IX. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408 (d), 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 acations published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **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: June 30, 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. Section 180.433 is amended by designating the existing text as paragraph (a) and adding a heading, by adding paragraph (b), and by adding and reserving paragraphs (c) and (d) to read as follows:

§ 180.433 Sodium salt of fomesafen; tolerance for residues.

(a) *General .* * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of the herbicide fomesafen, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Bean, snap	0.05	June 30, 1998

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

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

[FR Doc. 97–17933 Filed 7–8–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300508; FRL–5728–3]

RIN 2070–AB78

Azoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This regulation establishes tolerances for residues of the fungicide azoxystrobin (CAS Reg. No. 131860–33–8 and PC Code 128810) and its Z-isomer in or on the raw agricultural commodities bananas, grapes, peaches, peanuts, pecans, and tomatoes, and the processed foods peanut oil and tomato paste. Zeneca Ag Products submitted three petitions to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170) requesting the tolerances. Azoxystrobin has been processed as a reduced risk pesticide for its uses in/on bananas, grapes, peaches, peanuts, and tomatoes.

DATES: This regulation became effective on June 3, 1997. Written objections and requests for hearings must be received on or before September 8, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300508], may 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 should be identified by the document control number and submitted to: Public Information and Records Integrity Branch, Information Resources and Services (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

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 in 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–300508]. 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: Cynthia Giles-Parker, Product Manager (22), Registration Division, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number and e-mail address: Room 247, CM #2, 1921 Jefferson Davis Highway, Arlington, VA (703–305–7740). e-mail: giles-parker.cynthia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 12, 1997 (62 FR 11442)(FRL–5589–6), EPA issued a notice pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 346a(d), announcing the filing of three pesticide tolerance petitions (PP 5F4541, 6F4642, and 6F4762) by Zeneca Ag Products, 1800 Concord Pike, P.O. Box 15458, Wilmington, DE 19850–5458 to EPA requesting that the Administrator amend 40 CFR part 180 by establishing tolerances for residues of the fungicide, azoxystrobin, [methyl(e)-2-(2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] and the Z-isomer of azoxystrobin, [methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3 methoxyacrylate] in or on the food commodities: grapes at 1.0 ppm; pecans at 0.01 ppm; tomato at 0.2 ppm; tomato paste at 0.6 ppm; peanut at 0.01 ppm; peanut oil at 0.03 ppm; peanut hay at 1.5 ppm; peach at 0.80 ppm; banana (whole fruit including peel) at 0.5 ppm; banana pulp at 0.05 ppm; wheat grain at 0.04 ppm; wheat bran at 0.12 ppm; wheat hay at 13.0 ppm; wheat straw at 4.0 ppm; fat of cattle, goats, poultry, sheep, hogs, and horses at 0.01 ppm; mbyp of cattle, goats, poultry, sheep, hogs, and horses at 0.01 ppm; meat of cattle, goats, poultry, sheep, hogs, and horses at 0.01 ppm; poultry liver at 0.01 ppm; and milk at 0.006 ppm.

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act of 1996 (FQPA), Pub. L. 104–170, Zeneca Ag Products included in the notice of filing a summary of the petition and authorization for the summary to be published in the **Federal Register** in a notice of receipt of the petition. The summary of the petition prepared by the petitioner contained conclusions and assessments to support its contention that the petition complied with the FQPA elements set forth in section 408(d)(3) of the FFDCA. There were no comments received in response to the notice of filing.

On May 7, 1997, Zeneca Ag Products withdrew the proposed tolerances in/on peanut hay; banana pulp; wheat grain, bran, hay, and straw; cattle, goat, hog, horse, and sheep fat, meat byproducts, and meat; poultry fat, liver, meat byproducts, and meat; and milk. This leaves the proposed bananas (whole fruit including peel), grapes, peaches, peanuts, peanut oil, pecans, tomatoes, and tomato paste tolerances, at their originally proposed values.

I. Statutory Background

Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., as amended by the FQPA, Pub. L. 104–170, authorizes the establishment of tolerances (maximum residue levels), exemptions from the requirement of a tolerance, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on food commodities and processed foods. Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore ''adulterated'' under section 402(a) of the FFDCA, and hence may not legally be moved in interstate commerce. For a pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under the FFDCA, but also must be registered under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. 135 *et seq.*).

Section 408 was substantially amended by the FQPA. Among other things, the FQPA amends the FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. 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 food, drinking water, and from pesticide use in gardens, lawns, or buildings (residential and other indoor uses) 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....''

II. Risk Assessment and Statutory Findings

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

A. Toxicity

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

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA addresses the potential risks to infants and children

based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This hundredfold margin of exposure is based on the same rationale as the hundredfold 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 relationships. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or margin of exposure (MOE) calculations based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

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

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

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

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

iv. *Chronic risk assessment.* Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

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

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

III. 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 caused by azoxystrobin is discussed below.

1. *Acute toxicity.* The acute oral toxicity study in rats of technical azoxystrobin resulted in an LD_{50} of >

5,000 milligrams/kilogram (limit test) for both males and females. The acute dermal toxicity study in rats of technical azoxystrobin resulted in an LD_{50} of > 2,000 milligrams/kilogram (limit dose). The acute inhalation study of technical azoxystrobin in rats resulted in an LC_{50} of 0.962 milligrams/liter in males and 0.698 milligrams/liter in females. In an acute oral neurotoxicity study in rats dosed once by gavage with 0, 200, 600, or 2,000 milligrams/kilogram azoxystrobin, the systemic toxicity NOEL was <200 milligrams/kilogram and the systemic toxicity LOEL was 200 milligrams/kilogram, based on the occurrence of transient diarrhea in both sexes. There was no indication of neurotoxicity at the doses tested. This acute neurotoxicity study is considered supplementary (upgradeable) but the data required are considered only to be confirmatory. The company has submitted the required confirmatory data; these data have been scheduled for review by the Agency.

2. *Mutagenicity.* Azoxystrobin was negative for mutagenicity in the salmonella/mammalian activation gene mutation assay, the mouse micronucleus test, and the unscheduled DNA synthesis in rat hepatocytes/mammalian cells (*in vivo/in vitro* procedure study). In the forward mutation study using L5178 mouse lymphoma cells in culture, azoxystrobin tested positive for forward gene mutation at the TK locus. In the *in vitro* human lymphocytes cytogenetics assay of azoxystrobin, there was evidence of a concentration related induction of chromosomal aberrations over background in the presence of moderate to severe cytotoxicity.

3. *Rat metabolism*. In this study, azoxystrobin—unlabeled or with a pyrimidinyl, phenylacrylate, or cyanophenyl label—was administered to rats by gavage as a single or 14–day repeated doses. Less than 0.5% of the administered dose was detected in the tissues and carcass up to 7 days post-dosing and most of it was in excretion-related organs. There was no evidence of potential for bioaccumulation. The primary route of excretion was via the feces, though 9 to 18% was detected in the urine of the various dose groups. Absorbed azoxystrobin appeared to be extensively metabolized. A metabolic pathway was proposed showing hydrolysis and subsequent glucuronide conjugation as the major biotransformation process. This study was classified as supplementary but upgradeable; the company has submitted data intended to upgrade the study to acceptable and these data have been scheduled for review.

4. *Sub-chronic toxicity.* i. In a 90–day rat feeding study the NOEL was 20.4 mg/kg/day for males and females. The LOEL was 211.0 mg/kg/day based on decreased weight gain in both sexes, clinical observations of distended abdomens and reduced body size, and clinical pathology findings attributable to reduced nutritional status.

ii. In a subchronic toxicity study in which azoxystrobin was administered to dogs by capsule for 92 or 93 days, the NOEL for both males and females was 50 mg/kg/day. The LOEL was 250 mg/kg/day, based on treatment-related clinical observations and clinical chemistry alterations at this dose.

iii. In a 21–day repeated-dose dermal rat study using azoxystrobin, the NOEL for both males and females was greater than or equal to 1000 mg/kg/day (the highest dosing regimen); a LOEL was therefore not determined.

5. *Chronic feeding toxicity and carcinogenicity.* i. In a 2–year feeding study in rats fed diets containing 0, 60, 300, and 750/1,500 ppm (males/females), the systemic toxicity NOEL was 18.2 mg/kg/day for males and 22.3 mg/kg/day for females. The systemic toxicity LOEL for males was 34 mg/kg/day, based on reduced body weights, food consumption, and food efficiency; and bile duct lesions. The systemic toxicity LOEL for females was 117.1 mg/kg/day, based on reduced body weights. There was no evidence of carcinogenic activity in this study.

ii. In a 1–year feeding study in dogs to which azoxystrobin was fed by capsule at doses of 0, 3, 25, or 200 mg/kg/day, the NOEL for both males and females was 25 mg/kg/day and the LOEL was 200 mg/kg/day for both sexes, based on clinical observations, clinical chemistry changes, and liver weight increases that were observed in both sexes.

iii. In a 2–year carcinogenicity feeding study in mice using dosing concentrations of 0, 50, 300, or 2,000 ppm, the systemic toxicity NOEL was 37.5 mg/kg/day for both males and females. The systemic toxicity LOEL was 272.4 mg/kg/day for both sexes, based on reduced body weights in both at this dose. There was no evidence of carcinogenicity at the dose levels tested.

According to the new proposed guidelines for Carcinogen Risk Assessment (April, 1996), the appropriate descriptor for human carcinogenic potential of azoxystrobin is ''Not Likely.'' The appropriate subdescriptor is ''has been evaluated in at least two well conducted studies in two appropriate species without demonstrating carcinogenic effects.''

6. *Developmental and reproductive toxicity.* i. In a prenatal development study in rats gavaged with azoxystrobin at dose levels of 0, 25, 100, or 300 mg/kg/day during days 7 through 16 of gestation, lethality at the highest dose caused the discontinuation of dosing at that level. The developmental NOEL was greater than or equal to 100 mg/kg/day and the developmental LOEL was > 100 mg/kg/day because no significant adverse developmental effects were observed. In this same study, the maternal NOEL was not established; the maternal LOEL was 25 mg/kg/day, based on increased salivation.

ii. In a prenatal developmental study in rabbits gavaged with 0, 50, 150, or 500 mg/kg/day during days 8 through 20 of gestation, the developmental NOEL was 500 mg/kg/day and the developmental LOEL was > 500 mg/kg/day because no treatment-related adverse effects on development were seen. The maternal NOEL was 150 mg/kg/day and the maternal LOEL was 500 mg/kg/day, based on decreased body weight gain.

iii. in a two-generation reproduction study, rats were fed 0, 60, 300, or 1,500 ppm of azoxystrobin. The reproductive NOEL was 32.2 mg/kg/day. The reproductive LOEL was 165.4 mg/kg/day; reproductive toxicity was demonstrated as treatment-related reductions in adjusted pup body weights as observed in the F1a and F2a pups dosed at 1,500 ppm (165.4 mg/kg/day).

IV. Aggregate Exposures

1. *From food and feed uses.* The primary route of human exposure to azoxystrobin is expected to be dietary ingestion of both raw and processed agricultural commodities from Bananas, Grapes, Peaches, Peanuts, Pecans, and Tomatoes. A Dietary Risk Evaluation System (DRES) chronic exposure analysis was conducted using tolerance level residues and 100% crop treated information to estimate the TMRC for the general population and 22 subgroups.

2. *From potable water.* There is no established Maximum Concentration Level for residues of azoxystrobin in drinking water. Data indicate moderate potential for soil mobility or leaching and azoxystrobin is moderately persistent. In examining aggregate exposure, the 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).

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 for identifying 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 (RfDs or acute dietary NOELs) and assumptions about body weight and consumption to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. The Agency has not yet pinpointed the appropriate bounding figure for consumption of water contaminated with azoxystrobin but the ranges the Agency is continuing to examine are all below the level that would cause azoxystrobin to exceed the RfD if the proposed food uses 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 proposed uses of bananas, grapes, peaches, peanuts, pecans, and tomatoes were granted.

3. *From non-dietary uses.* The Agency evaluated the existing toxicological database for azoxystrobin and assessed appropriate toxicological endpoints and dose levels of concern that should be assessed for risk assessment purposes. Dermal absorption data indicate that absorption is less than or equal to 4%. No appropriate endpoints were identified for acute dietary or short term, intermediate term, and chronic term (noncancer) dermal and inhalation occupational or residential exposure. Therefore, risk assessments are not required for these exposure scenarios and there are no residential risk assessments to aggregate with the chronic dietary risk assessment.

4. *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 examinations 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 be structurally similar to any other pesticide chemical at this time. No metabolites of azoxystrobin that are of toxicological concern are known to the Agency. Azoxystrobin appears to be the only pesticide member of its class of chemistry and there are no reliable data to indicate that this chemical is structurally or toxicologically similar to existing chemical substances at this time. Therefore, it appears unlikely that azoxystrobin bears a common mechanism of activity with 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.

V. Determination of Safety

A. Chronic Risk

The Reference Dose (RfD) for azoxystrobin is 0.18 mg/kg/day, based on the NOEL of 18.2 mg/kg/day from the rat chronic toxicity/carcinogenicity feeding study in which decreased body weight and bile duct lesions were observed in male rats at the LOEL of 34 mg/kg/day. This NOEL was divided by an Uncertainty Factor of 100, to allow for interspecies sensitivity and intraspecies variability.

The chronic dietary exposure analysis showed that exposure from the proposed new tolerances in or on banana, grape, peach, peanut, peanut oil, pecan, tomato, and tomato paste for Non-nursing Infants (the subgroup with the highest exposure) would be 1% of the RfD. The exposure for the general U.S. population would be less than 1% of the RfD. This analysis used a value of 0.05 ppm for banana pulp rather than the value of 0.5 that has been established for banana (whole fruit including peel) because adequate data were submitted to support use of the lower value in the dietary risk analyses. When the chronic dietary exposure analysis was performed with the addition of the tolerances for rice, milk, meat, eggs, and poultry that result from the granting of section 18 registrations for use on rice to Louisiana and Mississippi, about 1% of the RfD is used for the U.S. Population and about 5% of the RfD is used for Non-nursing Infants.

As is discussed above, there is no established Maximum Concentration Level for residues of azoxystrobin in drinking water. The Agency has not yet pinpointed the appropriate bounding figure for consumption of water contaminated with azoxystrobin but the ranges the Agency is continuing to examine are all below the level that would cause azoxystrobin to exceed the RfD if the proposed food uses 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 proposed uses on bananas, grapes, peaches, peanuts, pecans, and tomatoes were granted.

B. Acute Risk

As part of the hazard assessment process, the Agency reviews the available toxicological database to determine if there are toxicological endpoints of concern. For azoxystrobin, the Agency does not have a concern for acute dietary exposure since the available data do not indicate any evidence of significant toxicity from a one-day or single event exposure by the oral route. Therefore, an acute dietary risk assessment is not required for azoxystrobin at this time.

C. Conclusion

Based on these risk estimates EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to azoxystrobin for consumers, including major identifiable subgroups and infants and children.

VI. Additional Safety Factor for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the no observed effect level in the animal study appropriate to the particular risk assessment. This hundredfold uncertainty (safety) factor/margin of exposure (safety) is designed to account for combined inter- and intra-species variability. EPA believes that reliable data support using the standard hundredfold margin/factor but not the additional tenfold margin/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 margin/factor. The data base for azoxystrobin is complete except that the acute and subchronic neurotoxicity studies require upgrading. The upgrade data are confirmatory only, have been submitted by the company, and await review by the Agency.

There was no evidence of increased susceptibility of infants or children to azoxystrobin. Therefore, no additional uncertainty factors are considered necessary at this time.

VII. Other Considerations

1. *Endocrine effects.* EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...''. The Agency is currently working with interested shareholders, including other government agencies, public interest groups, industry, and research scientists, to develop a screening and testing program and a priority setting scheme to implement this program. Congress has allowed three (3) years from the passage of FQPA (August 3, 1999) to implement this program. When this program is implemented, EPA may require further testing of azoxystrobin and end-use product formulations for endocrine disrupter effects.

2. *Metabolism in plants and animals.* The metabolism of azoxystrobin in plants is adequately understood for purposes of these tolerances. Since the proposed label does not contain any commodities that are considered to be significant items of livestock feed, the nature of the residue in animals is not of concern at this time. There are no Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs) for azoxystrobin. Adequate analytical methods, gas chromatography with nitrogen-phosphorous detection and high performance liquid chromatography with ultraviolet detection, are available for enforcement purposes. Because of the long lead time from establishing these tolerances to publication of the enforcement methodology in the Pesticide Analytical Manual, Vol. II, the analytical method is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, 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. Office location and telephone number: Room 1130A, CM #2, 1021 Jefferson Davis Highway, Arlington, VA (703–305–5937).

3. *Data requirements.* In accordance with section 408(b)(2)(E)(ii) of the Federal Food, Drug, and Cosmetic Act (FFDCA), because anticipated or actual residue levels are being relied on for banana pulp, the Agency is requiring, pursuant to section 408(f)(1), that data be provided 5 years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under section 408(e)(1), or an order under section 408(f)(2), as appropriate, to modify or revoke the tolerance.

VIII. Summary of Findings

The analysis for azoxystrobin for all population subgroups examined by EPA shows that the proposed uses on bananas, grapes, peaches, peanuts, pecans, and tomatoes will not cause exposure at which the Agency believes there is an appreciable risk.

Based on the information cited above, the Agency has determined that the establishment of the tolerances by amending 40 CFR part 180 will be safe; therefore, the tolerances are established as set forth below.

IX. 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 (1)(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 these modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by September 8, 1997, 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 proscribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contention on such issues, and a summary of any evidence relied upon by the objector (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 a 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 issue(s) 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.

X. Public Docket

A record has been established for this rulemaking under the docket number [OPP–300508] (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 1132, 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.

Electronic comments can 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 rule-making record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

XI. Regulatory Assessment Requirements

This final rule establishes tolerances under section 408 of the FFDCA and is in response to petitions received by the Agency requesting the establishment of such tolerances. 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). In addition, 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, because tolerances that are established on the basis of a petition under section 408(d) of FFDCA, 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. Prior to the recent amendments to the FFDCA, however, EPA had treated such actions as subject to the RFA. The amendments to the FFDCA clarify that no proposed rule is required for such regulatory actions, which makes the RFA inapplicable to these actions. 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 (46 FR 24950, May 4, 1981). In accordance with Small Business Administration (SBA) policy, this determination will be provided to the Chief Counsel for Advocacy of the SBA upon request.

XII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **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

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements

Dated: July 1, 1997.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 236a and 371.

2. Section 180.507 is amended by adding the text of paragraph (a) to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide, azoxystrobin, [methyl(*E*)-2-(2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] and the Z-isomer of azoxystrobin, [methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3 methoxyacrylate] in or on the following raw agricultural commodities and processed food:

Commodity	Parts per million
Bananas	0.5
Grapes	1.0
Peaches	0.80
Peanuts	0.01
Peanut Oil	0.03
Pecans	0.01
Tomatoes	0.2

Commodity	Parts per million
Tomato Paste	0.6

* * * * *

[FR Doc. 97–17931 Filed 7–8–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300511; FRL–5729–4]

RIN 2070–AB78

Imidacloprid; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of imidacloprid in or on the crop group citrus fruits and processed commodity dried citrus pulp. 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 citrus. This regulation establishes a maximum permissible level for residues of imidacloprid in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and are revoked on December 31, 1998.

DATES: This regulation is effective July 9, 1997. Objections and requests for hearings must be received by EPA on or before September 8, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300511], 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–300511], must also 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–300511]. 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: 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: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9367, e-mail: ertman.andrew@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 tolerances for combined residues of the insecticide imidacloprid, in or on the crop group citrus fruits at 1 part per million (ppm) and the processed commodity dried citrus pulp at 5 ppm. These tolerances will expire and are revoked on December 31, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerances 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 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 Imidacloprid on Citrus and FFDCA Tolerances

The State of Florida has requested a specific exemption for the use of imidacloprid on citrus for the control of