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: May 5, 2000.

Peter Caulkins,

Acting 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), 346(a) and 371.

§ 180.176 [Amended]

2. In § 180.176, amend the table in paragraph (b) by revising the date ''12/31/99'' to read ''12/31/01''.

[FR Doc. 00–12524 Filed 5–23–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300999; FRL–6555–1]

RIN 2070–AB78

Tebufenozide; Benzoic Acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tebufenozide [benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide], in or on the tree nut crop group (including pistachios) at 0.1 part per million (ppm) and on almond hulls at 25 ppm. Rohm and Haas Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective May 24, 2000. Objections and requests for hearings, identified by docket control number OPP–300999, must be received by EPA on or before July 24, 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–300999 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: tavano.joseph@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be affected by this action if you sell, distribute, manufacture, or use pesticides for agricultural applications, process food, distribute or sell food, or implement governmental pesticide regulations. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311	Crop production Animal production Food manufacturing
	32532	Pesticide manufacturing
Agricultural Stakeholders		Growers/Agricultural Workers, Contractors (Certified/Commercial Applicators, Handlers, Advisors, etc.), Commercial Processors, Pesticide Manufacturers, User Groups, Food Consumers
Food Distributors		Wholesale Contractors, Retail Vendors, Commercial Traders/Importers
Inter governmental Stakeholders		State, Local, and/or Tribal Government Agencies
Foreign Entities		Governments, Growers, Trade Groups, Exporters

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–300999. 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 August 19, 1998 (63 FR 44439) (FRL 6019–6), and February 17, 1999 (64 FR 7883) (FRL 6060–1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP) 7F4815 for a tolerance by Rohm and Haas Company, 100 Independence Mall West, Philadelphia, 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 180.482 be amended by establishing tolerances for residues of the insecticide tebufenozide in or on the tree nut crop group (including pistachios) at 0.1 ppm and on almond hulls at 25 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish tolerances (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 food and 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 (62 FR 62961, November 26, 1997) (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 tolerances for residues of tebufenozide on the tree nut crop group (including pistachios) at 0.1 ppm and on almond hulls at 25 ppm. EPA's assessment of the 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 tebufenozide are discussed in this unit.

B. Toxicological Endpoints

1. *Acute toxicity*— i. Acute toxicity studies with technical grade: Oral LD_{50} in the rat is > 5 grams for males and females—Toxicity Category IV; dermal LD_{50} in the rat is = 5,000 milligrams/kilogram (mg/kg) for males and females—Toxicity Category III; inhalation LC_{50} in the rat is >4.5 milligram/Liter (mg/L) - Toxicity Category III; primary eye irritation study in the rabbit is a non-irritant; primary skin irritation in the rabbit >5 mg/kg—Toxicity Category IV. Tebufenozide is not a sensitizer.

ii. In a 21–day dermal toxicity study, Crl:CD rats (6/sex/dose) received repeated dermal administration of either the technical (96.1%) product (RH–75,992) at 1,000 (mg/kg/day) (Limit-Dose) or the formulation (23.1% active ingredient (a.i.)) product (RH–755,992 2F) at 0, 62.5, 250, or 1,000 milligram/kilogram/day (mg/kg/day), 6 hours/day, 5 days/week for 21 days. Under conditions of this study, RH–75,992 Technical or RH–75,992 2F demonstrated no systemic toxicity or dermal irritation at the highest dose tested (HDT) 1,000 mg/kg during the 21–day study. Based on these results, the no-observed adverse effect level (NOAEL) for systemic toxicity and dermal irritation in both sexes is 1,000 mg/kg/day HDT. A lowest-observed

adverse effect level (LOAEL) for systemic toxicity and dermal irritation was not established.

iii. A 1–year dog feeding study with a LOAEL of 250 ppm (9 mg/kg/day for male and female dogs) based on decreases in RBC, HCT, and HGB, increases in Heinz bodies, methemoglobin, MCV, MCH, reticulocytes, platelets, plasma total bilirubin, spleen weight, and spleen/body weight ratio, and liver/body weight ratio. Hematopoiesis and sinusoidal engorgement occurred in the spleen, and hyperplasia occurred in the marrow of the femur and sternum. The liver showed an increased pigment in the Kupffer cells. The NOAEL for systemic toxicity in both sexes is 50 ppm (1.9 mg/kg/day).

iv. An 18–month mouse carcinogenicity study with no carcinogenicity observed at dosage levels up to and including 1,000 ppm.

v. A 2–year rat carcinogenicity study with no carcinogenicity observed at dosage levels up to and including 2,000 ppm (97 mg/kg/day and 125 mg/kg/day for males and females, respectively)

vi. In a prenatal developmental toxicity study in Sprague-Dawley rats (25/group), tebufenozide was administered on gestation days 6–15 by gavage in aqueous methyl cellulose at dose levels of 50, 250, or 1,000 mg/kg/day and a dose volume of 10 ml/kg. There was no evidence of maternal or developmental toxicity; the maternal and developmental toxicity NOAEL was 1,000 mg/kg/day.

vii. In a prenatal developmental toxicity study conducted in New Zealand white rabbits (20/group), tebufenozide was administered in 5 ml/kg of aqueous methyl cellulose at gavage doses of 50, 250, or 1,000 mg/kg/day on gestation days 7–19. No evidence of maternal or developmental toxicity was observed; the maternal and developmental toxicity NOAEL was 1,000 mg/kg/day.

viii. In a 1993 2-generation reproduction study in Sprague-Dawley rats, tebufenozide was administered at dietary concentrations of 0, 10, 150, or 1,000 ppm (0, 0.8, 11.5, or 154.8 mg/kg/day for males and 0, 0.9, 12.8, or 171.1 mg/kg/day for females). The parental systemic NOAEL was 10 ppm (0.8/0.9 mg/kg/day for males and females, respectively) and the LOAEL was 150 ppm (11.5/12.8 mg/kg/day for males and females, respectively) based on decreased body weight, body weight gain, and food consumption in males, and increased incidence and/or severity of splenic pigmentation. In addition, there was an increased incidence and severity of extramedullary hematopoiesis at 2,000 ppm. The reproductive NOAEL was 150 ppm. (11.5/12.8 mg/kg/day for males and females, respectively) and the LOAEL was 2,000 ppm (154.8/171.1 mg/kg/day for males and females, respectively) based on an increase in the number of pregnant females with increased gestation duration and dystopia. Effects in the offspring consisted of decreased number of pups per litter on postnatal days 0 and/or 4 at 2,000 ppm (154.8/171.1 mg/kg/day for males and females, respectively) with a NOAEL of 150 ppm (11.5/12.8 mg/kg/day for males and females, respectively).

ix. In a 1995 2-generation reproduction study in rats, tebufenozide was administered at dietary concentrations of 0, 25, 200, or 2,000 ppm (0, 1.6, 12.6, or 126.0 mg/kg/day for males and 0, 1.8, 14.6, or 143.2 mg/kg/day for females). For parental systemic toxicity, the NOAEL was 25 ppm (1.6/1.8 mg/kg/day in males and females, respectively), and the LOAEL was 200 ppm (12.6/14.6 mg/kg/day in males and females), based on histopathological findings (congestion and extramedullary hematopoiesis) in the spleen. Additionally, at 2,000 ppm (126.0/143.2 mg/kg/day in M/F), treatment-related findings included reduced parental body weight gain and increased incidence of hemosiderin-laden cells in the spleen. Columnar changes in the vaginal squamous epithelium and reduced uterine and ovarian weights were also observed at 2,000 ppm, but the toxicological significance was unknown. For offspring, the systemic NOAEL was 200 ppm (12.6/14.6 mg/kg/day in males and females), and the LOAEL was 2,000 ppm (126.0/143.2 mg/kg/day in M/F) based on decreased body weight on postnatal days 14 and 21.

x. Several mutagenicity tests which were all negative. These include an Ames assay with and without metabolic activation, an *in vivo* cytogenetic assay in rat bone marrow cells, and *in vitro* chromosome aberration assay in CHO cells, a CHO/HGPRT assay, a reverse mutation assay with *E. Coli*, and an unscheduled DNA synthesis assay (UDS) in rat hepatocytes.

xi. The pharmacokinetics and metabolism of tebufenozide were studied in female Sprague-Dawley rats (3–6/sex/group) receiving a single oral dose of 3 or 250 mg/kg of RH–5992, ^{14}C labeled in one of three positions (A-ring, B-ring or N-butylcarbon). The extent of absorption was not established. The majority of the radio labeled material was eliminated or excreted in the feces within 48 hours; small amounts (1 to 7% of the administered dose) were excreted in the urine and only traces were excreted in expired air or remained in the tissues. There was no tendency for bioaccumulation. Absorption and excretion were rapid. A total of 11 metabolites, in addition to the parent compound, were identified in the feces; the parent compound accounted for 96 to 99% of the administered radioactivity in the high dose group and 35 to 43% in the low dose group. No parent compound was found in the urine; urinary metabolites were not characterized. The identity of several fecal metabolites was confirmed by mass spectral analysis and other fecal metabolites were tentatively identified by cochromatography with synthetic standards. A pathway of metabolism was proposed based on these data. Metabolism proceeded primarily by oxidation of the three benzyl carbons, two methyl groups on the B-ring and an ethyl group on the A-ring to alcohols, aldehydes or acids. The type of metabolite produced varies depending on the position oxidized and extent of oxidation. The butyl group on the quaternary nitrogen also can be cleaved (minor), but there was no fragmentation of the molecule between the benzyl rings.

No qualitative differences in metabolism were observed between sexes, when high or low dose groups were compared or when different labeled versions of the molecule were compared.

xii. The absorption and metabolism of tebufenozide were studied in a group of males and female bile-duct cannulated rats. Over a 72–hour period, biliary excretion accounted for 30% females to 34% males of the administered dose while urinary excretion accounted for $\simeq$55% of the administered dose and the carcass accounted for <0.5% of the administered dose for both males and females. Thus, systemic absorption (percent of dose recovered in the bile, urine and carcass) was 35% females to 39% males. The majority of the radioactivity in the bile (20% females to 24% males of the administered dose) was excreted within the first 6 hours postdosing indicating rapid absorption. Furthermore, urinary excretion of the metabolites was essentially complete within 24 hours postdosing. A large amount (67% males to 70% females) of the administered dose was unabsorbed and excreted in the feces by 72 hours. Total recovery of radioactivity was 105% of the administered dose.

A total of 13 metabolites were identified in the bile; the parent compound was not identified (i.e. -unabsorbed compound) nor were the primary oxidation products seen in the

feces in the pharmacokinetics study. The proposed metabolic pathway proceeded by primary oxidation of the benzylic carbons to alcohols, aldehydes or acids. Bile contained most of the other highly oxidized products found in the feces. The most significant individual bile metabolites accounted for 5% to 18% of the total radioactivity (males and/or females). Bile also contained the previously undetected (in the pharmacokinetics study) ''A'' Ring ketone and the ''B'' Ring diol. The other major components were characterized as high molecular weight conjugates. No individual bile metabolite accounted for >5% of the total administered dose. Total bile radioactivity accounted for ≈17% of the total administered dose. No major qualitative differences in biliary metabolites were observed between sexes. The metabolic profile in the bile was similar to the metabolic profile in the feces and urine.

2. *Short- and intermediate-term toxicity*. No dermal or systemic toxicity was seen in rats receiving 15 repeated dermal applications of the technical (97.2%) product at 1,000 mg/kg/day (Limit-Dose) as well as a formulated (23% active ingredient (a.i)) product at 0, 62.5, 250, or 1,000 mg/kg/day over a 21–day period. The Agency noted that in spite of the hematological effects seen in the dog study, similar effects were not seen in the rats receiving the compound via the dermal route indicating poor dermal absorption. Also, no developmental endpoints of concern were evident due to the lack of developmental toxicity in either rat or rabbit studies. This risk is considered to be negligible.

3. *Chronic toxicity*. EPA has established the chronic population adjusted dose (cPAD) for tebufenozide at 0.018 mg/kg/day. This reference dose (RfD) is based on a NOAEL of 1.8 mg/kg/day and an uncertainty factor (UF) of 100. The NOAEL was established from the chronic toxicity study in dogs where the NOAEL was 1.8 mg/kg/day based on growth retardation, alterations in hematology parameters, changes in organ weights, and histopathological lesions in the bone, spleen and liver at 8.7 mg/kg/day. EPA determined that the 10x factor to protect children and infants (as required by FQPA) should be reduced to 1x. Therefore, the cPAD is the same as the RfD: 0.018 mg/kg/day.

4. *Carcinogenicity*. Tebufenozide has been classified as a Group E, ''no evidence of carcinogenicity for humans,'' chemical by EPA.

C. Exposures and Risks

1. *Dietary*— i. *From food and feed uses*. Tolerances have been established (40 CFR 180.482) for the residues of tebufenozide, in or on a variety of raw agricultural commodities. In today's action tolerances will be established for the residues of tebufenozide in or on the tree nut crop group including pistachios at 0.1 ppm, and on almond hulls at 25.0 ppm. Risk assessments were conducted by EPA to assess dietary exposures from tebufenozide as follows:

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not under estimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

a. *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. Neither neurotoxicity nor systemic toxicity was observed in rats given a single oral administration of tebufenozide at 0, 500, 1,000 or 2,000 mg/kg. No maternal or developmental toxicity was observed following oral administration of tebufenozide at 1,000 mg/kg/day (Limit-Dose) during gestation to pregnant rabbits. This risk is considered to be negligible.

b. *Chronic exposure and risk*. In conducting the DEEM (Dietary Exposure Evaluation Model) analysis for chronic exposure to and risk from tebufenozide residues in food, the Agency used tolerance level residues and some PCT (Tier 2). For the subject crops, the tolerances used are: 0.1 ppm for tree nuts (including pistachios) and 25.0 ppm for almond hulls. The analysis evaluates individual food consumption as reported by respondents in the USDA, Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. Summaries of the exposures and their representations as percentages of the cPAD for the general population and subgroups of interest are presented in Table 1.

TABLE 1. CHRONIC EXPOSURE ANALYSIS BY THE DEEM SYSTEM FOR TEBUFENOZIDE

Population subgroup	Exposure (mg/kg/day)	cPAD%
U.S. population (48 continguous states).	0.0026	14%
Non-nursing infants (<1 years old).	0.0097	54%
Females (13+/nursing).	0.0024	13%

In the table, ''cPAD%'' means cPAD% = Exposure x 100% divide by cPAD.

The subgroups listed above are: (1) The U.S. population (48 continguous states); (2) highest exposed population subgroup that includes infants and children; and (3) females 13+.

This chronic dietary (food only) risk assessment should be viewed as conservative. Further refinement using anticipated residue values and additional PCT information would result in a lower estimate of chronic dietary exposure from food.

The estimates of PCT were used as follows. In all cases the maximum estimates were used.

Crop	Average	Maximum
Almonds	<1%	<1%
Apples	1%	2%
Beans/Peas, Dry	0%	1%
Cabbage, Fresh	2%	3%
Cole Crops	1%	2%
Cotton	1%	4%
Spinach, Fresh	2%	3%
Spinach, Processed.	20%	29%
Sugarcane	3%	5%
Walnuts	10%	16%

ii. *From drinking water*— a. *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.

b.*Chronic exposure and risk*. The Agency calculated the Tier I Estimated Environmental Concentrations (EECs) for tebufenozide using generic expected environmental concentration (GENEEC) (surface water) and screening concentration in ground water (SCI–GROW) (ground water) models for use in the human health risk assessment. For chronic exposure, the worst case EECs for surface water and ground water

were 16.5 parts per billion (ppb) and 1.04 ppb, respectively. These values represent upper-bound estimates of the concentrations that might be found in surface and ground water. These modeling data were compared to the chronic drinking water levels of comparison (DWLOC) for tebufenozide in ground and surface water (SOP for Drinking Water Exposure and Risk Assessments, November 20, 1997).

For purposes of chronic risk assessment, the estimated maximum concentration for tebufenozide in surface and ground waters (16.5 ppb=16.5 µg/L) was compared to the back-calculated human health DWLOCs for the chronic (non-cancer) endpoint. These DWLOCs for various population categories are summarized in Table 2.

TABLE 2. DRINKING WATER LEVELS OF COMPARISON FOR CHRONIC EXPOSURE TO TEBUFENOZIDE[1]

Population Category[2]	Chronic RfD (mg/kg/day)	Food exposure (mg/kg/day)	Max. water exposure[3] (mg/kg/day)	DWLOC [4,5,6] (µg/L)	EEC[7] calc. max. (µg/L)
U.S. population (48 continguous states)	0.018	0.0026	0.0154	540	16.5
Females (13+ years)	0.018	0.0024	0.0156	470	16.5
Non-nursing infants (<1 year)	0.018	0.0097	0.0083	83	16.5

[1]Values are expressed to 2 significant figures.
[2]Within each of these categories, the subgroup with the highest food exposure was selected.
[3]Maximum water exposure (chronic) (mg/kg/day) = Chronic PAD (mg/kg/day)—Food exposure (mg/kg/day).
[4]DWLOC(µg/L) = Max. water exposure (mg/kg/day) x body wt (kg) ÷ [(10^{-3} mg/µg) x water consumed daily (L/day)].
[5]HED Default body weights are: General U.S. population, 70 kg; females (13+ years old), 60 kg; other adult populations, 70 kg; and, all infants/children, 10 kg.
[6]HED Default daily drinking rates are 2 L/day for adults and 1 L/day for children.
[7]EEC: Estimated Environmental Concentration. (Chronic 56-day value).

2. *From non-dietary exposure*. There is a potential for occupational exposure to tebufenozide during mixing, loading, and application activities. However, the Agency did not identify dermal or inhalation endpoints for tebufenozide and determined that risks from these routes of exposure are negligible.

3. *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 tebufenozide 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, tebufenozide 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 tebufenozide 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 (62 FR 62961, November 26, 1997).

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

1. *Acute risk*. The Agency did not identify an acute dietary toxicological endpoint, therefore, the risk from this route of exposure is negligible.

2. *Chronic risk*. Using the exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, the Agency has concluded that dietary (food only) exposure to tebufenozide will utilize 14% of the cPAD for the U.S. population, and 54% of the cPAD for the most highly exposed population subgroup (non- nursing infants <1 yr). EPA generally has no concern for exposures below 100% of the cPAD. Submitted environmental fate studies suggest that tebufenozide is moderately persistent to persistent and mobile; thus, tebufenozide could potentially leach to ground water and runoff to surface water under certain environmental conditions. The modeling data for tebufenozide indicate levels less than the Agency's DWLOCs. There are no chronic non- occupational/ residential exposures expected for tebufenozide. Therefore, the Agency concludes that there is a reasonable certainty that no harm will result to adults, infants and children from chronic aggregate exposure to tebufenozide residues.

3. *Short- and intermediate-term risk*. There are potential non-occupational/ residential short-term post application exposures (incidental non-dietary ingestion) to toddlers from the use of tebufenozide on ornamentals. However, since the Agency did not identify acute dietary endpoint, the short-term post application exposure risk assessment is expected to be negligible. Intermediate-term incidental non-dietary exposures are not expected.

4. *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 tebufenozide residues.

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

1. *Safety factor for infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of tebufenozide, 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 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/uncertainty factor 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. *Conclusion*. There is a complete toxicity data base for tebufenozide and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. For the reasons summarized above, the Agency concludes that an additional safety factor is not needed to protect the safety of infants and children.

3. *Acute risk*. Since no acute toxicological endpoints were established, it is unlikely that acute aggregate risk exists.

4. *Chronic risk*. Using the exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, the Agency has concluded that dietary (food only) exposure to tebufenozide will utilize 14% of the cPAD for the U.S. population, and 54% of the cPAD for the most highly exposed population subgroup (non-nursing infants <1 yr). EPA generally has no concern for exposures below 100% of the cPAD. Despite the potential for exposure to tebufenozide in drinking water and from non-dietary, non- occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

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

6. *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 tebufenozide residues.

IV. Other Considerations

A. Metabolism in Plants and Animals

1. Nature of the residue—Plants. The qualitative nature of the residue in plants is adequately understood based upon acceptable apple, sugar beet, and rice metabolism studies. The Agency has concluded that the residue of regulatory concern is tebufenozide *per se*.

2. Nature of the residue—Animal. The results of the ruminant and poultry metabolism studies have been reviewed by the Agency and the determination was made that the tebufenozide residues of regulatory concern in animals are the parent tebufenozide and the four metabolites designated: RH–2703 [benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-((4-carboxymethyl)benzoyl)hydrazide], RH–9886 [benzoic acid, 3-hydroxymethyl,5-methyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide], the stearic acid conjugate of RH–9886, and RH–0282 [benzoic acid, 3-hydroxymethyl-5-methyl-1-(1,1- dimethylethyl)-2-(4-(1-hydroxyethyl) benzoyl)hydrazide].

B. Analytical Enforcement Methodology

1. *Analytical methods—Plant tissues*. The Rohm and Haas method TR 34–95–20, with minor modifications, was used to determine tebufenozide residue levels in/on pecans and almonds (MRID 44414304). This method has been validated by EPA and was submitted to the Food and Drug Administration (FDA) for inclusion in PAM II. The method limit of quantitation (LOQ) and limit of detection (LOD) for tebufenozide are 0.01 ppm and 0.003 ppm, respectively.

2. *Analytical methods—Animal tissues*. A submitted HPLC/UV Method, Rohm and Haas Method TR 34–96–109, has been determined to be adequate for collecting data on residues of tebufenozide in animal tissues. The validated LOQ for tebufenozide in animal tissue is 0.02 ppm. The LOQ for each of the metabolites studied are as follows: RH–2703 in liver, 0.02 ppm; RH–9886 and RH–0282 in meat, 0.02 ppm; RH–9526 in fat, 0.02 ppm. The LODs for the analytes are 0.006 ppm in tissues.

3. *Multi-residue methods*. Rohm and Haas has previously submitted data involving multi-residue method testing.

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

C. Magnitude of Residues

1. The petitioner submitted data from tests on pecans, almonds, and almond hulls. A bridging study was also submitted showing that there were no differences in the amount of RH–5992 residues on pecans (nutmeat) from the two formulations. Residues of tebufenozide were determined in/on nuts harvested 11–14 days following the last of 4 foliar applications of tebufenozide for a total of ~2.0 lbs ai/acre per season (1x the proposed seasonal rate). Tebufenozide residues in/on pecans were below the LOQ of 0.01 ppm: values ranged from <0.003 ppm (the LOD) to 0.0058 ppm. Tebufenozide residues in/on almonds were < 0.003–0.052 ppm, and in/on almond hulls were 7.880–19.9 ppm.

2. The inclusion of pistachios into the tree nut crop group without a change in the representative crops, pecans and almonds, has been recommended but has not as yet been published. The submitted pecan, almond, and almond hull field trial residue studies are adequate to support the proposed 0.1 ppm tolerance for the tree nut crop group including pistachios and the 25.0 ppm tolerance for almond hulls.

3. *Processed food/feed*. There are no tree nut (including pistachio) processed commodities of regulatory interest.

D. International Residue Limits

Codex MRLs have been established for residues of tebufenozide in/on pome fruit (1.0 ppm), husked rice (0.1 ppm) and walnuts (0.05 ppm). Tebufenozide is registered in Canada, and a tolerance for residues in/on apples is established at 1.0 ppm. EPA has set the pome fruit tolerance at 1.0 ppm to harmonize with the Codex and Canadian levels.

E. Rotational Crop Restrictions

Since tree nuts and pistachios are perennial crops, rotational crop restrictions are not required for the tree nut crop group and pistachios.

V. Conclusion

Therefore, the tolerances are established for residues of tebufenozide, in or on the tree nut crop group (including pistachios) at 0.1 ppm, and on almond hulls at 25 ppm.

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–300999 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 July 24, 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 issue(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. C400, 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, 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–300999, 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. 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 issue(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* (58 FR 51735, October 4, 1993). 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* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require 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 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* (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 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 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: May 10, 2000.

James Jones,

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. In § 180.482, by alphabetically adding the following entries to the table in paragraph (a)(1) to read as follows.

§ 180.482 Tebufenozide; tolerances for residues.

* * * * *

(a) *General.* (1) ***

Commodity	Parts per million
* * * *	*
Almond hulls	25
* * * *	*
Tree nut crop group including pistachios	0.1
* * * *	*

[FR Doc. 00–13071 Filed 5–23–00; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL MARITIME COMMISSION

46 CFR Part 515, 545

[Docket No. 00–06]

Interpretations and Statements of Policy Regarding Ocean Transportation Intermediaries

AGENCY: Federal Maritime Commission.

ACTION: Interpretive rule.

SUMMARY: The Federal Maritime Commission amends its regulations for interpretive statements of policy to interpret a section of its regulations regarding ocean transportation intermediaries to clarify the claim settlement procedures.

DATES: This rule is effective June 23, 2000.

FOR FURTHER INFORMATION CONTACT: Thomas Panebianco, General Counsel, Federal Maritime Commission, 800 North Capitol St. NW, Room 1018, Washington, DC 20573–0001; (202) 523–5740.

SUPPLEMENTARY INFORMATION: On March 8, 1999, the Federal Maritime Commission published a final rule and interim final rule to add new regulations at 46 CFR part 515 to implement changes made by the Ocean Shipping Reform Act of 1998 (''OSRA''), Public Law 105–258, 112 Stat. 1902, to the Shipping Act of 1984 (''Shipping Act''), 46 U.S.C. app. 1701 *et seq.*, relating to ocean transportation intermediaries (''OTIs''). 64 FR 11156–11183. Section 515.23(b) sets forth the claim settlement procedure for claimants seeking to pursue a claim against an OTI. The Interpretive Rule seeks to clarify the Commission's intention with respect to this procedure, as there have been reported misunderstandings in the industry as to the responsibilities inherent in this requirement.

Section 515.23(b)(1) sets forth the claim settlement procedures and provides, in part, that:

If a party does not file a complaint with the Commission pursuant to section 11 of the Act, but otherwise seeks to pursue a claim against an ocean transportation intermediary bond, insurance or other surety for damages arising from its transportation-related activities, it shall attempt to resolve its claim with the financial responsibility provider prior to seeking payment on any judgment for damages obtained.

It is the Commission's intention that a claimant seeking to settle a claim in accordance with this section should promptly provide to the financial responsibility provider all documents and information relating to and supporting its claim for the purpose of evaluating the validity and subject matter of the claim. The information relevant to the claim settlement procedure includes documents such as bills of lading, as well as the existence of pending court claims or judgments obtained.

In addition, the financial responsibility provider is allowed to evaluate the validity of the claim during the settlement process in § 515.23(b)(1). However, if the parties do not reach a settlement of the claim, the financial responsibility provider, in accordance with section 19 of the Shipping Act, 46 U.S.C. app. 1718 (1999), and 46 CFR 515.23(b)(2), must pay on a final judgment and may only inquire into the extent that the damages claimed arise from the transportation-related activities of the OTI, under section 3(17) of the Shipping Act, 46 U.S.C. app. 1702(17).

Furthermore, if settlement of the claim is not reached, the financial responsibility provider may not unilaterally reduce the amount awarded in a final court judgment; Congress has determined that, at that point, a financial responsibility provider must pay on a final judgment for damages arising from the transportation-related activities of the OTI, and the Commission cannot nullify that statutory requirement. However, the financial responsibility provider and the claimant are not precluded from mutually agreeing to compromise the amount awarded in a final judgment. In the event that the financial responsibility provider believes that a judgment against its OTI bond principal was obtained fraudulently, or that the claim underlying the judgment is itself fraudulent, the financial responsibility provider is not precluded from challenging a judgment if permitted in the jurisdiction where it was obtained.