(ix) Feather River Air Quality Management District, 1007 Live Oak Blvd., Suite B–3, Yuba City, CA 95991.
(x) Glenn County Air Pollution Control District, 720 N. Colusa Street, P.O. Box 351, Willows, CA 95988–0351.
(xi) Great Basin Unified Air Pollution Control District, 157 Short Street, Suite 6, Bishop, CA 93514–3537.
(xii) Imperial County Air Pollution Control District, 150 South Ninth Street, El Centro, CA 92243–2801.
(xiii) Lake County Air Quality Management District, 885 Lakeport Blvd., Lakeport, CA 95453–5405.
(xiv) Lassen County Air Pollution Control District, 707 Nevada Street, Suite 1, Susanville, CA 96130.
(xv) Mariposa County Air Pollution Control District, P.O. Box 5, Mariposa, CA 95338.
(xvi) Mendocino County Air Quality Management District, 306 E. Gobbi Street, Ukiah, CA 95482–5511.
(xvii) Modoc County Air Pollution Control District, 619 North Main Street, Alturas, CA 96101.
(xviii) Mojave Desert Air Quality Management District, 14306 Park Avenue, Victorville, CA 92392–2310.
(xix) Monterey Bay Unified Air Pollution Control District, 24580 Silver Cloud Court, Monterey, CA 93940.
(xx) North Coast Unified Air Quality Management District, 2300 Myrtle Avenue, Eureka, CA 95501–3327.
(xxi) Northern Sierra Air Quality Management District, 200 Litton Drive, Suite 320, P.O. Box 2509, Grass Valley, CA 95945–2509.
(xxii) Northern Sonoma County Air Pollution Control District, 150 Matheson Street, Healdsburg, CA 95448–4908.
(xxiii) Placer County Air Pollution Control District, 3091 County Center Drive, Suite 240, Auburn, CA 95603.
(xxiv) Sacramento Metropolitan Air Quality Management District, 777 12th Street, Third Floor, Sacramento, CA 95814–1908.
(xxv) San Diego County Air Pollution Control District, 10124 Old Grove Road, San Diego, CA 92131–1649.
(xxvi) San Joaquin Valley Air Pollution Control District, 1990 E. Gettysburg, Fresno, CA 93726.
(xxvii) San Luis Obispo County Air Pollution Control District, 3433 Roberto Court, San Luis Obispo, CA 93401–7126.
(xxviii) Santa Barbara County Air Pollution Control District, 260 North San Antonio Road, Suite A, Santa Barbara, CA 93110–1315.
(xxix) Shasta County Air Quality Management District, 1855 Placer Street, Suite 101, Redding, CA 96001–1759.
(xxx) Siskiyou County Air Pollution Control District, 525 So. Foothill Drive, Yreka, CA 96097–3036.
(xxxi) South Coast Air Quality Management District, 21865 Copley Drive, Diamond Bar, CA 91765–4182.
(xxxii) Tehama County Air Pollution Control District, P.O. Box 8069 (1750 Walnut Street), Red Bluff, CA 96080–0038.
(xxxiii) Tuolumne County Air Pollution Control District, 22365 Airport, Columbia, CA 95310.
(xxxiv) Ventura County Air Pollution Control District, 669 County Square Drive, 2nd Floor, Ventura, CA 93003–5417.
(xxxv) Yolo-Solano Air Quality Management District, 1947 Galileo Court, Suite 103, Davis, CA 95616–4882.
* * * * *
(11) Hawaii. Clean Air Branch, Hawaii Department of Health, 919 Ala Moana Blvd., Suite 203, Honolulu, HI 96814.
* * * * *
(28) Nevada. Nevada Division of Environmental Protection, 901 South Stewart Street, Suite 4001, Carson City, NV 89701–5249.
* * * * *

PART 707—[AMENDED]

■ 18. The authority citation for part 707 continues to read as follows:

Authority: 15 U.S.C. 2611(b) and 2612.

Subpart B—General Import Requirements and Restrictions

■ 19. Section 707.20 is amended by revising the address for Region IX in paragraph (c)(2)(ii) to read as follows:

§ 707.20 Chemical substances import policy.

* * * * *
(c) * * *
(2) * * *
(ii) * * *
Region IX
75 Hawthorne Street, San Francisco, CA 94105 (415) 947–4402.
* * * * *

PART 763—[AMENDED]

■ 20. The authority citation for part 763 continues to read as follows:

Authority: 15 U.S.C. 2605, 2607(c), 2643, and 2646.

■ 21. Appendix C to Subpart E is amended by revising the address for EPA Region IX under II.C.3 to read as follows:

Appendix C to Subpart E of Part 763—Asbestos Model Accreditation Plan

* * * * *
II. * * *
C. * * *
3. * * *
EPA, Region IX, Asbestos NESHAPs Contact, Air Division (A–5), 75 Hawthorne Street, San Francisco, CA 94105, (415) 972–3989.
* * * * *

■ 22. Appendix D to Subpart E is amended by revising the address for Region IX to read as follows:

Appendix D to Subpart E of Part 763—Transport and Disposal of Asbestos Waste

* * * * *
Region IX
Asbestos NESHAPs Contact, Air Division, USEPA, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, (415) 972–3989.
* * * * *

[FR Doc. 2010–28134 Filed 11–10–10; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0504; FRL–8845–6]

Isoxaben; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of isoxaben in or on almond, hulls; grape; nut, tree, group 14; and pistachio. Dow AgroSciences requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 12, 2010. Objections and requests for hearings must be received on or before January 11, 2011, 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–2007–0504. All documents in the docket are listed in the docket index available at *http://www.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 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 Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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 those engaged in the following activities:

- 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 to provide 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 get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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–2007–0504 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 11, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2007–0504, 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 Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility'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. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 1, 2007 (72 FR 42072) (FRL–8138–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F7222) by Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR part 180 be amended by adding a section for the herbicide, isoxaben, and establishing tolerances therein for residues of isoxaben, N-[3-(1-ethyl-1-methylpropyl)-5-isoxazolyl]-2, 6-dimethoxybenzamide, in or on almond, hulls at 0.35 parts per million (ppm); grape; grape, juice; and grape, raisin at 0.01 ppm; and nut, tree, group 14 and pistachio at 0.03 ppm. That notice referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has reduced the tolerances for nut, tree, group 14 and pistachio from 0.03 ppm to 0.02 ppm and increased the tolerance for almond, hulls from 0.35 ppm to 0.40 ppm. EPA has also determined that the proposed tolerances for grape, juice and grape, raisin are not needed. Finally, EPA has revised the requested tolerance expression in accordance with current policy. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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 * * *."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in 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 for isoxaben including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with isoxaben 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.

Isoxaben is of low acute toxicity when administered orally, dermally, or via inhalation. It is not a dermal sensitizer or skin irritant and causes only minor transient irritation to the eye.

The primary target organs identified for isoxaben in repeated-dose studies are the liver and kidney. Although liver effects were observed in all species tested (rat, dog, mouse), adverse changes were only observed in the mouse following chronic oral exposure. These effects included histopathology and increased blood alkaline phosphatase and alanine aminotransferase activities at high doses. In the dog and rat, liver effects were considered adaptive and consisted of enlargement, hepatocellular hypertrophy and induction of hepatic microsomal enzymes. Increased incidence and severity of nephropathy was observed in the rat following chronic (2-year) exposure. No adverse renal effects were reported in the dog or mouse. There was no indication of neurotoxicity or immunotoxicity in the available studies, which generally tested up to or above the limit dose.

No maternal or developmental effects were seen in the rabbit or rat developmental studies. In the rat reproductive toxicity study, two matings (a and b generations) per F0 and F1 parental generations were conducted, plus two additional matings ($F2_c$ and $F3_a$) to examine developmental effects on gestation day 20. Effects included a decrease in corpora lutea, resulting in a decrease in the mean number of implantations and mean live fetuses per litter. Nursing pups showed decreased body weight gain at the highest dose tested. An increase in the incidence of several malformations (exencephaly, microphthalmia/coloboma and hydroureter) was seen in the $F2_b$, $F2_c$ and $F3_a$ mating generations at the limit dose of 1,000 milligrams/kilogram/day (mg/kg/day highest dose tested (HDT)), but not in the $F1_a$, $F1_b$ or $F2_a$ offspring. The relationship of these findings to treatment is unclear because an examination of the genealogy of these offspring suggests a possible heritable component. A large percentage of the affected litters were the result of either cousin matings or had in common F0 progenitors derived from several F0 litters from the supplier. However, because the relationship to treatment could not be ruled out, the malformations were considered a possible treatment-related effect.

No effects of treatment were reported in a 21-day repeated-application dermal toxicity study in the rabbit. This is consistent with relatively low dermal absorption (≤11% of administered dose) observed in a dermal penetration study in the monkey and the low oral toxicity observed in subchronic oral studies in the rat, mouse and dog.

Isoxaben is classified as having "Suggestive Evidence of Carcinogenic Potential" based on an increased incidence of benign liver tumors observed in male and female mice at the high dose only. EPA has concluded that the chronic risk assessment, based on the chronic RfD/PAD, is protective of potential carcinogenicity for the following reasons. The liver tumors were observed only in one species (mice), were not malignant, and were observed in the presence of liver toxicity at dietary levels exceeding the limit dose (1,000 mg/kg/day). The chronic RfD/PAD is based on the chronic toxicity NOAEL of 5 mg/kg/day in the rat, which is more than 200-fold lower than the dose at which tumors were observed in the mouse and, therefore, protective of potential carcinogenicity.

Specific information on the studies received and the nature of the adverse effects caused by isoxaben as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document "Isoxaben. Human Health Risk Assessment for the First Food Uses of the Herbicide on Grapes, Tree Nuts and Pistachio" at page 50 in docket ID number EPA–HQ–OPP–2007–0504.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for isoxaben used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ISOXABEN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All Populations, including Females 13–50 years of age, Infants and Children).	Not Applicable	Not Applicable	An appropriate endpoint was not identified that could occur following a single exposure.
Chronic dietary (All populations)	NOAEL= 5.0 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x.	Chronic RfD = 0.05 mg/kg/day cPAD = 0.05 mg/kg/day.	Chronic oral toxicity/carcinogenicity in the rat. LOAEL = 50.7 mg/kg/day based on renal toxicity in males.
Incidental oral short-term (1 to 30 days).	Not Applicable	Not Applicable	An appropriate endpoint was not identified for short-term oral exposures.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ISOXABEN FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Incidental oral intermediate-term (1 to 6 months).	NOAEL= 200 mg/kg/day UF_A= 10x. UF_H= 10x FQPA SF = 1x	LOC for MOE = 100	Reproductive toxicity in the rat (oral). Offspring LOAEL = 1,000 mg/kg/day based on decreased body weight gain in F1 females on Day 70. One year dietary study in the rat (co-critical supporting study). LOAEL = 625 mg/kg/day based on decreased body weight gain in females during the first six months with a NOAEL of 62.5 mg/kg/day.
Dermal short-term (1 to 30 days) ..	Not Applicable	Not Applicable	An appropriate endpoint was not identified for short-term dermal exposures.
Dermal intermediate-term (1 to 6 months).	Not Applicable	Not Applicable	An appropriate endpoint was not identified for intermediate-term dermal exposures.
Inhalation short-term (1 to 30 days).	Inhalation (or oral) study NOAEL= 200 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Reproductive toxicity in the rat (oral). LOAEL = 1,000 mg/kg/day based on increased incidence of malformations.
Inhalation intermediate-term (1 to 6 months).	Inhalation (or oral) study NOAEL = 200 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Reproductive toxicity in the rat (oral). LOAEL = 1,000 mg/kg/day based on decreased body weight gain in F1 females on Day 70, decreased F2 pup weights, gestation survival and live pups/litter, and increased incidence of malformations. One year dietary study in the rat (co-critical supporting study). LOAEL = 625 mg/kg/day based on decreased body weight gain in females during the first six months with a NOAEL of 62.5 mg/kg/day.
Cancer (Oral, dermal, inhalation) ..	Classification: Suggestive Evidence of Carcinogenic Potential, based on increased incidence of hepatocellular adenomas in male and female mice. The chronic risk assessment, based on the chronic RfD/PAD, is considered protective of potential carcinogenicity; a separate exposure assessment to evaluate cancer risk is unnecessary.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. LOAEL = lowest observed adverse effect level. NOAEL = no observed adverse effect level.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to isoxaben, EPA considered exposure under the petitioned-for tolerances. There are no tolerances currently established for isoxaben. EPA assessed dietary exposures from isoxaben in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and 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. No such effects were identified in the toxicological studies for isoxaben; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed that residues are present in all commodities at the tolerance level and that 100% of commodities are treated with isoxaben. DEEM™ 7.81 default concentration factors were used to estimate residues of isoxaben in processed commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA classified isoxaben as having "Suggestive Evidence of Carcinogenic Potential" but determined that the chronic risk assessment will be protective of both non-cancer and cancer effects. Therefore, a separate exposure assessment to evaluate cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for isoxaben. Tolerance level residues and 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The residues of concern in drinking water following applications of isoxaben include isoxaben and its degradates hydroxyisoxaben (N-[3-(1-hydroxyl-1-methylpropyl)-5-isoxazoyl]-2,6-dimethoxy-benzamide); dimethoxybenzamide (2,6-dimethoxybenzamide); methoxyphenylpyrimidinol (6-(1-ethyl-1-methylpropyl)-2-(2-hydroxy-6-methoxyphenyl)-4-pyrimidinol); and AEM hexenoylisoxaben (N-[3-amino-4-ethyl-4-methyl-2-hexenoyl]-2,6-dimethoxybenzamide). The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for isoxaben and its degradates in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of isoxaben and its degradates. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of isoxaben and its degradates for chronic exposures for non-cancer assessments (the only dietary exposure scenario of concern for isoxaben) are estimated to be 120 parts per billion (ppb) for surface water and 43.6 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 120 ppb was used to assess the contribution to drinking 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). Isoxaben is currently registered for the following uses that could result in residential exposures: Home lawns, recreational turf areas and ornamental plantings. EPA assessed residential exposure using the following assumptions: There is a potential for exposure of homeowners applying products containing isoxaben on home lawns (i.e., residential handler exposure). There is also a potential for post-application exposure of adults and children entering lawn and recreation areas which have been treated with isoxaben and for bystander exposure of adults and children in areas adjacent to pesticide applications.

For residential handlers, dermal and inhalation exposures of short-term duration are expected. Since EPA did not identify an endpoint of concern for dermal exposures, only short-term inhalation exposures were assessed.

The following types of residential exposure may occur following applications of isoxaben on lawns and recreational turf areas: Short- and intermediate-term dermal and inhalation exposure of adults and children entering treated areas; short-term incidental oral hand-to-mouth and/or object-to-mouth exposure of children playing on treated turf; short- and intermediate-term incidental oral exposure of children ingesting soil from treated areas; and episodic oral exposure of children ingesting pesticide granules following applications of granular isoxaben formulations on lawns. Post-application inhalation exposures are expected to be negligible due to the low volatility of isoxaben, label recommendations for incorporation of the product (by rainfall or irrigation) after application, and the types of application equipment used to apply isoxaben (i.e., isoxaben is not applied using air blast or aerial equipment that would increase the potential for inhalation exposure). EPA did not identify an endpoint of concern for acute or short-term oral exposures or for short- or intermediate-term dermal exposures. Therefore, in its post-application exposure assessment for isoxaben, EPA assessed only intermediate-term oral exposure of children ingesting treated soil. EPA does not typically consider soil ingestion to occur over intermediate-term durations, i.e., from 1–6 months, largely due to use patterns and the fact that residues are removed by precipitation or through microbial degradation in soil. In the case of isoxaben, the Agency estimated incidental oral exposure from ingestion of soil because the use pattern calls for repeat applications and the environmental fate data indicate that isoxaben is persistent in the soil. EPA conducted a conservative assessment of potential intermediate-term oral risk from soil ingestion using an application rate of 3.0 lb ai/A, equivalent to 3X the maximum single rate of 1.0 lb ai/A. The higher rate was assumed to account for build-up in the soil due to the pesticide's persistence.

Bystander exposure of adults and children is possible on areas adjacent to application sites. EPA's concern for bystander exposures is low based on several considerations:

i. Low acute toxicity of isoxaben via the inhalation route of exposure;

ii. Label recommendations for incorporation of the product (by rainfall or irrigation) after application;

iii. Isoxaben's low volatility; and

iv. The types of application equipment used to apply isoxaben (i.e., isoxaben is not applied using air blast or aerial equipment that would increase the potential for inhalation exposure).

In addition, EPA notes that MOEs calculated for residential handlers of isoxaben are very high, ranging from 2.9 million to 28 million (See Unit III.E.3.). Bystander exposures of both adults and children are expected to be substantially lower than residential handler exposures, resulting in even higher MOEs and lower risk for bystanders. For these reasons, EPA's concern for bystander exposure of adults and children is low, and a quantitative assessment of bystander exposure and risk is considered unnecessary.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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."

EPA has not found isoxaben to share a common mechanism of toxicity with any other substances, and isoxaben does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that isoxaben does not have 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 Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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. This additional margin of

safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The pre- and postnatal toxicity database for isoxaben includes guideline rat and rabbit developmental toxicity studies and a three-generation reproduction toxicity study in rats. There was no maternal or developmental toxicity observed in the developmental studies in rats and rabbits. Increased qualitative susceptibility was observed in the rat reproductive toxicity study as decreased live pups/litter and decreased gestation survival in $F2_b$ litters (relative to body weight effects in mothers).

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for isoxaben is largely complete, missing only acute and subchronic neurotoxicity studies, an immunotoxicity study and a subchronic inhalation study. EPA has determined that an additional uncertainty factor is not needed to account for the lack of these studies for the following reasons:

- There is no evidence in the existing studies that isoxaben targets either the nervous system or the immune system.
- EPA's concern for inhalation toxicity from subchronic exposures is low, based on isoxaben's low vapor pressure and frequency of application.
- Overall, the toxicity of isoxaben is low. The available oral studies of short-term (e.g., developmental toxicity) or subchronic exposure duration indicated no toxicity up to the limit dose. Effects observed in adult animals (decreased body weight) at exposures of intermediate-term duration were minimal, and malformations seen in offspring in the rat reproduction study were of uncertain relationship to treatment. The endpoints were assumed by EPA to be treatment-related, a conservative assumption intended to ensure the risk assessment is protective of potential effects.

Based on these considerations, EPA does not expect the required studies to provide lower points of departure than those currently selected for risk assessment, and an additional uncertainty factor is not needed to account for the lack of these studies.

ii. There is no evidence of neurotoxicity in the available toxicology database and no evidence of developmental toxicity in either the rat or rabbit developmental toxicity studies at doses up to the limit dose. Based on these considerations, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There was no evidence of increased susceptibility in the rat and rabbit developmental toxicity studies. Although increased qualitative susceptibility was observed in the rat reproductive toxicity study as decreased live pups/litter and decreased gestation survival in $F2_b$ litters (relative to body weight effects in mothers), EPA's concern for qualitative susceptibility is low. Offspring effects were seen only at the limit dose in later generations and not observed in the developmental studies. Additionally, since there is evidence that observed malformations were due in part to heritable factors, the relationship of these effects to treatment is unclear. There are low concerns for effects on offspring viability, because they were only observed at the limit dose and may have been secondary to effects on the dams. The endpoints and points of departure selected for risk assessment are protective of these effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed assuming tolerance-level residues and 100% crop treated for all commodities. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to isoxaben in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by isoxaben.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, isoxaben is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to isoxaben from food and water will utilize 17% of the cPAD for infants, less than 1 year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of isoxaben is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Isoxaben is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to isoxaben.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 82,000 for adults. The MOE for adults includes chronic exposure from food and water plus short-term residential handler exposure of adult females, based on the worst-case granular push-type applicator scenario. Because EPA's level of concern for isoxaben is a MOE of 100 or below, this MOE is not of concern. For children, no short-term oral or dermal endpoints of concern were identified, and residential post-application inhalation exposure is expected to be negligible. Therefore, EPA relies on the chronic dietary risk assessment discussed in Unit III.E.2. for evaluating children's short-term risk from isoxaben.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Isoxaben is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to isoxaben.

Using the exposure assumptions described in this unit for intermediate-

term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 51,000 for children. The MOE for children includes chronic exposure from food and water plus intermediate-term oral exposure of children ingesting treated soil. Because EPA's level of concern for isoxaben is a MOE of 100 or below, the MOE for children is not of concern. For adults, no intermediate-term dermal endpoint of concern was identified, and residential post-application inhalation exposure is expected to be negligible. Therefore, EPA relies on the chronic dietary risk assessment discussed in Unit III.E.2. for evaluating adults' intermediate-term risk from isoxaben.

5. *Aggregate cancer risk for U.S. population.* As explained in Unit III.A., risk assessments based on the endpoint selected for chronic risk assessment are considered to be protective of any potential carcinogenic risk from exposure to isoxaben. Based on the results of the chronic risk assessment discussed above in Unit III.E.2., EPA concludes that isoxaben 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, or to infants and children from aggregate exposure to isoxaben residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography with tandem mass spectromectric detection (LC/MS/MS), method GRM 02.26.S.1) 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

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for isoxaben.

C. Revisions to Petitioned-For Tolerances

Based on the maximum residue of 0.015 ppm observed in field trials with almonds and pecans, the proposed tolerances for nut, tree, group 14 and pistachio were reduced from 0.03 ppm to 0.02 ppm. The proposed tolerance for almond hulls was increased from 0.35 ppm to 0.40 ppm based on analysis of the field trial data using the Agency's Tolerance Spreadsheet in accordance with the "Guidance for Setting Pesticide Tolerances Based on Field Trial Data." EPA has also determined that, since the tolerance for grape will cover residues in/on grape juice and raisins, separate tolerances are not needed for these commodities.

Finally, EPA is revising the requested tolerance expression to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be measured. The revised tolerance expression makes clear that the tolerances cover residues of the herbicide isoxaben, including its metabolites and degradates, but that compliance with the specified tolerance levels is to be determined by measuring only isoxaben N-[3-(1-ethyl-1-methylpropyl)-5-isoxazolyl]-2, 6-dimethoxybenzamide, in or on the commodities.

V. Conclusion

Therefore, tolerances are established for residues of isoxaben, including its metabolites and degradates, in or on almond, hulls at 0.40 ppm; grape at 0.01 ppm; nut, tree, group 14 at 0.02 ppm; and pistachio at 0.02 ppm. Compliance with these tolerances is to be determined by measuring only isoxaben *N*-[3-(1-ethyl-1-methylpropyl)-5-isoxazolyl]-2, 6-dimethoxybenzamide, in or on the commodities.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *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 9, 2000) do not apply to this final rule. In addition, this final 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) (Pub. L. 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).

VII. 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: October 29, 2010.

Steven Bradbury,

Director, 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. Add § 180.650 to subpart C to read as follows:

§ 180.650 Isoxaben; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide isoxaben, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only isoxaben, *N*-[3-(1-ethyl-1-methylpropyl)-5-isoxazolyl]-2, 6-dimethoxybenzamide, in or on the commodity.

Commodity	Parts per million
Almond, hulls	0.40
Grape	0.01
Nut, tree, Group 14	0.02
Pistachio	0.02

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

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

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

[FR Doc. 2010–28499 Filed 11–10–10; 8:45 am]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 216 and 252

Defense Federal Acquisition Regulation Supplement; Award-Fee Reductions for Health and Safety Issues (DFARS Case 2009–D039)

AGENCY: Defense Acquisition Regulations System; Department of Defense (DoD).

ACTION: Interim rule with request for comments.

SUMMARY: DoD is issuing an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement section 823 of the National Defense Authorization Act for Fiscal Year 2010. Section 823 requires contracting officers to consider reduction or denial of award fee if contractor or subcontractor actions jeopardize the health or safety of Government personnel.

DATES: *Effective Date:* November 12, 2010.

Comment Date: Comments on the interim rule should be submitted to the address shown below on or before January 11, 2011, to be considered in the formation of the final rule.

ADDRESSES: You may submit comments, identified by DFARS Case 2009–D039, using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *E-mail: dfars@osd.mil.* Include DFARS Case 2009–D039 in the subject line of the message.
- *Fax:* 703–602–0350.
- *Mail:* Defense Acquisition Regulations Council, Attn: Ms. Amy G. Williams, OUSD (AT&L) DPAP (DARS), Room 3B855, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov*, including any personal information provided. To confirm receipt of your comment, please check *http://www.regulations.gov* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Amy G. Williams, 703–602–0328.

SUPPLEMENTARY INFORMATION:

I. Background

Section 823 of the National Defense Authorization Act for Fiscal Year 2010 (Pub. L. 111–84), requires DoD to revise guidance issued pursuant to section 814 of the National Defense Authorization Act for Fiscal Year 2007 (Pub. L. 109–364). Section 823 is entitled "Authority for Secretary of Defense to Reduce or Deny Award Fees to Companies Found to Jeopardize Health or Safety of Government Personnel." For covered contracts that include award fees, if a contractor or its subcontractor acts with gross negligence or reckless disregard for health or safety, causing serious bodily injury or death of Government personnel, then the contracting officer must consider reduction or denial of award fee for the period in which that action occurred. This interim rule provides a clause to detail those dispositions where a reduction or denial of award fee is applicable. The clause also allows for the recovery of all or part of any award fees paid for any previous award fee evaluation period during which contractor actions caused serious bodily injury or death of Government personnel.

II. Executive Order 12866

This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993.

III. Regulatory Flexibility Act:

DoD does not expect this interim rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because most contracts awarded to small entities use simplified acquisition procedures or, based on the circumstances, may be awarded on a competitive fixed-price basis or a cost-plus-fixed-fee basis. Contracts awarded to small businesses do not generally utilize award-fee type incentive fee structure. Therefore, DoD has not performed an initial regulatory flexibility analysis. DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2009–D039) in correspondence.

IV. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the rule does not impose any information collection requirements that require the approval