unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

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

C. Executive Order 13084

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

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

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and 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: October 21, 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. In §180.515 is amended by revising paragraph (b) to read as follows:

§ 180.515 Carfentrazone-ethyl; tolerances for residues

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of the herbicide carfentrazone-ethyl and its chloropropionic acid metabolite in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. These tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Rice, grain	0.1	10/31/99
Rice, straw	1.0	10/31/99

* * * * *

[FR Doc. 98–31546 Filed 11–24–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300759; FRL 6045–4]

RIN 2070–AB78

Azoxystrobin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of azoxystrobin or methyl (*E*)-2-(2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl)-3-methoxyacrylate) and its *Z isomer* in or on sugar beets and soybeans. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on sugar beets and soybeans. This regulation establishes maximum permissible levels for residues of azoxystrobin in these food commodities 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 will be revoked on June 30, 2000.

DATES: This regulation is effective November 25, 1998. Objections and requests for hearings must be received by EPA on or before January 25, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300759], 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–300759], 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 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300759]. 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: Jacqueline Gwaltney, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6792; e-mail: gwaltney.jackie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for combined residues of fungicide azoxystrobin and its *Z isomer*, in or on sugar beets, and soybeans at 0.05 and 1.0 part per million (ppm), respectively. These tolerances will expire and will be revoked on June 30, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (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 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 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 Sugar Beets and Soybeans, and FFDCA Tolerances

The Minnesota Department of Agriculture requested an emergency exemption in April of 1998 for the control of cercospora leafspots on sugar beets. The registered alternative fungicides benomyl, thiabendazole thiophanate methyl, triphenyl tin hydroxide (TPTH), EBDCs (Mancozeb and Maneb), and copper hydroxide for controlling cercospora leaf spots do not control the disease effectively because of resistance and/or tolerance in the pathogen. Moderately resistant cultivars of sugar beet are available, but their yield potentials are lower than the susceptible. Cultural practices are not very effective in managing the disease. During 1998, the disease severity is expected to be higher and yield losses significant due to mild winter temperature (El Nino effects).

Minnesota also claims that TPTH is still used in controlling the disease, but it is significantly less effective than in the past.

In August 1998, the Arkansas Department of Agriculture also requested an emergency exemption for the control of aerial blight on soybeans. The disease is particularly aggressive in years of above-normal night temperatures, high humidity, and frequent rainfall. Conditions in 1998 have been near perfect for development of sheath blight of rice, with night temperatures in the 78–82 degree range and oppressively high relative humidity within crop canopies. Rainfall in northeast Arkansas has also contributed to the problem. Soybean has just entered the most susceptible flowering and early pod formation stages and aerial blight has become exceptionally aggressive as weather conditions continue to favor its development. Damage to soybean yield is through destruction of foliage, and to a greater extent-flowers, pods and seeds. Yield losses in some Arkansas fields in the past have been estimated as high as 50%, however, this is a very rare occurrence most years.

For these reasons, EPA has authorized under FIFRA section 18 the use of azoxystrobin on sugar beets for control of cercospora leafspots in Minnesota, and the use of azoxystrobin on soybeans for control of aerial blight in Arkansas.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of azoxystrobin in or on sugar beets and

soybeans. 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 will be revoked on June 30, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on sugar beets and soybeans 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 sugar beets and soybeans 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 Minnesota or Arkansas to use this pesticide on these 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. 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.

3. *Chronic toxicity*. EPA has established the reference dose (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 no observed adverse effect level (NOAEL) of 18.2 mg/kg/day. Reduced body weights and bile duct lesions were observed at the lowest effect level (LEL) of 34 mg/kg/day. An Uncertainty Factor (UF) of 100 was used to account for both the interspecies extrapolation and the intraspecies variability.

4. *Carcinogenicity*. The Agency 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:

2. *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.

3. *Chronic exposure and risk*. In conducting this chronic dietary risk assessment, EPA has made very conservative assumptions -- 100% of all commodities having azoxystrobin tolerances will contain azoxystrobin residues and those residues would be at the level of the tolerance with the exception of raisins and grape juice -- which result in an over estimation of human dietary exposure. Thus, in making a safety determination for this tolerance, The Agency 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).	0.0026	1.5%
All Infants (<1 year old).	0.0079	4.4%
Nursing Infants (<1 year old).	0.0026	1.5%
Non-Nursing Infants (<1 year old).	0.010	5.6%
Children (1–6 years old).	0.0065	3.6%
Children (7–12 years old).	0.0035	1.9%
U.S. Population (Summer Season).	0.0030	1.7%
Northeast Region ...	0.0029	1.6%
Western Region	0.0029	1.6%
Hispanics	0.0036	2.0%
Non-Hispanics Blacks.	0.0029	1.6%
Non-Hispanics (Other Than Black or White).	0.0045	2.5%

The subgroups listed above are:

i. The U.S. population (48 states).

ii. Those for infants and children.

iii. The other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

4. *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.

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

6. *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 the following table. 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 EPA level of concern.

	Chronic RfD (mg/kg/day)	TMRC Food Exposure (mg/kg/day)	Max Water Exposure[1] (mg/kg/day)	DWLOC [2,3,4] (µg/L)
US Population (48 States)	0.18	0.0026	0.18	6200
Females (13 + years old, not pregnant or nursing)	0.18	0.0029	0.18	5300
Non-nursing Infants (< 1 year old)	0.18	0.010	0.17	1700

[1] Maximum Water Exposure (mg/kg/day) = Chronic 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

7. *From non-dietary exposure.* Azoxystrobin is not currently registered for any residential uses.

8. *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, EPA has estimated the exposure to azoxystrobin from food will utilize 1.5% of the RfD for the U.S. population. 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, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Under current EPA guidelines, the registered non-dietary uses of azoxystrobin do not constitute a chronic exposure scenario. EPA 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 Cancer Risk for U.S. Population

The Agency determined that azoxystrobin should be classified as

''Not Likely'' to be a human carcinogen according to the proposed revised Cancer Guidelines. The Agency has therefore not conducted a cancer risk assessment.

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

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

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the 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.

ii. *Developmental toxicity studies* — a. *Rabbit*. In the developmental toxicity study in rabbits, developmental NOAEL 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 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 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. *Pre- and post-natal sensitivity*. The pre- and post-natal toxicology data base for azoxystrobin is complete with respect to current toxicological data requirements.

v. *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 the Agency.

2. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to azoxystrobin from food will utilize 1.9% to 5.6% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to azoxystrobin in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. 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. These data are being translated for sugar beets for this section 18 temporary tolerance.

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*.

As sugar beet commodities are not considered to be major poultry feed items, the nature and the magnitude of residues in poultry and eggs are not of concern for the this section 18.

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. RAB2 concludes this method is adequate for enforcement of the necessary section 18 tolerances on livestock commodities.

C. Magnitude of Residues

Residue data for azoxystrobin and its *Z-isomer* in banana pulp and in watercress were translated to sugar beet roots and tops, respectively. Residues are not expected to exceed 0.05 ppm in sugar beet roots and 0.2 ppm in sugar beet tops as a result of this section 18 use.

According to the OPPTS Test Guidelines (860.1520), a maximum theoretical concentration factor of 12.5 is noted for the processing of sugar beet roots to refined sugar. The Agency has applied this factor to the tolerance level of sugar beet roots to determine the tolerance level for refined sugar and molasses. Thus, the tolerance level for azoxystrobin and its *Z-isomer* in beet, sugar, refined sugar and molasses will be set at 0.7 ppm. The Agency applied a factor of 20 to the tolerance level of sugar beet roots to determine the tolerance level for the dried pulp. Therefore, the tolerance level for

azoxystrobin and its *Z-isomer* in beet, sugar, pulp, dried will be set at 1.0 ppm.

The existing ruminant tolerances established in conjunction with a previous section 18 request are adequate to cover the proposed uses. The addition of sugar beet commodities to the diet of ruminants will not significantly increase the dietary burden for azoxystrobin residues. The expiration date of livestock commodity tolerances will be extended to the expiration date of the sugar beet tolerances established with this section 18 request. In addition, EPA will establish tolerances for residues of azoxystrobin and its *Z-isomer* in/on kidney of goats, hogs, horses, and sheep at 0.06 ppm.

D. International Residue Limits

There are no Codex, Canadian, or Mexican Maximum Residue Limits (MRL) for azoxystrobin on sugar beet commodities. Thus, harmonization is not an issue for these section 18 requests.

E. Rotational Crop Restrictions

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

VI. Conclusion

Therefore, tolerances are established for combined residues of azoxystrobin and its *Z isomer* in sugar beets and soybeans at 0.05 ppm, and 1.0 ppm respectively .

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 January 25, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given 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 Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300759] (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

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under FFDCA section 408(l)(6). 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.

B. Executive Order 12875

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

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

C. Executive Order 13084

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

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

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 submitted a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 10, 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. In §180.507, by alphabetically adding the following commodities to the table in paragraph (b) to read as follows:

§180.507 Azoxystrobin; tolerances for residues.

* * * * *

(b)* * *

Commodity	Parts per million	Expiration/Revocation Date
Aspirated soybean grain fractions	10.	6/30/00
* * *	* * * *	
Kidney of goats, hogs, and sheep grazed on sugar beets	0.06	6/30/00
* * *	* * * *	
Sugar beet roots	0.05	6/30/00
Sugar beet tops	0.20	6/30/00
Sugar beet, molasses	0.70	6/30/00
Sugar beet, pulp, dried	1.0	6/30/00
Sugar beet, refined sugar	0.70	6/30/00
Soybean hay	1.0	6/30/00
Soybean forage	0.2	6/30/00
Soybean hulls	2.0	6/30/00
Soybean meal	0.3	6/30/00
Soybean oil	2.0	6/30/00

Commodity	Parts per million	Expiration/Revocation Date
Soybean seed	0.1	6/30/00
Soybean silage	2.0	6/30/00
* * *	* * * *	

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[FR Doc. 98–31545 Filed 11–24–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300754; FRL 6041–4]

RIN 2070–AB78

Tebufenozide; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule extends a time-limited tolerance for residues of the insecticide tebufenozide and its metabolites in or on leafy vegetables (Crop Group 4) and brassica leafy vegetables (Crop Group 5) at 5.0 parts per million (ppm) for an additional 18–month period, to August 31, 2000. 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 leafy vegetables (Crop Group 4) and brassica leafy vegetables (Crop Group 5). Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement of 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.

DATES: This regulation becomes effective November 25, 1998. Objections and requests for hearings must be received by EPA, on or before January 25, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300754], 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–300754], 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. Follow the instructions in Unit II. of this preamble. No Confidential Business Information (CBI) should be submitted through e-mail.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 272, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 308–9367; e-mail: ertman.andrew@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of March 18, 1998; (63 FR 13126) (FRL 5773–1), which announced that on its own initiative under section 408(e) of the FFDCA, 21 U.S.C. 346a(e) and (l)(6), it established a time-limited tolerance for the residues of tebufenozide and its metabolites in or on leafy vegetables (except brassica leafy vegetables; Crop Group 4) and brassica leafy vegetables (Crop Group 5) at 5.0 ppm, with an expiration date of February 28, 1999. EPA established the tolerance because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement of a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of tebufenozide on leafy vegetables and brassica leafy vegetables for this year growing season due to the continuing emergencies in both California and Arizona. The beet armyworm (BAW) has been causing crop damage due to infestations all season long because the pest will attack crops at emergence, often causing severe loss. Infestations later in the crop cycle will stunt growth, damage and contaminate the harvestable portion of the crop.

Because of the BAW's ability to feed on such a wide array of plants, it has demonstrated an enormous capacity for detoxifying plant defense chemicals and insecticides. In the leafy vegetable and cole crop groups, there are few efficacious products for BAW control. The last 5 years have seen a marked increase in the amounts of active ingredient necessary to achieve control of the beet armyworm in vegetables with failures being reported with all products and combinations. After having reviewed the submission, EPA concurs that emergency conditions exist for this state. EPA has authorized under FIFRA section 18 the use of tebufenozide on leafy vegetables (except brassica leafy vegetables; Crop Group 4) and brassica leafy vegetables (Crop Group 5) for control of the beet armyworm in Arizona and California.

EPA assessed the potential risks presented by residues of tebufenozide in or on leafy vegetables (except brassica leafy vegetables; Crop Group 4) and brassica leafy vegetables (Crop Group 5). In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of March 18, 1998. Based on that data and information considered, the Agency reaffirms that extension of the time-limited tolerance will continue to meet