely to be substantially lower than this.

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 acute risk assessment was not appropriate since no toxicological endpoint of concern was identified for this scenario during review of the available data.

ii. *Short- and intermediate-term toxicity.* A short- and intermediate-term risk assessment was not appropriate since no toxicological endpoint of concern was identified for this scenario during review of the available data.

iii. *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 generic expected environmental concentration modeling (GENEEC) for azoxystrobin on bananas, grapes, peaches, peanuts, pecans, tomatoes, and wheat are listed in the 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 drinking water levels of concern (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

Population Subgroup	RfD(mg/kg/day)	TMRC Food Exposure (mg/kg/day)	Max Water Exposure (mg/kg/day)[1]	DWLOC [2,3,4] (µg/L)
US Population (48 States)	0.18	0.0027	0.178	6200
Females (13 + years old, not pregnant or nursing)	0.18	0.0019	0.178	5300
Non-nursing Infants (< 1 year old)	0.18	0.0113	0.169	1680

[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. The Agency has recently registered another strobilurin type pesticide for a nonfood use. 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. 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. *Acute risk.* This risk assessment is not necessary since no acute toxicological end-point of concern was identified for this exposure scenario during review of the available data.

2. *Chronic risk.* Using the conservative TMRC exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, the Agency has estimated that exposure to azoxystrobin from food will utilize 2% of the RfD for the U.S. population as a whole. The Agency generally is not concerned about exposures below 100 percent 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, the Agency does not expect the aggregate exposure to exceed 100% of the RfD. Under current Agency guidelines, the registered non-dietary uses of azoxystrobin do not constitute a chronic exposure scenario and EPA concludes that there is a reasonable

certainty that no harm will result from aggregate exposure to currently registered azoxystrobin residues.

3. *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 needed for azoxystrobin because no dermal or systemic effects were seen in the repeated dose dermal study at the limit dose. Additionally, no indoor or outdoor residential exposure uses are currently registered for azoxystrobin.

4. *Aggregate cancer risk for U.S. population.* This risk assessment is also not needed. Azoxystrobin is classified as ''not likely'' to be a carcinogen under the proposed revised Carcinogenicity Guidelines because carcinogenicity testing was performed on two appropriate species and no evidence of carcinogenicity was found.

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

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 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*— a. *Rabbit.* In the developmental toxicity study in rabbits, developmental NOAEL was 500 mg/kg/day, the highest dose tested (HDT). Because there were no treatment-related effects, the developmental LEL was >500 mg/kg/day. The maternal NOAEL 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— Rat.* In the reproductive toxicity study (MRID #43678144) 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. *Conclusion.* The pre- and post-natal toxicology database for azoxystrobin is complete with respect to current toxicological data requirements. The results of these studies indicate that infants and children are no more sensitive to exposure to azoxystrobin than are adults, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation reproductive toxicity study in rats. Accordingly, EPA has determined that the standard margin of safety will protect the safety of infants and children and the additional tenfold safety factor can therefore be removed.

2. *Chronic risk.* Using the exposure assumptions described above, EPA has concluded that aggregate exposure to azoxystrobin from food will utilize 2 to 8% 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.

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

IV. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of azoxystrobin as well as the nature of the residues is adequately understood for purposes of the time-limited tolerance. Plant metabolism has been evaluated in three diverse crops; grapes, wheat and peanuts, which is required to define similar metabolism of azoxystrobin in a wide range of crops. Parent azoxystrobin is the major component found in crops. Azoxystrobin does not accumulate in crop seeds or fruits. Metabolism of azoxystrobin in plants is complex, with more than 15 metabolites identified. These metabolites are present at low levels, typically much less than 5% of the total radioactive residue level.

The qualitative nature of the residue in animals is adequately understood for the purposes of this proposed 1-year time-limited tolerance. Establishment of a time-limited tolerance of 0.03 ppm for azoxystrobin in/on potatoes is not expected to lead to detectable azoxystrobin residues in animal commodities.

B. Analytical Enforcement Methodology

An analytical method, gas chromatography with nitrogen-phosphorus detection (GC-NPD) or, in mobile phase, by high performance liquid chromatography with ultraviolet detection (HPLC-UV), is available for enforcement purposes with a limit of detection that allows monitoring of food with residues at or above the level proposed for this time-limited tolerance. The Agency has concluded that the method is adequate for enforcement of tolerances in/on other non-oily raw agricultural commodities. The Agency also concludes that this method is adequate for enforcement of the proposed time-limited tolerance in/on potatoes. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703-305-5229).

C. Magnitude of Residues

Residues of azoxystrobin and its *Z* isomer are not expected to exceed 0.03 ppm in/on potatoes as a result of this EUP use. A time-limited tolerance should be established at this level.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits for azoxystrobin in/on potatoes.

E. Rotational Crop Restrictions

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

V. Conclusion

Therefore, a time-limited tolerance is established for combined residues of azoxystrobin and its *Z* isomer in potatoes at 0.03 ppm. This tolerance will expire and is revoked on October 18, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

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(e) and (r) 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 December 15, 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.

VII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300744] (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.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a time-limited tolerance under FFDCA section 408(d). EPA is establishing this tolerance in cooperation with Wisconsin potato growers, University extension specialists, and Zeneca Ag Products, Inc. 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 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).

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Agency previously assessed whether establishing tolerances, exemption 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 Intergovernmental Partnerships* (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 the Office of Management and Budget (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 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 to the Comptroller General of the United States. EPA has submitted 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 today's publication of this 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, Feed additives, Food additives, Reporting and recordkeeping requirements.

Dated: October 6, 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(a) is amended by designating the text following the paragraph heading as paragraph (a)(1) and adding paragraph (a)(2) to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a) * * *

(2) *Time-limited tolerance.* A tolerance to expire on October 18, 1999, is established for the combined residues of azoxystrobin [methyl(*E*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] and its *Z* isomer in or on the following commodity.

Commodity	Parts per million	Expiration Date
Potatoes	0.03	October 18, 1999

* * * * *

[FR Doc. 98–27835 Filed 10–15–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300732; FRL–6035–2]

RIN 2070–AB78

Hexythiazox; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of hexythiazox [trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide] (CAS No. 78587–05–0) and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parts per million (ppm) of the parent compound) in or on dried hops. BASF Corporation, Agricultural Products requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective October 16, 1998. Objections and requests for hearings must be received by EPA on or before December 15, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300732], 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–300732], 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