63994

herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2cyclohexen-1-one (CAS Reg. No. 74051-80–2) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the following commodities:

Parts per

million

40.0

40.0 2.0

0.8

8.0

0.2

4.0

20.0

15.0

50.0 15.0

10.0

3.0

4.0

10

6.0

25

19 5.0

35.0

40.0

0.2

0.2

1.0

0.2

0.2

1.5 1.5

35.0

50.0

4.0

0.5

2.5

2.0

3.0

0.4

3.5

15

5.0

2.0

10

2.0

5.0 2.0

0.5

0.2

0.2

0.2

1.0

1.0

2.0

0.2

0.2

1.0

0.2

0.2

1.0

5.0

30.0

5.0

0.5

0.2

Co	mmodity
Alfalfa, forage	ə
Alfalfa, hav	
Almond, hulls	3
Apple, dry po	mace
Apple, wet po	omace
Apricot	
Asparagus	
Bean, dry, se	ed
Bean, lolage Rean hav	
Bean, succul	ent
Beet, sugar,	molasses
Beet, sugar,	tops
Blueberry	
Borage, mea	l
Borage, seed	l
Buckwheat, f	lour
Buckwheat, g	grain
Caneberry St	ibgroup 13A
Canola/rapes	eed meal
Cattle fat	eed, meal
Cattle meat	
Cattle, meat	byproducts
Cherry, swee	t
Cherry, tart	t
Citrus, molas	ses
Citrus, dried	nulp aluq
Clover, forag	e
Clover, hay	
Coriander	
Corn, field, g	rain
Corn todder .	
Com sweet	forage
Corn. sweet.	kernel plus cob
	removed
Corn, sweet,	stover
Cotton, seed.	soapstock
Cotton, unde	linted seed
Cranberry	
Dillweed, fres	sh leaves
Flax, meal	
Goat fat	
Goat, nat Goat, meat	
Goat, meat b	yproducts
Grape, raisin	
Hog, meat	
Hog, meat by	products
	humandu ata
	byproducts
Juneberry	
necianne	

Commodity	Parts per million
Okra	2.5
Peach	0.2
Pea, dry, seed	40.0
Pea, field, hay	40.0
Pea, field, vines	20.0
Peanut	25.0
Peanut, soapstock	75.0
Pea, succulent	10.0
Peppermint, tops	30.0
Pistachio	0.2
Potato, flakes	8.0
Potato, granules	8.0
Potato, processed potato waste	8.0
Poultry, fat	0.2
Poultry, meat	0.2
Poultry, meat byproducts	2.0
Radish, tops	4.5
Salal	5.0
Safflower	15.0
Sheep, fat	0.2
Sheep, meat	0.2
Sheep, meat byproducts	1.0
Soybean	16.0
Soybean, hay	10.0
Spearmint, tops	30.0
Strawberry	10.0
Sunflower, meal	20.0
Sunflower, seed	7.0
Tomato, concentrated products	24
Tomato, dry pomace	12.0
Turnip, greens	5.0
Vegetable, brassica, leafy,	
group 5	5.0
Vegetable, bulb, group 3	1.0
Vegetable, cucurbit, group 9	4.0
Vegetable, fruiting, group 8	4.0
Vegetable, leafy, except bras-	
sica, group 4	4.0
Vegetable, root and tuger,	
group 1	4.0

[FR Doc. E7-22220 Filed 11-13-07; 8:45 am] BILLING CODE 6560-50-S

#### **ENVIRONMENTAL PROTECTION AGENCY**

40 CFR Part 180

[EPA-HQ-OPP-2005-0305; FRL-8156-6]

#### Isoxadifen-ethyl; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of isoxadifenethyl (ethyl 5,5-diphenyl-2-isoxazoline-3-carboxylate; CAS Reg. No. 163520-33-0) and its metabolite 4,5-dihydro-5,5,diphenyl-3-isoxazolecarboxylic acid when used as an inert ingredient (safener) in or on corn, sweet, kernel plus cob with husks removed; corn. sweet, forage; corn, sweet, stover; corn, pop, grain; corn, pop, stover; and corn,

oil. EPA is also revising existing

tolerances for residues of isoxadifenethyl in or on corn, field, forage and corn, field, hay, and removing the seasonal application rate specification from existing tolerances. Interregional Research Project Number 4 (IR-4) and Bayer CropScience requested certain tolerance amendments for the inert ingredient safener isoxadifen-ethyl under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective November 14, 2007. Objections and requests for hearings must be received on or before January 14, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION). ADDRESSES: EPA has established a docket for this action under docket

identification (ID) number EPA-HQ-OPP-2005-0305. To access the electronic docket, go to http:// www.regulations.gov, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., 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 in the electronic docket at http://www.regulations.gov, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The 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:

Tracy Ward, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 703-308-9361; e-mail address: ward.tracyh@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?

In addition to accessing an electronic copy of this Federal Register document through the electronic docket at http://www.regulations.gov, you may access this Federal Register document electronically through the EPA Internet under the "Federal Register" listings at http://www.epa.gov/fedrgstr. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at http://www.gpoaccess.gov/ecfr.

# C. Can I File an Objection or Hearing Request?

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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2005-0305 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 January 14, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA—HQ—OPP—2005—0305, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the on-line instructions for submitting comments.
- Mail: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

#### II. Background and Statutory Findings

EPA received several petitions requesting new tolerances and amendments to existing tolerances for the inert ingredient (safener) isoxadifenethyl (ethyl 5,5-diphenyl-2-isoxazoline-3-carboxylate; CAS Reg. No. 163520-33-0). The most recent final rule that established tolerances for this safener was published in the Federal Register (69 FR 29882) on May 26, 2004 (http:// www.epa.gov/fedrgstr/EPA-PEST/2004/ May/Day-26/p11561.htm). That final rule provides a description of the toxicity data and risk assessments for isoxadifen-ethyl, and the reader is referred to it for additional information. The new petitions received by the Agency are summarized below.

In the Federal Register of January 18, 2006 (81 FR 2926) (FRL-7750-1), the Agency issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a announcing the filing of pesticide petition (PP 5E6962) by Bayer CropScience, 2 Alexander Drive, Research Triangle Park, NC 27709. The petition requested an increase in the tolerances under 40 CFR 180.570 for residues of isoxadifen-ethyl and its metabolite 4,5-dihydro-5,5, diphenyl-3isoxazolecarboxylic acid when used as an inert ingredient (safener) in or on the food commodities corn, field, forage at 0.20 parts per million (ppm) (increased from existing tolerance of 0.10 ppm) and corn, field, stover at 0.40 ppm (increased from existing tolerance of

0.20 ppm). No substantive comments were received for this Notice.

The Agency also issued a notice in the April 4, 2007 Federal Register (72 FR 163552) announcing the filing of pesticide petition (PP 5E7007) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. The petition requested the establishment of tolerances for residues of isoxadifenethyl and its metabolite in or on corn, sweet, kernel plus cob with husks removed (K+CWHR) at 0.05 ppm; corn, sweet, forage at 0.40 ppm; corn, sweet, stover at 0.40 ppm; corn, pop, grain at 0.02 ppm; and corn, pop, stover at 0.40 ppm. No comments were received for this Notice.

In the same **Federal Register** of April 4, 2007, it was also noted that the seasonal application rates could be removed from the existing tolerances under 40 CFR 180.570. Seasonal application rates are not necessary when numerical tolerances are already established. No comments were received for this Notice.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for 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(c)(2)(A)(ii) of the 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 the 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...." These provisions were added to the FFDCA by the Food Quality Protection Act (FQPA) of 1996.

# III. Risk Characterization and Conclusion

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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 this unit. EPA has sufficient data to assess the hazards of and make a determination on aggregate exposure for the chemical.

The following provides a brief summary of the risk assessment and conclusions for the Agency's review of isoxadifen-ethyl. The Agency's full decision document and risk assessments for this action are available on EPA's Electronic Docket at <a href="http://www.regulations.gov/">http://www.regulations.gov/</a> under docket number EPA-HQ-OPP-2005-0305. For the full toxicity data and information on which this risk assessment is based, the reader is referred to a Final Rule establishing tolerances for isoxadifenethyl that published in the May 26, 2004 Federal Register (69 FR 29882).

### A. Human Health

The Agency reviewed the available information on isoxadifen-ethyl submitted by the petitioners as well as additional information available to EPA. The toxicity database is sufficient for isoxadifen-ethyl. Isoxadifen-ethyl has low acute oral, dermal and inhalational toxicity to rats. It is non-irritating to rabbit skin, moderately irritating to the eye, and is a skin sensitizer in guinea pigs. The chemical did not produce systemic toxicity in a subchronic dermal toxicity study up to the limit dose. Isoxadifen-ethyl tested negative overall for mutagenicity, and it was classified as "not likely to be a human carcinogen." In subchronic and chronic oral toxicity studies, kidney and liver effects and decreased body weight and weight gain were observed. Concerning developmental toxicity, the Agency concluded that there is no concern for increased susceptibility in offspring. For additional information on the human health toxicity data for isoxadifen-ethyl, see the docket and the Federal Register of May 26, 2004 (69 FR 29882).

#### B. Exposure Assessment

The Agency conducted a dietary exposure assessment using the Dietary Exposure Evaluation Model-Food Consumption Intake Database (DEEM-FCID<sup>TM</sup>) for all uses requested by the petitioners. Dietary food and drinking water exposures from the inert ingredient safener use of isoxadifenethyl are low for all population subgroups, and therefore, not of concern. The highest dietary exposure value estimated was 2.3% of the chronic population adjusted dose (PAD) for infants (< 1 year old).

The Agency conducted a residential exposure assessment. Residential dermal and inhalation exposures for the general population (including toddlers) are also not of concern given that the estimated margins of exposure (MOEs) range from 790 to 1,500. Isoxadifenethyl is currently in pesticide formulations applied by professional pesticide applicators to commercial and residential lawns, recreational facilities, etc. There are no non-pesticidal uses of this chemical. Therefore, no further aggregate assessment is necessary. For additional information on the exposure assessment for isoxadifen-ethyl, see the docket and the Federal Register of May 26, 2004 (69 FR 29882).

### C. Safety Factor for Infants and Children

Section 408 of the 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 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. The toxicity database is sufficient for isoxadifen-ethyl and potential exposure is adequately characterized based on modeling. In terms of hazard, there are low concerns and no residual uncertainties regarding prenatal and/or postnatal toxicity. Accordingly, EPA concludes that the additional tenfold safety factor for the protection of infants and children is unnecessary. For additional information on the Safety Factor determination for infants and children for isoxadifen ethyl, see the docket and the Federal Register of May 26, 2004 (69 FR 29882).

#### D. Cumulative Exposure

Section 408(b)(2)(D)(v) of the 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 the chemical 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 EPA's website at <a href="http://www.epa.gov/pesticides/cumulative">http://www.epa.gov/pesticides/cumulative</a>.

#### E. Other Considerations

- 1. Analytical methods. Adequate enforcement methodology 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; email address: residuemethods@epa.gov. For the complete description of Analytical Methods for isoxadifen-ethyl, see the docket and the **Federal Register** of May 26, 2004 (69 FR 29882).
- 2. International tolerances. There are no Codex tolerances established for isoxadifen-ethyl. Canada has established a Maximum Residue Limits for isoxadifen-ethyl on corn, field, grain at 0.08 ppm.

## F. Determination of Safety and Conclusions

The Agency is granting the requested tolerances for isoxadifen-ethyl and its metabolite on corn, field, forage at 0.20 ppm and corn, field, stover at 0.40 ppm. Although the petitioner requested tolerances in or on corn, sweet, kernal plus cob with husk removed at 0.05 ppm; corn, sweet, forage at 0.40 ppm; corn, sweet, stover at 0.40 ppm; corn, pop, grain at 0.02 ppm; and corn, pop, stover at 0.40 ppm, based on the Agency's review of the data and information available for isoxadifenethyl, including toxicity endpoints and previously submitted field trial data, the Agency is granting tolerances for these uses under 40 CFR 180.570 as follows: corn, sweet, kernal plus cob with husk removed at 0.04 ppm; corn, sweet, forage at 0.30 ppm; corn, sweet, stover at 0.45 ppm; corn, pop, grain at 0.04 ppm; and corn, pop, stover at 0.25 ppm. In addition, based on the results of the risk assessment, the Agency is lowering the current tolerance on corn, field, grain to 0.08 ppm (from the established 0.10 ppm) and establishing an exemption for corn, oil at 0.50 ppm. A new field corn processing study is needed if the petitioner wishes to remove the corn, oil tolerance.

Finally, the Agency is removing the seasonal application rates from the existing tolerance expression of 40 CFR 180.570. Seasonal application rates are not necessary when numerical tolerances are already established.

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm to the general population, including infants and children, from aggregate exposure to residues of isoxadifen-ethyl and its metabolite. Accordingly, EPA finds that the tolerances described above for residues of isoxadifen-ethyl and its metabolite will be safe. EPA is establishing tolerances for residues of isoxadifen-ethyl and its metabolite when it is used as an inert ingredient safener in pesticide formulations.

## IV. Statutory and Executive Order Reviews

This final rule establishes a tolerance exemption 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, 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) or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). 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., 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).

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.

This final rule directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct

effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not 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).

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).

#### V. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: November 5, 2007.

#### Lois Rossi,

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), 346a and 371.

■ 2. Section 180.570 is amended by revising paragraph (a) to read as follows:

### § 180.570 Isoxadifen-ethyl; tolerances for residues.

(a) General. (1) Tolerances are established for residues of isoxadifenethyl (ethyl 5,5-diphenyl-2-isoxazoline-3-carboxylate, (CAS No. 163520–33–0), and its metabolite: 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylic acid, when used as an inert ingredient (safener) in or on the following raw agricultural commodities:

Commodity	Parts per million
Corn, field, grain	0.08 0.20 0.40 0.50 0.04 0.25 0.30

(2) Tolerances are established for the residues of isoxadifen-ethyl (3-isoxazolecarboxylic acid, 4,5-dihydro-5,5-diphenyl-, ethyl ester (CAS No. 164520–33–0)), and its metabolites 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylic acid and  $\beta$ -hydroxy- $\beta$ -benzenepropanenitrile when used as an inert ingredient (safener) in or on the following raw agricultural commodities:

Commodity	Parts per million
Rice, grainRice, hulls	0.10 0.50 0.25

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2005-0119; FRL-8156-8]

## Cyprodinil; Time-Limited Pesticide Tolerance

**AGENCY:** Environmental Protection

Agency (EPA). **ACTION:** Final rule.

**SUMMARY:** This regulation extends timelimited tolerances for residues of cyprodinil in or on onion, dry bulb; onion, green; and strawberry. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The tolerances will expire on December 31, 2009.