entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 16, 2004.

Lois Rossi,

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. Section 180.432 is revised to read as follows:

§ 180.432 Lactofen; tolerances for residues.

(a) Tolerances are established for residues of the herbicide lactofen, 1-(carboethoxy)ethyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate, in or on the following raw agricultural commodities:

Commodity	Parts per million
Beans, snap, succulent (excluding limas)	0.01
Cotton, gin byproducts	0.02
Cotton, undelinted seed	0.01
Peanut	0.01
Soybean, seed	0.01

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 04–21500 Filed 9–23–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0209; FRL–7680–9]

Tebufenozide; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tebufenozide in or on tuberous and corm vegetables (except potato) subgroup 1D, grape, citrus (crop group 10), and citrus oil and 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-(1,1dimethylethyl)-2-[4-(1-hydroxyethyl)benzoyl]hydrazide in or on forage, fodder, hay and straw of cereal grain; forage, fodder, straw and hay of non-grass animal feed; forage, fodder and hay of grass and foliage of legume vegetables. Dow AgroSciences and Interregional Research Project Number 4 (IR-4) requested these tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 24, 2004. Objections and requests for hearings must be received on or before November 23, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0209. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Joseph M. Tavano, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6411; e-mail address: *tavano.joseph@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 affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of March 19, 2001 (66 FR 15443–15459) (FRL–6766–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F6176) by Rohm and Haas, 100 Independence Mall West, Philadelphia, PA 19106, which has been subsequently purchased by Dow AgroSciences LLC, 9330 Zionsville Rd., Indianapolis, IN 46268. The petition requested that 40 CFR 180.482 be amended by establishing a tolerance for residues of the insecticide tebufenozide, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide, in or on citrus (crop group 10) and citrus oil at 0.80 and 10 parts per million (ppm), respectively. That notice included a summary of the petition prepared by Rohm and Haas, the registrant at the time. There were no comments received in response to the notice of filing.

In the **Federal Register** of March 12, 2003 (68 FR 11846–11850) (FRL–7295–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 2E6397 and PP 2E 6413), by Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1, South Brunswick, NJ 08902. The petitions requested that 40 CFR 180.482 be amended by establishing tolerances for residues of the insecticide, tebufenozide, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide, in or on grape at 3.0 ppm (PP 2E6413) and vegetable, tuberous and corm (except potato) subgroup 1D at 0.01 ppm (PP 2E6397). That notice included a summary of the petition prepared by IR-4. There were no comments received in response to the notice of filing.

In the **Federal Register** of January 28, 2004 (69 FR 4147–4151) (FRL–7335–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F4824), by Dow AgroSciences LLC, 9330 Zionsville Rd., Indianapolis, IN 46268. The petition requested that 40 CFR 180.482 be amended by establishing tolerances for 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-(1,1dimethylethyl)-2-[4-(1-hydroxyethyl)benzoyl]hydrazide in or on forage, fodder, hay and straw of cereal grain; forage, fodder, straw and hay of non-grass animal feed; forage, fodder and hay of grass and foliage of legume vegetables at 0.5, 0.5, 0.5, and 0.1 ppm, respectively. That notice included a summary of the petition prepared by Dow AgroSciences, the registrant. One comment was received in response to this notice. The commentator stated that there should be a zero tolerance since the data supporting the tolerance was too old. EPA, however, believes that the data submitted in 1999 are still relevant and reliable. The submitted studies were conducted pursuant to EPA regulations and guidelines and the commentor has offered no reason as to why the data from these studies is unreliable.

Section 408(b)(2)(A)(i) of 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) of FFDCA 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) of FFDCA 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 of FFDCA 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) of FFDCA, 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) of FFDCA, for a tolerance for residues of tebufenozide on tuberous and corm vegetables (except potato) subgroup 1D, grape, citrus (crop group 10), and citrus oil at 0.015, 3.0, 0.80, and 15.0 ppm and 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-(1,1dimethylethyl)-2-[4-(1-hydroxyethyl)benzoyl]hydrazide in or on forage, fodder, hay and straw of ceral grain; forage, fodder, straw and hay of non-grass animal feed; forage, fodder and hay of grass and foliage of legume vegetables at 1.0, 1.0, 1.0, and 0.20 ppm. EPA'assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by tebufenozide as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of October 21, 1999 (64 FR 56690–56697) (FRL–6382–6).

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest

dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for tebufenozide used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of October 21, 1999 (64 FR 56690–56697) (FRL–6382–6).

C. Exposure Assessment

1. *Dietary exposure 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. Risk assessments were conducted by EPA to assess dietary exposures from tebufenozide in food as follows:

i. *Acute exposure.* 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. An appropriate endpoint attributable to a single dose was not identified. This risk is considered to be negligible.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the U.S. Department of Agriculture 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: For the tolerances established in this action it was assumed that 100% of the crops would be treated with tebufenozide. Percent crop treated (PCT) estimates were used for some already existing tolerances. No anticipated residues were used.

iii. *Cancer.* Tebufenozide has been classified as a Group E ''No evidence of carcinogenicity for humans.'' Thus, tebufenozide is considered to pose at most a negligible risk of cancer and a quantitative exposure assessment for assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings:

Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue.

Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group.

Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.
In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information in Table 1 of this unit as follows:

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

TABLE 1.—PERCENT CROP TREATED

Commodity	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 listed in this unit have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are

reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which tebufenozide may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for tebufenozide in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of tebufenozide.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentration in Ground Water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to tebufenozide they are further discussed in the aggregate risk sections in Unit III.E.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of tebufenozide for acute exposures are estimated to be 15 parts per billion (ppb) for surface water and 1.19 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Tebufenozide is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to tebufenozide and any other substances and 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 policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. EPA evaluated the potential for increased susceptibility of infants and children from exposure to tebufenozide. EPA concluded that there are no

concerns or residual uncertainties for prenatal and postnatal toxicity.

3. *Conclusion*. There is a complete toxicity database for tebufenozide and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on these data, EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is removed because:

i. The toxicology database is complete.

ii. There is no indication of increased susceptibility of rats or rabbit fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity data.

iii. Dietary exposure estimates are only partially refined by use of PCT information and therefore provide a very conservative (health-protective) estimate of dietary exposure through food.

iv. Modeling is used for the ground and surface source drinking water exposure assessments, resulting in estimates that are conservative upper-bound concentrations.

v. There are currently no registered residential uses for tebufenozide and therefore, non-dietary exposure to infants and children is not expected.

vi. No evidence of neurotoxicity was reported.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. An acute exposure risk assessment was not performed since no toxicity endpoint for tebufenozide attributable to a single dose was identified. Acute risk from exposure to tebufenozide is expected to be negligible.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to tebufenozide from food will utilize 25% of the cPAD for the U.S. population, 27% of the cPAD for all infants (1 year), and 92% of the cPAD for children 1–2 years. There are no residential uses for tebufenozide that result in chronic residential exposure to tebufenozide. In addition, there is potential for chronic dietary exposure to tebufenozide in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO TEBUFENOZIDE

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.02 milligram/kilogram/day (mg/kg/day)	25	15	1.19	530
All Infants (<1year)	0.02 mg/kg/day	27	15	1.19	150
Children 1–2 years	0.02 mg/kg/day	92	15	1.19	16
Children 3–5 years	0.02 mg/kg/day	64	15	1.19	75
Children 6–12 years	0.02 mg/kg/day	32	15	1.19	140
Youth 13–19 years	0.02 mg/kg/day	17	15	1.19	170
Adults 20–29 years	0.02 mg/kg/day	18	15	1.19	580
Adults 50+ years	0.02 mg/kg/day	21	15	1.19	560
Females 13–49 years	0.02 mg/kg/day	18	15	1.19	490

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Tebufenozide is not registered for use on any sites that would result in residential exposure. Therefore, the

aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Tebufenozide is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* Tebufenozide is classified as ''no evidence of carcinogenic for humans;'' therefore, tebufenozide is expected to pose no greater than a negligible cancer risk.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Citrus (Crop Group 10)

The analytical method used for analysis of tebufenozide residues in/on oranges, lemons, and grapefruit was *Preliminary Residue Method for RH–5992 in Citrus (Orange, Grapefruit, Lemon and Mandarin Orange)*, Y.Meng and D.W.Chu, Rohm and Haas Analytical Method TR 34–96–184, 12/4/96. This (high performance liquid chromatography using ultraviolet (HPLC-UV) detection) method is very similar to the proposed food tolerance enforcement method for plant commodities (TR 34–94–38) and thus is adequate for collection of residue data, ergo, the method is suitable for the quantitation of tebufenozide in/on citrus commodities. The Agency has previously requested that the petitioner revise the analytical method submitted for enforcement purposes on directly treated crops (TR 34–94–38) to correct deficiencies noted during Agency method validation. Adequate recovery data for citrus samples (fortified with tebufenozide) were provided. The limit of detection (LOD) for tebufenozide in/on citrus was 0.006 ppm. The limit of quantitation (LOQ) for tebufenozide in/on citrus was 0.020 ppm.

Grape

Grape samples were analyzed for tebufenozide, via HPLC/UV, using the Del Monte Research Center Tebufenozide Working Method. This working method was based on Tolerance Enforcement Method for RH–5992 in Vegetables (Cabbage, Lettuce, Mustard Greens, Spinach, Broccoli and Celery), Rohm and Haas Analytical Method TR 34–94–41, 11/3/94. Minor modifications were made that would not negatively affect the performance of the method. Adequate recovery data for grape samples (fortified with tebufenozide) were provided. Method TR 34–94–41 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 grapes. The LOD for tebufenozide in/on grape was 0.004 ppm. The LOQ for tebufenozide in/on grape was 0.013 ppm.

Sweet Potato and Yam

Sweet potato root samples were analyzed for tebufenozide, via HPLC/UV, using the Del Monte Research Center Tebufenozide Working Method. This working method was based on Tolerance Enforcement Method for RH–5992 in Vegetables (Cabbage, Lettuce, Mustard Greens, Spinach, Broccoli and Celery), Rohm and Haas Analytical Method TR 34–94–41, 11/3/94. Minor modifications were made that would not negatively affect the performance of the method. Adequate recovery data for sweet potato root samples (fortified with tebufenozide) were provided. Method TR 34–94–41 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 PMV trial. This method is considered adequate for the enforcement of tebufenozide residues in/on sweet potato roots. The LOD for tebufenozide in/on sweet potato was 0.005 ppm. The LOQ for tebufenozide in/on sweet potato was 0.015 ppm.

Field Accumulation in Rotational Crops

Quantitative analysis of tebufenozide and RH–1788 residues in/on foliage of cereal grains and foliage of legumes (as well as cereal grain and legume seeds) was performed via the (HPLC/mass spectroscopy (MS)/MS) method, *Determination of Residues of Tebufenozide and Metabolite in Low Moisture Rotational Crops by Liquid Chromatography with Tandem Mass Spectrometry*, Dow AgroSciences Analytical Method GRM 02.20, 2002. As stated in the Dow AgroSciences method validation report, the LOD was 0.006 ppm (for both tebufenozide and RH–1788) in low-moisture foliage samples and the LOQ, as demonstrated by the lowest acceptable recovery level, was 0.020 ppm. Fortified samples were analyzed over a validation range of 0.020 ppm (LOQ) to 1.00 ppm. The recovery results from these samples indicate the method's acceptability as a data-gathering method, at minimum. The original proposed analytical method for the enforcement of tebufenozide residues in/on rotated crops is Rohm and Haas Analytical Method TR 34–99–10. This HPLC/MS method has been validated with LOQs for tebufenozide and its metabolite in low moisture plant commodities at 0.02 ppm; the reported LODs for the analytes were 0.002 ppm. The results of the PMV trial demonstrated that, although the third validation attempt was successful for the parent compound, the method trial was unsuccessful for the metabolite, RH–1788, due to excessive interferences in the chromatograms. EPA recommended that the method be returned to the petitioner for modifications to improve the cleanup step and recovery of the metabolite. As EPA considers DAS Method GRM 02.20 to be the superior technique for quantitation of tebufenozide and RH–1788 residues in low-moisture rotational crops, the registrant has proposed it as the tolerance enforcement method, rather than Rohm and Haas Method TR 34–99–10. EPA will review the method; an independent method validation (ILV) or PMV or possibly both could be required before DAS Method GRM 02.20 is deemed acceptable for tolerance enforcement purposes.

These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

No Canadian or Mexican maximum residue limits (MRL) have been established for tebufenozide residues. Codex MRLs have been established for grapes at 2.0 ppm. The Codex MRL for grapes was based on data from France and Australia. No U.S. data was submitted to Codex.

V. Conclusion

Therefore, the tolerance is established for residues of tebufenozide on tuberous and corm vegetables (except potato) subgroup 1D, grape, citrus (crop group 10), and citrus oil at 0.015, 3.0, 0.80, and 15.0 ppm and 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-(1,1dimethylethyl)-2-[4-(1-hydroxyethyl)benzoyl]hydrazide in or on forage, fodder, hay and straw of ceral grain; forage, fodder, straw and hay of non-grass animal feed; forage, fodder and hay of grass and foliage of legume vegetables at 1.0, 1.0, 1.0, and 0.20 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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 ID number OPP–2004–0209 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 23, 2004.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0209, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 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. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations 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 OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that

have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 16, 2004.

Lois Rossi,

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. Section 180.482 is amended by alphabetically adding commodities to the table in paragraph (a)(1) and by revising paragraph (d) to read as follows:

§ 180.482 Tebufenozide; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	*
Citrus oil	15.0
* * * * *	*
Fruit, citrus, group 10	0.80
* * * * *	*
Grape	3.0
* * * * *	*
Vegetable, tuberous and corm (except potato), subgroup 1D	0.015
* * * * *	*

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(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-(1,1dimethylethyl)-2-[4-(1-hydroxyethyl)benzoyl]hydrazide in or on the raw agricultural commodities when present therein 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
Forage, fodder, hay and straw of grain, cereal, group 16	1.0
Forage, fodder, straw and hay of non-grass animal feed, group 18	1.0
Grass, forage, fodder and hay, group 17	1.0
Vegetable, foliage of legume, group 7	0.20

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