

The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

#### F. Unfunded Mandates

Under sections 202 of the Unfunded Mandates Reform Act of 1995 (“Unfunded Mandates Act”), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of \$100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

#### G. Submission to Congress and the Comptroller General

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. Section 804, however, exempts from section 801 the following types of rules: Rules of particular applicability; rules relating to agency management or personnel; and rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). EPA is not required to submit a rule report regarding this action under section 801 because this is a rule of particular applicability.

#### H. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use “voluntary consensus standards” (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today’s action does not require the public to perform activities conducive to the use of VCS.

#### I. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 5, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter.

Dated: May 31, 2000.

David A. Ullrich,

Acting Regional Administrator, Region 5.

For the reasons stated in the preamble, part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

#### PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

#### Subpart P—Indiana

2. Section 52.770 is amended by adding paragraph (c)(135) to read as follows:

#### § 52.770 Identification of plan.

\* \* \* \* \*

(c) \* \* \*

(135) On January 1, 2000, Indiana submitted revised opacity limits for three processes at ALCOA Warrick

Operations. The revised limits allow higher opacity emissions during fluxing operations at three casting complexes. This action does not change mass emissions limits for these sources.

#### (i) Incorporation by reference.

(A) Modifications to Operating Permits OP 87–07–91–0112 thru 0116: Permit I.D. 173–10913, Issued on October 1, 1999, to ALCOA, Inc.—Warrick Operations. Effective October 1, 1999.

(B) Modifications to Operating Permit OP 87–07–91–0113: Permit I.D. 173–11414, Issued on December 15, 1999, to ALCOA, Inc.—Warrick Operations. Effective December 15, 1999.

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP–300983; FRL–6496–5]

RIN 2070–AB78

### Methoxyfenozide; Benzoic Acid, 3-methoxy-2-methyl-2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of methoxyfenozide in or on cotton, undelinted seed; cotton gin byproducts; pome fruit; apple pomace, wet; milk, meat of cattle, goats, hogs, horses and sheep and fat of cattle, goats, hogs, horses and sheep; and tolerances for the combined residues of methoxyfenozide and its glucuronide metabolite in meat byproduct (except liver) and liver of cattle, goats, hogs, horses and sheep. Rohm and Haas Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective July 5, 2000. Objections and requests for hearings, identified by docket control number OPP–300983, must be received by EPA on or before September 5, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, your objections and hearing requests must identify

docket control number OPP-300983 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Joseph Tavano, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-6411; and e-mail address: tavanoseph@epa.gov.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

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

| Categories | NAICS codes | Examples of potentially affected entities |
|------------|-------------|---|
| Industry   | 111         | Crop production                           |
|            | 112         | Animal production                         |
|            | 311         | Food manufacturing                        |
|            | 32532       | Pesticide manufacturing                   |

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "**Federal Register**—Environmental

Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-300983. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

**II. Background and Statutory Findings**

In the **Federal Register** of (October 6, 1998, 63 FR 53656) (FRL-6033-8), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the FQPA of 1996 (Public Law 104-170) announcing the filing of a pesticide petition for tolerance by Rohm and Haas Company, 100 Independence Mall West, Philadelphia, PA 19106-2399. This notice included a summary of the petition prepared by Rohm and Haas Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide, methoxyfenozide, in or on cottonseed; cotton gin trash; pome fruit; meat, kidney, meat byproducts and milk of cattle, goats, sheep and hogs and fat of cattle, goats, sheep and hogs at 2.0, 25.0, 1.25, 0.02, 0.1 parts per million (ppm) respectively and tolerances for the combined residues of methoxyfenozide and its glucuronide metabolite in or on liver of cattle, goats, sheep, and hogs at 0.1 ppm.

Methoxyfenozide is a reduced risk pesticide which will be sold under the trade name of Intrepid 2F. Methoxyfenozide controls codling moth, green fruitworm, lesser appleworm, Oriental fruit moth, obliquebanded leafroller, eyespotted bud moth, fruittree leafroller, pandemis leafroller,

redbanded leafroller, variegated leafroller, tufted apple bud moth, spotted tentiform leafminer and Western tentiform leafminer on pome fruit and cotton bollworm, tobacco budworm, beet armyworm, cabbage looper, cotton leafworm, fall armyworm, Southern armyworm, soybean looper and true armyworm on cotton.

Section 408(b)(2)(A)(i) of the 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) 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) 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 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances November 26, 1997 (62 FR 62961) (FRL-5754-7).

**III. Aggregate Risk Assessment and Determination of Safety**

Consistent with section 408(b)(2)(D), 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), for a tolerance for residues of methoxyfenozide on cotton, undelinted seed; cotton gin byproducts; pome fruit; apple pomace, wet; milk; meat of cattle, goats, hogs, horses, and sheep and fat of cattle, goats, hogs, horses, and sheep at 2.0, 35.0, 1.5, 7.0, 0.02, 0.02, 0.1 ppm respectively, and tolerances for the combined residues of methoxyfenozide and its glucuronide metabolite in liver of cattle, goats, hogs, horses and sheep and meat byproducts (except liver) of cattle, goats, hogs, horses and sheep at 0.1 and 0.02 ppm respectively. EPA's assessment of the

dietary 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 are discussed in this unit.

Acute toxicity studies with technical grade: Oral LD<sub>50</sub> in the rat is > 5,000 milligrams/kilograms (mg/kg) for males and females-Toxicity Category IV; Oral LD<sub>50</sub> in the mouse is > 5,000 mg/kg for males and females-Toxicity Category IV; Dermal LD<sub>50</sub> in the rat is > 2,000 mg/kg-Toxicity Category III; Inhalation LC<sub>50</sub> in the rat is > 4.3 milligram/liter (mg/L)-Toxicity Category IV; Primary Eye Irritation in the rabbit -very mild irritant-Toxicity Category IV; Primary skin irritation in the rabbit-not a skin irritant-Toxicity Category IV. Methoxyfenozide is not a skin sensitizer.

In an acute neurotoxicity study in rats, statistically significant decreased hindlimb grip strength was observed in male rats at 3 hours (approximate time of peak effect) following a single oral dose of 2,000 mg/kg (limit dose) of methoxyfenozide. Decreased hindlimb grip strength was also observed in the male rats at 7 and 14 days, but was not statistically significant. No other systemic or neurotoxic effects were observed in the male rats or in the female rats at any time in this study. Since this marginal effect occurred only in one sex, was statistically significant at only one time, was observed only at the high dose (limit dose) and no other signs of toxicity were observed in the rats in this study, this possible effect is not considered to be biologically significant. In addition, neither decreased hindlimb grip strength nor any other signs of neurotoxicity were observed in any of the animals at any time in a 90-day subchronic neurotoxicity study in rats.

In a 2-week range-finding dietary study in rats, treatment-related effects were observed at > 5,000 ppm in the liver (increased liver weights and hepatocellular hypertrophy in males and females), in the thyroid gland (hypertrophy/hyperplasia of follicular cells in males and females), and in the adrenal gland (increased adrenal weights and/or hypertrophy of the zona fasciculata in females). Hypertrophy/

hyperplasia of thyroid follicular cells was also observed in males and females at 1,000 ppm, the lowest observed adverse effect level (LOAEL) in this study. The no observed adverse effect level (NOAEL) was 250 ppm. Treatment-related hematological changes were not observed in the rats in this study.

In a 3-month feeding study in rats, the predominant treatment-related effects were increased liver weights in males and females and periportal hepatocellular hypertrophy in all males and females at 20,000 ppm highest dose tested (HDT) and at 5,000 ppm. In addition, at 20,000 ppm, a slightly decreased (7-8%) RBC count and slightly decreased (7-8%) hemoglobin concentration, compared to control rats, were observed in the females. The LOAEL in this study was 5,000 ppm (353/379 mg/kg/day in males/females, respectively). The NOAEL was 1,000 ppm (69/72 mg/kg/day in males/females, respectively). Although observed in the 2-week dietary study and in the 2-year chronic feeding/carcinogenicity study in rats, treatment-related effects in the thyroid and adrenal glands were not observed in the rats in this 3-month study. There is no available biological explanation for this difference in findings in the studies.

In a 2-year combined chronic feeding/carcinogenicity study in rats, the following treatment-related effects were observed at 20,000 ppm (highest dose tested): decreased survival in males, decreased body weight and food efficiency in females during the last year of the study, hematological changes (decreased RBC counts, hemoglobin concentrations, and/or hematocrits; methemoglobinemia; and increased platelet counts) in males and females, increased liver weights and periportal hepatocellular hypertrophy in males and females, thyroid follicular cell hypertrophy in males, altered thyroid colloid in males and females, and increased adrenal weights in males and females. At 8,000 ppm, the following treatment-related effects were observed: hematological changes (decreased RBC counts, hemoglobin concentrations, and/or hematocrits in males and females), liver toxicity (increased liver weights in males and periportal hepatocellular hypertrophy in males and females), histopathological changes in the thyroid (increased follicular cell hypertrophy in males and altered colloid in males) and possible adrenal toxicity (increased adrenal weights in males and females). The LOAEL in this study was 8,000 ppm (411/491 mg/kg/day in males/females, respectively), based on the effects described above.

The NOAEL was 200 ppm (10.2/11.9 mg/kg/day in males/females, respectively). This NOAEL was used to establish the reference dose (RfD) for methoxyfenozide. Utilizing an uncertainty factor of 100 to account for both interspecies extrapolation (10x) and intraspecies variability (10x), the chronic RfD for methoxyfenozide was calculated to be 0.10 mg/kg/day. No evidence of carcinogenicity was observed in this study. Dosing was considered adequate because of the decreased survival in males and the decreased body weights and food efficiency in females at 20,000 ppm. In addition, the HDT for both males and females, 20,000 ppm (1,045/1,248 mg/kg/day in males/females, respectively), is higher than the limit dose of 1,000 mg/kg/day.

In a 2-week range-finding study in dogs, treatment-related hematological changes were observed in both males and females at 3,500 ppm, 7,000 ppm, 15,000 ppm, and 30,000 ppm (HDT). These changes included decreased RBC counts, decreased hemoglobin concentrations, decreased hematocrits, decreased MCHC, increased MCV, increased MCH, increased Heinz bodies, methemoglobinemia, changes in RBC morphology such as Howell-Jolly bodies and polychromasia, increased reticulocyte counts, increased nucleated RBC and increased platelet counts. At the same dose levels (> 3,500 ppm), increased spleen weights and/or enlarged spleens were also observed. At 7,000 ppm, plasma total bilirubin was increased. The LOAEL in this study was 3,500 ppm (90-184 mg/kg/day in males and females). The NOAEL was 300 ppm (11-16 mg/kg/day in males and females).

In a 3-month feeding study in dogs, no treatment-related effects other than a suggestion of decreased body weight gains in males and females were observed in either males or females at the HDT viz. 5,000 ppm (198/209 mg/kg/day in males/females, respectively). Although hematological effects were noted in dogs in the 2-week range-finding study at > 3,500 ppm (90-184 mg/kg/day) and in the 1-year chronic feeding study at > 3,000 ppm (106/111 mg/kg/day), hematological changes were not observed in this 3-month study at 5,000 ppm (198/209 mg/kg/day). There is no available biological explanation for this difference in findings in the studies.

As part of the 3-month study in dogs, some male and female dogs were given 15 ppm (0.6 mg/kg/day) of methoxyfenozide in the diet for 15 weeks followed by an increase in the dietary dose to 15,000 ppm (422/460 mg/kg/day in males/females,

respectively) for an additional 6 weeks. After about 2 weeks and 6 weeks at 15,000 ppm, hematological examinations were conducted. No hematological changes in these dogs were observed. Apparently, pretreatment of the dogs at 15 ppm for 15 weeks prevented the occurrence of hematological changes which would have been expected to occur based on results in the 2-week and 1-year feeding studies. One possible explanation is that the liver microsomal enzyme system may have been stimulated so much during pretreatment at 15 ppm that the metabolic (detoxification) rate of methoxyfenozide was increased to the point where blood levels of methoxyfenozide may have remained below critical effect levels at 15,000 ppm. Another possible explanation is that compensatory mechanisms for replacing damaged RBC in pretreated dogs may have been so efficient that hematological changes were not observed in these dogs even at 15,000 ppm. Other explanations for this finding are also possible.

In a 1-year chronic feeding study in dogs, the predominant toxic effects were anemia and signs of an associated compensatory response. At 30,000 ppm, the HDT, the following treatment-related effects were observed in both males and females: decreased RBC counts, decreased hemoglobin concentrations, decreased hematocrits, methemoglobinemia, nucleated RBC, increased platelets, increased serum total bilirubin, bilirubinuria, increased hemosiderin in macrophages in liver and spleen, and increased hyperplasia in bone marrow of rib and sternum. Increased liver weights in males and females and increased thyroid weights in males were also observed at 30,000 ppm. Signs of anemia were also noted at 3,000 ppm and included decreased RBC counts, decreased hemoglobin concentrations, decreased hematocrits, methemoglobinemia, increased platelets, and increased serum total bilirubin and bilirubinuria. The LOAEL in this study was 3,000 ppm (106/111 mg/kg/day in males/females, respectively). The NOAEL was 300 ppm (9.8/12.6 mg/kg/day in males/females, respectively).

In a 3-month feeding study in mice, the only treatment-related effect was decreased body weight gain in males and females at 7,000 ppm, the HDT. The LOAEL in this study was 7,000 ppm (1,149/1,742 mg/kg/day in males/females, respectively) and the NOAEL was 2,500 ppm (428/589 mg/kg/day in males/females, respectively). In an 18-month carcinogenicity study in mice (MRID 44617729), no treatment-related

effects were observed at doses up to and including the limit dose of 7,000 ppm (1,020/1,354 mg/kg/day in males/females, respectively). No evidence of carcinogenicity was observed in this study. Dosing was considered adequate because the HDT for both males and females, 7,000 ppm (1,020/1,354 mg/kg/day in males/females, respectively), is higher than the limit dose of 1,000 mg/kg/day.

In a battery of four mutagenicity studies (with and without metabolic activation, as appropriate for the specific study), technical grade methoxyfenozide was negative for genotoxicity in all four studies. The four studies satisfy the new revised mutagenicity guideline requirements for a new chemical (published in 1991). An additional mutagenicity study, performed on RH-117,236 (Metabolite M-B), a metabolite of methoxyfenozide, was also negative for genotoxicity.

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, methoxyfenozide is classified as a "not likely" human carcinogen according to the EPA.

In a developmental toxicity study in rats, no signs of maternal toxicity in dams or of developmental toxicity in fetuses were observed at the limit dose of 1,000 mg/kg/day. The NOAEL in this study for both maternal toxicity and developmental toxicity was 1,000 mg/kg/day. Similarly, in a developmental toxicity study in rabbits, no signs of maternal toxicity or of developmental toxicity were observed at the limit dose of 1,000 mg/kg/day. The NOAEL in this study for both maternal toxicity and developmental toxicity was 1,000 mg/kg/day. The LOAEL was > 1,000 mg/kg/day.

In neither the developmental toxicity study in rats nor in the developmental toxicity study in rabbits was there any evidence for increased susceptibility of fetuses to *in utero* exposure to methoxyfenozide. In these studies, methoxyfenozide was determined not to be a developmental toxicant.

In a 2-generation (1 litter/generation) reproduction study in rats, treatment-related parental toxicity was observed only at 20,000 ppm, the HDT. At this dose, increased liver weights were observed in males and females of both generations and midzonal to periportal hepatocellular hypertrophy was observed in the livers of all males and females of both generations. The LOAEL for parental toxicity was 20,000 ppm (1,552/1,821 mg/kg/day for males/

females, respectively) and the NOAEL was 2,000 ppm (153/181 mg/kg/day for males/females, respectively). There were no treatment-related effects on reproductive parameters for adult (parent) animals. The NOAEL for reproductive toxicity was 20,000 ppm. Since no treatment-related effects were observed in the pups, the NOAEL for neonatal toxicity was also, 20,000 ppm. The NOAEL for parental toxicity in this reproduction study is higher than the NOAEL for the 2-year combined chronic feeding/carcinogenicity study in rats because many of the toxic effects observed in the 2-year study at the LOAEL (hematological changes, liver toxicity, histopathological changes in the thyroid gland and increased adrenal weights) were not examined in the reproduction study.

In a metabolism study in rats, <sup>14</sup>C-methoxyfenozide was rapidly absorbed, distributed, metabolized and almost completely excreted within 48 hours. The major route of excretion was feces (86–97%) with lesser amounts in the urine (5–13%). An enterohepatic circulation was observed. The test material was metabolized principally by O-demethylation of the A-ring methoxy group and oxidative hydroxylation of the B-ring methyl groups followed by conjugation with glucuronic acid. No significant sex-related or dose-dependent differences in metabolic disposition were noted. Seven metabolites and the parent accounted for 74–90% of the administered dose in all groups. The glucuronide conjugates are considered to be less toxic than the parent compound because glucuronide conjugation is well known to be a commonly occurring "detoxification" mechanism in mammalian species since it results in the formation of more polar, more water-soluble metabolites which are readily and easily excreted from the body (in this case, in the bile and urine). Further, based on similarities of chemical structure, the non-conjugated metabolites would be expected to be no more toxic than the parent compound. In a dermal absorption study in rats using an 80% wettable powder formulation as the test material, the cumulative dermal absorption of test material after a 10- or 24-hour dermal exposure was determined to be 2%. In a 28-day dermal toxicity study in rats, no treatment-related systemic or skin effects were observed at the limit dose of 1,000 mg/kg/day (HDT). Regarding effects on endocrine organs, methoxyfenozide affected the thyroid gland and adrenal gland in the 2-week and 2-year feeding studies in rats. In the thyroid gland, hypertrophy/hyperplasia

of follicular cells and altered colloid were observed in males and females at or near the LOAEL in both of these studies. In the adrenal gland, increased adrenal weights and hypertrophy of the zona fasciculata were also observed in males and females at or near the LOAEL. In addition, in the 1-year chronic feeding study in dogs, increased thyroid weight in males was observed, but only at the very high dose of 30,000 ppm. Since the definition and regulatory significance of the term "endocrine disruptor chemical" has not yet been established by the Agency, it is not clear whether methoxyfenozide, on the basis of these effects on the thyroid gland and adrenal gland, should be considered to be an "endocrine disruptor chemical." Other than the morphological changes described above, there were no signs of thyroid or adrenal dysfunction in these or in any other studies on methoxyfenozide.

#### B. Toxicological Endpoints

1. *Acute toxicity.* No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on methoxyfenozide including the acute neurotoxicity study in rats, the developmental toxicity study in rats and the developmental toxicity study in rabbits. In the acute neurotoxicity study in rats, statistically significant decreased hindlimb grip strength was observed in male rats at 3 hours (approximate time of peak effect) following a single oral dose of 2,000 mg/kg (limit dose) of methoxyfenozide. Decreased hindlimb grip strength was also observed in the male rats at 2,000 mg/kg at 7 and 14 days, but was not statistically significant. Decreased hindlimb grip strength was not observed in the male rats at 1,000 mg/kg. No other systemic or neurotoxic effects were observed in the male rats or in the female rats at any time in the study. Since this marginal effect occurred only in one sex, was statistically significant only one time, was observed only at the high dose (limit dose) and no other signs of toxicity were observed in the rats in the study, this equivocal effect is not considered to be an appropriate toxicological endpoint for acute dietary risk assessments. In addition, decreased hindlimb grip strength was not observed in a subchronic neurotoxicity study in rats in any of the animals at any time. It is also noted that the acute oral LD<sub>50</sub> for male and female rats for technical grade methoxyfenozide (98% active ingredient (a.i.) is > 5,000 mg/kg (Toxicity Category IV). No treatment-related effects were observed in either dams or pups in the developmental

toxicity studies in rats or rabbits at doses up to the limit dose of 1,000 mg/kg/day. Thus the risk from acute exposure is considered negligible.

2. *Short- and intermediate-term toxicity.* In a 28-day repeated dose dermal toxicity study in rats, no systemic or dermal toxicity was observed at 1,000 mg/kg/day, the HDT (limit dose). By applying the dermal absorption factor of 2% (derived from a dermal absorption study in rats, to the NOAEL of 10.2 mg/kg/day and the LOAEL of 411 mg/kg/day in the 2-year combined chronic feeding/carcinogenicity study in rats, the oral NOAEL and LOAEL in this study are equivalent to a dermal NOAEL of 510 mg/kg/day and a dermal LOAEL of 20,550 mg/kg/day. By applying the dermal absorption factor of 2% to the NOAEL of 9.8 mg/kg/day and the LOAEL of 106.1 mg/kg/day in the 1-year chronic feeding study in dogs, the oral NOAEL and LOAEL in this study are equivalent to a dermal NOAEL of 490 mg/kg/day and a dermal LOAEL of 5,305 mg/kg/day. The likelihood of toxic effects resulting from repeated dermal exposure to methoxyfenozide is quite low. Further, based on the use pattern, no long-term dermal exposure is expected to occur.

Methoxyfenozide is a non-volatile solid with a very low vapor pressure of  $> 1 \times 10^{-7}$  torr (or  $> 1.33 \times 10^{-5}$  pascal). In an acute inhalation toxicity study in rats, the acute inhalation LC<sub>50</sub> for technical grade methoxyfenozide dust (98% a.i.) was determined to be  $> 4.3$  mg/L ( $> 2x$  limit dose, Toxicity Category IV) for both male and female rats. In another acute inhalation toxicity study in rats, the acute inhalation LC<sub>50</sub> for RH-112,485 80WP formulation 80% a.i. was determined to be  $> 4.5$  mg/L ( $> 2x$  limit dose, Toxicity Category IV) for both male and female rats. In both of these acute inhalation toxicity studies, there were no mortalities, treatment-related clinical signs, changes in body weights or necropsy findings. Based on the low vapor pressure, the low acute inhalation toxicity (Toxicity Category IV) of the technical grade product and the formulated product (the packaging of the formulated product (water soluble pouches), the application rate (0.05 to 0.4 lb. a.i./acre for a maximum of 2.0 lb. ai/season), and the application method, there is minimal concern for potential inhalation risk. Further, based on the use pattern, no long-term inhalation exposure is expected to occur.

3. *Chronic toxicity.* EPA has established the RfD for methoxyfenozide at 0.10 mg/kg/day. This RfD is based on a NOAEL of 10.2 mg/kg/day and an UF of 100 accounting for both interspecies

extrapolation (10x) and intraspecies variability (10x). This chronic RfD is based on the 2-year combined chronic feeding/carcinogenicity study in rats, in which the following effects were observed at the LOAEL of 411/491 mg/kg/day in males/females: hematological changes (decreased RBC counts, hemoglobin concentrations, and/or hematocrit in males and females), liver toxicity (increased liver weights in males and periportal hepatocellular hypertrophy in males and females), histopathological changes in the thyroid (increased follicular cell hypertrophy and altered colloid in males) and possible adrenal toxicity (increased adrenal weights in males and females). EPA determined that the 10x Safety Factor for the protection of infants and children (as required by FQPA) should be reduced to 1x. Therefore, the chronic Population Adjusted Dose (cPAD) is the same as the RfD. This cPAD is used in assessing chronic risk and applies to all population subgroups. Reducing the 10x safety factor to 1x is supported by the following factors:

i. The toxicology data base for methoxyfenozide is complete for assessment of potential hazard to infants and children.

ii. Based on weight-of-the-evidence considerations, EPA determined that a developmental neurotoxicity study in rats is not required to support the registration of methoxyfenozide.

iii. In developmental toxicity studies in rats and rabbits, no increased susceptibility in fetuses as compared to maternal animals was observed following *in utero* exposures.

iv. In a 2-generation reproduction study in rats, no increased susceptibility in pups as compared to adults was observed following *in utero* and postnatal exposures.

v. The exposure assessments will not underestimate the potential dietary (food and drinking water) or non-dietary exposures for infants and children from the use of methoxyfenozide.

4. *Carcinogenicity.* Methoxyfenozide has been classified as a "not likely" human carcinogen. 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.

#### C. Exposures and Risks

1. *From food and feed uses.* In today's action tolerances will be established (40 CFR part 180) for the residues of methoxyfenozide on cotton, undelinted seed; cotton gin byproducts; pome fruit; apple pomace, wet; milk; meat of cattle,

goats, hogs, horses and sheep and fat of cattle, goats, hogs, horses and sheep at 2.0, 35.0, 1.5, 7.0, 0.02, 0.02, 0.1 ppm and tolerances for the combined residues of methoxyfenozide and its glucuronide metabolite in liver of cattle, goats, hogs, horses and sheep and meat byproducts (except liver) of cattle, goats, hogs, horses and sheep at 0.1 and 0.02 ppm respectively. Risk assessments were conducted by EPA to assess dietary exposures from methoxyfenozide as follows.

i. *Acute exposure and risk.* 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. No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on methoxyfenozide including the acute neurotoxicity study in rats, the developmental toxicity study in rats and the developmental toxicity study in rabbits. This risk is considered to be negligible.

ii. *Chronic exposure and risk.* EPA used the Dietary Exposure Evaluation Model (DEEM) software for conducting a chronic dietary (food) risk analysis. DEEM is a dietary exposure analysis system that is used to estimate exposure to a pesticide chemical in foods comprising the diets of the U.S. population, including population subgroups. DEEM contains food consumption data as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989-1992. EPA has made the assumptions that 100% of pome fruit and cotton would be treated and contain methoxyfenozide residues at the tolerance level. The following tolerance levels were used in the analysis:

| Commodity                        | Tolerance Level (parts per million) (ppm) |
|----------------------------------|---|
| Cotton, underlinted seed.        | 2.0 ppm                                   |
| Pome fruits .....                | 1.5 ppm                                   |
| Milk .....                       | 0.02 ppm                                  |
| Meat* .....                      | 0.02 ppm                                  |
| Meat byproducts* (except liver). | 0.02 ppm                                  |
| Fat* .....                       | 0.1 ppm                                   |
| Liver .....                      | 0.1 ppm                                   |

\*of cattle, goats, hogs, horses and sheep.

Processing factors were also applied to apple juice concentrate (3x), dried apples (8x), dried beef (1.92x), dried pears (6.25x), and dried veal (1.92x).

The processing factors are default values from DEEM.

As shown in the following table, the resulting dietary food exposures occupy up to 11% of the Chronic PAD for the most highly exposed population subgroup, non-nursing infants. These results should be viewed as conservative (health protective) risk estimates. Refinements such as use of percent crop-treated information and/or anticipated residue values would yield even lower estimates of chronic dietary exposure.

**SUMMARY: CHRONIC DIETARY EXPOSURE ANALYSIS BY DEEM (TIER 1)**

| Population Subgroup <sup>1</sup>  | Exposure (mg/kg/day) | % of Chronic PAD <sup>2</sup> |
|-----------------------------------|----------------------|-------------------------------|
| U.S. population (total).          | 0.001839             | 1.8                           |
| All infants (> 1 year).           | 0.009617             | 9.6                           |
| Nursing infants ..                | 0.005605             | 5.6                           |
| Non-nursing infants.              | 0.011306             | 11                            |
| Children (1-6 years).             | 0.007350             | 6.8                           |
| Children (7-12 years).            | 0.003103             | 2.8                           |
| U.S. population (autumn season).  | 0.002285             | 2.3                           |
| U.S. population (winter season).  | 0.001891             | 1.9                           |
| Northeast region                  | 0.002014             | 2.0                           |
| Western region                    | 0.002004             | 2.0                           |
| Non-hispanic whites.              | 0.001917             | 1.9                           |
| Non-hispanic/non-white/non-black. | 0.002025             | 2.0                           |
| Females (> 13 years, nursing).    | 0.002479             | 2.5                           |
| Pacific region ....               | 0.002023             | 2.0                           |

<sup>1</sup> The subgroups listed are: (1) The U.S. population (total); (2) those for infants and children; (3) the other subgroup(s), if any, for which the percentage of the Chronic PAD occupied is greater than that occupied by the subgroup U.S. population (total); and, (4) the most highly exposed of the females subgroups (in this case, females, > 13 years, nursing).

<sup>2</sup> Percent chronic PAD = (Exposure ÷ Chronic PAD) x 100%.

2. *From drinking water.* The Agency currently lacks sufficient water-related exposure data from monitoring to complete a quantitative drinking water exposure analysis and risk assessment for methoxyfenozide. Therefore, the Agency is presently relying on computer-generated estimated environmental concentrations (EECs). GENEEC and/or PRZM/EXAMS (both produce estimates of pesticide concentration in a farm pond) are used to generate EECs for surface water and SCI-GROW (an empirical model based

upon actual monitoring data collected for a number of pesticides that serve as benchmarks) predicts EECs in ground water. These models take into account the use patterns and the environmental profile of a pesticide, but do not include consideration of the impact that processing 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 coarse screen for assessing whether a pesticide is likely to be present in drinking water at concentrations which would exceed human health levels of concern.

A drinking water level of comparison (DWLOC) is the concentration of a pesticide in drinking water that would be acceptable as a theoretical upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses. HED uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for a pesticide, the DWLOC is used as a point of comparison against the conservative EECs provided by computer modeling (SCI-GROW, GENEEC, PRZM/EXAMS).

i. *Acute exposure and risk.* Because no acute dietary endpoint was determined, the Agency concludes that there is a reasonable certainty of no harm from acute exposure from drinking water.

ii. *Chronic exposure and risk.* EPA conducted its Tier II screening-level assessments using the simulation models SCI-GROW and PRZM/EXAMS to generate EECs for ground and surface water, respectively. The modeling was conducted based on the environmental profile and the maximum seasonal application rate proposed for methoxyfenozide (0.4 lb ai/acre x 5 applications/acre/year on cotton). PRZM/EXAMS was used to generate the surface water EECs, because it can factor the persistent nature of the chemical into the estimates.

The EECs for assessing chronic aggregate dietary risk are 312 parts per billion (ppb) (in ground water, based on SCI-GROW) and 3,197 ppb (in surface water, based on the PRZM/EXAMS, long-term mean). The back-calculated DWLOCs for assessing chronic aggregate dietary risk range from 890 ppb for the most highly exposed population subgroup (Non-nursing infants, > 1-year old) to 3,400 ppb for the U.S. population (48 contiguous States—all seasons) and the U.S. population (autumn season).

The SCI-GROW and PRZM/EXAMS chronic EECs are less than the Agency's

level of comparison (the DWLOC value for each population subgroup) for methoxyfenozide residues in drinking water as a contribution to chronic aggregate exposure. EPA thus concludes with reasonable certainty that residues of methoxyfenozide in drinking water will not contribute significantly to the aggregate chronic human health risk and that the chronic aggregate exposure from methoxyfenozide residues in food and drinking water will not exceed the Agency's level of concern (100% of the cPAD) for chronic dietary aggregate exposure by any population subgroup. EPA generally has no concern for exposures below 100% of the cPAD, because it is a level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to the health and safety of any population subgroup. This risk assessment is considered high confidence, conservative, and very protective of human health.

3. *From non-dietary exposure.* Methoxyfenozide is not currently registered for use on any residential non-food sites. Therefore, there is no non-dietary acute, chronic, short- or intermediate-term exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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 does not have, at this time, available data to determine whether methoxyfenozide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 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 final rule for Bifenthrin Pesticide Tolerances November 26, 1997 (62 FR 62961) (5754-7).

#### *D. Aggregate Risks and Determination of Safety for U.S. Population*

1. *Acute risk.* Since no acute toxicological endpoints were established, EPA considers acute aggregate risk to be negligible.

2. *Chronic risk.* Using the DEEM exposure assumptions described in this unit, EPA has concluded that aggregate exposure to methoxyfenozide from food will utilize 1.8% of the cPAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants (> 1-year old) at 11% of the cPAD and is discussed below. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to methoxyfenozide in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to methoxyfenozide residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

Since there are currently no registered indoor or outdoor residential non-dietary uses of methoxyfenozide and no short or intermediate term toxic endpoints, EPA considers short or intermediate term aggregate risks to be negligible.

4. *Aggregate cancer risk for U.S. population.* Methoxyfenozide is classified as a "not likely" human carcinogen. Therefore this risk does is negligible.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to methoxyfenozide residues.

#### *E. Aggregate Risks and Determination of Safety for Infants and Children*

1. *Safety factor for infants and children—In general.* In assessing the potential for additional sensitivity of infants and children to residues of methoxyfenozide, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during

gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 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 unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/UF when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

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. Based on the completeness of the data base and the lack of prenatal and postnatal toxicity, EPA determined that an additional safety factor was not needed for the protection of infants and children.

4. *Acute risk.* Since no acute toxicological endpoints were established, EPA considers acute aggregate risk to be negligible.

5. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to methoxyfenozide from food will utilize 11% of the cPAD for infants and children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to

methoxyfenozide in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

6. *Short- or intermediate-term risk.* Short and intermediate term risks are judged to be negligible due to the lack of significant toxicological effects observed.

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

#### IV. Other Considerations

##### A. Metabolism in Plants and Animals

The qualitative nature of methoxyfenozide residues in plants is adequately understood based upon acceptable cotton, apple and grape metabolism studies. EPA has determined that the residue of concern for dietary exposure and tolerance setting purposes in primary crops and water is the parent compound, methoxyfenozide.

The qualitative nature of the residue in animals is adequately understood based on acceptable studies conducted on goats and laying hens. EPA has determined that the residue of concern in milk and ruminant tissues (other than liver and kidney) is the parent compound, methoxyfenozide. The residue of concern in ruminant liver and kidney is the parent compound, methoxyfenozide, and its glucuronide metabolite designated as RH-141,518 (also referred to as RH-1518). The glucuronide metabolite was included in the tolerance expression for liver and kidney because the conjugation may be reversible and it comprises a significant portion of the total radioactive residues (TRR) (up to 42% TRR in kidney and up to 29% TRR in liver) in those tissues.

##### B. Analytical Enforcement Methodology

The petitioner has proposed HPLC/UV Method TR 34-98-87 for the enforcement of tolerances for pome fruits. Adequate confirmatory method validation, radiovalidation, and independent method validation data have been submitted for this method. This method was sent to the EPA laboratory for a petition method validation (PMV). The laboratory has reported that the pome fruit method (Method TR 34-98-87) is adequate in the interim for enforcement of the proposed tolerances for methoxyfenozide in/on pome fruit. Initial recoveries (60%) in the PMV were just below the minimum acceptable recovery level (70%) as specified in OPPTS Harmonized Test Guidelines

860.1340. The laboratory modified the method and achieved acceptable recoveries with the modified method. EPA will require that Rohm and Haas Company revise and modify the method. Additional recovery data will be required for the revised method.

The petitioner has proposed Method TR 43-96-88 for the enforcement of tolerances for cotton. This method is a shortened version of the pome fruit method. Thus, EPA concludes that Method TR 34-96-87 is adequate for enforcement of the proposed tolerances for residues of methoxyfenozide in/on cotton commodities. The validation of the cotton method is in progress. EPA expects that Method TR 43-96-88 will need to be modified or revised and additional recovery data may be required. EPA will require Rohm and Haas Company to revise and modify the cotton method and submit any additional recovery data if necessary.

The petitioner has proposed Method TR 34-98-106 for the enforcement of tolerances in animal commodities. This method determines residues of methoxyfenozide (HPLC/UV) in fat, cream, milk, and muscle and residues of methoxyfenozide and its glucuronide metabolite, RH-141,518 (HPLC/MS) in liver and kidney. Adequate confirmatory method validation, radiovalidation, and independent method validation data, have been submitted for this method. This method has been forwarded to the EPA laboratory for petition method validation (PMV). The method has passed the PMV, however it requires some minor revisions. EPA will require that Rohm and Haas Company revise the method and resubmit the final revised method.

The petitioner submitted data concerning the recovery of residues of methoxyfenozide using Food and Drug Administration (FDA) multiresidue method protocols (PAM Vol. I). Methoxyfenozide was not recoverable by these methods. These data will be forwarded to FDA for evaluation.

EPA has determined that the residues of concern in ruminant liver and kidney are methoxyfenozide and its metabolite RH-141,518. Data concerning the recovery of residues of RH-141,518 using FDA multiresidue method protocols (PAM Vol. I) will be required. This will be made a condition of the registration for methoxyfenozide.

Adequate enforcement methodology is available to enforce the tolerance expression. The methods may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington,

DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

##### C. Magnitude of Residues

1. *Magnitude of the residue in apples and pears.* An adequate number of geographically representative field trials were submitted to support the proposed use on pome fruits. Apples and pears are the representative commodities of this crop group. These studies were conducted via use patterns approximating those proposed by this petition. Residues of methoxyfenozide ranged from 0.16 to 1.2 ppm in/on apples and from 0.21 to 0.93 ppm in/on pears treated with the 80% WP formulation according to the maximum proposed use patterns. The results of the field trials indicate that residues of methoxyfenozide will not exceed 1.5 ppm in/on pome fruit when treated as proposed. Rohm and Haas Company proposed a tolerance level of 1.25 ppm for residues of methoxyfenozide in/on pome fruit. EPA concludes that the proposed tolerance must be raised to 1.5 ppm for methoxyfenozide in/on the "Crop Group 11; Pome Fruits Group."

2. *Magnitude of the residue in cotton.* An adequate number of geographically representative field trials were submitted to support the proposed use on cotton. These studies were conducted via use patterns approximating those proposed by this petition. The results of the cotton field trials indicate that residues of methoxyfenozide will not exceed the proposed tolerance level of 2.0 ppm in/on cottonseed when treated as proposed. Residues of methoxyfenozide ranged from 0.060 to 1.8 ppm in/on cottonseed treated with the 80% WP formulation according to the maximum proposed use pattern. Residues of methoxyfenozide did not vary significantly in cotton treated with ULV spray applications (1 GPA) versus standard volume applications (10-30 GPA). Residues ranged from 0.13 to 0.32 ppm and from 0.12 to 0.66 ppm in/on cotton treated in side-by-side plots with ULV and standard volume applications, respectively. Rohm and Haas Company requested the proposed tolerance on cottonseed at 2.0 ppm. However, EPA has determined that it should be "cotton, undelinted seed" at 2.0 ppm.

The results of the cotton field trials indicate that residues of methoxyfenozide may exceed the proposed tolerance level of 25 ppm in/on cotton gin byproducts when treated as proposed. Residues of methoxyfenozide ranged from 3.8 to 31.2 ppm in/on cotton gin byproducts treated with the 80% WP formulation

according to the maximum proposed use pattern. Based on these data, the tolerance for residues of methoxyfenozide in/on cotton gin byproducts must be raised to 35 ppm.

3. *Magnitude of the residue in apple processed commodities.* The submitted apple processing data are adequate for the purposes of this petition. Residues of methoxyfenozide did not concentrate in juice but concentrated 6x in wet pomace processed from whole apples bearing detectable residues. Based on the results of the apple processing study, a tolerance for residues of methoxyfenozide in apple juice is not required. Rohm and Haas proposed a tolerance level of 7.5 ppm for residues of methoxyfenozide in/on apple wet pomace. The maximum residue level of methoxyfenozide expected in apple wet pomace was 6.06 ppm, calculated by multiplying the HAFT residue (1.01 ppm; see apple field trial) and the observed concentration factor (6x). Based on this calculation, a tolerance of 7.0 ppm for residues of methoxyfenozide in/on "apple pomace, wet" is appropriate.

4. *Magnitude of the residue in cottonseed processed commodities.* The submitted cotton processing data are adequate for the purposes of this petition. No concentration of methoxyfenozide residues was observed in hulls, meal, and oil processed from undelinted cottonseed bearing detectable residues. Based on the results of the current processing study, tolerances for residues of methoxyfenozide in the processed commodities of cotton are not required.

5. *Residues in meat, milk, poultry, and eggs.* The submitted dairy cattle feeding study is adequate for the purpose of establishing tolerances for secondary transfer of methoxyfenozide residues in milk and ruminant tissues. EPA has determined that the residues of concern in milk and ruminant tissues (except kidney and liver) are the parent compound, methoxyfenozide. For liver and kidney, the residues of concern are the parent compound, methoxyfenozide, and its metabolite RH-141,518. EPA concludes that residues of methoxyfenozide are not likely to exceed the proposed tolerances of 0.02 ppm in the milk and meat of cattle, goats, hogs, horses, and sheep. EPA further concludes that residues of methoxyfenozide are not likely to exceed the proposed tolerance of 0.1 ppm in the fat of cattle, goats, hogs, horses, and sheep as a result of the proposed uses. EPA also concludes that residues of methoxyfenozide and its metabolite RH-141,518 are not likely to exceed 0.1 ppm in liver and 0.02 ppm

in meat byproduct (except liver) of cattle, goat, hogs, horses, and sheep. The proposed tolerances did not include residues in tissues of horses. However, horses must be a part of the tolerance.

Rohm and Haas Company requested a waiver from the requirements to: (i) Conduct a poultry feeding study; (ii) propose tolerances for methoxyfenozide residues of concern in eggs and poultry tissues; and (iii) provide enforcement method(s) for determination of methoxyfenozide residues of concern in eggs and poultry tissues. The waiver request is based on the maximum theoretical dietary burden of methoxyfenozide for poultry animals as well as the results of the poultry metabolism study. The only poultry feed item associated with this petition is cotton meal, which would contribute a maximum theoretical dietary burden for methoxyfenozide at 0.4 ppm.

The poultry metabolism study reviewed in this petition was conducted at feeding levels of 58 ppm (MOP-label), 60 ppm (DMP-label), and 68 ppm (TB-label) which are equivalent to 145x, 150x, and 170x, respectively, the maximum theoretical dietary burden for poultry. Assuming a linear relationship between dose and residues, the expected residues in eggs and poultry tissues would be below the LOD for methods used to measure residues in poultry products. EPA concludes that there is no reasonable expectation of finite residues in eggs and poultry tissues and that a poultry feeding study is not required at this time. However, should the dietary burden for poultry increase due to the addition of methoxyfenozide-treated poultry feed items through new uses, a poultry feeding study may be required. If a poultry feeding study is required in the future, then all tissues should be analyzed for residues of methoxyfenozide and its metabolite RH-141,518.

#### D. International Residue Limits

There are no established or proposed Codex, Canadian or Mexican limits for residues of methoxyfenozide in/on plant or animal commodities. Therefore, no compatibility issues exist with regard to the proposed U.S. tolerances discussed in this petition review.

#### E. Rotational Crop Restrictions

A confined rotational crop study was submitted and reviewed. The petitioner has proposed a 30-day plantback interval for all crops not listed on the product label. The confined rotational crop study demonstrated that methoxyfenozide may accumulate in rotational crop commodities at > 0.01

ppm at 30- and 90-day plantback intervals. The rotational crop restrictions included on the submitted label are not adequate. The label must include the following rotational crop restrictions: Cotton may be rotated to treated fields at any time. Leafy vegetables (except Brassica vegetables) and root and tuber vegetables may be rotated to treated fields 1-year following application of methoxyfenozide. Rotation to all other crops is prohibited.

#### V. Conclusion

Therefore, the tolerances are established for residues of methoxyfenozide in or on cotton, undelinted seed; cotton gin byproducts; pome fruit; apple pomace, wet; milk; meat of cattle, goats, hogs, horses and sheep and fat of cattle, goats, hogs, horses and sheep at 2.0, 35.0, 1.5, 7.0, 0.02, 0.02, 0.1 ppm respectively and for the combined residues of methoxyfenozide and its glucuronide metabolite in liver of cattle, goats, hogs, horses and sheep and meat byproducts (except liver) of cattle, goats, hogs, horses and sheep at 0.1 and 0.02 ppm respectively.

#### VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP-300983 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 September 5, 2000.

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 (1900), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to:

James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-300983, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto: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 file format 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. Regulatory Assessment Requirements**

This final rule establishes a tolerance under FFDCA section 408(d) 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* (October 4, 1993, 58 FR 51735). 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (May 19, 1998, 63 FR 27655); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (February 16, 1994, 59 FR 7629); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (April 23, 1997, 62 FR 19885). 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 FFDCA section 408(d), 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* (August 4, 1999, 64 FR 43255). 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 FFDCA section 408(n)(4).

**VIII. Submission to Congress and the Comptroller General**

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 United States 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: June 13, 2000.  
**Suzan B. Hazen,**  
*Acting 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 180.544 is added to read as follows:

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

(a) *General.* (1) Tolerances are established 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 agricultural commodities:

| Commodity   | Parts per million |
|---|-------------------|
| Apple pomace, wet .....                             | 7.0               |
| Cotton gin byproducts .....                         | 35                |
| Cotton, undelinted seed .....                       | 2.0               |
| Fat of cattle, goats, hogs, horses and sheep .....  | 0.1               |
| Meat of cattle, goats, hogs, horses and sheep ..... | 0.02              |
| Milk .....  | 0.02              |
| Pome fruits crop group .....                        | 1.5               |

(2) Tolerances are established for the combined residues of methoxyfenozide; benzoic acid, 3-methoxy-2-methyl-2-

(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide and its

glucuronide metabolite in or on the following agricultural commodities:

| Commodity   | Parts per million |
|---|-------------------|
| Liver of cattle, goats, hogs, horses and sheep .....                          | 0.1               |
| Meat byproducts (except liver) of cattle, goats, hogs, horses and sheep ..... | 0.02              |

(b) *Section 18 emergency exemptions.* [Reserved]  
 (c) *Tolerances with regional registrations.* [Reserved]  
 (d) *Indirect or inadvertent residues.* [Reserved]  
 [FR Doc. 00-16801 Filed 7-3-00; 8:45 am]  
**BILLING CODE 6560-50-F**

**ACTION:** Final rule.  
**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of the *Bacillus subtilis* strain QST 713 in or on all raw agricultural commodities when applied/used according to label instructions. AgraQuest, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus subtilis* strain QST 713.  
**DATES:** This regulation is effective July 5, 2000. Objections and requests for hearings, identified by docket control number [OPP-300997], must be received by EPA, on or before September 5, 2000.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number [OPP-300997] in the subject line on the first page of your response.  
**FOR FURTHER INFORMATION CONTACT:** By mail: Susanne Cerrelli, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8077; and e-mail address: cerrelli.susanne@epa.gov.

**ENVIRONMENTAL PROTECTION AGENCY**  
**40 CFR Part 180**  
**[OPP-300997; FRL-6555-3]**  
**RIN 2070-AB78**  
**Bacillus subtilis Strain QST 713; Exemption from the Requirement of a Tolerance**  
**AGENCY:** Environmental Protection Agency (EPA).

**SUPPLEMENTARY INFORMATION:**