

implications because it does not 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a State rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 *note*) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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 action is not a "major rule" as defined by 5 U.S.C. 804(2).

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 July 26, 2004. 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, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: May 3, 2004.

Wayne Nastri,
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 52.220 is amended by adding paragraphs (c)(190)(i)(C) to (G) and (c)(194)(i)(I) and (J) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(190) * * *

(i) * * *

(C) El Dorado County Air Pollution Control District.

(1) Rule 1000 adopted on September 21, 1992.

(D) Feather River Air Pollution Control District.

(1) Rule 4.8 adopted on September 14, 1992.

(E) Kern County Air Pollution Control District.

(1) Rule 108.2 adopted on July 13, 1992.

(F) San Bernardino County Air Pollution Control District (now Mojave Desert Air Quality Management District).

(1) Rule 107 adopted on September 14, 1992.

(G) Santa Barbara County Air Pollution Control District.

(1) Rule 212 adopted on October 20, 1992.

* * * * *

(194) * * *

(i) * * *

(I) Sacramento Metropolitan Air Quality Management District.

(1) Rule 105 adopted on April 20, 1993.

(J) Yolo-Solano Air Quality Management District.

(1) Rule 3.18 adopted on July 28, 1993.

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[FR Doc. 04-11769 Filed 5-25-04; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0093; FRL-7355-8]

Isoxadifen-Ethyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes three tolerances for the combined residues of the herbicide safener isoxadifen-ethyl in or on rice, grain; rice, straw; and rice, hulls. Bayer CropScience (formerly Aventis CropScience) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective May 26, 2004. Objections and requests for hearings must be received on or before July 26, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket ID number OPP-2004-0093. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 2121 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: James Parker, Registration Division

(7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0371; e-mail address: parker.james@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgrstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

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(d)(3) of FFDCA, 21 U.S.C.

346a(d)(3), announcing the filing of a pesticide petition (PP 9E5060) by Aventis CropScience, formerly AgrEvo USA, now doing business as Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. That notice included a summary of the petition prepared by the petitioner.

The petition requested that 40 CFR 180.570 be amended by establishing tolerances for the combined residues of the herbicide 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 -benzenepropanenitrile, in or on the following rice commodities: rice, grain; rice, straw; rice hulls; and rice bran at 0.10, 0.25, 0.50, and 0.80 parts per million (ppm), respectively. There were no comments received in response to the notice of filing.

In the **Federal Register** of June 21, 2001 (66 FR 33179) (FRL-6786-1), EPA established time-limited tolerances (expiring June 21, 2004) for isoxadifen-ethyl in or on rice commodities. Submission of the following data was required: Confined/field accumulation in rotational crops study; rice processed commodity study; successful petition method validation of the analytical enforcement method; and adequate storage stability data.

Section 408(b)(2)(A)(i) of 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) of FFDCA 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) of FFDCA 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 of FFDCA 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) of FFDCA, 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) of FFDCA, for a tolerance for combined residues of isoxadifen-ethyl (CAS No. 163520-33-0) and its metabolites: 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylic acid and β -hydroxy- β -benzenepropanenitrile on rice commodities. EPA’s assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by isoxadifen ethyl as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed by the Agency are discussed in the **Federal Register** of June 21, 2001 (66 FR 33179) (FRL-6786-1). At that time the Agency considered the toxicity database to be complete. No additional toxicity studies have been submitted by the petitioner.

B. Toxicological Endpoints

The dose at which the 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 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.

Three other types of safety or uncertainty factors may be used: “Traditional uncertainty factors;” the “special FQPA safety factor;” and the

“default FQPA safety factor.” By the term “traditional uncertainty factor,” EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term “special FQPA safety factor” refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The “default FQPA safety factor” is the additional 10X safety factor that is mandated by the statute unless it is

decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate ($RfD = NOAEL/UF$). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 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.

A summary of the toxicological endpoints for isoxadifen-ethyl used for human risk assessment is shown in Table 1. of this unit:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR ISOXADIFEN-ETHYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–50 years of age)	NOAEL = 15 milligrams/kilograms/day (mg/kg/day) UF = 100 Acute RfD = 0.15 mg/kg/day	Special FQPA SF = 1X aPAD = acute RfD ÷ Special FQPA SF = 0.15 mg/kg/day	Rat developmental study LOAEL = 120 mg/kg/day based on bent scapula in rat fetuses
Chronic dietary (all populations)	NOAEL = 3.3 mg/kg/day UF = 100 Chronic RfD = 0.033 mg/kg/day	Special FQPA SF = 1X cPAD = chronic RfD ÷ Special FQPA SF = 0.033 mg/kg/day	1–Year dog feeding study, (co-critical) 90–day dog feeding study LOAEL = 6.1 mg/kg/day based on kidney histopathology in both sexes of dogs in both studies
Short-term dermal, inhalation, and incidental oral (1 to 7 days) (Residential)	Dermal (or oral) study NOAEL = 13.8 mg/kg/day (dermal absorption rate = 14%) (inhalation absorption rate = 100%)	LOC for MOE = <100% (Residential)	90–day rat feeding study LOAEL = 137.9 mg/kg/day based on decreased body weight and weight gain at Day 8
Intermediate-term dermal, inhalation, and incidental oral (1 week to several months) (Residential)	Dermal (or oral) study NOAEL = 3.3 mg/kg/day (dermal absorption rate = 14%) (inhalation absorption rate = 100%)	LOC for MOE = <100% (Residential)	1–Year dog feeding study (co-critical) 90–day dog feeding study LOAEL = 6.1 mg/kg/day based on kidney histopathology in both sexes of dogs in both studies
Cancer (oral, dermal, inhalation)	Cancer classification “not likely to be a human carcinogen”	Risk assessment not required	No evidence of carcinogenicity

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Permanent tolerances on corn commodities and time-limited tolerances on rice commodities are established (40 CFR 180.570) for the combined residues of isoxadifen-ethyl. The time-limited tolerances will expire on June 21, 2004. To convert these time-limited tolerances to permanent tolerances, risk assessments were conducted by EPA to assess dietary exposures from isoxadifen-ethyl.

At this time there is a time-limited tolerance for rice, bran at 0.80 ppm. The

Agency’s review of residue chemistry data indicated that residues of isoxadifen-ethyl do not concentrate in rice, bran. Therefore, the rice, grain tolerance will cover this processed commodity. The existing time-limited tolerance for rice, bran is therefore not needed and will be removed. Hence, a permanent tolerance for rice, bran is not established in this final rule.

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. In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 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: Tolerance level

residues, 100% crop treated and DEEM (version 7.76) default concentration factors for all commodities. No anticipated residues were used.

The Agency estimated the acute dietary food exposure for females (ages 13–49 years old) to be 0.000511 mg/kg/day. The Agency's LOC for acute dietary risk is greater than 100% of the aPAD. When compared to the aPAD of 0.15 mg/kg/day for isoxadifen-ethyl, the dietary risk is less than 1.0% of the

aPAD and therefore less than the Agency's LOC.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments:

Tolerance level residues, 100% crop treated and DEEM (version 7.76) default processing factors. No anticipated residues were used. The chronic dietary exposure estimates were all less than or equal to 1.5% of the cPAD for all population subgroups and are therefore less than the LOC (greater than 100% of the cPAD). The chronic dietary exposure estimates for representative population subgroups are presented below in Table 2:

TABLE 2.—SUMMARY OF CHRONIC DIETARY EXPOSURE FOR ISOXADIFEN-ETHYL

Subgroup	Exposure (mg/kg/day)	% cPAD
U.S. population (total)	0.000216	<1.0
All infants (<1-year old)	0.000339	1
Children (1–2 years old)	0.000427	1.3
Children (3–5 years old)	0.000486	1.5
Children (6–12 years old)	0.000373	1.1
Youth (13–19 years old)	0.000294	<1.0
Adults (20–49 years old)	0.000182	<1.0
Adults (50+ years old)	0.000099	<1.0
Females (13–49 years old)	0.000177	<1.0

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 Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentration in Ground Water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier I model) before using PRZM/EXAMS (a Tier II 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 incorporates an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health LOCs.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water, used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOC) 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 in Unit III.E.

Based on the GENEEC, FQPA Index Reservoir Screening Tool (FIRST) and SCI-GROW models, the 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.

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). The petitioner has requested to use isoxadifen-ethyl on turf, which could result in residential exposures.

The proposed turf use is intended for professional application to Bermudagrass on golf courses, sod farms, residential and commercial site

lawns, parks, recreational facilities, and similar sites. It is not intended for use by homeowners or other non-professional applications. Therefore, residential mixer/loader and applicator exposures are not anticipated. The following short-term post-application residential exposures are anticipated: Adult (dermal - golf course and residential lawn), children (dermal - residential lawn), and toddler (dermal and incidental oral - residential lawn). However, dermal exposures for golfers are considered to be less than those resulting from a residential turf application, and were therefore not assessed.

Hand to mouth (HTM), object to mouth (OTM), and soil hand to mouth short-term incidental oral exposures may occur as a result of the proposed turf use. However, the soil hand to mouth exposure is considered to be very small in comparison to the other exposures. MOEs were estimated to be 790 (for a 15 kg child) and 1,500 (for an adult). MOEs greater than 100 are not of concern.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to isoxadifen-ethyl and any other substances and 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at <http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* A summary of the developmental toxicity studies for isoxadifen-ethyl which have been reviewed and evaluated by the Agency published in the **Federal Register** of June 21, 2001 (66 FR 33179) (FRL-6786-1).

3. *Conclusion.* Based on the following considerations, the Agency concluded that the special FQPA safety factor is reduced to 1X.

- No neurotoxicity studies are available. However, no clinical signs of neurotoxicity were observed in the available toxicity studies conducted with isoxadifen-ethyl in rats, rabbits, or dogs, other than those neurotoxic clinical signs associated with agonal toxicity in these species.

- There was no evidence of enhanced susceptibility in the rabbit developmental study or the 2-generation rat reproduction study.

- In the developmental rat study, quantitative susceptibility was evidenced as increased fetal incidences of bent scapula at (120 mg/kg/day) a dose lower than that evoking maternal toxicity (mortality, reduced body weights, body weight gains, and food consumption at 1,000 mg/kg/day). The overall toxicity profile and the doses and endpoints selected for risk assessment for isoxadifen-ethyl, characterize the degree of concern for the effects observed in this study as low. There is a clear NOAEL and well-characterized dose response for the developmental effects observed. No residual uncertainties were identified. The NOAEL for developmental effects

in this study (15 mg/kg/day) is used as the basis for the aRfD for the females 13–50 population subgroup. For all other toxicity endpoints established for isoxadifen-ethyl, a NOAEL lower than this developmental NOAEL is used.

- The residue chemistry and environmental fate databases are complete.
- The acute and chronic dietary food exposure assessments assumed tolerance level residues and 100% crop treated for all crops. Therefore dietary exposures/risks are unlikely to be underestimated.
- The drinking water assessment utilizes water concentration values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of drinking water concentrations.
- The residential assessment is considered a Tier I assessment. Therefore residential exposures/risks are unlikely to be underestimated.

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 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 EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/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. For isoxadifen-ethyl DWLOCs are calculated for: Acute, short-term, and chronic scenarios.

When EECs for surface water and ground water are less than the

calculated DWLOCs, 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.* Using the exposure assumptions previously discussed in this unit for acute exposure, the acute

dietary exposure from food to isoxadifen-ethyl will occupy <1.0% of the aPAD for females ages 13 and 50 years old. In addition, there is potential for acute dietary exposure to isoxadifen-ethyl in drinking water. The DWLOC is much greater than the EECs. Therefore, EPA does not expect acute aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 of this unit:

TABLE 3.—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 (13–50 years old)	0.15	<1.0	80	5	4,500

2. *Chronic risk.* Using the chronic dietary exposure analysis discussed previously, EPA has concluded that exposure to isoxadifen-ethyl from food will utilize <1.0% of the cPAD for the U.S. population, 1.0% of the cPAD for all infants (<1 year old), and 1.5% of the

cPAD for children 3–5 years old. Based on the use pattern, chronic residential exposure to residues of isoxadifen-ethyl is not expected. But, there is potential for chronic dietary exposure to isoxadifen-ethyl in drinking water. For each population subgroup, the DWLOC

is much greater than the estimated EEC. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD. Thus, there is no concern for chronic aggregate exposure to isoxadifen-ethyl, as shown in Table 4. below:

TABLE 4.—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	<1.0	40	5	1,100
All infants (< 1 year old)	0.033	1.0	40	5	330
Children (1–2 years old)	0.033	1.3	40	5	330
Children (3–5 years old)	0.033	1.5	40	5	330
Children (6–12 years old)	0.033	1.1	40	5	330
Youth (13–19 years old)	0.033	<1.0	40	5	980
Adults (20–49 years old)	0.033	<1.0	40	5	1,100
Adults (50+ years old)	0.033	< 1.0	40	5	1,200
Females (13–49 years old)	0.033	<1.0	40	5	980

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 proposed for a use that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic food and water, and short-term exposures for isoxadifen-ethyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that aggregated food and residential exposures result in the following aggregate MOEs: U.S. population (1,450), all infants <1 year old (780), children 1–2 years old (776), children 3–5 years old (774), children 6–12 years old (779), youth 13–19 years old (1,438), adults 20–49 years old (1,455), adults 50+ years old (1,468) and females 13–49 years old (1,456). These aggregate MOEs

do not exceed the Agency's LOC (<100) for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the chronic EECs of isoxadifen-ethyl in ground water and surface water. DWLOCs were calculated and then compared to the EECs for surface water and ground water. All DWLOCs are greater than the EECs. Therefore, EPA does not expect short-term aggregate exposure to exceed the Agency's LOC, as shown in Table 5 below:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO ISOXADIFEN-ETHYL

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate LOC	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. population	1450	100	40	5	4,500
All Infants (<1 year old)	780	100	40	5	1,200
Children (1–2 years old)	776	100	40	5	1,200
Children (3–5 years old)	774	100	40	5	1,200
Children (6–12 years old)	779	100	40	5	1,200
Youth (13–19 years old)	1,438	100	40	5	3,900
Adults (20–49 years old)	1,455	100	40	5	4,500
Adults (50+ years old)	1,468	100	40	5	4,500
Females (13–49 years old)	1,456	100	40	5	3,900

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 used or proposed for use on any sites that would result in intermediate-term residential exposure. Therefore an intermediate-term risk assessment is not needed.

5. *Aggregate cancer risk for U.S. population.* The Agency has classified isoxadifen-ethyl as “not likely to be a carcinogen.” Therefore, isoxadifen-ethyl is not expected to pose a cancer risk.

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 isoxadifen-ethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The Agency has reviewed the analytical method validation data submitted by Bayer CropScience and the data submitted with the Independent Laboratory Validation (ILV). The ILV reported that the method worked well. The Agency believes the method is suitable for enforcement.

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

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

V. Conclusion

Therefore, tolerances are established for combined residues of isoxadifen-ethyl, ethyl 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylate (CAS 163520–33–0) and its metabolites: 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylic acid and β -hydroxy- β -benzenepropanenitrile, in or on rice commodities: Rice, grain; rice, straw; and rice, hulls at 0.10, 0.25, and 0.50 ppm, respectively.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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 ID number OPP–2004–0093 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 July 26, 2004.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603-0061.

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 20460-0001.

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 20460-0001.

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 **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2004-0093, 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 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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 under 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 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 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. 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 section 408(n)(4) of FFDCA. 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. Congressional Review Act

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.

■ 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 amended by revising paragraph (a)(2) to read as follows:

§ 180.570 Isoxadifen-ethyl; tolerances for residues.

(a) * * *

(2) Tolerances are established for the residues of isoxadifen-ethyl (3-isoxazolecarboxylic acid, 4,5-dihydro-5,5-diphenyl-, ethyl ester (CAS No. 163520-33-0)), and its metabolites 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylic acid and β -hydroxy- β -benzenepropanenitrile when used as an inert ingredient (safener) in or on the following raw agricultural commodities, when applied at an annual application rate of 0.17 pounds isoxadifen-ethyl/acre.

Commodity	Parts per million
Rice, grain	0.10
Rice, hulls	0.50
Rice, straw	0.25

* * * * *

Dated: May 11, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 04-11561 Filed 5-25-04; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0056; FRL-7357-6]

Ultramarine Blue; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of ultramarine blue when used as an inert ingredient in pesticide products. Holliday Pigments Limited submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ultramarine blue.

DATES: This regulation is effective May 26, 2004. Objections and requests for hearings must be received on or before July 26, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket ID number OPP-2004-0056. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT:

James Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0371; e-mail address: parker.james@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

II. Background and Statutory Findings

In the **Federal Register** of March 12, 2003 (68 FR 11843) (FRL-7295-3), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104-170), announcing the filing of a pesticide petition (3E6549) by Holliday Pigments Limited, Morley Street, Hull, East Yorkshire, England, HU88DN. That notice included a summary of the petition prepared by the petitioner.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of ultramarine blue, which is also known as C.I. Pigment Blue 29 (CAS Reg. No. 57455-37-5). There were no comments received in response to the notice of filing.