

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

**VIII. Congressional Review Act**

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

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure,

Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 22, 2004.

**Lois Rossi,**  
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(g), 346a and 371.

■ 2. Section 180.516 is amended as follows:

a. By alphabetically adding commodities to the table in paragraph (a).

b. By removing the commodities “Apricot,” “Caneberry,” “Nectarine,” “Peach,” and “Plum” in the table in paragraph (b).

**§ 180.516 Fludioxonil; tolerances for residues.**

(a) \* \* \*

| Commodity                                      | Parts per million |
|--|-------------------|
| Bean, dry .....                                | 0.4               |
| Bean, succulent .....                          | 0.4               |
| * * *  | *                 |
| Citrus, crop group 10 .....                    | 10                |
| * * *  | *                 |
| Fruit, pome, group 11 .....                    | 5.0               |
| * * *  | *                 |
| Grapefruit, oil .....                          | 500               |
| * * *  | *                 |
| Kiwifruit .....                                | 20                |
| Leafy greens subgroup 4A, except spinach ..... | 30                |
| * * *  | *                 |
| Melon subgroup 9A .....                        | 0.03              |
| * * *  | *                 |
| Yam, true .....                                | 8.0               |
| * * * * *                                      |                   |

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-2004-0312; FRL-7681-6]

**Methoxyfenozide; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of methoxyfenozide (benzoic acid, 3-methyl-2-methyl-,2-(3,5-methylbenzoyl)-2-(1,1-dimethylethyl)hydrazide) in or on black sapote; canistel; coriander, leaves; mamey sapote; mango; papaya; pea and bean, succulent shelled, subgroup 6B; peppermint; sapodilla; spearmint; star apple; strawberries; vegetable, foliage of legume (except soybean), subgroup 7A; vegetable, leaves of root and tuber, group 2; vegetable, legume, edible podded, subgroup 6A; vegetable, root, subgroup 1A. Interregional Research Project Number 4 (IR-4) and Dow AgroSciences are requesting these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective September 29, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

**ADDRESSES :** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket identification (ID) number OPP-2004-0312. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Joseph Tavano, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6411; e-mail address: [tavano.joseph@epa.gov](mailto:tavano.joseph@epa.gov).

**SUPPLEMENTARY INFORMATION:**

## I. General Information

### A. Does this Action Apply to Me?

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

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

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

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

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

## II. Background and Statutory Findings

In the **Federal Register** of August 18, 2004 (69 FR 51298) (FRL-7361-1), 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 3E6768, PP 3E6784, PP 3E6790, PP 3E6796, and PP 3E6801) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. The petition requested that 40 CFR 180.544 be amended by establishing a tolerance for residues of the insecticide methoxyfenozide, benzoic acid, 3-methoxy-2-methyl, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide, in or on the following raw agricultural commodities: Spearmint, tops at 7.0 parts per million (ppm); peppermint, tops at 7.0 ppm; and dill at 7.0 ppm (PP 3E6768); strawberry at 1.5 ppm (PP 3E6784); vegetable, root, subgroup 1A at 0.5 ppm, and vegetable, leaves of root and tuber, group 2 at 30 ppm (PP 3E6790); papaya; star apple;

sapote, black; mango; sapodilla; canistel; and sapote, mamey at 0.5 ppm (PP 3E6796); coriander, leaves at 30 ppm (PP 3E6796); and vegetable, legume, edible podded, subgroup 6A at 1.5 ppm; pea and bean, succulent shelled, subgroup 6B at 0.2 ppm; and vegetable, foliage of legume, except soybean, subgroup 7A at 35 ppm (PP 3E6801). That notice included a summary of the petition prepared by Dow AgroScience, 9330 Zionsville Road, Indianapolis, IN 46268, the registrant. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . ."

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

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of methoxyfenozide, benzoic acid, 3-methoxy-2-methyl, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide, in or on edible podded legumes (Crop Group 6A), mint, root vegetables (Crop Group

1A), strawberries, succulent shelled pea and bean (Crop Group 6B), and tropical/subtropical fruit crop: black sapote, canistel, mamey sapote, mango, papaya, sapodilla, and star apple) at 1.5, 7.0, 0.5, 1.5, 0.2, 0.5 ppm respectively. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by methoxyfenozide as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of September 20, 2002 (67 FR 59193) (FRL-7198-5).

### B. Toxicological Endpoints

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

Three other types of safety or uncertainty factors may be used: "Traditional uncertainty factors;" the "special FQPA safety factor;" and the "default FQPA safety factor." By the term "traditional uncertainty factor," EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for data base deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term "special FQPA safety factor" refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The "default FQPA safety factor"

is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

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

The linear default risk methodology (Q\*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q\* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q\* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand ( $1 \times 10^{-5}$ ), one in a million ( $1 \times 10^{-6}$ ), or one in ten million ( $1 \times 10^{-7}$ ). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ( $MOE_{\text{cancer}} = \text{point of departure} / \text{exposures}$ ) is calculated.

A summary of the toxicological endpoints for methoxyfenozide used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of September 20, 2002 (67 FR 59193) (FRL-7198-5).

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.544) for the residues of methoxyfenozide, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from methoxyfenozide in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Acute dietary risk assessments are performed for a food use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on methoxyfenozide. Thus, the risk from acute exposure is considered negligible. A summary of the acute dietary risk assessment for methoxyfenozide used for human risk assessment is discussed in Unit III.C.1.i. of the final rule published in the **Federal Register** of September 20, 2002 (67 FR 59193).

ii. *Chronic exposure.* Conducting the chronic dietary risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A Tier 1 (assumptions: tolerance level residues and 100 percent crop treated) chronic dietary risk assessment was conducted via DEEM-FCID. The established tolerances of 40 CFR 180.544 and the proposed tolerances were included in the analysis. DEEM default processing factors (from DEEM Version 7.76) were used for all processed commodities that do not have individual tolerances. Tolerances are not being recommended for animal commodities as a result of the proposed uses.

iii. *Cancer.* Methoxyfenozide is classified as a "not likely" human carcinogen. Therefore this risk is considered negligible.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure

analysis and risk assessment for methoxyfenozide in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of methoxyfenozide.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentration in Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

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

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of

methoxyfenozide for acute exposures are estimated to be 43 parts per billion (ppb) for surface water and 3.5 ppb for ground water. The EECs for chronic exposures are estimated to be 30 ppb for surface water and 3.5 ppb for ground water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Methoxyfenozide is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to methoxyfenozide and any other substances and methoxyfenozide 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 methoxyfenozide has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at <http://www.epa.gov/pesticides/cumulative/>.

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an

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

2. *Prenatal and postnatal sensitivity.* The toxicology data base for methoxyfenozide included acceptable developmental toxicity studies in both rats and rabbits as well as a 2-generation reproductive toxicity study in rats. The data provided no indication of increased sensitivity of rats or rabbits to in utero and/or postnatal exposure to methoxyfenozide.

3. *Conclusion.* There is a complete toxicity data base for methoxyfenozide and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The 10X FQPA factor was removed and reduced to 1X as discussed in the final rule published in the **Federal Register** of September 20, 2002 (67 FR 59193).

#### E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential

uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

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

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

1. *Acute risk.* No appropriate endpoint was identified in the oral toxicity studies including the acute neurotoxicity study in rats and the developmental toxicity studies in rats and rabbits. Accordingly, no acute risk is expected from exposure to methoxyfenozide.

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO METHOXYFENOZIDE

| Population Subgroup                | cPAD mg/kg/day | % cPAD (Food) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Chronic DWLOC (ppb) |
|------------------------------------|----------------|---------------|-------------------------|------------------------|---------------------|
| U.S. population                    | 0.102          | 22.9          | 30                      | 3.5                    | 2800                |
| All Infants (less than 1 year old) | 0.102          | 37.3          | 30                      | 3.5                    | 290                 |

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO METHOXYFENOZIDE—Continued

| Population Subgroup       | cPAD mg/<br>kg/day | % cPAD<br>(Food) | Surface<br>Water EEC<br>(ppb) | Ground<br>Water EEC<br>(ppb) | Chronic<br>DWLOC<br>(ppb) |
|---------------------------|--------------------|------------------|-------------------------------|------------------------------|---------------------------|
| Children (1-2 years old)  | 0.102              | 71.3             | 30                            | 3.5                          | 2900                      |
| Children (3-5 years old)  | 0.102              | 50.1             | 30                            | 3.5                          | 2900                      |
| Children (6-12 years old) | 0.102              | 27.1             | 30                            | 3.5                          | 2900                      |
| Youth (13-19 years old)   | 0.102              | 18.1             | 30                            | 3.5                          | 2900                      |
| Adults (20-49 years old)  | 0.102              | 18.6             | 30                            | 3.5                          | 2900                      |
| Females (13-49 years old) | 0.102              | 19.1             | 30                            | 3.5                          | 2500                      |
| Adults (50+ years old)    | 0.102              | 18.8             | 30                            | 3.5                          | 2900                      |

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to methoxyfenozide from food will utilize 22.9% of the cPAD for the U.S. population, 37.3% of the cPAD for all infants (less than 1 year old), and 71.3% of the cPAD for children, 1-2 years old. There are no residential uses for methoxyfenozide that result in chronic residential exposure to methoxyfenozide.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Methoxyfenozide is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Methoxyfenozide is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* The Agency has classified methoxyfenozide as a "not likely" human carcinogen according to the "EPA Proposed Guidelines for Carcinogen Risk Assessment (April 10, 1996)." This classification is based on the lack of evidence of carcinogenicity in male and female rats as well as in male and female mice and on the lack of genotoxicity in an acceptable battery of mutagenicity studies. Therefore, methoxyfenozide is not expected to pose a cancer risk.

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

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methods are available for determination of methoxyfenozide residues in plant commodities. The available Analytical Enforcement Methodology was previously reviewed in the **Federal Register** of September 20, 2002 (67 FR 59193)

##### B. International Residue Limits

There are no Codex or Canadian MRLs established for residues of methoxyfenozide. Mexican MRLs are established for residues of methoxyfenozide in cottonseed (0.05 ppm) and maize (0.01 ppm). The U.S. tolerances on these commodities are 2.0 ppm and 0.05 ppm, respectively. Based on the current use patterns, the U.S. tolerance levels cannot be reduced to harmonize with the Mexican MRLs, so incompatibility will exist.

#### V. Conclusion

Therefore, tolerances are established for residues of methoxyfenozide, in or on black sapote; canistel; coriander, leaves; mamey sapote; mango; papaya; pea and bean succulent shelled, subgroup 6B; peppermint; sapodilla; spearmint; star apple; strawberries; vegetable, foliage of legume (except soybean), subgroup 7A; vegetable, leaves of root and tuber, group 2; vegetable, legume, edible podded, subgroup 6A; vegetable, root, subgroup 1A at 0.5, 0.5, 30, 0.5, 0.5, 0.5, 0.2, 7.0, 0.5, 7.0, 0.5, 1.5, 35, 30, 1.5, 0.5, respectively.

The original petition submitted by the petitioner requested a tolerance for dill, but data was not provided to the Agency to support the establishment of a tolerance.

#### VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2004-0312 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 November 29, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR

178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564-6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2004-0312, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue

of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

#### **VII. Statutory and Executive Order Reviews**

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States,

or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

#### **VIII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the

Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 22, 2004.

**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 180.544 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

**§ 180.544 Methoxyfenozide; tolerances for residues.**

(a) \* \* \*

| Commodity  | Parts per million |
|--|-------------------|
| * * *  | * * *             |
| Black sapote .....   | 0.5               |
| Canistel .....   | 0.5               |
| Coriander, leaves  | 30                |
| Mamey sapote .....   | 0.5               |
| Mango .....  | 0.5               |
| Papaya .....   | 0.5               |
| Pea and bean, succulent shelled, subgroup 6B .....               | 0.2               |
| Peppermint .....   | 7.0               |
| Sapodilla .....  | 0.5               |
| Spearmint .....  | 7.0               |
| Star apple .....   | 0.5               |
| Strawberries .....   | 1.5               |
| Vegetable, foliage of legume, (except soybean) subgroup 7A ..... | 35                |

| Commodity   | Parts per million |
|---|-------------------|
| Vegetable, leaves of root and tuber, group 2 ...    | 30                |
| Vegetable, legume, edible podded, subgroup 6A ..... | 1.5               |
| Vegetable, root, subgroup 1A .....                  | 0.5               |

\* \* \* \* \*

[FR Doc. 04-21804 Filed 9-28-04; 8:45 am]

**BILLING CODE 6560-50-S**

**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Part 0**

[DA 04-2923]

**Commission Organization**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document amends part 0 of the Commission's rules to update the geographical coordinate locations of the Commission's protected field installations where radio spectrum monitoring operations are conducted to delete the Commission's Anchorage, Alaska monitoring facility.

**DATES:** Effective September 29, 2004.

**FOR FURTHER INFORMATION CONTACT:** Gabriel Collazo, Enforcement Bureau, Spectrum Enforcement Division, (202) 418-1160.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Order, DA 04-2923, adopted on September 8, 2004, and released on September 13, 2004. The complete text of this Order is available for inspection and copying during normal business hours in the FCC Reference Information Center, 445 12th Street, SW., Room CY-A257, Washington, DC 20554. In addition, the complete text may be retrieved from the FCC's Web site at <http://www.fcc.gov>. The text may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone (202) 488-5300, or (800) 378-3160.

The Order amends § 0.121(b) of the rules to update the geographical coordinate locations of the Commission's protected field installations where radio spectrum monitoring operations are conducted. Specifically, the Order deletes the geographical coordinates of the Commission's Anchorage, Alaska

monitoring facility from the list of protected field installations set forth in § 0.121(b) of the rules. These locations are protected from harmful radio frequency interference to the Commission's monitoring activities that could be produced by the proximity of any nearby radio transmitting facilities.

Pursuant to the authority contained in sections 4(i) and (5) of the Communications Act of 1934, as amended, and § 0.231(b) of the rules, part 0 of the rules is amended as set forth in the rule changes.

As the rule amendment adopted in the Order pertains to agency organization, procedure and practice, the notice and comment provision of the Administrative Procedure Act contained in 5 U.S.C. 553(b) is inapplicable.

The Commission will not send a copy of this Order pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A), because the adopted rule are rules of agency organization, procedure, or practice that do not "substantially affect the rights or obligations of non-agency parties."

The rule amendment set forth in the rule changes will become effective September 29, 2004.

**List of Subjects in 47 CFR Part 0**

Organization and functions (Government agencies).

Federal Communications Commission.

**Joseph P. Casey,**

*Spectrum Enforcement Division Enforcement Bureau*

**Rule Changes**

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 0 as follows:

**PART 0—COMMISSION ORGANIZATION**

■ 1. The authority citation for part 0 continues to read as follows:

**Authority:** Secs. 5, 48 Stat. 1068, as amended; 47 U.S.C. 155.

**§ 0.121 [Amended]**

■ 2. Section 0.121 is amended by revising paragraph (b) to read as follows:

\* \* \* \* \*

(b) Protected field offices are located at the following geographical coordinates (coordinates are referenced to North American Datum 1983 (NAD83)):

- Allegan, Michigan, 42°36'20.1" N. Latitude, 85°57'20.1" W. Longitude
- Belfast, Maine, 44°26'42.3" N. Latitude, 69°04'56.1" W. Longitude
- Canandaigua, New York, 42°54'48.2" N. Latitude, 77°15'57.9" W. Longitude