

a. Revising "Petroleum oils and non-petroleum oils other than animal fats and vegetable oils" to read "Petroleum Oils and Non-Petroleum Oils Other Than Animal Fats and Vegetable Oils" in sections 3.0 and 4.0;

b. Revising "near shore" to read "nearshore" in the last sentence of section 7.7, the last sentence of section 10.2.3, and the last sentence of section 10.7;

c. Revising "petroleum" to read "animal fats and vegetable" in the last sentence of section 8.2.1;

d. Removing section 9.2.1 and revising section 9.2 to read as set forth below;

e. Revising section 10.5.2 to read as set forth below;

f. Revising "Near shore" to read "Nearshore" in section 10.5.4; and

g. Revising "Environments" to read "Environments" in section 13.3(2).

The revisions read as follows:

Appendix E to Part 112—Determination and Evaluation of Required Response Resources for Facility Response Plans

* * * * *

9.0 Determining Response Resources Required for Medium Discharges—Animal Fats and Vegetable Oils

* * * * *

9.2 Complexes that are regulated by EPA and the USCG must also consider planning quantities for the transportation-related transfer portion of the facility. Owners or operators of complexes that handle, store, or transport animal fats or vegetable oils must plan for oil discharge volumes for a medium discharge. For non-petroleum oils, there is no USCG planning level that directly corresponds to EPA's "medium discharge." Although the USCG does not have planning requirements for medium discharges, they do have requirements (at 33 CFR 154.545) to identify equipment to contain oil resulting from an operational discharge.

* * * * *

10.0 Calculating Planning Volumes for a Worst Case Discharge—Animal Fats and Vegetable Oils.

* * * * *

10.5.2 With a specific worst case discharge identified, the planning volume for on-water recovery can be identified as follows:

Worst case discharge: 21 million gallons (500,000 barrels) of Group B vegetable oil

Operating Area: Inland

Planned percent recovered floating vegetable oil (from Table 6, column Nearshore/Inland/Great Lakes): Inland, Group B is 20%

Emulsion factor (from Table 7): 2.0

Planning volumes for on-water recovery: 21,000,000 gallons x 0.2 x 2.0 = 8,400,000 gallons or 200,000 barrels.

Determine required resources for on-water recovery for each of the three tiers using mobilization factors (from Table 4, column Inland/Nearshore/Great Lakes)

Table with 4 columns: Inland Operating Area, Tier 1, Tier 2, Tier 3. Rows include Mobilization factor by which you multiply planning volume and Estimated Daily Recovery Capacity (bbbls).

* * * * *

4. Amend Tables 2, 6, and 7 to appendix E to Part 112 by:

a. Revising "Oil" to read "oil" in the heading of the middle column under Rivers and canals in Table 2;

b. Revising "Near shore/Inland" to read "Nearshore/Inland/Great Lakes" in the heading of the column in Table 2;

c. Revising "Near shore/Inland Great Lakes" to read "Nearshore/Inland/Great Lakes" in the heading of the column in Table 6; and

d. Revising "section 1.2.1 and 1.2.9" to read "sections 1.2.1 and 1.2.9" in the Note following Table 6 and the Note following Table 7.

Appendix F to Part 112 [Amended]

5. Amend appendix F to part 112 by revising "fax 267-4085/4065" to read "fax (202) 267-4085" in section 1.8.3.

[FR Doc. 01-16294 Filed 6-28-01; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301143; FRL-6788-5]

RIN 2070-AB78

Bifenazate; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of bifenazate in or on tomato. 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 tomato. This regulation establishes a maximum permissible level for residues of bifenazate in this food commodity. The tolerance will expire and is revoked on June 30, 2003.

DATES: This regulation is effective June 29, 2001. Objections and requests for hearings, identified by docket control number OPP-301143, must be received by EPA on or before August 28, 2001.

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-301143 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; and 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:

Categories	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," "Regulations and Proposed Rules," 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/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301143. 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, 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(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for combined residues of the insecticide bifentazate, (hydrazine carboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl-, 1-methylethyl ester) and diazenecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl-, 1-methylethyl ester, in or on tomato at 0.70 part per million (ppm). This tolerance will expire and is revoked on June 30, 2003. 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(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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 Bifentazate on Tomato and FFDCA Tolerances

Texas has the greatest acreage of tomatoes under greenhouse production in the United States. Major production facilities are located in Jefferson Davis, Presidio, Atascosa, Frio, Limestone, Russ, Dallas, Tarrant, Willbarger, Comanche, and Lubbock counties. Small scale production facilities are located throughout the state. Virginia has approximately 50 acres of greenhouse tomatoes.

Greenhouse tomatoes are indeterminate varieties so production can be continuous. In general, most production facilities are planted twice annually. In the past 3 years there has been a continuing trend of greater early season pest mite densities. Spider mites feeding on the underside of leaves usually results in leaf yellowing and browning, but with high densities can result in plant death. Acaricides used to control spider mites must be efficacious over a wide range of pest mite species and should be effective against all life stages (egg to adult). In addition, maintenance of natural beneficial predatory mite species is desired for development of integrated pest management (IPM) programs. Bifenazate has been shown in tests on other crops to fulfill these requirements.

Numerous spider mites species can be pests in greenhouse tomato production. Nine insecticides are registered for mite control on greenhouses tomatoes. However, each of these has limited efficacy or does not fit into a continuous harvest operation or IPM program. Dicofol, endosulfan, malathion, dimethoate, and disulfoton are not effective against all pest mite species and are hard on beneficials. Due to the lack of efficacy against a broad spectrum of mites, use of these acaricides may require augmentation with additional insecticides in order to control multiple pest species. Use of these insecticides would disrupt the ongoing biological control programs established for other

tomato pests (i.e. it would take 2-8 weeks to re-establish beneficial populations to acceptable levels).

Abamectin has good efficacy but the extended REI (7 days) and PHI (7 days) make it impractical for use in indeterminate tomato production. Cinnamaldehyde is only moderately efficacious and can be phytotoxic to some tomato plants. Neem and M-pepe (insecticidal soap) are only useful for spotty outbreaks where individual plants can be treated as both products cause leaf scorch.

No effective non-chemical practices are available which would provide adequate control of spider mites in greenhouse tomato production. Biological agents can provide some benefits but their use is minimal due to unfavorable economics, slow activity, difficulty to use, and host selectivity. Mite pest species are often capable of increasing population densities faster than the associate biological control agents, resulting in crop loss. In order to produce a high value tomato crop, growers must combine selective insecticides with biological control agents.

During the 2001 growing season for greenhouse tomato production, growers could possibly incur up to a 25% yield loss from spider mite infestation. EPA has authorized under FIFRA section 18 the use of bifentazate on tomato for control of spider mites in Texas and Virginia. After having reviewed the submission, EPA concurs that emergency conditions exist in these states.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of bifentazate in or on tomato. In doing so, EPA considered the safety standard in FFDC section 408(b)(2), and EPA decided that the necessary tolerance under FFDC 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 June 30, 2003, under FFDC section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on tomato 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 bifentazate meets EPA's registration requirements for use on tomato 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 bifentazate 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 Texas and Virginia 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 bifentazate, 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 bifentazate and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of bifentazate in or on tomato at 0.70 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. 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 endpoint. 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 intra species differences. Discuss any additional uncertainty factors (other than the FQPA SF) used in the assessment.

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 1×10^{-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 ($MOE_{cancer} = \text{point of departure/exposures}$) is calculated. A summary of the toxicological endpoints for bifentazate used for human risk assessment is shown in the following Table 1.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR BIFENAZATE 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 and general population including infants and children	None	None	None
Chronic dietary all populations	NOAEL= 1.01 mg/kg/day UF = 100 Chronic RfD = 0.01 mg/kg/day	FQPA SF = 10 cPAD = chronic RfD FQPA SF = 0.001 mg/kg/day	One-year oral toxicity study in dogs LOAEL = 8.95 mg/kg/day based on changes in hematological and clinical chemistry parameters, and histopathology in the bone marrow, liver, and kidneys of both sexes.
Short-term incidental oral exposure (Residential)	NOAEL= 10 mg/kg/day	LOC for MOE = 1,000 (Residential)	Developmental toxicity study in rats LOAEL= 100 mg/kg/day based on clinical signs and decreased body weight gain and food consumption.
Short-term dermal (1 to 7 days) and Intermediate-term dermal (1 week to several months) (Residential)	Dermal study NOAEL= 80 mg/kg/day	LOC for MOE = 1,000 (Residential)	21-Day dermal toxicity study in rats LOAEL = 400 mg/kg/day based on decreased body weight and food consumption in females and an increased incidence of extramedullary hematopoiesis in the spleen in both sexes.
Long-term dermal (several months to lifetime) (Residential)	None	None	None
Short-term inhalation (1 to 7 days) (Residential)	Inhalation (or oral) study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential)	Developmental toxicity study in rats LOAEL = 100 mg/kg/day based on decreased body weight and food consumption.
Intermediate-term inhalation (1 week to several months) (Residential)	Inhalation (or oral) study NOAEL= 1.0 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 1,000 (Residential)	90-day feeding study in dogs LOAEL = 10.4 mg/kg/day based on changes in hematological parameters and histopathological effects in the liver.
Long-term inhalation (several months to lifetime) (Residential)	None	None	None
Cancer (oral, dermal, inhalation)	Bifenazate has been classified as "not likely" to be a human carcinogen.		Carcinogenicity studies in mice and rats in which there were an absence of treatment-related tumors.

*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.* Bifenazate is currently only registered for use on ornamental plants and trees. Therefore, there are no tolerances established for the combined residues of bifenazate, in or on any raw agricultural commodities. This is the first food use for bifenazate. Risk assessments were conducted by EPA to assess dietary exposures from bifenazate 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 one day or single exposure. An acute dietary endpoint for females 13-50 years old or the general U.S. population was not

selected due to the absence of an effect of concern occurring as a result of a one day or single exposure.

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: Tolerance level residues, 100% crop treated, and DEEM[®] default processing factors for all proposed commodities.

iii. *Cancer.* Bifenazate has been classified as "not likely" to be a human

carcinogen based on carcinogenicity studies in mice and rats in which there was an absence of treatment-related tumors.

2. *Dietary exposure from drinking water.* The emergency exemption request is for the use of bifenazate on tomatoes grown in greenhouses and therefore, is not expected to have an impact on drinking water. However, the current registration for application of bifenazate to public, commercial, industrial, and institutional areas may impact drinking water resources.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for bifenazate 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 bifentazate.

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 Concentrations 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 bifentazate they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the estimated environmental concentrations (EECs) of bifentazate for chronic exposures are estimated to be

0.02 parts per billion (ppb) for surface water and 0.02 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).

Bifenazate is currently registered for use on the following residential non-dietary sites: Ornamental plants and trees. The risk assessment was conducted using the following exposure assumptions: there is a potential for residential exposures, including homeowner applicator exposure and postapplication exposures, for the currently registered uses of bifentazate. However, since broad spectrum insecticides are generally used in the residential setting, application of bifentazate (a selective insecticide) by a homeowner is expected to be limited. Nevertheless, a homeowner applicator is anticipated to have short-term dermal and inhalation exposures. Exposure estimates were based on the applicator wearing short pants and short sleeves.

The registered use of bifentazate on ornamentals is also expected to result in residential post-application exposure. The exposure estimate for homeowners and children was based on the default assumptions for treatment to garden plants from the Agency's Standard Operating Procedures (SOPs) for Residential Exposure Assessment (December 18, 1997). Only short-term dermal exposures are anticipated.

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 bifentazate 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, bifentazate 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 bifentazate 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.* FFDC 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 margin of exposure (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 a developmental toxicity study in rats the maternal toxicity NOAEL was 10 mg/kg/day based on clinical signs and decreased body weight gains and food consumption at the LOAEL of 100 mg/kg/day. The developmental NOAEL was greater than 500 mg/kg/day (HDT) and the developmental LOAEL was not established. Therefore, there were no developmental effects observed in the presence of maternal toxicity in this study.

In a developmental toxicity study in rabbits there were no toxic effects up to the highest dose tested of 200 mg/kg/day in either the maternal animals or the fetuses. Although no toxicity was observed in this study, sufficient evidence of adequate dose selection was based on a range-finding study which was performed at doses of 0, 125, 250, 500, 750, or 1,000 mg/kg/day. Abortions were seen at 250 mg/kg/day and above and deaths and decreased body weight were seen at 750 mg/kg/day and 1,000 mg/kg/day. Based on these results, doses of 10, 50, and 200 mg/kg/day were selected for the main study.

iii. *Reproductive toxicity study.* In a 2-generation reproductive toxicity study in rats, the parental toxicity NOAEL was 20 ppm (equivalent to 1.6/1.8 mg/kg/day M/F) based on decreased body weight and cumulative weight gain in males and females at the LOAEL of 80 ppm (equivalent to 6.5/7.4 mg/kg/day M/F). The NOAEL for offspring toxicity and reproductive toxicity was 200 ppm (equivalent to 16.4/18.3 mg/kg/day M/F) which was the highest dose tested. A LOAEL for offspring toxicity and reproductive toxicity was not established.

iv. *Prenatal and postnatal sensitivity.* Based on the results of the developmental and reproduction studies, there is no indication of increased sensitivity in rats or rabbits to *in utero* and/or postnatal exposure to bifenazate.

v. *Conclusion.* There were no developmental or reproductive effects observed in the presence of maternal toxicity. However, bifenazate has not been evaluated by the Agency's FQPA Safety Factor Committee. Therefore, for the purposes of this emergency exemption, the FQPA safety factor of 10X, to protect infants and children has been retained for all dietary and residential risk assessments.

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 the USEPA Office of Water are used to calculate DWLOCs: 2L/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, the Office of Pesticide Programs (OPP) concludes with reasonable certainty that exposures to bifenazate 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 bifenazate on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* An acute dietary endpoint for females 13-50 years old or the general U.S. population was not selected due to the absence of an effect of concern in studies conducted for bifenazate occurring as a result of a one day or single exposure. Therefore, no acute dietary risk assessments were conducted for bifenazate.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to bifenazate from food will utilize 29% of the cPAD for the U.S. population, 6% of the cPAD for infants and 43% of the cPAD for children (7-12 years old), the most highly exposed subgroup. Based the use pattern, chronic residential exposure to residues of bifenazate is not expected. In addition, despite the potential for chronic dietary exposure to bifenazate in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of bifenazate in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2.

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

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.001	29	0.02	0.02	25
All Infants (<1 year)	0.001	6	0.02	0.02	9
Children (7-12 years)	0.001	43	0.02	0.02	6

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). Bifenazate is currently registered for use(s) that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for bifenazate.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,300 to 1,500 for short-term dermal, inhalation and incidental oral exposures. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were

calculated and compared to the EECs for chronic exposure of bifenazate in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 3.

TABLE 3.— AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO BIFENAZATE

Population Subgroup	Aggregate MOE (Food +Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. Population	1,300	1,000	0.02	0.02	80
All Infants (<1 year)	1,500	1,000	0.02	0.02	100
Children (7-12 years)	1,400	1,000	0.02	0.02	100

4. Intermediate-term risk.

Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Though residential exposure could occur with the use of bifentazate, currently, only short-term dermal and short-term inhalation residential exposures are expected. Therefore, an aggregate risk assessment for intermediate-term exposures was not conducted.

5. *Aggregate cancer risk for U.S. population.* Bifenazate has been classified as “not likely” to be a human carcinogen based on carcinogenicity studies in mice and rats in which there was an absence of treatment-related tumors. Therefore, an aggregate risk assessment to estimate cancer risk was not conducted.

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 bifentazate residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (multiresidue method) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, 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 is neither a Codex proposal, nor Canadian or Mexican limits, for residues of bifentazate and its metabolite in or on tomato. Therefore, harmonization is not an issue for this use.

C. Conditions

The request is for application to greenhouse grown tomatoes. Therefore, rotational crop restrictions are not relevant for the greenhouse. A

maximum of two applications per crop are permitted and the seasonal rate is not to exceed 0.50 lbs active ingredient per acre. The product is not to be applied within 3 days of harvest.

VI. Conclusion

Therefore, the tolerance is established for combined residues of bifentazate, (hydrazine carboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl)-, 1-methylethyl ester) and diazenecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl)-, 1-methylethyl ester, in or on tomato at 0.70 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-301143 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 August 28, 2001.

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-301143, 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 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 FFDCCA 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 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 other 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 exemption under FFDCCA 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 FFDCCA section 408(n)(4). 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.

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 13, 2001.

Joseph Merenda,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.572 is added to read as follows:

§ 180.572 Bifenazate; tolerance for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.*

Time limited tolerances are established for combined residues of bifenazate, (hydrazine carboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl-, 1-

methylethyl ester) and diazenecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl-, 1-methylethyl ester in connection with use of the pesticide under section 18 emergency exemptions granted by the EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Tomato	0.70	6/30/03

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

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

[FR Doc. 01-16441 Filed 6-28-01; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[CS Docket Nos. 97-98 and 97-151; FCC 01-170]

Rules and Policies Governing Pole Attachments; Implementation of Section 703(e) of the Telecommunications Act of 1996

AGENCY: Federal Communications Commission.

ACTION: Final rule; petitions for reconsideration.

SUMMARY: This document responds to petitions for reconsideration of the Report and Order in CS Docket No. 97-151, and the Report and Order in CS Docket No. 97-98. This document consolidates two reconsideration proceedings raising similar and interrelated issues concerning the rates, terms and conditions of access for attachments by cable operators and telecommunications carriers to utility poles, ducts, conduits and rights-of-way pursuant to section 224 of the Communications Act of 1934, as amended. This document reconsiders affirms and clarifies the pole attachment rate formula for cable attachers as well as the formula for telecommunications attachers.

DATES: Effective July 30, 2001.

FOR FURTHER INFORMATION CONTACT: Kathleen Costello at (202) 418-7200 or via the Internet at kcostell@fcc.gov, or Cheryl King at (202) 418-2284 or via the Internet at cking@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Order on*

Reconsideration, CS Dkt. Nos. 97-98 and 97-151, FCC 01-170, adopted May 22, 2001; release May 25, 2001. The full text of the Commission's *Order on Reconsideration* is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY-A257) at its headquarters, 445 12th Street, SW., Washington, DC 20554, or may be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857-3800, 1231 20th Street, NW., Washington, DC 20036, or may be reviewed via Internet at <http://www.fcc.gov/csb/>.

Paperwork Reduction Act

The requirements adopted in the *Order on Reconsideration* have been analyzed with respect to the Paperwork Reduction Act of 1995 ("1995 Act") and found to impose no new or modified information collection requirements on the public.

Synopsis of the Order on Reconsideration

I. Introduction

1. This *Order on Reconsideration* grants in part and denies in part petitions for reconsideration and/or clarification of Report and Order, Implementation of Section 703(e) of the Telecommunications Act of 1996, Amendment to the Commission's Rules and Policies Governing Pole Attachments, CS Docket No. 97-151, FCC 98-20, 63 FR 12013, published March 12, 1998, 13 FCC Rcd 6777 (1998) ("Telecom Order") and Report and Order, Amendment of Rules and Policies Governing Pole Attachments, CS Docket No. 97-98, FCC 00-116, 65 FR 31270, published May 17, 2000, corrected 65 FR 34820, May 31, 2000, 15 FCC Rcd 6453 (2000) ("Fee Order"), concerning the rates, terms and conditions of access for attachments by cable operators and telecommunications carriers to utility poles, ducts, conduits and rights-of-way pursuant to Section 224 of the Communications Act of 1934,

as amended ("Pole Attachment Act"), 47 U.S.C. 224 and Subpart J of the Commission's Rules, 47 CFR 1.1401-1.1418.

2. This *Order on Reconsideration* affirms our decision not to impose additional regulation on the negotiation process or on the rules for resolution of pole attachment complaints; affirms the continued use, in the pole attachment rate calculation formulas, of specific regulatory accounts maintained by utilities and identify the actual costs incurred by the utilities for the poles, ducts, conduits and rights-of-way that are the subject of the attachment; reconsiders and clarifies the way in which entities are counted for the purpose of allocating and apportioning costs of unusable space for telecommunications attachers after February 8, 2001; reconsiders and clarifies the geographic areas used to determine average numbers of attaching entities for use in calculations of the formulas of telecommunications pole attachment rates, and establish two presumptive averages that may be used in our formulas after February 8, 2001; affirms and clarifies decisions regarding third party overloading; affirms the presumption that a pole attachment occupies one foot of usable space and that this presumption is rebuttable by either party; affirms that the formula adopted in the Fee Order, for calculating the rate for use of capacity in a conduit, is applicable to telecommunications systems; affirms the use in the formula of the actual percentage of the conduit capacity occupied, with a rebuttable presumption that an attacher occupies one-half duct; affirms that there is no unusable capacity in a conduit; affirms our decision that a utility may not exclude reserved capacity within a conduit system when calculating total capacity upon which the pole attachment rate in a conduit is based; affirms that complaints regarding nondiscriminatory access, rates, terms and conditions for non-traditional pole attachments, such as attachments to