EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action acts on pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

EPA believes that VCS are inapplicable to today's action because it does not require the public to perform activities conducive to the use of VCS.

H. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not a ''major'' rule as defined by 5 U.S.C. 804(2).

I. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 20, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: May 24, 2001.

Jane Diamond,

Acting Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

2. Section 52.269 is amended by adding paragraph (b)(3)(iii) to read as follows:

§ 52.269 Control strategy and regulations: Photochemical oxidants (hydrocarbons) and carbon monoxide.

* * * * *

(b) * * *

(3) * * *

(iii) Antelope Valley APCD.

(A) Rule 461, Gasoline Transfer and Dispensing, submitted on May 13, 1999, is disapproved. The version of this rule submitted on January 31, 1996 (same title and number), which was previously approved in 40 CFR 52.220, is retained.

* * * * *

[FR Doc. 01–15617 Filed 6–20–01; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301135; FRL–6786–1]

RIN 2070–AB78

Isoxadifen-ethyl; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of the safener isoxadifen-ethyl in or on rice, grain; rice, straw; rice, hulls; and rice, bran. Aventis CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996. The tolerance will expire on June 21, 2004.

DATES: This regulation is effective June 21, 2001. Objections and requests for hearings, identified by docket control number OPP–301135, must be received by EPA on or before August 20, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301135 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Vera Soltero, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9359; and e-mail address: soltero.vera@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301135. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Registers** of June 9, 1999 (64 FR–30997) (FRL–6082–6) and June 30, 2000 (65 FR–40632) (FRL–6592–6), EPA issued notices pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the FQPA of 1996 (Public Law 104–170) announcing the filing of a pesticide petition (PP 9E5060) for tolerance by Aventis CropScience, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. These notices included a summary of the petition prepared by Aventis CropScience, the petitioner. There were no comments received in response to these notices of filing.

The petition requested that 40 CFR 180.570 be amended by establishing a tolerance for the combined residues of the safener isoxadifen-ethyl, (ethyl 5,5-diphenyl-2-isoxazoline-3-carboxylate, CAS No. 163520–33–0) and its metabolites: 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylic acid and β-hydroxy-β-benezenepropanenitrile, in or on rice, grain; and rice, straw at 0.050 and 0.20 part per million (ppm) respectively. The Agency determined that the tolerance levels should be raised and that tolerances for two additional rice commodities are appropriate due to the lack of a rice processing study. Thus, the tolerance levels for the safener isoxadifen-ethyl and its metabolites for the following commodities are: rice, grain; rice, straw; rice, hulls; and rice, bran at 0.10, 0.25, 0.50, and 0.80 ppm respectively. The tolerances will expire on June 21, 2004.

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. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for the combined residues of isoxadifen-ethyl and its metabolites on rice, grain; rice, straw; rice, hulls; and rice, bran at 0.10, 0.25, 0.50, and 0.80 ppm respectively. EPA's assessment of exposures and risks associated with establishing the tolerances follow.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results on 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 isoxadifen-ethyl are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity mouse	NOAEL = 19.8 miligram/killogram/day(mg/kg/day) in males, 254 mg/kg/day in females LOAEL = 191 mg/kg/day in males, 573 mg/kg/day infemales based on pathological changes in the liverconsisting of hepatocellular hypertrophy, hepatocellularvacuolation and fatty deposits in liver (males and females).

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents- rat	NOAEL = 13.8 mg/kg/day in males, 333.2mg/kg/day in females highest dose tested (HDT) LOAEL = 137.9 mg/kg/day in males based on decreasedbody weight and body weight gain.
870.3150	90–Day oral toxicity in nonrodents-dog	NOAEL = 1.2 mg/kg/day in males, 6.5mg/kg/day in females. LOAEL = 6.1 mg/kg/day in males, and 47.5 mg/kg/day infemales based on slight fat deposits in the collecting ductsof the kidney and aspermia (males) and decreased bodyweight gain, differences in various hematological parameters,and moderate fat deposits in the collecting ducts of the kidneys (females).
870.3200	28–Day dermal toxicity	NOAEL= 1,000 mg/kg/day LOAEL= not established
870.3700a	Prenatal developmental in rodents-rat	Maternal NOAEL = 120 mg/kg/day LOAEL = 1,000 mg/kg/day based on mortality,and reduced body weight, body weight gain and food consumption. Developmental NOAEL = 15 mg/kg/day LOAEL = 120 mg/kg/day based on increased incidence ofbent scapula.
870.3700b	Prenatal developmental in nonrodents-rabbit	Maternal NOAEL = 50 mg/kg/day LOAEL = 500 mg/kg/day based on mortality. Developmental NOAEL = 50 mg/kg/day LOAEL = 500 mg/kg/day based on increased litterincidence of fused, aplastic, dislocated or fragmentedcaudal vertebrae centers.
70.3800	Reproduction and fertility effects- rat	Parental/Systemic NOAEL = 12.6 mg/kg/dayin males, 16.7 mg.kg.day in females LOAEL = 249.8 mg/kg/day in males, 346.5 mg/kg/day infemales based on decreased body weight and body weightgain and increased kidney lesions in males and females. Reproductive NOAEL ≥249.8 mg/kg/day in males, 346.5mg/kg/day in females LOAEL = not established Offspring NOAEL = 12.6 mg/kg/day in males, 16.7mg/kg/day in females LOAEL = 249.8 mg/kg/day in males, 346.5 mg/kg/day in females based on decreased body weight in male pups and delayed sexual maturation in males and females.
870.4100b	Chronic toxicity dogs	NOAEL = 3.3 mg/kg/day in males, 3.6mg/kg/day in females LOAEL = 24 mg/kg/day based on increased bloodcreatinine in females, decreased urinary specific graviy inboth sexes, increased partial thromboplastin time in bothsexes, and increased incidence and severity of straighttubule vacuolation in the kidney of both sexes.
870.4200	Carcinogenicity rats	NOAEL = 84 mg/kg/day in males, 118mg/kg/day in females LOAEL = 171 mg/kg/day in males, 249 mg/kg/day infemales based on decreases in body weight and bodyweight gain for both sexes, proteinaceous plugs in theurinary bladder of males and increased severity ofprogressive nephropathy in females. No evidence of carcinogenicity
870.4300	Carcinogenicity mice	NOAEL = 16.6 mg/kg/day in males, 202.5 mg/kg/day in females LOAEL = 169.6 mg/kg/day in males, 407.3 mg/kg/day infemales based on significant decreased survival in males and females. No evidence of carcinogenicity
870.5265	Gene mutation	Non-mutagenic when tested yp to 5,000µg/plate, in presence and absence of activation, in*S.typhimurium* strains TA98, TA1000, TA1535 and TA1537and *E.coli* strain WP2uvra.
870.5300	Cytogenetics	Non-mutagenic at the HGPRT locus inChinese hamster (CH) lung V79 cells tested up to cytotoxicconcentrations or limit of solubility, in presence andabsence of activation.
870.5375	Chromosome aberration	Did not induce structural chromosomeaberration in CH lung V79 cell cultures in theabsence of activation, but did induce increased levels ofnumerical aberrations, in presence of activation.
870.5395	Micronucleus	Non-mutagenic in mouse bone marrowmicronucleus assay up to 200 mg/kg.
870.5550	Unscheduled DNA synthesis	There was no evidence that unschedulesDNA synthesis, as determined by radioactive tracerprocedures (nuclear silver grain counts) was induced in ratsexposed up to 2,000 mg/kg (limit dose).
870.7485	Metabolism and pharmacokinetics	Absorption was 46% in males and 82% infemales. Urinary excretion was the primary route ofelimination. Fecal excretion was greater in males thanfemales. The free acid and hydroxy free acid were theprincipal components detected in excreta.

B. Toxicological Endpoints

The dose at which no observed adverse effect level (NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR ISOXADIFEN-ETHYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for RiskAssessment	Study and Toxicological Effects
Acute dietaryfemales 13–50 years of age	NOAEL = 15 mg/kg/day UF = 100 Acute RfD = 0.15 mg/kg/day	FQPA SF = 3X aPAD = acute RfD ÷ FQPA SF = 0.05 mg/kg/day	Developmental toxicity - rat LOAEL = 120 mg/kg/daybased on increased incidence of bent scapula.
Chronic dietaryall populations	NOAEL = 3.3 mg/kg/day UF = 100 Chronic RfD = 0.033 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD ÷ FQPA SF = 0.033 mg/kg/day	Subchronic toxicity (feeding) - dog;chronic toxicity (feeding) - dog LOAEL = 6.1 mg/kg/day based on fat deposits incollecting ducts of nephron (males).
Short-termdermal (1 to 7 days) (occupational)	Oral study NOAEL= 13.8 mg/kg/day (dermalabsorption rate = 14%)	LOC for MOE = 100 (occupational)	90–Day feeding study - rat LOAEL = 137.9 mg/kg/day based on decreased bodyweight and body weight gain after 8 days of exposure (males).
Intermediate-termdermal (1 week to several months) occupational)	Oral study NOAEL = 3.3 mg/kg/day (dermal absorption rate = 14%)	LOC for MOE = 100	Subchronic toxicity (feeding) - dog (co-critical); chronictoxicity (feeding) - dog LOAEL = 6.1 mg/kg/day based on fat deposits in collecting ducts of nephron (males).
Short-term inhalation(1 to 7 days) (occupational)	Oral study NOAEL=13.8 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100	90–Day feeding study - rat LOAEL = 137.9 mg/kg/daybased on decreased body weight and body weight gainafter 8 days of exposure (males).
Intermediate-terminhalation (1 week to several months) (occupational)	Oral study NOAEL = 3.3 mg/kg/day(inhalation absorption rate = 100%)	LOC for MOE = 100	Subchronic toxicity (feeding) - dogco-critical); chronic toxicity (feeding) - dog LOAEL = 6.1 mg/kg/day based on fat deposits incollecting ducts of nephron (males).
Cancer (oral, dermal, inhalation)	Cancer classification (''not likely'')	Risk assessment not required.	No evidence of carcinogenicity

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* There are no permanent or time-limited tolerances for isoxadifen-ethyl. Tolerances are unnecessary for ruminant or poultry commodities at this time. Risk assessments were conducted by EPA to assess dietary exposures from isoxadifen-ethyl in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated in the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments. A copnservative acute analysis was performed using tolerance level residues, default processing factors, and assuming 100% of the crops were. No anticipated residues were used. In addition, to account for the lack of rotational crop data, a value of 0.25 ppm for soybean seed was used inthe DEEM® analysis along with maximum theoretical concentration factors for soybean meal (2.2X), hulls (11.3X), and oil (12.0X).

For acute dietary risk, the Agency's level of concern is > 100% aPAD. The acute dietary exposure estimate for the females 13–50 years old subgroup, at the 95th percentile of exposure, is 5% aPAD,

which is below the Agency's level of concern.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The chronic dietary exposure analysis made use of the same assumptions that went into the acute dietary previously described. For chronic dietary risk, the Agency's level of concern is >100% cPAD. Dietary exposure estimates for representative population subgroups are presented below:

TABLE 3.—SUMMARY OF RESULTS FROM CHRONIC DEEM ANALYSIS OF ISOXADIFEN-ETHYL

Subgroup	Exposure (mg/kg/day)	% cPAD
U.S. population (total)	0.001297	4
All infants (< 1–year old)	0.005080	15
Children 1–6 years old	0.002458	7
Children 7–12 years old	0.001952	6
Females 13–50 years old	0.001001	3
Males 13–19 years old	0.001483	5
Males 20+ years old	0.001035	3
Seniors 55+ years old	0.000854	3

The results of the chronic analysis indicate that for all population subgroups the estimated chronic dietary risk associated with the uses of isoxadifen-ethyl is below the Agency's level of concern.

iii. *Cancer*. After consideration of the Agency's ''Proposed Guidelines for Carcinogen Risk Assessment (April 10, 1996),'' EPA has classified isoxadifen-ethyl as ''not likely to be a human carcinogen.'' This classification is based on the lack of evidence of carcinogenicity in mice and rats. Therefore, a cancer risk analysis is not necessary.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for isoxadifen-ethyl in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of isoxadifen-ethyl.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentrations in Ground Water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop (PC) area factor as an adjustment to account for the maximum PC coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to isoxadifen-ethyl they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models, the estimated environmental concentrations (EECs) of isoxadifen-ethyl for acute exposures are estimated to be 80 parts per billion (ppb) for surface water and 5 ppb for ground water. The EECs for chronic exposures are estimated to be 40 ppb for surface water and 5 ppb for ground water. It has been determined that the 56–day GENEEC model estimate would routinely overestimate drinking water residues by at least a factor of three. Therefore, the chronic exposure estimate for surface water (40 ppb) was divided by 3 in Table 5 below.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). There are no residential uses of isoxadifen-ethyl.

4. *Cumulative exposure to substances with a 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.''

EPA does not have, at this time, available data to determine whether isoxadifen-ethyl 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, isoxadifen-ethyl 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 isoxadifen-ethyl has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. 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 prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity*. Based in the available data, both quantitative and qualitative evidence of increased susceptibility was observed following *in utero* isoxadifen-ethyl exposure to rats. In the prenatal rat developmental toxicity study, the developmental toxicity NOAEL/LOAEL of 15/120 mg/kg/day occurs below level of the maternally toxic NOAEL/LOAEL of 120/1,000 mg/kg/day. This finding established the quantitative susceptibility for isoxadifen-ethyl. Additionally, the developmental effect observed (increased incidence of bent scapula) is considered more severe and permanent that the maternal effects of reduced body weight, body weight gain and food consumption. The finding established the qualitative susceptibility for isoxadifen-ethyl. However, there was no evidence of increased susceptibility in the rabbit prenatal toxicity study or following prenatal/postnatal exposure in the 2-generation reproduction study.

iii. *Conclusion*. EPA determined that the 10X safety factor would be reduced to 3X because the toxicology data base is complete; a developmental neurotoxicity study was not required; the dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children; and there are currently no residential uses.

The FQPA safety factor for isoxadifen-ethyl is applicable to females 13–50 population subgroup for acute dietary risk assessment since there is concern for increased susceptibility of the young, as demonstrated in the prenatal developmental study in rats.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculatedDWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. The acute dietary exposure analysis assumed tolerance level residues and 100% crop treated for all proposed commodities, in addition to estimating from possible contributions from soybeans based on the rotational crop use. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to isoxadifen-ethyl will occupy 5% of the aPAD for females 13 years and older. In addition, there is potential for acute dietary exposure to isoxadifen-ethyl in drinking water. The EECs for surface and ground water are less than the DWLOC. Thus, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO ISOXADIFEN-ETHYL

Population Subgroup	aPAD (mg/kg)	%aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females 13–50years old	0.050	5	80	5	14,000

2. *Chronic risk*. The chronic exposure analysis assumed tolerance level residues and 100% crop treated for all commodities, in addition to estimating from possible contributions from soybeans based on the rotational crop use. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to isoxadifen-ethyl from food will utilize 4% of the cPAD for the U.S. population, 15% of the cPAD for all infants and 7% of the cPAD for children 1–6 years old. There are no residential uses for isoxadifen-ethyl that result in

chronic residential exposure to isoxadifen-ethyl. In addition, there is potential for chronic dietary exposure to isoxadifen-ethyl in drinking water. The EECs for surface and ground water are less than the DWLOC. Thus, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO ISOXADIFEN-ETHYL

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.033	4	13	5	1100
All infants (<1 year old)	0.033	15	13	5	280
Children (1–6 years old)	0.033	7	13	5	310
Children (7–12 years old)	0.033	6	13	5	310
Females (13–50 years old)	0.033	3	13	5	960
Males (13–19 years old)	0.033	5	13	5	1100
Males (20+ years old)	0.033	3	13	5	1100
Seniors (55+ years old)	0.033	3	13	5	1100

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Isoxadifen-ethyl is not registered for use on any sites that would result in residential exposure. Therefore, no short-term risk assessment was performed.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Isoxadifen-ethyl is not registered for use on any sites that would result in residential exposure. Therefore, no intermediate-term risk assessment was performed.

5. *Aggregate cancer risk for U.S. population*. The Agency has classified isoxadifen-ethyl as ''not likely to be a carcinogen.'' Therefore, an aggregate cancer risk assessment was not performed.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to combined residues of isoxadifen-ethyl and its metabolites.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner proposed using a multiresidue method (MRM) for enforcement of tolerances of isoxadifen-ethyl residues and its metabolites on rice. Data were submitted pertaining to the behavior of isoxadifen-ethyl using FDA MRM protocols (PAM Vol 1). Residues of the parent compound were recovered from rice using Protocol E, Method 303. There were also quantitative recoveries of 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylic acid (metabolite 1) using protocol B. No results concerning the behavior of metabolite β-hydroxy-β benezenepropanenitrile (metabolite 2) in rice using the multiresidue protocols were reported.

The petitioner also submitted an Independent Laboratory Validation (ILV) for the parent and metabolite 2 in rice grain, using gas chromatography with a mass-selective detector (GC/MSD). Validation of this method was successful.

At this time there is not one analytical method that can detect the parent and both metabolites in rice. However, if a situation should arise, then the Agency could perform both the MRM and the GC/MSD methods which would detect residues of isoxadifen-ethyl and both its metabolites in rice.

The Agency is requiring the petitioner to resubmit the analytical method and an ILV for the parent and both of the metabolites to satisfy the requirement for an enforcement analytical method. Following successful Agency validation of the MRM and the enforcement analytical methods, and review and evaluation of the other required data, the Agency will consider establishing permanent tolerances.

B. International Residue Limits

There are no CODEX, Canadian, or Mexican tolerances/MRLs for isoxadifen-ethyl residues.

C. Conditions

The following data are required to establish permanent tolerances for isoxadifen-ethyl: Confined/field accumulation in rotational crops study; rice processed commodity study; successful method validation of the analytical enforcement method; and adequate storage stability data. Additionally, as a condition of registration, rotational crops are limited to soybeans and there will be a 9–month plantback interval for isoxadifen-ethyl in rice agricultural commodities.

V. Conclusion

Therefore, the time-limited tolerances are established for combined residues of isoxadifen-ethyl, and its metabolites, in or on rice, grain; rice, straw; rice, hulls; and rice, bran at 0.10, 0.25, 0.50 and 0.80 ppm respectively.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new

section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301135 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before August 20, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301135, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. 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) (Public Law 104-–4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any other Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have'' substantial direct effects on the States, on the relationship between the national government and the States, or on the

distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final 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: June 11, 2001.

Peter Caulkins,

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. 321(q), 346(a) and 371.

2. Section 180.570 is added to read as follows:

§ 180.570 Isoxadifen-ethyl; tolerances for residues.

(a) *General.* Tolerances to expire on June 21, 2004 are established for residues of isoxadifen-ethyl (ethyl 5,5-diphenyl-2-isoxazoline-3-carboxylate, CAS No. 163520–33–0) and its metabolites: 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylic acid and β-hydroxy-β-benezenepropanenitrile when in the commodities listed below. This safener will be used only in conjunction with the active ingredient fenoxaprop-p-ethyl, at a rate of 0.17 pound of safener per pound of active ingredient.

Commodity	Parts per million	Expiration/Revocation Date
Rice, bran	0.80 ppm	June 21, 2004
Rice, grain	0.10 ppm	June 21, 2004
Rice, hulls	0.50 ppm	June 21, 2004
Rice, straw	0.25 ppm	June 21, 2004

(b) *Section 18 emergency exemptions.* [*Reserved*]

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

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

[FR Doc. 01–15613 Filed 6–20–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301138; FRL–6787–7]

RIN 2070–AB78

Mesotrione; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues ofmesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in or on field corn. Syngenta Crop Protection Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective June 21, 2001. Objections and requests for hearings, identified by docket control number OPP–301138, must be received by EPA on or before August 20, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control numberOPP–301138 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne Miller,Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: 703-305-6224; and e-mail address: Miller.Joanne@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing