

§ 52.2423 [Amended]

3. In § 52.2423(f), the citation "Section 120-04-02.A.3." is revised to read "Section 9 VAC 5-40-20.A.3."

[FR Doc. 00-16366 Filed 7-5-00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 63**

[AD-FRL-6730-6]

RIN 2060-AE86

National Emission Standards for Hazardous Air Pollutants for Polyether Polyols Production; Synthetic Organic Chemical Manufacturing Industry; Epoxy Resins Production and Non-Nylon Polyamides Production; and Petroleum Refineries

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of amendment in direct final rule.

SUMMARY: Due to an adverse comment, the EPA is withdrawing an amendment from the May 8, 2000 direct final rule for National Emission Standards for Hazardous Air Pollutants (NESHAP) for Polyether Polyols Production; Synthetic Organic Chemical Manufacturing Industry; Epoxy Resins Production and Non-Nylon Polyamides Production; and Petroleum Refineries. The amendment being withdrawn deals with the definition of equipment leak in the Petroleum Refineries NESHAP. The withdrawal of the amendment from the direct final rule will only affect sources subject to the Petroleum Refineries NESHAP.

DATES: Amendment 6 in the direct final rule, which amends § 63.641, published on May 8, 2000 (65 FR 26491), is withdrawn as of July 6, 2000. The remaining amendments will be effective July 7, 2000, as stated in the May 8 rule.

ADDRESSES: Docket numbers A-90-20 (Hazardous Organic NESHAP); A-92-37 (Epoxy Resins Production and Non-Nylon Polyamides Production); A-93-48 (Petroleum Refineries); and A-96-38 (Polyether Polyols Production) contain supporting information used in developing the standards. The dockets are located at the U.S. Environmental Protection Agency, 401 M Street SW, Washington, DC 20460, in room M-1500, Waterside Mall (ground floor), and may be inspected from 8:30 a.m. to 5:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Robert E. Rosensteel at (919) 541-5608, Emission Standards Division (MD-13), Environmental Protection Agency, Research Triangle Park, North Carolina 27711, electronic mail address "rosensteel.bob@epa.gov".

SUPPLEMENTARY INFORMATION: On May 8, 2000, the EPA published a direct final rule (65 FR 26491) and a parallel proposal (65 FR 26544) to amend portions of the NESHAP for Polyether Polyols Production; Synthetic Organic Chemical Manufacturing Industry; Epoxy Resins Production and Non-Nylon Polyamides Production; and Petroleum Refineries. The EPA stated in the direct final rule that if relevant, adverse comments were received by June 7, 2000, the EPA would publish a document to withdraw the affected portions of the direct final rule before its effective date of July 7, 2000. The EPA received an adverse comment on Amendment 6 in the direct final rule and, therefore, is withdrawing Amendment 6. This withdrawal of Amendment 6 only affects sources subject to the Petroleum Refineries NESHAP (40 CFR part 63, subpart CC). Amendment 6 would have changed the definition of equipment leak to add the term "connectors" to the equipment leak provisions in the NESHAP.

The adverse comment stated that the EPA's rationale for adding connectors to the list of equipment in the definition of equipment leak was not supported by the record of the rulemaking for the Petroleum Refineries NESHAP. It indicated that meetings with, and correspondence from, EPA and Congress supported flexibility and the New Source Performance Standard (NSPS) option without connectors. Therefore, the EPA is withdrawing this amendment and will decide the appropriate response to this comment. The 19 amendments for which we did not receive adverse comments will become effective on July 7, 2000, as provided in the May 8, 2000 direct final rule (65 FR 26491).

Dated: June 30, 2000.

Robert Brenner,

Acting, Assistant Administrator for Air and Radiation.

[FR Doc. 00-17068 Filed 7-5-00; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-301008; FRL-6590-1]

RIN 2070-AB78

Tebufenozide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of tebufenozide (benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide) in or on grapes. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on grapes. This regulation establishes a maximum permissible level for residues of tebufenozide in this food commodity. The tolerance will expire and is revoked on December 31, 2001.

DATES: This regulation is effective July 6, 2000. Objections and requests for hearings, identified by docket control number OPP-301008, must be received by EPA on or before September 5, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII of the "SUPPLEMENTARY INFORMATION." To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301008 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number, 703-305-6463; e-mail address: madden.barbara@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 categories and entities may include, but are not limited to:

Cat-egories	NAICS codes	Examples of poten-tially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufac-turing

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 under "FOR FURTHER INFORMATION CONTACT."

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-301008. 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

EPA, on its own initiative, in accordance with sections 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the insecticide tebufenozide, in or on grapes at 3 parts per million (ppm). This tolerance will expire and is revoked on December 31, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

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. . . ."

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Tebufenozide on Grapes and FFDCA Tolerances

Grapes are California's number one ranked crop in dollar value, accounting for over 90% of the grapes grown in the United States. The European export market for California wines accounts for well over \$250 million. The Grape Leaf folder causes injury in the larval stages by rolling and feeding on the leaves, reducing photosynthetic function. The Omnivorous leaf roller directly reduces grape yields by injuring the flowers and developing berries it feeds on. The Omnivorous leaf roller also allows entry of bunch rot organisms that damage entire clusters which may result in rejection at the winery.

Cryolite is the registered alternative most often used to control both Grape Leaf folders and Omnivorous leaf rollers. However, for the 2000 crop year, nearly all major California wineries with export markets have advised their growers that they will not accept grapes which have been treated with cryolite or any other product which would affect the level of fluorides in wine. The European Community recently established strict tolerance levels of 1 ppm with respect to fluoride residues. There is a direct correlation between even limited use of cryolite on wine grapes which can result in fluoride levels in wine above 3 ppm. Therefore, the State claims that there is no feasible registered alternative available to wine growers to control these pests. EPA has authorized under FIFRA section 18 the use of tebufenozide on grapes for control of Omnivorous leaf roller and Grape leaf folder in California. After having reviewed the submission, EPA concurs that emergency conditions exist for wine grapes for the State. However, the Agency does not believe that an urgent and non-routine finding can be made for table grapes since growers can still use cryolite.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of tebufenozide in or on grapes. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although

this tolerance will expire and is revoked on December 31, 2001, under FFDC section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on grapes after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether tebufenozide meets EPA's registration requirements for use on grapes or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of tebufenozide by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than California to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for tebufenozide, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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).

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 a time-limited tolerance for residues of tebufenozide in or on grapes at 3 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

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

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 the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, 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 FQPA safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (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 is expressed as 1 x 10⁻⁶ or one in a million). 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.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TEBUFENOZIDE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary females 13–50 years of age	None	Not applicable	Not applicable
Acute dietary general population including infants and children	None	Not applicable	Not applicable
Chronic dietary all populations	NOAEL = 1.8 milligram/kilogram/day (mg/kg/day) UF = 100 Chronic RfD = 0.018 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF = 0.018 mg/kg/day	Chronic toxicity study in dogs LOAEL = 8.7 mg/kg/day based on growth retardation, alterations in hematology parameters, changes in organ weights, and histopathological lesions in the bone, spleen and liver.
Short-term dermal (1 to 7 days) (residential)	None	Not applicable	Not applicable

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TEBUFENOZIDE FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Intermediate-term dermal (1 week to several months) (residential)	None	Not applicable	Not applicable
Long-term dermal (several months to lifetime) (residential)	None	Not applicable	Not applicable
Short-term inhalation (1 to 7 days) (residential)	None	Not applicable	Not applicable
Intermediate-term inhalation (1 week to several months) (residential)	None	Not applicable	Not applicable
Long-term inhalation (several months to lifetime) (residential)	None	Not applicable	Not applicable
Cancer (oral, dermal, inhalation)	Tebufenozide is classified as Group E (no evidence of carcinogenicity in humans).	Not applicable	Not applicable

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

B. 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. Tolerances, listed under 40 CFR 180.482, currently exist for residues of tebufenozide on apples, berries, brassica crop group, canola, cotton, cranberries, pome fruits, pecans, mint, sugarcane, turnips, fruiting vegetables, leafy green vegetables, and walnuts. Additionally, time-limited tolerances for eggs, milk, pears, peanuts, peppers, rice, sugarcane, sweet potatoes, and livestock commodities of cattle, goats, hogs, horses, poultry and sheep have been established. 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. Toxicity observed in oral toxicity studies were not attributable to a single dose or 1 day exposure. Therefore, no toxicological endpoint was identified for acute toxicity and no acute dietary risk assessment is needed.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 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.

Data included in the application indicate no tebufenozide concentration in grape juice or raisins. For the chronic analysis, tolerance level residues and some percent crop treated (PCT) and some market share assumptions were used. Where market share information was available, it was used in preference over PCT data since it is the larger, more conservative number and therefore more protective of human health.

iii. *Cancer.* Tebufenozide is classified as Group E (no evidence of carcinogenicity in humans).

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(F) 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 under estimate exposure for any significant subpopulation group; and 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), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: < 1% almonds, 2% apples, 1% dry beans/peas, 3% fresh cabbage, 2% cole crops, 4% cotton, 3% fresh spinach, 29% processed spinach, 5% sugarcane and 16% walnuts.

The Agency used Percent Market Share information as follows: 10% pome fruit, 19% cotton, 82% sugarcane, 10% fruiting vegetables, 14% leafy vegetables, 18% cole crop vegetables, and 25% blueberries.

The Agency believes that the three conditions listed above 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 under estimate 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. The Agency is reasonably certain that the percentage of the food treated is not likely to be an under estimation. 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/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 coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would

ever 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) from these models 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 below.

Based on the GENEEC and SCI-GROW models the estimated environmental concentrations (EECs) of tebufenozide for chronic exposures are estimated to be 17 parts per billion (ppb) for surface water and 1 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 exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether tebufenozide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, tebufenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that tebufenozide has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for

Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. *Safety factor for infants and children*

1. *Safety factor for infants and children—i. In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Developmental toxicity studies.* In prenatal developmental toxicity studies in rats and rabbits, there was no evidence of maternal or developmental toxicity; the maternal and developmental NOAELs were 1,000 mg/kg/day (highest dose tested).

iii. *Reproductive toxicity study.* In 2-generation reproduction studies in rats, toxicity to the fetuses/offspring, when observed, occurred at equivalent or higher doses than in the maternal/parental animals.

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

v. *Conclusion.* There is a complete toxicity data base for tebufenozide and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures. Data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to tebufenozide. Based on this, EPA concludes that reliable data support the use of the standard 100-fold uncertainty factor, and that the 10X safety factor to protect infants and children should be removed.

D. *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 the model

estimates of a pesticide's concentration in water (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 + chronic non-dietary, non-occupational 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 EPA to calculate DWLOCs: 2 Liter/70 kilograms (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 groundwater are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to tebufenozide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA will reassess the potential impacts of tebufenozide on drinking

water as a part of the aggregate risk assessment process.

1. *Acute risk.* No toxicological endpoint was identified for acute toxicity. Therefore, no acute aggregate risk assessment is needed.

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 20% of the cPAD for the U.S. population, 75% of the cPAD for non-nursing infants and 51% of the cPAD for children (1–6 years old). There are no residential uses for tebufenozide that result in chronic residential exposure to tebufenozide. In addition, despite the potential for chronic dietary exposure to tebufenozide in drinking water, after calculating the DWLOCs and comparing them to conservative model estimated environmental concentrations of tebufenozide in surface and ground water. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

Population Subgroup	cPAD mg/kg/day	% cPAD (food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.018	20%	17	1	500
Non-nursing infants (<1 year old)	0.018	75%	17	1	50
Females (13+, nursing)	0.018	23%	17	1	400

3. *Short-term and intermediate-term risk.* Short-term and 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. Additionally, no toxicological effects have been identified for short-term and intermediate-term toxicity. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

5. *Aggregate cancer risk for U.S. population.* Tebufenozide is classified as Group E (no evidence of carcinogenicity in humans).

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.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be

requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no Mexican Maximum Residue Limits (MRL) for tebufenozide in or on grapes. Codex has a 1.0 ppm MRL on grapes for fat soluble tebufenozide. Canada has a tebufenozide MRL on grapes at 0.5 ppm. International harmonization is not feasible for this action.

C. Conditions

Grapes are not rotated; therefore, a discussion of rotational crop requirements is not germane to this action.

VI. Conclusion

Therefore, the tolerance is established for residues of benzoic acid, 3,5-dimethyl-1-(1,1dimethylethyl)-2-(4-ethylbenzoyl)hydrazide, tebufenozide, in or on grapes at 3 ppm.

VII. 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-301008 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 September 5, 2000.

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, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

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

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., 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, 1200 Pennsylvania Ave., NW., 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 VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP-301008, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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 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).

VIII. Regulatory Assessment Requirements

This final rule establishes a time limited tolerance under FFDC section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44

U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review 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 FIFRA section 18 petition under FFDC section 408, 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 FFDCa section 408(n)(4).

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 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: June 6, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), (346a) and 371.

2. In §180.482, by alphabetically adding "Grapes" to the table in paragraph (b) to read as follows:

§ 180.482 Tebufenozide; tolerances for residues

* * * * *

(b)Section 18 emergency exemptions.

* * * * *

Commodity	Parts per million	Expiration/Revocation Date
* * * * *		
Grapes	3.0	12/31/01
* * * * *		

* * * * *

[FR Doc. 00-17043 Filed 6-30-00; 3:20 pm]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301007; FRL-6590-3]

RIN 2070-AB

Fludioxonil; Extension of Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends a time-limited tolerance for residues of the fungicide fludioxonil in or on strawberries at 2 parts per million (ppm) for an additional 1-year period. This tolerance will expire and is revoked on May 31, 2001. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on strawberries. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

DATES: This regulation is effective July 6, 2000. Objections and requests for hearings, identified by docket control number OPP-301007, must be received by EPA on or before September 5, 2000.

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 III. of the "SUPPLEMENTARY INFORMATION." To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301007 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Stephen Schaible, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703 308-9362; and e-mail address: schaible.stephen@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 codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

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-301007. 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