specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950, May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104-121, 110 Stat. 847), EPA 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 General Accounting Office prior to publication of the rule in today's **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: May 28, 1997.

James Jones,

Acting 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 § 180.434, paragraph (b) is amended by alphabetically adding the tolerances to the table to read as follows:

§ 180.434 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ Revocation Date
* * * *	*	*
Dry bean forage	8.0	December 31, 1998
Dry bean hay	8.0	December 31, 1998
Dry beans	0.5	December 31, 1998
* * * *	*	*

* * * * *

[FR Doc. 97–15373 Filed 6–12–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300497; FRL–5718–6]

RIN 2070-AC78

Azoxystrobin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the fungicide azoxystrobin in or on the raw agricultural commodities rice and rice straw and hulls, liver of cattle, hog, goat, horse, sheep, and poultry; meat and fat of cattle, goat, horse, sheep, poultry, and swine; kidney and milk of cattle; and eggs in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of azoxystrobin on rice in Mississippi. This regulation establishes maximum permissible levels for residues of azoxystrobin on the commodities listed above 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 May 30, 1999.

DATES: This regulation becomes effective June 13, 1997. Objections and requests for hearings must be received by EPA on August 12, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP–300497, 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 document control number, OPP–300497, should be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), 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. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number OPP–300497. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Virginia Dietrich, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Document Processing Desk, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 308–9359, e-mail: dietrich.virginia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, 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 tolerances for residues of the fungicide azoxystrobin (methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate) in or on rice grain at 4 ppm, rice straw at 10 ppm, and rice hulls at 20 ppm. These tolerances will expire and are revoked on May 30, 1999. After May 30, 1999, EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The 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 CFR 58135, November 13, 1996) (FRL–5572–9).

New section 408(b)(2)(A)(i) 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, 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) 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. Section 408(l)(6) also requires EPA to promulgate regulations by August 3, 1997, governing the establishment of tolerances and exemptions under section 408(l)(6) and requires that the regulations be consistent with section 408(b)(2) and (c)(2) and FIFRA section 18.

Section 408(l)(6) allows EPA to establish tolerances or exemptions from the requirement for a tolerance, in connection with EPA's granting of FIFRA section 18 emergency exemptions, without providing notice or a period for public comment. Thus, consistent with the need to act expeditiously on requests for emergency exemptions under FIFRA, EPA can establish such tolerances or exemptions under the authority of section 408(e) and (l)(6) without notice and comment rulemaking.

In establishing section 18-related tolerances and exemptions during this interim period before EPA issues the section 408(l)(6) procedural regulation and before EPA makes its broad policy decisions concerning the interpretation and implementation of the new section 408, EPA does not intend to set precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Rather, these early section 18 tolerance and exemption decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further rulemaking and policy development. EPA intends to act on section 18-related tolerances and exemptions that clearly qualify under the new law.

II. Emergency Exemptions for Azoxystrobin on Rice and FFDCA Tolerances

On January 30, 1997, the State of Mississippi, Department of Agriculture and Commerce requested a specific exemption under FIFRA section 18 for the use of azoxystrobin to control sheath blight on rice. Similar requests were received from Arkansas, Louisiana, Missouri, and Texas. The applicant stated that growers will experience significant economic loss if the pest is not adequately controlled. After having reviewed their submission, EPA concurs that an emergency condition exists.

As part of its assessment of these applications for emergency exemption, EPA assessed the potential risks presented by residues of azoxystrobin on rice. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided to grant the section 18 exemptions only after concluding that the necessary tolerance under FFDCA section 408(l)(6) would clearly be consistent with the new safety standard and with FIFRA section 18. These tolerances for azoxystrobin will permit the marketing of rice treated in accordance with the provisions of the section 18 emergency exemptions. Consistent with the need to move quickly on the emergency exemptions 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 these tolerances will expire and are revoked on May 30, 1999, under FFDCA section 408(l)(5), residues of azoxystrobin not in excess of the amount specified in the tolerances remaining in or on rice after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, the emergency exemptions. 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.

EPA has not made any decisions about whether azoxystrobin meets the requirements for registration under FIFRA section 3 for use on rice or whether permanent tolerances for azoxystrobin for rice would be appropriate. This action by EPA does not serve as a basis for registration of azoxystrobin by a State for special local needs under FIFRA section 24(c). Nor does this action serve as the basis for any State other than California to use this product on this rice under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR 180.166. For additional information regarding the emergency exemptions 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. For many of these studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered by EPA to pose a reasonable certainty of no harm.

EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

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

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, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water. 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. 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 percent of the rice 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 rice treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. Azoxystrobin is not registered by EPA for indoor or outdoor residential use. 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 the time-limited tolerances for residues of azoxystrobin in or on rice grain at 4 parts per million (ppm); rice straw at 10 ppm; rice hulls at 20 ppm; liver of cattle, goat, horse, and sheep at 0.3 ppm, meat and fat of cattle, goat, horse, sheep, poultry, and swine at 0.01 ppm; cattle kidney at 0.06 ppm; milk at 0.006 ppm; poultry liver at 0.4 ppm; hog liver at 0.2 ppm; and eggs at 0.4 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

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

2. *Chronic risk*. The RfD, based on a chronic toxicity study in rats with a NOEL of 18.2 milligrams/kilograms/day (mg/kg/day), was established at 0.18 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 extra-polation and the intraspecies variability.

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

4. *Cancer risk*. Azoxystrobin has been classified by the Agency's RfD Committee (November 7, 1996) as ''Not Likely'' to be carcinogenic to humans via relevant routes of exposure. This decision was made according to the 1996 proposed guidelines. Therefore, cancer risk was not assessed.

5. *Risk to infants and children*--i. *Developmental toxicity studies*--a. Rabbit. In the developmental toxicity study in rabbits, the developmental NOEL was 500 mg/kg/day, at the highest dose tested (HDT). Because there were no treatment-related effects, the developmental LEL was ≥500 mg/kg/day. The maternal NOEL was 150 mg/kg/day. The maternal LEL of 500 mg/kg/day was based on decreased body weight gain during dosing.

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

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

B. Aggregate Exposure and Risk

Tolerances for residues of azoxystrobin do not exist. In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide

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

At present there are no tolerances for residues of azoxystrobin because it is currently registered under section 3 of FIFRA only for use on golf courses and commercial turf farms. Short and intermediate term aggregate risk assessments were not conducted on azoxystrobin since no toxic endpoints for these durations of exposure were identified in the toxicological data base.

The Agency identified chronic exposure as appropriate for aggregate risk assessment. The Agency determined that an acute exposure analysis is not required because no acute dietary endpoints for azoxystrobin were identified.

The Agency identified chronic exposure as appropriate for aggregate risk assessment. The aggregate chronic risk is equal to the sum of the chronic risk from exposure from food + water + residential (indoor and outdoor) uses. Azoxystrobin is not registered for any residential uses so no exposure from this route is expected. The Agency estimates that aggregate risk (food plus drinking water) would not exceed the RfD for azoxystrobin.

The chronic dietary (food only) risk assessment used the TMRC. Therefore, the resulting exposure estimates should be viewed as conservative; further refinement using anticipated residues and/or percent of crop treated would result in lower dietary exposure estimates. For chronic dietary (food only) risk estimates, the population subgroup with the largest percentage of the RfD occupied is non-nursing infants less than 1 year old at 3.9% of the RfD.

Azoxystrobin and its transformation products may potentially contaminate surface waters through spray drift or surface water run-off. In addition, transformation products of azoxystrobin exhibit properties of pesticides found in ground water; some persistence and mobility in laboratory and field studies. For this reason, exposure to azoxystrobin through drinking water was considered during the risk assessment.

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges the Agency is continuing to examine are all well below the level that would cause azoxystrobin to exceed the RfD if the tolerances being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with azoxystrobin in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerances are granted.

Using these conservative estimates, the sum total of the aggregate chronic risk estimates (food, water, residential indoor, and outdoor) for azoxystrobin for the population subgroup with the largest percentage of the RfD occupied, non-nursing infants less than 1 year old, is 13.9%. In the best scientific judgement of the Agency, the azoxystrobin aggregate chronic risk does not exceed our level of concern.

C. Cumulative Exposure to Substances with Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' 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.

D. Safety Determinations for U.S. Population

Based on the completeness and reliability of the toxicity data and the conservative TMRC dietary exposure assumptions, EPA has concluded that dietary exposure from food to azoxystrobin will occupy 1 percent of the RfD for the U.S. population. EPA generally has no concern for 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. Whatever reasonable bounding figure the Agency eventually decides upon for the contribution from water, that number is expected to be well below 99 percent of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to azoxystrobin residues.

E. Determination of Safety for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional 10-fold MOE (safety factor) for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the data base unless EPA determines that a different MOE (safety) will be safe for infants and children. MOE (safety) are often referred to as uncertainty (safety) factors. EPA believes that reliable data support using the standard MOE (usually 100x for combined inter- and intra-species variability) and not the additional 10-fold MOE 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. Based on current toxicological data requirements, the data base for azoxystrobin relative to pre (provided by rat and rabbit developmental studies) and post-natal (provided by the rat reproduction study) toxicity is complete.

In assessing the adequacy of the standard uncertainty factor for 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 pesticide exposure during pre-natal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

Developmental toxicity from azoxystrobin was not observed in developmental studies using rats and rabbits. The pre- and post-natal toxicology data base for azoxystrobin is complete with respect to current toxicological data requirements. The results of these studies indicate that infants and children are not more sensitive to exposure, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation reproductive toxicity study in rats.

The results of the rabbit developmental toxicity study did not indicate that an acute dietary risk assessment needed to be performed. For rabbits, the developmental toxicity NOEL was 500 mg/kg/day, at the HDT. The maternal NOEL of 150 mg/kg/day was based on decreased body weight gain at the LEL of 500 mg/kg/day. For rats, the developmental toxicity NOEL was 100 mg/kg/day at the HDT. The maternal NOEL was not determined and the maternal LEL of 25 mg/kg/day at the LDT was based on increased salivation.

In the 2-generation reproductive toxicity study, the reproductive and parental (systemic) NOEL were both 32.3 mg/kg/day. The reproductive LEL of 165.4 mg/kg/day was based on increased weanling liver weights and decreased body weight in pups of both generations. These effects occurred in the presence of parental (systemic) toxicity. The parental (systemic) LEL of 165.4 mg/kg/day was based on decreased body weights, decreased food consumption and increased adjusted liver weights in females, and cholangitis generations. The Agency notes that the NOEL of 18.2 mg/kg/day used to establish the RfD is approximately 2-fold lower than the reproductive NOEL; therefore, the Agency concludes that this section 18 request does not represent any unacceptable pre- or post-natal risk to infants and children.

Despite the potential for exposure to drinking water, EPA has concluded that the percentage of the RfD that will be utilized by dietary exposure (including drinking water exposure) to residues of azoxystrobin does not exceed 100 percent for any of the population subgroups. Based on TMRC exposure estimates for food, as described above, EPA has concluded that the percentage of the RfD that will be utilized by dietary exposure to residues of azoxystrobin ranges from 11 percent for children 1 to 6 years old, and up to 13.9 percent for non-nursing infants (the most highly exposed population subgroup). Therefore, taking into account the completeness and reliability of the toxicity data and the conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to azoxystrobin residues. Therefore, EPA believes that reliable data show that the standard uncertainty factor will be protective of the safety of infants and children and an additional uncertainty factor is not needed.

Based on the above, EPA concludes that reliable data support use of the standard 100-fold MOE/uncertainty factor and that an additional safety factor is not needed to protect the safety of infants and children.

V. Other Considerations

The metabolism of azoxystrobin in plants is adequately understood for the purposes of this tolerance. There is no Codex maximum residue level established for residues of azoxystrobin on rice. An adequate enforcement method, GC-NPD or HPLC-UV, is available to enforce the tolerance expression on plant commodities. An enforcement method (GC-NPD) has been proposed for animal tissues in association with a recently submitted petition on wheat. The method has been submitted for a petition method validation. These methods are available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm 1128, 1921 Jefferson Davis Hwy., Arlington, VA, 703-305-5805.

VI. Conclusion

Therefore, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of azoxystrobin and its Z-isomer to support this section 18 specific exemption:

eggs: 0.4 ppm.
kidney, cattle: 0.06 ppm,
liver of cattle, goat, horse, and sheep: 0.3 ppm,
liver, hog: 0.2 ppm,
liver, poultry: 0.4 ppm,
meat and fat of cattle, goat, horse, sheep, poultry, and swine: 0.01 ppm,
milk: 0.006 ppm,
rice, grain: 4 ppm,
rice, straw: 10 ppm,
rice, hulls: 20 ppm,

These tolerances will expire and are revoked on May 30, 1999.

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 August 12, 1997, file written objections to any aspect of this regulation (including the automatic revocation provision) and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Docket

A record has been established for this rulemaking under docket number [OPP–300497]. A public version of this record, 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 Rm. 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing requests, 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. The official rulemaking record is the paper record maintained at the address in **ADDRESSES** at the beginning of this document.

IX. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines ''a significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

This action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), entitled Enhancing the Intergovernmental Partnership, or special consideration as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply.

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104-121, 110 Stat. 847), EPA 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 General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2) of the APA as amended.

List of Subjects in 40 CFR Part 180

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

Dated: June 2, 1997.

James Jones,

Acting 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. By adding § 180.507 to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* Time limited tolerances are established for residues of the fungicide azoxystrobin in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance is specified in the following table. The tolerance expires and will be revoked by EPA on the date specified in the table.

Commodity	Parts per million	Expiration/Revocation Date
Eggs	0.4	5/30/99
Kidney, cattle	0.06	5/30/99
Liver of cattle, goat, horse, and sheep	0.3	5/30/99
Liver, hog	0.2	5/30/99
Liver, poultry	0.4	5/30/99
Meat and fat of cattle, goat, horse, sheep, poultry, and swine	0.01	5/30/99
Milk	0.006	5/30/99
Rice, grain	4	5/30/99
Rice, hulls	20	5/30/99
Rice, straw	10	5/30/99

(c) *Tolerances with regional registration*. [Reserved]

(d) *Indirect or inadvertent residues*. [Reserved]

[FR Doc. 97–15564 Filed 6–12–97; 8:45 am]

BILLING CODE 6560–50–F

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

41 CFR Parts 51–3, 51–4, and 51–6

Miscellaneous Amendments to Committee Regulations

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Final rule.

SUMMARY: The Committee is making changes to four sections of its regulations to clarify them and improve the efficiency of operation of the Committee's Javits-Wagner-O'Day (JWOD) Program. The changes are necessary to assure consistency with an earlier regulation change, eliminate an unnecessary rule, encourage more efficient contracting, and inform the public of a change in Committee policy on military resale items.

EFFECTIVE DATE: July 14, 1997.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: G. John Heyer (703) 603–7740. Copies of this notice will be made available on request in computer diskette format.

SUPPLEMENTARY INFORMATION: Since the Committee's regulations were last amended on October 20, 1995 (60 FR 54199), the Committee has noticed several instances where minor changes or clarifications are needed. The Committee has decided to make these changes in one rulemaking rather than individually.

In a 1994 revision (59 FR 59342), 41 CFR 51–3.2(d), concerning the requirement for central nonprofit agencies to recommend to the Committee commodities and services for addition to the Procurement List, with initial fair market prices, was split into two paragraphs (41 CFR 51–3.2(d) and (e)) to make it consistent with the Committee's statute, which treats addition of commodities or services to the Procurement List and determination of fair market prices as two distinct Committee functions. However, the related provision at 41 CFR 51–3.2(c) requiring central nonprofit agencies to obtain from Federal contracting activities the information needed for the Committee to perform these functions was not similarly divided. The change to 41 CFR 51–3.2(c) makes this division.

The Committee's requirements for a nonprofit agency to maintain its qualification to participate in the JWOD Program (41 CFR 51–4.3) include compliance with applicable Department of Labor (DOL) compensation, employment, and occupational health and safety standards (paragraph (b)(2)), and establishment of written procedures to encourage filling of vacancies within the nonprofit agency by promotion of qualified employees who are blind or have other severe disabilities (paragraph (b)(9)). Because of the dollar value of their Federal contracts under the JWOD Program, most JWOD nonprofit agencies are required by DOL employment standards promulgated under authority of section 503 of the Rehabilitation Act to have procedures like those required by paragraph (b)(9). The Committee strongly endorses the policies underlying these DOL employment standards. Accordingly, the Committee is removing paragraph (b)(9) and revise paragraph (b)(2) to make clear to the public that the DOL standards it mentions include the procedures formerly required by paragraph (b)(9).

Commodities and services added to the Procurement List normally remain on it indefinitely. The Administration's reinvention of Government initiatives encourage the use of long-term contracts to minimize administrative delay and expense. The Committee is amending its existing regulation (41 CFR 51–6.3) on use of long-term ordering agreements for JWOD commodities to add a paragraph encouraging contracting activities to use the longest contract term available to them when buying commodities or services from the JWOD Program.

The Committee's regulation on military resale commodities (41 CFR 51–6.4) has traditionally identified the specific numbered commodity series to which it applies. The Committee is amending this regulation to include two new series which have been authorized by the Committee for the military resale program.

Public Comments on the Proposed Rule

The Committee published the proposed rule in the **Federal Register** of March 27, 1997 (62 FR 14660). No comments were received. Accordingly, the Committee's regulations are being amended as stated in the proposed rule.

Regulatory Flexibility Act

I certify that this revision of the Committee regulations will not have a significant economic impact on a substantial number of small entities because the revision clarifies program policies and does not essentially change the impact of the regulations on small entities.

Paperwork Reduction Act

The Paperwork Reduction Act does not apply to this final rule because it contains no information collection or recordkeeping requirements as defined in that Act and its regulations.

Executive Order No. 12866

The Committee has been exempted from the regulatory review requirements of the Executive Order by the Office of Information and Regulatory Affairs. Additionally, the final rule is not a significant regulatory action as defined in the Executive Order.