ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300928; FRL–6382–6]

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 time limited tolerance for the indirect or inadvertent combined residues of tebufenozide and its metabolite benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-4-(1-hydroxyethyl)benzoylhydrazide in or on foliage of legume vegetables at 0.1 parts per million (ppm); forage, fodder, hay and straw of cereal grains at 0.5 ppm; grass forage, fodder and hay at 0.5 ppm and forage, fodder, straw and hay of non-grass animal feeds at 0.5 ppm. Rohm and Haas Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective October 21, 1999. Objections and requests for hearings, identified by docket control number OPP–300928, must be received by EPA on or before December 20, 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–300928 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: tavano.joseph@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you 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–300928. 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 July 2, 1999 (64 FR 35999) (FRL–6085–6) and September 1, 1999 (64 FR 47795) (FRL–6096–8), 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) (Pub. L. 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 inresponse to these notices of filing.

The petition requested that 40 CFR 180. 482 be amended by establishing a tolerance for indirect or inadvertent residues of the insecticide, tebufenozide benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide and its metabolite benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-4-(hydroxyethyl)benzoyl]benzoyl in or on foliage of legume vegetables; forage, fodder, hay and straw of cereal grains; grass forage, fodder and hay; and forage, fodder, straw and hay of nongrass animal feeds at 0.1, 0.5, 0.5 and 0.5 part per million (ppm) respectively. Tebufenozide is a reduced risk pesticide.

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 the combined residues of tebufenozide and its metabolite benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-[4-(1-hydroxyethyl)benzoyl]hydrazide on foliage of legume vegetables; forage, fodder, hay and straw of cereal grains; grass forage, fodder and hay and forage, fodder, straw and hay of nongrass animal feeds at 0.1, 0,5, 0.5 and 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 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 milligram/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 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% 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/day 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 LOAEL for systemic toxicity and dermal irritation was not established.

3. A 1-year dog feeding study with a lowest-observable-adverse-effect level (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 1000 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 two-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 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 three benzyl carbons,. two methyl groups on the Bring 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% (Male) to 34% (Female) 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% (Male) to 39% (Female). The majority of the radioactivity in the bile (20% (Male) to 24% (Female) 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% (Female) to 70% (Male) 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 ((Female and/or Male). 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 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 inter- (10 x) and intra- (10 x) species variation resulting in a chronic RfD of 1.8 mg/kg/day ÷ 100 = 0.018 mg/kg/day. For chronic dietary risk assessment, the 10 x factor to account for the protection of infants and children (as required by FQPA) was removed. Therefore, the chronic population adjusted dose (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 the indirect or inadvertent combined residues of tebufenozide and its metabolite benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-[4-(1-hydroxyethyl)benzoyl]hydrazide in or on foliage of legume vegetables; forage, fodder, hay and straw of cereal grains; grass forage, fodder and hay and forage, fodder, straw and hay of nongrass animal feeds at 0.1, 0.5, 0.5 and 0.5 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 percent crop treated were used for the following crops. In all cases the maximum estimate was used.

Commodity	Percentage	
	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 percent crop treated (Tier 2). For the subject crops, the tolerances used are: 0.1 ppm for foliage of legume vegetables; 0.5 ppm for forage, fodder, hay and straw of cereal grains; 0.5 ppm for grass forage, fodder and hay and 0.5 ppm for forage, fodder, straw and hay of nongrass animal feeds. 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.

CHRONIC EXPOSURE ANALYSIS BY THE DEEM SYSTEM FOR TEBUFENOZIDE

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

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

The subgroups listed above are: (1) the U.S. population (48 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 % crop treated 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 tebufenozideusing 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 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 g/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.

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 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 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 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 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, 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 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, HED 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 yr). 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. Since there are no registered residential uses of tebufenozide, there is no potential for exposure to tebufenozide from residential uses. HED 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*— i. *In general.* 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 pre-and post-natal toxicity and the completeness of the database 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 intra-species 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.

ii. *Pre- and post-natal sensitivity.* The toxicology data base for tebufenozide included acceptable developmental toxicity studies in both rats and rabbits as well as a two-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 1000 mg/kg/day in rats and rabbits. In the two-generation reproduction studies in rats, effects occurred at the same or lower treatment levels in the adults as in the offspring.

iii. *Conclusion.* There is a complete toxicity database for tebufenozide and exposure data is 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 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.

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.

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

The petitioner has submitted method validation/concurrent recovery studies for a proposed enforcement method. This HPLC/MS method, Rohm and Haas Method TR 34-99-10 which is a combination of methods TR 34-97-91 and TR 34-98-149, is to be used for determining residues of tebufenozide in/on rotated crops. The method, entitled ''Tolerance Enforcement Method for RH-5992 and Its Metabolites in Rotation Crops'' has undergone successful independent laboratory validation . It also has been adequately radiovalidated and an HPLC/MS-MS confirmatory method exists. The proposed enforcement method for rotated crops for determining residues of tebufenozide and metabolites, is adequate for collection of residue data.A copy of the method has been forwarded to the Analytical Chemistry Branch (ACB) for petition method validation (PMV) as a possible enforcement method. The proposed enforcement method has not been subjected to a complete Agency method validation at this time. EPA has conducted a preliminary review of the method that indicates that it appears to be suitable for enforcement purposes pending the outcome of the actual method validation. Given that the registrant has provided concurrent fortification data to demonstrate that the method is adequate for data collection purposes and has provided the Agency with a successful Independent Laboratory Validation, coupled with EPA's preliminary review, EPA concludes that the method is suitable as an enforcement method to support tolerances associated with a conditional registration only. As a condition of the registration, the Agency will require a successful method validation and the registrant will be required to make any necessary modifications to the method resulting from the laboratory validation.

This method 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

The foliage portions of representative crops from the cereal grain and legume crop groups show quantifiable residues of the tebufenozide metabolite RH-1788 at the 30-day plantback interval. A tolerance is required on those commodities which have quantifiable residues: cereal grain straw and hay, and foliage of legume vegetables. Given the limited amount of data, the cereal grain tolerances should be extended to forage and fodder as well. Tolerances on rotated crops would normally require the same number and geographic location of residue field trials as those required were they primary crops. In this case, the crops for which rotational crop tolerances are requested, small grains and legumes, have much greater production acreage and geographic distribution than most of the registered tebufenozide primary crop uses. Rather than requiring the number and geographic diversity of the rotated crop field trials, which would entail trying to grow and treat primary crops in regions where tebufenozide is unlikely to be used, EPA will require using the number and geographic diversity for field trials of a primary crop likely to be rotated to grains/legumes and with a use pattern which would produce the conditions for highest possible residue in rotated crops.

The most significant crops or crop groups which are rotated and have registered tebufenozide uses are Brassica (cole) and leafy vegetables, cotton, and fruiting vegetables. The primary crops which have the essentially the highest use pattern, (0.92 lb ai/A/season), shortest PHI (7 days), highest current tolerances (2-10 ppm vs 0.8 for fruiting vegetables), and are most likely to be rotated are Brassica (cole) and leafy vegetables. Leaf lettuce is the crop within these crop groups with the highest consumption by the general population. Eight trials are normally required to establish a tolerance on leaf lettuce. The registrant has submitted two trials each on small grains and legumes. Therefore, EPA will require 6 additional crop field trials (the number of residue trials required for leaf lettuce) for the foliages of both rotated small cereal grains (e.g., wheat, barley, or oats) and legumes, for a total of 12 additional trials, to establish the requested tolerances on cereal grains and legumes for a 30-day plantback interval. The guidelines would normally require 63 total trials on these crops groups. A significant reduction in data will be acceptable in this case since this is a reduced risk pesticide, residues are found only in livestock feed items, and those residues do not impact tolerances for animal commodities. Additional data will not be required for grass forage, fodder, and straw and on non-grass animal feeds (forage, fodder, straw, and hay).The small grain and legume foliage data will be translated to these commodities. Up to 4 years may be required to generate and review the additional rotational crop data. To allow the rotation of crops while additional data are generated, EPA is issuing time-limited tolerances on cereal grain forage, fodder, straw, and hay; grass forage, fodder, and straw and non-grass animal feeds (forage, fodder, straw, and hay) at 0.5 ppm, and legume forage at 0.1 ppm. Upon receipt of the additional data, the proposed tolerance levels will be revisited.

D. International Residue Limits

No CODEX, Canadian or Mexican limits for tebufenozide have been were established on cereal grain forage, fodder, straw, and hay; grass forage,

fodder, and straw and non-grass animal feeds (forage, fodder, straw, and hay) and legume forage. Therefore, international harminization is not an issue at this time.

E. Rotational Crop Restrictions

EPA has determined that crops which the label allows to be treated directly can be planted at any time. All other crops can not be planted within 30 days of application.

V. Conclusion

Therefore, time limited tolerances are established for the combined residues of tebufenozide benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide and its metabolite benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-[4-(1-hydroxyethyl)benzoyl]hydrazide in cereal grain forage, fodder, straw, and hay; grass forage, fodder, and straw and non-grass animal feeds (forage, fodder, straw, and hay) at 0.5 ppm, and legume forage at 0.1 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–300928 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 December 20, 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 be 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.'' (cite). 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 PIRB for its inclusion in the official record that is described in Unit I.B.2. of this preamble. Mail your copies, identified by docket number OPP–300928, 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 PRIB 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: October 12, 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 text to paragraph (d) to read as follows:

§ 180.482 Tebufenozide; tolerances for residues.

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent combined residues of tebufenozide benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide and its metabolite benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2- [4-(1-hydroxyethyl)benzoyl]hydrazide in or on the raw agricultural commodities when present therin as a result of the application of tebufenozide to growing crops listed in paragraph (a) of this section to read as follows:

Commodity	Parts per million	Expiration/ Revocation Date
Foliage of legume vegetables.	0.1	9/30/03
Forage, fodder, hay and straw of cereal grains.	0.5	9/30/03
Forage, fodder, straw and hay of non-grass animal feeds.	0.5	9/30/03
Grass forage, fodder and hay.	0.5	9/30/03

[FR Doc. 99–27393 Filed 10–20–99; 8:45 am]

Billing Code 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300932; FRL–6385–9]

RIN 2070–AB78

Sethoxydim; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on buckwheat. This action is in connection with a crisis exemption declared under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on buckwheat. This regulation establishes a maximum permissible level for residues of sethoxydim in this food commodity. The tolerance will expire and is revoked on December 31, 2001.

DATES: This regulation is effective October 21, 1999. Objections and requests for hearings, identified by docket control number OPP–300932, must be received by EPA on or before December 20, 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 VII. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300932 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308–9364; and e-mail address: pemberton.libby@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially