

action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of the FFDCIA, 21 U.S.C. 346a(n)(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 under FFDCIA section 408(l)(6), 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.

**IX. 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 14, 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.

2. In § 180.377, by adding text to paragraph (b) to read as follows:

**§ 180.377 Diflubenzuron; tolerances for residues.**

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of diflubenzuron and its metabolites, PCA (4-chloroaniline) and CPU (4-chlorophenylurea), expressed as the parent diflubenzuron, in connection with use of this pesticide under a section 18 emergency exemption granted by EPA. The tolerances will expire on the dates specified in the following table.

Commodity	Parts per million	Expiration/ revocation date
Pears .....	0.5	3/31/00

\* \* \* \* \*  
 [FR Doc. 99-25312 Filed 9-28-99; 8:45 am]  
 BILLING CODE 6560-50-F

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-300923; FRL-6383-6]

RIN 2070-AB78

**Tebufenozide; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of Tebufenozide benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide in or on turnips and canola. The Interregional Research Project Number 4 (IR-4) 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 29, 1999. Objections and requests for hearings, identified by docket control number OPP-300923, must be received by EPA on or before November 29, 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-300923 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide

Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308-3194; and e-mail address: brothers.shaja@epamail.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:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed 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-300923. 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 February 9, 1999 (64 FR 6351) (FRL-6058-3), 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 pesticide petitions (PP) for tolerance by IR-4. This notice included a summary of the petitions prepared by the Rohm and Haas Company, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.482 be amended by establishing tolerances for residues of the insecticide tebufenozide, in or on turnip tops, turnip roots, canola seed, and refined canola oil at 9.0, 0.25, 1.75, and 3.75 part per million (ppm), respectively. The petitions were subsequently amended by IR-4 to propose tolerances for turnip tops at 9.0 ppm, turnip roots at 0.3 ppm, canola seed at 2.0 ppm, and canola oil, refined at 4.0 ppm.

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 tebufenozide and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of tebufenozide on turnip tops, turnip roots, canola seed, and refined canola oil at 9.0, 0.3, 2.0, and 4.0 ppm, respectively. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances 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 unit II.A. of the Final rule on Tebufenozide Pesticide Tolerances published in the **Federal Register** on April 7, 1999 (64 FR 16850) (FRL-6072-6).

### B. Toxicological Endpoints

The toxicology endpoints for tebufenozide are discussed in Unit II.B. of the Final rule on Tebufenozide Pesticide Tolerances published in the **Federal Register** of April 7, 1999.

### 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. Canola meal and turnip tops are ruminant feed item. Permanent tolerances for livestock commodities (excluding poultry) were published in the **Federal Register** (64 FR 39060, July 21, 1999). Risk assessments were conducted by EPA to assess dietary exposures from tebufenozide as follows:

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of 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. Almonds: average < 1% maximum < 1%, apples: average 1% maximum 2%, beans/peas, dry: average 0% maximum 1%, cotton: average 1% maximum 4%, sugarcane: average 3% maximum 5%, and walnuts: average 10% maximum 16%.

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

have available information on the regional consumption of food to which 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 neurological 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 assessment is not required. The Agency considers acute exposure/risk to be negligible.

ii. *Chronic exposure and risk.* The residue of concern for tebufenozide in plant and animal commodities is the parent compound per se. The chronic population adjusted dose (cPAD) used for the chronic dietary analysis is 0.018 mg/kg/day. In performing chronic dietary exposure and risk analysis, the Agency used the Dietary Exposure Evaluation Model (DEEM), which incorporates data from the Continuing Survey of Food Intake by Individuals (CSFII) for the period, 1989 to 1992. Some refinement to the dietary exposure estimates was made through the use of percent-of-crop-treated data. The resulting Anticipated Residue Contributions (ARC) for the U.S. population and various DEEM population subgroups can be determined. Of these subgroups, the highest exposure is projected for children ages 1-6 years, whose chronic intake is estimated as 73% of the cPAD. Percent cPAD values for other subgroups include: U.S. Population for the 48 states (36%), all infants less than 1 yr. (52%), and children 7 to 12 yrs. (46%). Generally, in the absence of additional safety factors, the Agency is not concerned with exposures less than 100% of the cPAD. Thus, for all populations, the chronic human health risk from exposure to tebufenozide in foods is below the Agency's level of concern.

2. *From drinking water.* Available data suggest that tebufenozide ranges from moderately persistent to persistent and is mobile; thus, tebufenozide could potentially leach to ground water and runoff to surface water under certain environmental conditions. There is no Maximum Contaminant Level (MCL) for residues of tebufenozide in drinking water. No drinking water Health

Advisories have been issued for tebufenozide. There is no entry for tebufenozide in the "Pesticides in Groundwater Database (EPA 734-12-92-001, September 1992).

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

ii. *Chronic exposure and risk.* Submitted environmental fate studies suggest that tebufenozide ranges from moderately persistent to persistent and is mobile; thus, tebufenozide could potentially leach to ground water and runoff to surface water under certain environmental conditions. There is no established MCL for residues of tebufenozide in drinking water. No drinking water Health Advisories have been issued for tebufenozide. There is no entry for tebufenozide in the "Pesticides in Groundwater Database." Monitoring data are not available to assess the human exposure to tebufenozide via drinking water. In lieu of these, EPA has calculated the Tier I estimated environmental concentrations in drinking water (EECs) for tebufenozide using generic expected environmental concentration (GENEEC) (surface water) and screening concentration in ground water (SCIGROW) (ground water) for use in the human health risk assessment. The maximum application rate for tebufenozide is 0.25 pound (lb) active ingredient (a.i.) with 5 applications per year on pecans. This application scenario was used to calculate the EECs for the human health risk assessment. Due to the wide range of aerobic soil half-life values, GENEEC and SCIGROW were run based on aerobic half-lives of 66 (California Loam) and 729 (worst-case soil with low microbial activity) days. For surface water, the chronic (56-day) values are 13.3 parts per billion (ppb) and 16.5 ppb for the half-lives of 66 and 729 days, respectively. The ground water screening concentrations are 0.16 ppb and 1.04 ppb for the half-lives of 66 and 729 days, respectively. These values represent upper-bound estimates of the concentrations that might be found in surface and ground water due to the use of tebufenozide on pecans. In performing this risk assessment, EPA has calculated drinking water levels of comparison (DWLOCs) for each of the DEEM population subgroups. Within each subgroup, the population with the highest estimated exposure was used to determine the maximum concentration of tebufenozide that can occur in drinking water without causing an

unacceptable human health risk. As a comparison value, EPA has used the 16.5 ppb value in this risk assessment, as this represents a worst-case scenario. The DWLOCs for tebufenozide are above the drinking water estimated concentrations (DWEC) of 16.5 ppb for all population subgroups. Therefore, the human health risk from exposure to tebufenozide through drinking water is not likely to exceed EPA's level of concern.

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints cPADs or acute dietary no observed adverse effect levels (NOAELs) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause to exceed the cPAD if the tolerances being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerances are granted.

3. *From non-dietary exposure.* Tebufenozide is not currently registered for use on residential non-food sites. The Agency concludes that there are no acute, chronic, short- or intermediate-term non-dietary 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 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 toxicity endpoints were identified for tebufenozide, the Agency concludes that acute aggregate risk from the use of the pesticide will not pose an unacceptable risk to human health.

2. *Chronic risk.* Using the ARC exposure assumptions described in this unit, EPA has concluded that aggregate exposure from food will utilize 10% of the cPAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children (1–6 years old) at 21% of the cPAD discussed below. Submitted environmental fate studies suggest that tebufenozide is moderately persistent to persistent and mobile; thus, tebufenozide could potentially leach to ground water and runoff to surface water under certain environmental conditions. The modeling data for tebufenozide indicate levels less than EPA's DWLOC. EPA generally has no concern for exposures below 100% of the 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 is no potential for exposure to tebufenozide from residential uses, EPA does not expect the aggregate exposure to exceed 100% of the cPAD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to 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. Due to lack of endpoints and/or residential use registrations, the Agency concludes that short- and

intermediate-term risk via non-dietary routes (e.g., dermal, inhalation, non-dietary oral) will not pose an unacceptable risk to human health.

4. *Aggregate cancer risk for U.S. population.* Tebufenozide has been classified as a Group E chemical (no evidence of carcinogenicity for humans). The Agency concludes that the aggregate cancer risk for the U.S. population is not impacted by the establishment of these tolerances.

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

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

1. *Safety factor for infants and children-- i. In general.* In assessing the potential for additional sensitivity of infants and children to residues of tebufenozide, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for 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. *Developmental toxicity studies.* Developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following

in utero exposures in rats and rabbits. See discussion under Unit II.A of the Final rule for tebufenozide tolerances published in the **Federal Register** on April 7, 1999.

iii. *Reproductive toxicity study.* Multi-generation reproduction toxicity studies in rats showed no increased sensitivity in pups as compared to adults and offsprings. See discussion under Unit II.A of the Final Rule for tebufenozide tolerances published in the **Federal Register** on April 7, 1999.

iv. *Pre- and post-natal sensitivity.* The Agency determined that available data provide no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to tebufenozide.

v. *Conclusion.* The Agency believes that reliable data support using the standard 100-fold safety factor for assessing sensitivity to residues of tebufenozide and that an additional 10-fold margin of safety for infants and children is not warranted. There is a complete toxicity database for tebufenozide and exposure data are complete or estimated based on data that reasonably account for potential exposures.

2. *Acute risk.* No acute toxicity endpoints for tebufenozide have been identified and this risk assessment is not required. No acute aggregate risk exist.

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 children (1–6) the most highly exposed population subgroup. 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. EPA does not expect the aggregate exposure from tebufenozide in food, drinking water, and from non-dietary exposure to exceed the Agency's level of concern.

4. *Short- or intermediate-term risk.* Since no short- or intermediate-term toxicological endpoints were identified by the Agency for tebufenozide and there are no registered uses that would result in residential exposure, the Agency concludes that this risk criterion is negligible and the subject tolerances adequately protect the safety of infants and children.

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

**Turnips.** IR-4 used Rohm and Haas High Performance Liquid Chromatographic (HPLC)/Ultra Violet (UV) analytical method TR-34-94-41 to collect residue data from the field trials on turnips. IR-4 slightly modified the HPLC system used to quantify tebufenozide residues, but made no substantive changes. Adequate recovery data and representative chromatograms for turnip roots and tops were provided. The limit of quantitation (LOQ) in turnip roots and tops is 0.01 ppm. This method has been conditionally approved by the Agency as an analytical enforcement method, pending incorporation of the corrections noted during the Analytical Chemistry Branch/BEAD's petition method validation (PMV) trial. This method is considered adequate for the enforcement of tebufenozide residues in/on turnip roots and tops. A copy of the corrected version of TR-34-94-41 will be submitted for publication in the Pesticide Analytical Manual, Volume II (PAM II).

**Canola.** IR-4 used Rohm and Haas HPLC/UV analytical method TR-34-96-135 to collect residue data from the field trials on canola. Adequate validation data and representative chromatograms for canola commodities (seed, meal, oil, soapstock) were provided. The LOQ is 0.01 ppm for the seed and meal and 0.03 ppm for the oil and soapstock. A PMV is not required, as this method is similar to those for walnuts and apples which

have been successfully validated. A copy of TR-34-96-135 incorporating the corrections specified in the Independent Laboratory Validation (ILV) study will be submitted for publication in PAM II.

Adequate enforcement methodology (example - gas chromatography) is available to enforce the tolerance expression for canola seed and refined oil and turnip roots and tops. 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

**Turnips.** The submitted turnip top and root residue data are adequate to support the proposed use. The six studies on turnips adequately address the number and geographic representation of studies suggested in the OPPTS Test Guidelines. Residues of tebufenozide ranged from 0.02 to 0.23 ppm for turnip roots and from 0.31 to 8.31 ppm for turnip tops. The proposed tolerances of 9.0 ppm and 0.3 ppm are appropriate on turnip tops and turnip roots respectively.

**Canola.** The submitted canola residue data are adequate to support the proposed use. Residues of tebufenozide ranged from 0.29 to 1.64 ppm for canola seed. The proposed tolerance 2.0 ppm on canola seed is appropriate. Processed commodities from canola (meal, oil, and soapstock) were generated using procedures that mimic commercial practice. Residues of tebufenozide did not concentrate in canola meal (average concentration factor = 0.16X) or soapstock (1.1X), but did concentrate in refined oil (an average of 2.3X). Based on the highest average field trial value for canola seed (1.58 ppm), a tolerance of 4.0 ppm is appropriate for refined canola oil.

##### D. International Residue Limits

No CODEX, Canadian or Mexican limits for tebufenozide were established on the subject crops at the time of this review.

#### V. Conclusion

Therefore, the tolerance is established for residues of tebufenozide; benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide in turnip tops, turnip roots, canola seed, and refined canola oil at 9.0, 0.3, 2.0, and 4.0 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-300923 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 29, 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](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 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-300923, 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](mailto:opp-docket@epa.gov). Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 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 tolerances 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 tolerances 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 20, 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, the table to paragraph (a)(1) is amended by adding entries for canola, seed; canola, refined oil; turnip, tops; and turnip, roots, to read as follows:

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

(a) \* \* \*

Commodity	Parts per million
* * * *	*
Canola, refined oil .....	4.0
Canola, seed .....	2.0
* * * *	*
Turnip, roots .....	0.3
Turnip, tops .....	9.0

\* \* \* \*

[FR Doc. 99-25314 Filed 9-28-99; 8:45 am

BILLING CODE 6560-50-F

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 300**

[FRL-6445-5]

**National Oil and Hazardous Substance Pollution Contingency Plan; National Priorities List**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of deletion of the Darling Hill Dump Site from the National Priorities List.

**SUMMARY:** The Environmental Protection Agency (EPA) Region I announces the deletion of the Darling Hill Dump Site from the National Priorities List (NPL) and requests public comment on this action. The NPL constitutes Appendix B (40 CFR Part 300), to the National Oil and Hazardous Substance Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended by the Superfund Amendments and Reauthorization Act. After consultation with the State of Vermont, EPA has determined that the responsible parties have implemented all appropriate response actions required.

**EFFECTIVE DATE:** September 29, 1999.

**FOR FURTHER INFORMATION CONTACT:** William Lovely, Remedial Project Manager, U.S. EPA Region I, 1 Congress St., Suite 1100 (HBT), Boston, MA 02114-2023, (617) 918-1240.

**SUPPLEMENTARY INFORMATION:**

The site to be deleted from the NPL is: Darling Hill Dump Site, Lyndon, Vermont.

A Notice of Intent to Delete for this site was published on August 16, 1999, 64 FR 44452. The closing date for comments on the Notice of Intent to Delete was September 15, 1999. EPA received no comments.

EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and maintains the NPL as the list of these sites. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund Response Trust Fund (Fund). Pursuant to § 300.425 (e)(3) of the NCP, any site deleted from the NPL remains eligible for Fund-financed remedial actions if conditions at the site warrant such action. Deletion of a site from the NPL does not affect responsible party liability or impede agency efforts to recover costs associated with response efforts.

**List of Subjects in 40 CFR Part 300**

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: September 22, 1999.

**John P. DeVillars,**

*Administrator, US EPA Region I—New England.*

For the reasons set out in the preamble, 40 CFR part 300 is amended as follows:

**PART 300—[AMENDED]**

1. The authority citation for part 300 continues to read as follows:

**Authority:** 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601-9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p.351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

**Appendix B—[Amended]**

2. Table 1 of Appendix B to Part 300 is amended by removing the site "Darling Hill Dump, Lyndon, Vermont."

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BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 300**

[FRL-6445-8]

**National Oil and Hazardous Substance Pollution Contingency Plan; National Priorities List**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of deletion of the Saco Tannery Waste Pits Site From the National Priorities List.

**SUMMARY:** The Environmental Protection Agency (EPA) Region I announces the deletion of the Saco Tannery Waste Pits Site from the National Priorities List (NPL). The NPL constitutes Appendix B (40 CFR Part 300), to the National Oil and Hazardous Substance Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act, (CERCLA) as amended by the Superfund Amendments and Reauthorization Act. After consultation with the State of Maine, EPA has determined that all appropriate response actions have been implemented.

**EFFECTIVE DATE:** September 29, 1999.

**FOR FURTHER INFORMATION CONTACT:** Terrence Connelly, Remedial Project Manager, U.S. EPA Region I, 1 Congress St., Suite 1100 (HBT), Boston, MA 02114-2023, (617) 918-1373.

**SUPPLEMENTARY INFORMATION:**

The site to be deleted from the NPL is: Saco Tannery Waste Pits Site, Saco, Maine.

A Notice of Intent to Delete for this site was published on August 16, 1999, 64 FR 44458, which provided a thirty-day public comment period. The closing date for comments on the Notice of Intent to Delete was September 15, 1999. EPA received no comments.

EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and maintains the NPL as the list of these sites. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund Response Trust Fund (Fund). Pursuant to § 300.425 (e)(3) of the NCP, any site deleted from the NPL remains eligible for Fund-financed remedial actions if conditions at the site warrant such action. Deletion of a site from the NPL does not affect responsible party liability or impede agency efforts to recover costs associated with response efforts.