

to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Rita Kumar, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8291; e-mail address: [kumar.rita@epa.gov](mailto:kumar.rita@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Does this action apply to me?

The Agency included in the final rule a list of those who may be potentially affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

##### II. What does this technical amendment Do?

This technical amendment adds Bushberry, subgroup 13-07B to the table in paragraph (a) to 40 CFR 180.628. On July 27, 2011 (76 FR 44815) (FRL-8875-5), the Registration Division issued in the **Federal Register** an amendment to 40 CFR 180.628. In the preamble to the final rule RD discussed the addition of several commodities and tolerances, including a tolerance for Bushberry, subgroup 13-07B. However, the tolerance for Bushberry was inadvertently omitted from the regulatory amendment and the table in 180.628. This technical amendment corrects that omission.

##### III. Why is this correction issued as a final rule?

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the Agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making this technical amendment final without prior proposal and opportunity for comment, because this omission was a typographical error. The tolerance for Bushberry, subgroup 13-07B was included in the petitioned for tolerances, exposure and risk evaluation, determination of safety, and conclusion sections of the Final Rule, FR Doc. 2011-18708 published in the **Federal Register** of July 27, 2011 (76 FR 44815-44821). EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(3)(B).

#### IV. Do any of the statutory and Executive Order reviews apply to this action?

This technical amendment adds a tolerance that was inadvertently omitted from a previously published final rule and does not otherwise change the original requirements of the final rule. Since this rule corrects an omission, this action is not subject to the statutory and Executive Order review requirements. For information about the statutory and Executive Order review requirements as they related to the final rule, see Unit VI. in the **Federal Register** of July 27, 2011 (76 FR 44815-44821) (FRL-8875-5).

#### 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: September 15, 2011.

**Daniel J. Rosenblatt,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR part 180 is amended as follows:

#### PART 180—[AMENDED]

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

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.628, in the table to paragraph (a), add the entry for bushberry, subgroup 13-07B to read as follows:

#### § 180.628 Chlorantraniliprole; tolerances for residues.

(a) \* \* \*

Commodity	Parts per million
* * * * *	
Bushberry, subgroup 13-07B .....	2.5

Commodity	Parts per million
* * * * *	

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#### ENVIRONMENTAL PROTECTION AGENCY

##### 40 CFR Part 180

[EPA-HQ-OPP-2010-0186; FRL-8885-3]

##### Amisulbrom; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of amisulbrom in or on grapes and tomatoes. Nissan Chemical Industries, Inc., c/o Lewis & Harrison requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 28, 2011. Objections and requests for hearings must be received on or before November 28, 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-2010-0186. 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:** Olga Odiott, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,

DC 20460-0001; *telephone number*: (703) 308-9369; *e-mail address*: [odiott.olga@epa.gov](mailto:odiott.olga@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://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

###### *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-2010-0186 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 November 28, 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-2010-0186, 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 May 19, 2010 (75 FR 28009) (FRL-8823-2) and the **Federal Register** of February 25, 2011 (76 FR 10584) (FRL-8863-3), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 9E7650 and PP 0E7790) by Nissan Chemical Industries, Inc., c/o Lewis & Harrison, 122 C St., NW., Suite 740, Washington, DC 20001. The petitions requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide amisulbrom, 3-[(3-bromo-6-fluoro-2-methyl-1H-indole-1-yl) sulfonyl]-N,N-dimethyl-1H-1,2,4-triazole-1-sulfonamide, in or on grapes at 0.4 parts per million (ppm), raisins at 1.0 ppm (PP 9E7650), tomato at 0.5 ppm, and tomato paste at 1.2 ppm (PP 0E7790). The notices referenced summaries of the petitions prepared by Nissan Chemical Industries, Inc., the registrant, which are available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notices of filing.

##### **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 amisulbrom including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with amisulbrom 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.

Amisulbrom is of low acute toxicity by the oral, dermal and inhalation routes and is not irritating to the eyes and skin. Rat, mouse, and rabbit studies indicate that amisulbrom systemic toxicity is primarily characterized by decreases in body weight and body weight gain, and reduced food consumption and/or efficiency. Based on the results of the acute and subchronic oral neurotoxicity studies in rats, as well as other subchronic and chronic studies, a developmental neurotoxicity (DNT) study is not needed for amisulbrom. None of these studies indicated specific neurotoxicity responses to amisulbrom. The T-cell dependent antibody response (TDAR) assay showed no evidence of treatment-related effects in rat and mouse immunotoxicity studies. The rat

developmental toxicity study demonstrated cleft palate and other malformations only at the highest doses. There were no effects in the fetuses in the rabbit developmental toxicity study at the highest dose tested.

In accordance with the EPA's *Final Guidelines for Carcinogen Risk Assessment* (March 2005), amisulbrom is classified as "Suggestive Evidence of Carcinogenic Potential". This classification is based on: Liver tumors in male mice at both an adequate and excessive dose; liver tumors in both sexes of rats only at an excessive dose; and forestomach tumors in female rats also only at an excessive dose.

In the case of amisulbrom, a cancer risk from dietary exposure is of low concern based on the following considerations:

- The liver tumors seen in male mice only were benign with no progression to malignancy;
- The liver tumors in rats seen only at excessive doses (*i.e.*, greater than the Limit Dose of 1,000 milligrams/kilogram/day (mg/kg/day)) were also benign with no progression to malignancy;
- The forestomach tumors seen only in female rats occurred only at an excessive dose which was greater than the Limit-Dose;

- None of these tumors resulted in reduced latency; and

- There is no concern for mutagenicity/genotoxicity.

In sum, the only evidence showing any concern for carcinogenicity is the occurrence of benign liver tumors in one sex and one species (*i.e.*, male mice). Given the marginal evidence relating to potential carcinogenicity, the Agency has determined that the chronic population adjusted dose (PAD) will adequately account for all chronic effects, including carcinogenicity, likely to result from exposure to amisulbrom.

Specific information on the studies received and the nature of the adverse effects caused by amisulbrom 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 document "Amisulbrom. Human-Health Risk Assessment for the Establishment of Tolerances for Amisulbrom Fungicide in/on Imported Grape and Tomato" at page 23 in docket ID number EPA-HQ-OPP-2010-0186.

#### *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 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 amisulbrom used for human risk assessment is shown in the following Table 1.

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children)	NOAEL = 200 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Acute RfD = 2 mg/kg/day aPAD = 2 mg/kg/day	Rat acute neurotoxicity screen study. LOAEL = 2,000 mg/kg/day based on 7% decrease in brain weight.
Chronic dietary (All populations)	NOAEL = 54 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.54 mg/kg/day cPAD = 0.54 mg/kg/day	Multiple studies: Combined chronic toxicity/carcinogenicity study in rats, multigenerational reproduction study in rats, mouse carcinogenicity, and subchronic and chronic dog studies. NOAEL = 54 mg/kg/day from the multigenerational study (parental systemic NOAEL). The LOAEL of 96 mg/kg/day is from the combined chronic toxicity/carcinogenicity study in rats and is based on decreased body weight, body weight gains in both sexes, and indications of hepatotoxicity and nephrotoxicity. The mouse (98 mg/kg/day) and dog (100 mg/kg/day) LOAELs are similar.
Cancer (Oral, dermal, inhalation)	"Suggestive Evidence of Carcinogenic Potential". This classification is based on liver tumors in male mice at adequate and excessive doses and liver and stomach tumors in male and/or female rats at excessive doses. The chronic RfD is protective against potential carcinogenic effects.		

UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = 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.

#### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary

exposure to amisulbrom, EPA considered exposure under the petitioned-for tolerances. EPA assessed

dietary exposures from amisulbrom in food as follows:

- 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. Such effects were identified for amisulbrom. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance level residues, default processing factors, and 100% crop treated assumptions to characterize the acute dietary exposure assessment.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used tolerance level residues, default processing factors, and 100% crop treated assumptions to characterize the chronic dietary exposure assessment.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier non-cancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach will be protective of any cancer risk posed by amisulbrom. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure*.

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

2. *Dietary exposure from drinking water.* Pesticide residues in drinking water are not expected. These tolerances are for residues of amisulbrom in/on imported grapes and tomatoes and there are no pesticide registrations in the United States associated with the tolerances. Therefore, the presence of amisulbrom in drinking water in this country resulting from the treatment of crops is not expected.

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).

Amisulbrom is not registered for use in the United States; therefore, residential exposures are not expected.

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 amisulbrom to share a common mechanism of toxicity with any other substances, and amisulbrom does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that amisulbrom 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.* There was an apparent indication of prenatal sensitivity in the rat developmental toxicity study. There were no effects in the dams at the highest dose tested (1,000 mg/kg/day). However, several of the rat fetuses in two litters were noted to have malformations and alterations including cleft palate, bent scapula, humerus ulna and/or radius, constricted spinal cord in

the cervical region, cervical kyphosis, and medially thickened/kinked ribs with distorted ribcage. The NOAEL for the offspring in the rat developmental study was 300 mg/kg/day. There were no indications of increased postnatal offspring sensitivity in the rat reproduction study where the NOAEL (~54 mg/kg/day) and LOAEL (~274 mg/kg/day) for the pups was the same as for the parents. There were no effects in the rabbit developmental toxicity study at the highest dose tested (300 mg/kg/day). Since effects in the rat pups in the developmental toxicity study occur at a dose (1,000 mg/kg/day) well above the NOAELs used for risk assessment (54 and 200 mg/kg/day), no additional UF for sensitivity/susceptibility in the developing animal is needed because the application of the lower NOAEL will be protective against possible developmental effects in the offspring. Based on the available data and the selection of risk assessment endpoints that are protective of developmental effects, there are no residual uncertainties with regard to prenatal and/or postnatal toxicity.

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 amisulbrom is complete.

ii. Neither the rat subchronic neurotoxicity screen studies or the rat multigenerational reproduction study or other subchronic or chronic studies indicated specific neurotoxicity responses to amisulbrom. Although the acute neurotoxicity study observed decreased brain weight, this effect occurred only at the very high limit dose for acute neurotoxicity testing, in only one sex, and a NOAEL was identified. Therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Based on the developmental and reproductive toxicity studies discussed in Unit III.D.2., there are no residual uncertainties with regard to prenatal and/or postnatal toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. Since there are no currently registered or proposed uses of amisulbrom in the United States and adequate food residue data are available, these assessments will not underestimate the exposure and risks posed by amisulbrom.

### 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. Since the subject tolerances are for residues of amisulbrom in/on imported commodities a risk assessment was conducted for exposure to amisulbrom from food only, as there are no drinking water or residential exposures associated with imported grapes and tomatoes. The acute and the chronic dietary risk estimates from food are not of concern for the general population or any other population subgroup. Exposures were equivalent to < 1% aPAD and < 1% cPAD for all population subgroups. As discussed in Unit III.C.1.iii, EPA concluded that regulation based on the chronic reference dose will be protective for both chronic and carcinogenic risks. As noted in this unit there are no chronic risks of concern.

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 amisulbrom residues.

### IV. Other Considerations

#### A. Analytical Enforcement Methodology

A Liquid Chromatography-Mass Spectrometer/Mass Spectrometer (LC-MS/MS) method (NAS 490/042294) is available as an enforcement method for the determination of amisulbrom in plant commodities. The limit of quantitation (LOQ) of the method was 0.01 ppm for amisulbrom. This method was adequately validated for data collection purposes and a successful independent laboratory validation study was conducted. Additionally, amisulbrom is amenable to analysis using FDA multi-residue methods C and E, which are also suitable confirmatory and/or enforcement methods.

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](mailto: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 amisulbrom.

### V. Conclusion

Therefore, tolerances are established for residues of amisulbrom, 3-[(3-bromo-6-fluoro-2-methyl-1H-indole-1-yl)sulfonyl]-N,N-dimethyl-1H-1,2,4-triazole-1-sulfonamide, in or on grape at 0.40 ppm; grape, raisin at 1.0 ppm; tomato at 0.50 ppm; and tomato, paste at 1.2 ppm.

### 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: September 16, 2011.

**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. Section 180.656 is added to read as follows:

### **§ 180.656 Amisulbrom; tolerances for residues.**

(a) *General.* Tolerances are established for residues of the fungicide amisulbrom, including its metabolites and degradates, in or on the commodities listed below. Compliance with the tolerance levels is to be determined by measuring only amisulbrom, 3-[(3-bromo-6-fluoro-2-methyl-1*H*-indole-1-yl) sulfonyl]-*N*, *N*-dimethyl-1*H*-1, 2, 4-triazole-1-sulfonamide].

Commodity <sup>1</sup>	Parts per million
Grape .....	0.40
Grape, raisin .....	1.0
Tomato .....	0.50
Tomato, paste .....	1.2

<sup>1</sup> There is no U.S. registration for use of amisulbrom on grape or tomato.

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

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

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

[FR Doc. 2011-24685 Filed 9-27-11; 8:45 am]

**BILLING CODE 6560-50-P**

## **GENERAL SERVICES ADMINISTRATION**

### **41 CFR Parts 300-3, 301-30, 301-31, Appendix E to Chapter 301, 302-3, 302-4, 302-6, and 303-70**

**[FTR Amendment 2011-04; FTR Case 2010-303; Docket Number 2011-0019, Sequence 1]**

**RIN 3090-AJ06**

### **Federal Travel Regulation (FTR); Terms and Definitions for “Dependent”, “Domestic Partner”, “Domestic Partnership”, and “Immediate Family”**

**AGENCY:** Office of Governmentwide Policy, General Services Administration (GSA).

**ACTION:** Final rule.

**SUMMARY:** GSA has adopted as final, with two changes, an interim rule amending the Federal Travel Regulation (FTR) by adding terms and definitions for “Dependent”, “Domestic partner”, and “Domestic partnership”, and by revising the definition of “Immediate family” to include “Domestic partner” and children, dependent parents, and dependent brothers and sisters of the Domestic partner as named members of the employee’s household. This final rule also adds references to domestic partners and domestic partnerships, where applicable, in the FTR.

**DATES:** *Effective date:* September 28, 2011.

**FOR FURTHER INFORMATION CONTACT:** For clarification of content, contact Mr. Rick Miller, Office of Travel, Transportation, and Asset Management (MT), General Services Administration, at (202) 501-3822 or e-mail at [rodney.miller@gsa.gov](mailto:rodney.miller@gsa.gov). Contact the Regulatory Secretariat (MVCB), 1275 First Street, NE., Washington, DC 20417, (202) 501-4755, for information pertaining to status or publication schedules. Please cite FTR Amendment 2011-04; FTR case 2010-303.

### **SUPPLEMENTARY INFORMATION:**

#### **A. Background**

On June 17, 2009, President Obama signed a Presidential Memorandum on Federal Benefits and Non-Discrimination stating that “[t]he heads of all other executive departments and agencies, in consultation with the Office of Personnel Management, shall conduct a review of the benefits provided by their respective departments and agencies to determine what authority they have to extend such benefits to same-sex domestic partners of Federal employees.” GSA conducted its review

and, as part of that review, identified a number of changes to the FTR that could be made. Subsequently, on June 2, 2010, President Obama signed a Presidential Memorandum, “Extension of Benefits to Same-Sex Domestic Partners of Federal Employees,” which directed agencies to immediately take actions, consistent with existing law, to extend certain benefits, including travel and relocation benefits, to same-sex domestic partners of Federal employees, and, where applicable, to the children of same-sex domestic partners of Federal employees.

Pursuant to 5 U.S.C. 5707, the Administrator of General Services is authorized to prescribe necessary regulations to implement laws regarding Federal employees who are traveling while in the performance of official business away from their official stations. Similarly, 5 U.S.C. 5738 mandates that the Administrator of General Services prescribe regulations relating to official relocation. The overall implementing authority is the FTR, codified in Title 41 of the Code of Federal Regulations, Chapters 300-304 (41 CFR chapters 300-304).

Pursuant to this authority, this final rule adds the same terms and definitions, based on a published Office of Personnel Management (OPM) memorandum to agencies, dated June 2, 2010, “Implementation of the President’s Memorandum Regarding Extension of Benefits to Same-Sex Domestic Partners of Federal Employees,” and guidance from 5 CFR 875, “Federal Long Term Care Insurance Program,” for “Domestic partner” and “Domestic partnership”, adds a definition for “Dependent”, and revises the definition of “Immediate family” to include “Domestic partner” and children, dependent parents, and dependent brothers and sisters of the Domestic partner as named members of the employee’s household. This rule also adds references to “Domestic partners” and “domestic partnership,” where applicable, to travel and relocation allowances permitted under existing statutes. Due to current statutory restrictions, this final rule does not apply to house-hunting trip expense reimbursement, the relocation income tax allowance, the income tax reimbursement allowance, or non-Federal source travel.

#### **B. Summary of Comments Received**

GSA received 13 comments on the interim rule published in the **Federal Register** on November 3, 2010 (75 FR 67629).

- Three associations and three individuals supported the rule, four