*B. Executive Order 12875*

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

*C. Executive Order 13084*

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

## IV. 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 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 the rule in the **Federal Register**. This 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 25, 1999.

**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), 346(a) and 371.

### §180.355 [Amended]

2. In §180.355, by amending the table in paragraph (b), by revising the expiration/revocation date for Peas, succulent from ''6/30/99'' to read ''12/31/00''.

[FR Doc. 99–17350 Filed 7–13–99; 8:45 am]

BILLING CODE 6560–50–F

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–300886; FRL–6088–8]**

**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 a tolerance for residues of tebufenozide in or on kiwifruit. Rohm and Haas Company requested the tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

**DATES:** This regulation is effective July 14, 1999. Objections and requests for hearings must be received by EPA on or before September 13, 1999.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP–300886], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300886], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by

the docket control number [OPP–300886]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

**FOR FURTHER INFORMATION CONTACT:** By mail: Joseph M. Tavano, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 222, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6411, tavanojoseph@epa.gov.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 19, 1998 (63 FR 44439) (FRL–6019–6), 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) 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 180.482 be amended by establishing a tolerance for residues of the insecticide tebufenozide, in or on kiwifruit at 0.5 part per million (ppm). Tebufenozide controls light brown apple moth, green-headed leafroller, and brown-headed leafroller on kiwifruit.

## I. Background and Statutory Findings

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 (62 FR 62961, November 26, 1997) (FRL–5754–7).

## II. 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 tebufenozide, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of tebufenozide on imported kiwifruit at 0.5 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 tebufenozide are discussed in this unit.

1. 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/kilograms (mg/kg) for males and females - Toxicity Category III; inhalation $LC_{50}$ in the rat is >4.5 mg/l - Toxicity Category III; primary eye irritation study in the rabbit is a non- irritant; primary skin irritation in the rabbit >5mg - Toxicity Category IV. Tebufenozide is not a sentizer.

2. 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 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 Observable Adverse Effect Level (NOAEL) for systemic toxicity and dermal irritation in both sexes is 1,000 mg/kg/day HDT. A Lowest Observable Adverse Effect Level (LOAEL) for systemic toxicity and dermal irritation was not established.

3. 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 Red Blood Cells (RBC), Hematocrit (HCT), and Hemoglobin (HGB), increases in Heinz bodies, methemoglobin, Mean Corpuscular Volume (MCV), Mean Corpuscular Hematocrit (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).

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

5. 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).

6. 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 milliliter (ml)/kg. There was no evidence of maternal or developmental toxicity; the maternal and developmental toxicity NOAEL was 1,000 mg/kg/day.

7. 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.

8. 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 dystocia. 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).

9. 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.

10. 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 Chinese Hampster Ovary (CHO) cells, a CHO/Hypoxanthine guanine phophoribosyl transferase (HGPRT) assay, a reverse mutation assay with *E. Coli*, and an unscheduled DNA synthesis assay Unscheduled DNA Synthesis (UDS) in rat hepatocytes.

11. 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 1 of 3 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 bioacculmulation. 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 3 benzyl carbons, 2 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 leaved (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.

12. The absorption and metabolism of tebufenozide were studied in a group of male and female bile-duct cannulated rats. Over a 72–hour period, biliary excretion accounted for 30% (Female (F)) to 34% (Male (M)) of the administered dose while urinary excretion accounted for equivalent to 5% 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% (F) to 39% (M). The majority of the radioactivity in the bile 20% (F) to 24% (M) 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% (M) to 70% (F) 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 primary by 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 (M and/or F). 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 equivalent to 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.

*B. Toxicological Endpoints*

1. *Acute toxicity*. Toxicity observed in oral toxicity studies were not attributable to a single dose (exposure). No neuro or 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 rats or rabbits. Thus, the risk from acute exposure is considered negligible.

2. *Short- and intermediate termtoxicity*. 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% 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 negligable.

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. Reducing the 10x factor to 1x is supported by the following factors.

i. Developmental toxicity studies showed no increased sensitivity in fetuses when compared to maternal animals following *in utero* exposures in rats and rabbits.

ii. Multi-generation reproduction toxicity studies in rats showed no increased sensitivity in pups as compared to adults and offspring.

iii. There are no data gaps.

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

*C. Exposures and Risks*

1. *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 a tolerance will be established for the residues of tebufenozide in or on the raw agricultural commodity, kiwifruit at 0.50 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 (PCT) for assessing chronic dietary risk only if the Agency can make the following findings: 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; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and 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 PCT as required by the section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Estimates of PCT were used for the following crops. In all cases the maximum estimate was used.

Almonds: Average <1% Maximum <1%

Apples: Average 1% Maximum 2%

Beans/Peas, Dry: Average 0% Maximum 1%

Cotton: Average 1% Maximum 4%

Sugarcane: Average 3% Maximum 5%

Walnuts: Average 10% Maximum 16%

The Agency believes that the three conditions, discussed in section 408 (b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of the PCT, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. The regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which tebufenozide may be applied in a particular area.

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. Toxicity observed in oral toxicity studies were not attributable to a single dose (exposure). No neuro or 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 rats or rabbits. This risk is considered to be negligable.

ii. *Chronic exposure and risk*. The residue of concern for tebufenozide in plant and animal commodities is the parent compound *per se*. In performing this analysis, EPA used the Dietary Exposure Evaluation Model (DEEM), which incorporates data from the Continuing Survey of Food Intakes by Individuals (CSFII), 1989 to 1992. Some refinement to the food exposure estimates was made through the use of PCT data. The resulting estimated food exposures for the United States (U.S.) population and various DEEM population subgroups are shown in the following table. Of these subgroups, the highest exposure is projected for children ages 1–6, whose chronic intake is estimated at 73% of the RfD. Generally, in the absence of additional safety factors, EPA is not concerned with exposures less than 100% of the RfD. Thus, for all populations, the chronic human health risk from exposure to tebufenozide in foods is below EPA's level of concern. This estimate should be considered moderately refined. Further refinement to the exposure estimate, through the use of anticipated residues, more PCT data, or market-basket surveys, would likely result in lower exposure estimates.

Chronic Dietary Exposure to Tebufenozide and Associated Risk

| Population Subgroup[1] | Eposure, mg/kg body wt/day | % of cPAD |
|---|---|---|
| U.S. Pop. (48 contiguious states). | 0.006549 ... | 36 |
| U.S. Pop. (autumn) | 0.006634 ... | 37 |
| U.S. Pop. (winter) ... | 0.006742 ... | 38 |
| U.S. Pop. (Western region). | 0.007230 ... | 40 |
| U.S. Pop. (Pacific region). | 0.007419 ... | 41 |
| Non-hispanic Blacks | 0.006618 ... | 37 |
| Not Hispanic, Black, or White. | 0.007867 ... | 44 |
| All Infants (< 1 yr) .. | 0.009369 ... | 52 |
| Non-nursing Infants (< 1 yr). | 0.011223 ... | 62 |
| Children (1–6 yr) .... | 0.013202 ... | 73 |
| Children (7–12 yr) .. | 0.008301 ... | 46 |
| Females (13+ yr, nursing). | 0.007604 ... | 42 |
| Males (20+ yr) ..... | 0.005161 ... | 29 |

[1]Subpopulations include the general U.S. population, infants and children, females, males, and any other groups whose exposure is greater than that of the general U.S. population.

2. *From drinking water*— 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*. Submitted environmental fate studies suggest that tebufenozide ranges from moderately persistent to persistent and is mobile; thus, tebufenozide could potentially leach to ground water and runoff to surface water under certain environmental conditions. There is no established Maximum Contaminant Level (MCL) for residues of tebufenozide in drinking water. No drinking water Health Advisories have been issued for tebufenozide. There is no entry for tebufenozide in the ''Pesticides in Groundwater Database.''

Monitoring data are not available to assess the human exposure to tebufenozide via drinking water. In lieu of these, EPA has calculated the Tier I estimated concentrations in drinking water (DWECs) for tebufenozide using GENEEC (surface water) and SCIGROW (ground water) for use in the human health risk assessment. The maximum application rate for tebufenozide is 0.25 pound (lb) a.i. with 5 applications per year on pecans. This application scenario was used to calculate the DWECs for the human health risk assessment. Due to the wide range of aerobic soil half-life values, GENEEC and SCIGROW were run based on aerobic half-lives of 66 (California Loam) and 729 (worst-case soil with low microbial activity) days. For surface water, the chronic (56-day) values are 13.3 parts per billion (ppb) and 16.5 ppb for the half-lives of 66 and 729 days, respectively. The ground water screening concentrations are 0.16 ppb and 1.04 ppb for the half-lives of 66 and 729 days, respectively. These values represent upper-bound estimates of the concentrations that might be found in surface and ground water due to the use of tebufenozide on pecans.

In performing this risk assessment, EPA has calculated drinking water levels of comparison (DWLOCs) for each of the DEEM population subgroups. Within each subgroup, the population with the highest estimated exposure was used to determine the maximum concentration of tebufenozide that can occur in drinking water without causing an unacceptable human health risk. As a comparison value, EPA has used the 16.5 ppb value in this risk assessment, as this represents a worst-case scenario. The DWLOCs for tebufenozide are above the DWEC of 16.5 ppb for all population subgroups. Therefore, the human health risk from exposure to tebufenozide through drinking water in not likely to exceed EPA's level of concern.

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

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 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*. Since no acute toxicological endpoints were established, no acute aggregate risk exists.

2. *Chronic risk*. Using the Anticipated Residue Contribution (ARC) exposure assumptions described in this unit, EPA has concluded that aggregate exposure to tebufenozide from food will utilize 36% of the cPAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children (1–6 years old) at 73% of the cPAD and is discussed below. 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 EPA's DWLOC. EPA generally has no concern for exposures below 100% of the PAD because the PAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. There are no registered residential uses of tebufenozide. Since there is no potential for exposure to tebufenozide from residential uses, EPA does not expect the aggregate exposure to exceed 100% of the PAD.

3. *Short- and intermediate-term risk*. Short- and intermediat-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 tebufenozide and no short- or intermediate-term toxic endpoints, short- or intermediate-term aggregate risks do not exist.

4. *Aggregate cancer risk for U.S. population*. Since, tebufenozide has been classified as a Group E, ''no evidence of carcinogenicity for humans,'' this risk does not exist.

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 tebufenozide residues.

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

1. *Safety factor for infants and children— i. In general*. 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 inter- 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.

*Prenatal and postnatal sensitivity*. The toxicology data base for tebufenozide 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 tebufenozide. No maternal or developmental findings were observed in the prenatal developmental toxicity studies at doses up to 1,000 mg/kg/day in rats and rabbits. In the 2-generation reproduction studies in rats, effects occurred at the same or lower treatment levels in the adults as in the offspring.

*Conclusion*. There is a complete toxicity data base for tebufenozide and exposure data are complete and reasonably accounts for potential exposures. For the reasons summarized above, EPA concluded that an additional safety factor is not needed to protect the safety of infants and children.

2. *Acute risk*. Since no acute toxicological endpoints were established, no acute aggregate risk exists.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to tebufenozide from food will utilize 73% 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 tebufenozide in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the PAD.

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

5. *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.

## III. Other Considerations

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

The qualitative nature of the residue in plants is adequately understood based upon acceptable apple, sugar beet, and rice metabolism studies. EPA has concluded that the residue of regulatory concern is tebufenozide *per se*. There are no animal feed items associated with kiwifruit; consequently, a discussion of potential transfer of secondary residues to animal commodities is not relevant.

### *B. Analytical Enforcement Methodology*

The High Pressure Liquid Chromatography using ultra-violet detection (HPLC/UV) method (TR 34-95-66) used for determining residues of tebufenozide in/on kiwifruit is adequate for data collection. Adequate method validation and concurrent method recovery data have been submitted for this method. The limit of quantitation (LOQ) is 0.02 ppm for residues of tebufenozide in/on kiwifruit.

The Agency has requested that the petitioner revise the proposed enforcement method to correct the deficiencies noted during Agency method validation. Upon completion of the method revisions, the petitioner will be required to submit a copy suitable for publication in the Pesticide Analytical Manual, Volume II (PAM II).

The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

### *C. Magnitude of Residues*

Adequate residue data were provided to support the tolerance for kiwifruit at 0.5 ppm. There are no animal feed items associated with kiwifruit; consequently, a discussion of potential transfer of secondary residues to animal commodities is not relevant. There are no currently regulated processed food or feed items derived from kiwifruit; therefore, a discussion of tolerances for processed commodities is not relevant.

### *D. International Residue Limits*

A proposed Codex MRL of 0.5 ppm in/on kiwifruit is currently at Step 3. This is in harmonization with the proposed tolerance sought in this petition.

### *E. Rotational Crop Restrictions*

As kiwifruit is a perennial crop, confined and field rotational crop studies are not required for establishing a tolerance on kiwifruit.

## IV. Conclusion

Therefore, the tolerance is established for residues of tebufenozide in/on kiwifruit at 0.5ppm.

## V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by September 13, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this regulation. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor

(40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

## VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300886] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

## VII. Regulatory Assessment Requirements

### *A. Certain Acts and Executive Orders*

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations 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 in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

### *B. Executive Order 12875*

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

### *C. Executive Order 13084*

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

### 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 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 the rule in the **Federal Register**. This 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 25, 1999.

**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, in paragraph (a), by adding alphabetically the following commodity to the table and adding footnote 1 to the table to read as follows:

**§ 180.482 Tebufenozide; tolerances for residues.**

(a) * * *

| Commodity | Parts per million |
|---|---|
| * * | * * * |
| Kiwifruit[1] ..... | 0.5 |
| * * | * * * |

[1] There are no U.S. registrations on kiwifruit as of June 15, 1999.

* * * * *

[FR Doc. 99–17776 Filed 7–13–99; 8:45 am]

BILLING CODE 6560–50–F

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–300889; FRL–6089–8]**

**RIN 2070–AB78**

## Fosetyl-Al; Pesticide Tolerance for Emergency Exemptions

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for residues of fosetyl-Al [Aluminum tris (O-ethylphosphonate)] in or on succulent peas. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing seed treatment use of the pesticide on peas. This regulation establishes a maximum permissible level for residues of fosetyl-Al in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on September 31, 2000.

**DATES:** This regulation is effective July 14, 1999. Objections and requests for hearings must be received by EPA on or before September 13, 1999.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number [OPP–300889], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300889], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300889]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

**FOR FURTHER INFORMATION CONTACT:** By mail: Stephen Schaible, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 271, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703)308–9362, schaible.stephen@epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA, on its own initiative, pursuant to sections 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the fungicide fosetyl-Al, in or on peas, succulent at 1.0 parts per million (ppm). This tolerance will expire and is revoked on September 31, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

### I. Background and Statutory Findings

The Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described in this preamble and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

New 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