and pests, Reporting and recordkeeping requirements.

Dated: September 9, 1999.

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.

§ 180.474 [Amended]

2. In § 180.474, by amending paragraph (b) by changing the date ''12/31/99'' to read ''12/31/00''.

[FR Doc. 99–24693 Filed 9–21–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300914; FRL–6380–1]

RIN 2070–AB

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 sugarcane and sugarcane molasses. 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 September 22, 1999. Objections and requests for hearings, identified by docket control number OPP–300914, must be received by EPA on or before November 22, 1999.

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'' section. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300914 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, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–6411; and e-mail address: tavanojoseph@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

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–300914. 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), 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 7F4863) for a 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 sugarcane and sugarcane molasses at 0.3 and 1.0 parts per million (ppm) respectively. Tebufenozide is a reduced risk pesticide and controls sugarcane borer and Mexican rice borer on sugarcane.

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).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of tebufenozide on sugarcane and sugarcane molasses at 1.0 and 3.0 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/kilogram (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 sensitizer.

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% 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 1,000 mg/kg/ during the 21-day study. Based on these results, the 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 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 no observed adverse effect level (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 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 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 CHO cells, a CHO/HGPRT assay, a reverse mutation assay with E. Coli, and an unscheduled DNA synthesis assay (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 one of three positions (A-ring, B-ring or *N*-butylcarbon). The extent of absorption was not established. The

majority of the radiolabeled 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 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% males to 34% females of the administered dose while urinary excretion accounted for ≈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% (males) to 39% (females). The majority of the radioactivity in the bile (20% (males) to 24% (females) 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% (females) to 70% (males) 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 (females and/or males). 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.

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-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% 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 the chronic population adjusted dose (cPAD) for tebufenozide at 0.018 mg/kg/day. This endpoint is based on the NOAEL of 1.8 mg/kg/day from a chronic toxicity study in dogs. Growth retardation, alterations in hematology parameters, changes in organ weights, and histopathological lesions in the bone, spleen and liver were observed at the LOAEL of 8.7 mg/kg/day in this study. An uncertainty factor (UF) of 100 was applied to account for interspecies (10x) and intraspecies (10x) variation resulting in a chronic RfD of 1.8 mg/kg/day ÷ 100 = 0.018 mg/kg/day. For chronic dietary risk assessment, the 10x factor to account for the protection of infants and children (as required by FQPA) was removed. Therefore, the cPAD is identical to the chronic RfD, cPAD = chronic RfD = 0.018 mg/kg/day. Removing the 10x factor 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, tolerances will be established for residues of tebufenozide in or on sugarcane and sugarcane molasses at 1.0 and 3.0 ppm, respectively. Risk assessments were conducted by EPA to assess dietary exposures from as follows.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of crop 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 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.

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

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 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.* In conducting the DEEM (Dietary Exposure Evaluation Model) for chronic dietary (food only) analysis, EPA used tolerance level residues and some PCT (Tier 2). For the subject crops, the tolerances used are: 10 ppm for sugarcane, 3.0 ppm for sugarcane molasses. 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 ARC and their representations as percentages of the cPAD for the general population and subgroups of interest are presented in the following table.

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

Population Subgroup	Exposure (mg/kg/day)	cPAD%[1]
U.S. Population (48 Contiguous States)	0.0017	10%
Children (1-6 years old)	0.0038	21%
Females (13+/nursing)	0.0017	10%

[1] cPAD% = Exposure over cPAD X 100%

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

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.* EPA calculated the Tier I Estimated Environmental Concentrations (EECs) for tebufenozide using GENEEC (surface water) and SCI-GROW (ground water) 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 (DWLOCs) for tebufenozide in ground and surface water.

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 the following table.

TABLE 2.—DRINKING WATER LEVELS OF COMPARISON FOR CHRONIC EXPOSURE TO TEBUFENOZIDE

Population Category	Chronic RfD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day)	DWLOC (μg/L)	EEC Calc. Max. (μg/L)
U.S. Population (48 Contiguous States)	0.018	0.0017	0.016	560	16.5
Female (13+ years)	0.018	0.0017	0.016	480	16.5
Children (1-6)	0.018	0.0038	0.014	140	16.5

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 drinking water estimated concentration (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 are no non-dietary acute, chronic, short- or intermediate-term exposure scenarios.

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 somewhat conservative exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, EPA has concluded that dietary (food only) exposure to tebufenozide will utilize 10% of the cPAD for the U.S. population, and 21% of the cPAD for the most highly exposed population subgroup (Children 1-6 yrs). 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 DWLOCs. EPA generally has no concern for exposures below 100% of the cPAD. Since there are no registered residential uses of tebufenozide, there is no potential for exposure to tebufenozide from residential uses. EPA 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.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

Since there are currently no registered indoor or outdoor residential non-dietary uses of 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.* In assessing the potential for additional sensitivity of infants and children to residues of, 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. *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.

3. *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.

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

5. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to tebufenozide from food will utilize 21% of the cPAD for infants and children. 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 HED's DWLOCs. 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. Since there are no registered residential uses of tebufenozide, there is no potential for exposure to tebufenozide from residential uses. EPA concludes that there is a reasonable certainty that no harm will result to adults, infants and children from chronic aggregate exposure to tebufenozide residues.

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

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

IV. 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. The qualitative nature of the residues in animals is also adequately understood based on acceptable poultry and ruminant metabolism studies. For animals, EPA has concluded that the residues of regulatory concern are tebufenozide and its metabolites benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-((4-carboxymethyl) benzoyl)hydrazide), benzoic acid, 3-hydroxymethyl,5-methyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide, the stearic acid conjugate of benzoic acid, 3-hydroxymethyl,5-methyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide and benzoic acid, 3-hydroxymethyl-5-methyl-1-(1,1-dimethylethyl)-2-(4-(1-hydroxyethyl)benzoyl)hydrazide.

B. Analytical Enforcement Methodology

1. *Analytical methods - sugarcane*. The HPLC/UV methods (Rohm and Haas Method TR 34-95-66, TR 34-94-41, and TR34-97-115) used for determining residues of tebufenozide in/on sugarcane are adequate for collection of residue data. Adequate method validation and concurrent method recovery data have been submitted for these methods. The validated limit of quantitation (LOQ) is 0.01 ppm for residues of tebufenozide in/on sugarcane and sugarcane processed commodities.

2. *Analytical methods - sugarcane and sugarcane processed commodities*. The petitioner also submitted an enforcement method (TR34-97-115) for sugarcane and sugarcane processed commodities. This method has been adequately validated by an independent laboratory validation (ILV). EPA concludes that this proposed enforcement method (TR 34-97-115) is very similar to the previous enforcement method on apples, which has been successfully validated by the Agency Analytical Lab. Therefore EPA concludes that no Agency validation is needed for the proposed enforcement method (TR 34-97-115) for sugarcane and sugarcane processed commodities. The method is suitable for publication in the Pesticide Analytical Manual, Volume II (PAM II) with an alphabetical designation (i.e., letter method).

3. *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. 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 limits of detection (LODs) for the analytes are 0.006 ppm in tissues. The method has been sent to ACB/BEAD for validation as a possible enforcement method.

4. *Multiresidue methods*. Rohm and Haas has previously submitted data involving multiresidue method testing. Tebufenozide was not recoverable by FDA Test Protocols A, B, D, or E; analysis by Protocol C was marginally successful. No further data are required at this time.

These methods may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

C. Magnitude of Residues

Samples of sugarcane from the residue field trials were stored frozen for 5-14 months prior to analysis, and sugarcane processed commodities were stored frozen for 2-11 months. EPA concludes that the submitted residue data for sugarcane are adequate to support the permanent tolerance petition for sugarcane and sugarcane molasses.

EPA concludes that the geographic representation of the crop field trials on sugarcane is adequate and that data are sufficient to support the proposed 1.0 ppm tolerance for residues of tebufenozide in/on sugarcane.

The submitted sugarcane processing studies are adequate. The concentration factor for molasses is 4.5. Multiplying the average concentration factor (4.5) and the highest average field trial (HAFT) residue (0.63) gives 3.0 ppm. Therefore EPA has determined that tolerance for sugarcane molasses should be set at 3.0 ppm (instead of proposed 6.0 ppm) based on the available processing studies. No tolerance is needed for refined sugar. Tolerances for livestock commodities have been established; therefore, residues of tebufenozide in meat, milk, poultry and eggs from the use on sugarcane are covered.

D. International Residue Limits

No CODEX, Canadian or Mexican limits for tebufenozide have been established on sugarcane.

E. Rotational Crop Restrictions

EPA has determined that crops which the label allows tebufenozide to be treated directly can be planted at any time. All other crops can not be planted within 12 months of application.

V. Conclusion

Therefore, the tolerance is established for residues of tebufenozide in sugarcane and sugarcane molasses at 1.0 and 3.0 ppm, respectively.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–300914 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 22, 1999.

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

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Room M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

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

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., 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, 401 M St., SW., 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. of this preamble, 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. of this preamble. Mail your copies, identified by docket control number OPP–300914, 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 or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. of this preamble. 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 5.1/6.1 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under 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 prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), or special consideration of environmental justice related issues under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994) or 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). 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 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action 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 the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(b)(4). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). 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.

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 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: September 9, 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, by adding alphabetically in paragraph (b), the following commodities to the table to read as follows:

§ 180.482 Tebufenozide; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ Revocation Date
* *	* *	*
Sugarcane	1.0	N/A
Sugarcane molasses	3.0	N/A
* *	* *	*

* * * * *

[FR Doc. 99–24695 Filed 9–21–99; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0, 1, 61 and 69

[CC Docket Nos. 96–262, 94–1, 98–157; CCB/CPD File No. 98–63; FCC 99–206]

Access Charge Reform; Price Cap Performance Review for Local Exchange Carriers; Petition of U S West Communications, Inc. for Forbearance From Regulation as a Dominant Carrier in the Phoenix, AZ MSA; Interexchange Carrier Purchases of Switched Access Services Offered by Competitive Local Exchange Carriers

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document revises the rules that govern the provision of interstate access services by those incumbent local exchange carriers subject to price cap regulation to advance the pro-competitive, de-regulatory national policies embodied in the Telecommunications Act of 1996. With these revisions, the Commission continues the process it began in 1997 to reform the regulation of interstate access charges in order to accelerate the development of competition in all telecommunications markets and to ensure that the Commission's own regulations do not unduly interfere with the operation of these markets as competition develops.

DATES: Effective October 22, 1999, except for 47 CFR 1.774, 61.47, 69.709, 69.711, 69.713, 69.729, which contain information collection requirements that have not been approved by OMB. The Commission will publish a document in the **Federal Register** announcing the effective date.

FOR FURTHER INFORMATION CONTACT: Tamara Preiss, Deputy Division Chief, Common Carrier Bureau, Competitive Pricing Division, (202) 418–1520. For additional information concerning the information collections contained in this Report and Order contact Judy Boley at 202–418–0214, or via the Internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Access Reform Fifth Report and Order* adopted August 5, 1999, and released August 25, 1999. The Order was accompanied by a Further Notice of Proposed Rulemaking (Notice) printed elsewhere in this **Federal Register** issue. The full text of this Report and Order (and the accompanying Notice), as well as the complete files for the relevant dockets, is available for inspection and copying during the weekday hours of 9:00 a.m. to 4:30 p.m. in the Commission's Reference Center, 445 12th St. SW, Room CY–A257, Washington DC, or copies may be purchased from the Commission's duplicating contractor, ITS Inc., 1231 20th St. NW, Washington DC 20036; (202) 857–3088. The complete text of the Order also may be obtained through the World Wide Web, at http://www.fcc.gov/Bureaus/Common__Carrier/Orders/1999/fcc99206.wp.

This Report and Order contains new and/or modified information collections subject to the Paperwork Reduction Act of 1995 (PRA). It has been submitted to the Office of Management and Budget (OMB) for review under the PRA.

Paperwork Reduction Act

This Report and Order contains either a new or modified information collection. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collections contained in this Order, as required by the Paperwork Reduction Act of 1995, Public Law 104–12. Written comments by the public on the information collections are due 30 days after date of publication in the **Federal Register**. OMB notification of action is due November 22, 1999.