offset the emission reduction shortfall in order to attain the one-hour ozone standard by November 2007. Connecticut commits to adopt and submit additional restrictions on VOC emissions from mobile equipment and repair operations; and requirements to reduce VOC emissions from certain consumer products. Connecticut also commits to conduct a mid-course review to assess modeling and monitoring progress achieved toward the goal of attainment by 2007, and submit the results to EPA by December 31, 2004.

[FR Doc. 04–2267 Filed 2–3–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CT–057–7216f; FRL–7618–1]

Approval and Promulgation of Air Quality Implementation Plans; Connecticut; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to an adverse comment, EPA is withdrawing the direct final rule to approve Connecticut's 2005 and 2007 motor vehicle emissions budgets recalculated using MOBILE6.2 for the Connecticut portion of the New York-Northern New Jersey-Long Island nonattainment area and to approve Connecticut's 2007 motor vehicle emissions budgets for the Greater Connecticut nonattainment area also recalculated using MOBILE6.2. In the direct final rule published on December 18, 2003 (68 FR 70437), we stated that if we received adverse comment by January 20, 2004, the rule would be withdrawn and not take effect. EPA subsequently received an adverse comment. EPA will address the comment received in a subsequent final action based upon the proposed action also published on December 18, 2003 (68 FR 70484). EPA will not institute a second comment period on this action.

EFFECTIVE DATE: The Direct final rule is withdrawn as of February 4, 2004.

FOR FURTHER INFORMATION CONTACT: Donald O. Cooke, Environmental Scientist, Air Quality Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, One Congress Street, Suite 1100 (CAQ), Boston, MA 02114–2023, (617) 918–1668, *cooke.donald@epa.gov.*

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Oxides of Nitrogen, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: January 26, 2004.

Robert W. Varney,

Regional Administrator, EPA New England.

■ Accordingly, the revisions of 40 CFR 52.377(b), (c) and (d) (which published in the **Federal Register** on December 18, 2003 at 68 FR 70437) are withdrawn as of February 4, 2004.

[FR Doc. 04–2266 Filed 2–3–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0370; FRL–7335–6]

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 (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) and diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate) in or on potatoes. This action is in response to use of this chemical on potatoes under an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This regulation establishes a maximum permissible level for residues of bifenazate in this food commodity. The tolerance will expire and is revoked on December 31, 2006.

DATES: This regulation is effective February 4, 2004. Objections and requests for hearings, identified by docket ID number OPP–2003–0370, must be received on or before April 5, 2004.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *Sec-18-Mailbox@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0370. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://*

www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

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 bifenazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) and diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate) in or on potatoes at 0.05 parts per million (ppm). This tolerance will expire and is revoked on December 31, 2006. 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 of the FFDCA 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) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. * * *''

Section 18 of the 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 of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

EPA has received objections to a tolerance it established for bifenazate on a different food commodity. The objections were filed by the Natural Resources Defense Council (NRDC) and raised several issues regarding aggregate exposure estimates and the additional safety factor for the protection of infants and children. Although these objections concern separate rulemaking proceedings under the FFDCA, EPA has considered whether it is appropriate to establish this emergency exemption tolerance for bifenazate while the objections are still pending.

Factors taken into account by EPA included how close the Agency is to concluding the proceedings on the objections, the nature of the current action, whether NRDC's objections raised frivolous issues, and extent to which the issues raised by NRDC had already been considered by EPA. Although NRDC's objections are not frivolous, the other factors all support establishing this tolerance at this time. First, the objections proceeding is unlikely to conclude prior to when action is necessary on this petition. NRDC's objections raise complex legal, scientific, policy, and factual matters. EPA has published a notice describing the nature of the NRDC's objections in more detail. This notice offered an opportunity for the public to comment on this matter and published in the **Federal Register** of June 19, 2002 (67 FR 41628) (FRL–7167–7). EPA is now examining the extensive comments received. Second, the nature of the current action is extremely time-sensitive and addresses an emergency situation. Third, the issues raised by NRDC are not new matters but questions that have been the subject of considerable study by EPA and comment by stakeholders. Accordingly, EPA is proceeding with establishing the tolerance for bifenazate.

III. Emergency Exemption for Bifenazate on Potatoes and FFDCA Tolerances

The states of Oregon and Washington requested the emergency use of bifenazate on potatoes to control an outbreak of spider mites. The use of bifenazate on potatoes in these states took place under a section 18 crisis declaration. The states invoked the crisis authorities because of damage that spider mites cause to the crop.

EPA assessed the potential risks presented by residues of bifenazate in or on potatoes. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA 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) of the FFDCA. Although this tolerance will expire and is revoked on December 31, 2006, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on potatoes 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 bifenazate meets EPA's registration requirements for use on potatoes 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 bifenazate by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for

any States other than Oregon and Washington to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for bifenazate, 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 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

Consistent with section 408(b)(2)(D) of the FFDCA , EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of bifenazate and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for combined residues of bifenazate in or on potatoes at 0.05 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 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 lowest dose at which adverse effects of concern are identified (the lowest observed adverse effect level (LOAEL)) is sometimes used for risk assessment if the 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). The FQPA requires, in certain circumstances, an additional safety factor for the protection of infants and children. Where this FQPA safety factor applies, EPA calculates an acute or chronic Population Adjusted Dose (aPAD or cPAD) by dividing the RfD by the 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. The non-dietary risk (other than cancer) is expressed as the margin of exposure (MOE), a ratio of the NOAEL to estimated exposures (margin of exposure (MOE) = NOAEL/exposure). An MOE higher than the applicable LOC would indicate that the risk is not of concern.

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} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for bifenazate 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	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (general population and females 13–50 years old)	NA	NA	An acute dietary endpoint was not selected based on the absence of an appropriate endpoint attributed to a single dose
Chronic dietary; (all populations)	NOAEL= 1.0 milligram/kilogram/day (mg/kg/day) UF = 100 cRfD = 0.01 mg/kg/day	FQPA SF = 1X cPAD = 0.01 mg/kg/day	LOAEL = 8.9/10.4 mg/kg/day M/F based on changes in hematological and clinical chemistry parameters, and histopathology in bone marrow, liver, and kidney in the 1–Year Dog Feeding Study
Incidental oral, short-term (1–30 days)	Oral NOAEL = 10 mg/kg/day	LOC for MOE ≤ 100 (residential)	Maternal LOAEL = 100 mg/kg/day based on clinical signs, decreased body weight and food consumption during the dosing period in the Rat Developmental Study
Incidental oral, intermediate-term (30 days to 6 months)	Oral NOAEL = 0.9 mg/kg/day	LOC for MOE ≤ 100 (residential)	LOAEL = 10.4/10.7 mg/kg/day M/F based on changes in hematologic parameters in the 90–Day Subchronic Dog Study

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

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-, intermediate- and long-term dermal (1–30 days, 30 days to 6 months, and 6 months to lifetime)	Dermal NOAEL = 80 mg/kg/day	LOC for MOE ≤ 100 (residential)	LOAEL = 400 mg/kg/day based on decreased body weight and food consumption, hematologic effects, increased spleen weight and extramedullary hemapoiesis in the spleen in the 21–Day Dermal Toxicity Study in Rats
Short-term inhalation (1–30 days)	Oral NOAEL= 10 mg/kg/day inhalation absorption rate = 100%	LOC for MOE ≤ 100 (residential)	LOAEL = 100 mg/kg/day based on decreased body weight and food consumption in the Rat Developmental Study
Intermediate-term inhalation (30 days to 6 months)	Oral NOAEL= 0.9 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE ≤ 100 (residential)	LOAEL = 10.4/10.7 mg/kg/day based on changes in hematologic parameters in the 90–Day Dog Feeding Study
Long-term inhalation 6 months to lifetime)	Oral study NOAEL= 1.0 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE ≤ 100 (residential)	LOAEL = 8.9/10.4 mg/kg/day M/F based on changes in hematological and clinical chemistry parameters, and histopathology in bone marrow, liver, and kidney in the 1–Year Dog Feeding Study
Cancer (oral, dermal, inhalation)	NA	NA	Bifenazate is classified as ''not likely'' to be a human carcinogen

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.572) for the combined residues of bifenazate, (hydrazinecarboxylic acid, 2-(4-methoxy-1,1'-biphenyl]-3-yl), 1-methylethyl ester) and D3598 expressed as bifenazate (diazinecarboxylic acid, 2-(4-methoxy-1,1'-biphenyl]-3-yl), 1-methylethylester)], in or on apple, wet pomace; cattle, fat; cotton, gin byproducts; cotton, undelinted seed; fruit, pome, group 11; goat, fat; grape; grape, raisin; hog, fat; hog, dried cone; horse, fat; nectarine; peach; plum; sheep, fat, and strawberry, and bifenazate (hydrazinecarboxylic acid, 2-(4-methoxy-1,1'-biphenyl]-3-yl), 1-methylethyl ester) and D3598 expressed as bifenazate (diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethylester), A1530 (1,1'-biphenyl, 4-ol) and A1530-sulfate expressed as A1530 (1,1'-biphenyl, 4-oxysulfonic acid) in or on cattle, meat; cattle, meat byproducts; goat, meat; goat, meat byproducts; hog, meat; hog, meat byproducts; horse, meat; horse, meat byproducts; milk; sheep, meat; and sheep, meat byproducts.

Risk assessments were conducted by EPA to assess dietary exposures from bifenazate in food as follows:

i. *Acute exposure.* An acute dietary reference dose (RfD) for the females 13–50 years of age and the general population, including infants and children, was not selected because an acute oral endpoint attributed to a single-dose exposure could not be identified in any of the studies in the toxicology data base, including developmental and maternal toxicity in the developmental toxicity studies.

ii. *Chronic exposure.* In conducting this acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM/FCID™) which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessment: The chronic dietary exposure analysis assumed tolerance level residues and 100% crop treated for all registered and proposed crops excluding tomato where average field trial residues were used. DEEM (ver 7.73) default processing factors were assumed for all commodities excluding apple juice, grape juice, wine/sherry, tomato paste, and tomato puree. The processing factors for these commodities were reduced to 0.23, 0.17, 0.17, 5.0, and 5.0, respectively, based on data from processing studies.

iii. *Cancer.* EPA has classified bifenazate as ''not likely'' to be a human carcinogen. Therefore, a cancer dietary exposure and risk assessment was not performed.

2. *Dietary exposure from drinking water.* 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 bifenazate.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentrations in Groundwater (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water, EPA will generally use FIRST (a Tier 1 model) before using PRZM/

EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, 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 estimating the highest pesticide drinking water concentrations that might ever be encountered.

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, EPA determines the maximum permissible exposures (acute, short-term, intermediate-term and chronic) to the pesticide in drinking water, taking into account the expected exposure through food and residential uses. These maximum permissible level of exposure through drinking water are called drinking water levels of comparison (DWLOCs) and used as a point of comparison against the model estimates of a pesticide's concentration in water. So long as the estimated EECs from these screening models (which are designed to estimate theoretical upper limits on a pesticide's concentration in drinking water) do not exceed the applicable DWLOCs, EPA concludes that exposure to the pesticide in drinking water does not pose a risk of concern in light of total aggregate exposure to a pesticide in food, and from residential uses. Because DWLOCs address total aggregate exposure to bifenazate they are further discussed in the aggregate risk sections below.

Parent bifenazate degrades rapidly in aerobic soil conditions with a half-life of approximately 30 minutes. The first degradate formed (D3598; half-life of 7 hours) was reported in a concentration of 95% of the applied radioactivity . D3598 degrades to D1989 (reported at a maximum of 26% of the applied radioactivity), which is moderately persistent with an EPA- calculated half-life of approximately 96 days. Photodegradation and other routes of dissipation of parent bifenazate do not appear to be significant.

The Agency concluded that the residue of concern in drinking water is D1989. Parent and D3598 were not included as a residue of concern in drinking water due to the short half-lives of these compounds and the lack of an acute dietary endpoint (toxicity of D3598 is assumed to be equivalent to bifenazate). Since ground or surface water monitoring data to calculate a quantitative aggregate exposure are not available, EPA provided Tier I ground (SCI-GROW) and surface water (FIRST) EECs for D1989. Both EEC calculations with both models were based on the strawberry application scenario (one application at 0.75 lbs ai/acre;) because this is the highest registered/proposed application rate). The resulting ground and chronic surface water EECs are <0.001 ppb and 6.4 ppb, respectively.

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: Commercial application to ornamental plants (including bedding plants, flowering plants, foliage plants, bulb crops, perennials, trees and shrubs; not turf) and all fruit trees which will not bear fruit for a minimum of 12 months. The proposed label is amended to permit application by residents/homeowners. The risk assessment was conducted using the following residential exposure assumptions: EPA anticipates only short-term dermal and short-term inhalation exposure from the requested residential use. The proposed formulation is appropriate for application via pump up sprayers, garden hose-end sprayers or similar ''homeowner'' pesticide devices. The Agency believes that persons using a hose-end sprayer are likely to treat a larger area per day than those using a ''pump up'' compressed air sprayer, which in turn results in possibly greater contact with the pesticide active ingredient per day for applicators using hose-end sprayers. In order to avoid underestimating residential risk, exposure from a hose-end sprayer is assessed rather than that of a compressed air sprayer. For the treatment of shrubs and ornamentals, EPA assumed 100 gallons of finish spray are applied per day. The unit exposure value for a residential handler using open pour mixing/loading for a garden hose-end sprayer is 11 mg/lb handled (dermal) and 0.013 mg/lb handled. Exposures were calculated using the Agency's draft Residential Standard Operating Procedures.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether bifenazate has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to [bifenazate] and any other substances and bifenazate 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 bifenazate has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's Web site at *http://www.epa.gov/pesticides/cumulative/*.

C. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the 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.

2. *Prenatal and postnatal sensitivity*. Developmental toxicity and reproductive toxicity studies performed with bifenazate yield no qualitative or quantitative toxicity evidence of increased susceptibility among rats and rabbits during *in utero* exposure or during postnatal exposure.

3. *Conclusion*. There is a complete toxicity data base for bifenazate and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on the lack of increased susceptibility and the completeness of the toxicity and exposure databases, EPA has concluded that an additional 10X safety factor is not needed to protect infants and children.

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, instead, DWLOCs indicate the maximum pesticide concentration in drinking water that would be of no regulatory concern in light of total aggregate exposure to a pesticide in food and residential uses. A DWLOC represents 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)).

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

When EECs for surface water and groundwater are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to bifenazate 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. Before new uses are added in the future, EPA will reassess the potential impacts of bifenazate on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Because no acute oral toxicity endpoint attributed to a single-dose exposure was identified in any of the studies in the toxicology data base, including developmental and maternal toxicity in the developmental toxicity studies, an acute dietary risk assessment was not conducted.

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 25% of the cPAD for the U.S. population, 60% of the cPAD for all infants < 1 year old, 86% of the cPAD for children 1–2 years old (the most highly exposed population subgroup), and 17% of the cPAD for females 13–49 years old. Based on the use pattern, chronic residential exposure to residues of bifenazate is not expected. In addition, there is potential for chronic dietary exposure to bifenazate in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in 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	0.01	25	6.4	<0.001	260
All infants (<1 year old)	0.01	60	6.4	<0.001	75
Children (1-2 years old)	0.01	86	6.4	<0.001	14
Females (13-49 years old)	0.01	17	6.4	<0.001	290

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 uses 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 2,000 for the U.S. population, 2,100 for youth 13–19 years old, 2,400 for adults 20–49 years old, 2,200 for females 13–49 years old, and 2,300 for adults 50+ years old. 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 water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in 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	2,000	100	6.4	<0.001	3,500
Youth (13-19 years old)	2,100	100	6.4	<0.001	3,000
Adults (20-49 years old)	2,400	100	6.4	<0.001	3,500
Females (13-49 year old)	2,200	100	6.4	<0.001	3,000
Adults (50+ years old)	2,300	100	6.4	<0.001	3,500

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). Residential intermediate-term aggregate exposure (30 days to 6 months) is not expected from use of this chemical. Thus, the intermediate-term risk for the public consista od food and water exposures which were previously addressed.

5. *Aggregate cancer risk for U.S. population.* EPA has classified bifenazate as ''not likely'' to be a human carcinogen. Therefore, a cancer dietary exposure and risk assessment was not performed.

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

B. International Residue Limits

Canada, Codex, and Mexico do not have maximum residue limits (MRLs) for residues of bifenazate in/on the proposed crop. Therefore, harmonization is not an issue.

VI. Conclusion

Therefore, a time-limited tolerance is established for combined residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) and diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate) in or on potatoes at 0.05 ppm. This time-limited tolerance will expire on December 31, 2006.

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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0370 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 April 5, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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 20460–0001.

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 20460–0001.

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.1. Mail your copies, identified by the docket ID number OPP–2003–0370, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. 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. Statutory and Executive Order Reviews

This final rule establishes a time-limited tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: January 21, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

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

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

■ 2. Section 180.572 is amended by alphabetically adding the following commodity to the table in paragraph (b) to read as follows:

§ 180.572 Bifenazate; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
Potato	0.05	12/31/06

* * * * *

[FR Doc. 04–2271 Filed 2–3–04; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 001005281–0369–02; I.D. 012904D]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; Trip Limit Increase

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Inseason action; trip limit increase.

SUMMARY: NMFS increases the trip limit in the commercial hook-and-line fishery for king mackerel in the Florida east coast subzone from 50 to 75 fish per day in or from the exclusive economic zone (EEZ). This trip limit increase is necessary to maximize the socioeconomic benefits of the quota.

DATES: This rule is effective 12:01 a.m., local time, February 1, 2004, through March 31, 2004, unless changed by further notification in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Mark Godcharles, telephone: 727–570–5305, fax: 727–570–5727, e-mail: *Mark.Godcharles@noaa.gov*.

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, cero, cobia, little tunny, dolphin, and, in the Gulf of Mexico only, bluefish) is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils) and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

Based on the Councils' recommended total allowable catch and the allocation ratios in the FMP, on April 30, 2001 (66 FR 17368, March 30, 2001) NMFS implemented a commercial quota of 2.25 million lb (1.02 million kg) for the eastern zone (Florida) of the Gulf migratory group of king mackerel. That quota is further divided into separate quotas for the Florida east coast subzone and the northern and southern Florida west coast subzones. The quota implemented for the Florida east coast subzone is 1,040,625 lb (472,020 kg) (50 CFR 622.42(c)(1)(i)(A) (*1*)).

In accordance with 50 CFR 622.44(a)(2)(i), beginning on February 1, if less than 75 percent of the Florida east coast subzone's quota has been harvested by that date, king mackerel in or from that subzone's EEZ may be possessed on board or landed from a permitted commercial vessel in amounts not exceeding 75 fish per day. The 75–fish daily trip limit will continue until a closure of the subzone's fishery has been effected or the fishing year ends on March 31, 2004.

NMFS has determined that 75 percent of the quota for Gulf group king mackerel for vessels using hook-and-line gear in the Florida east coast subzone was not reached before February 1, 2004. Accordingly, a 75–fish trip limit applies to vessels in the commercial hook-and-line fishery for king mackerel in or from the EEZ in the Florida east coast subzone effective 12:01 a.m., local time, February 1, 2004. The 75–fish trip limit will remain in effect until the fishery closes or until the end of the current fishing season (March 31, 2004) for this subzone. From November 1 through March 31, the Florida east coast subzone of the Gulf group king mackerel is that part of the eastern zone north of 25°20.4′ N. lat. (a line directly east from the Miami-Dade County, FL, boundary).

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B), as such prior notice and opportunity for public comment is unnecessary and contrary to the public interest. Such procedures are unnecessary because the rule itself already has been subject to notice and comment, and all that remains is to notify the public of the trip limit increase. Allowing prior notice and opportunity for public comment is contrary to the public interest because it requires time, thus delaying fishermen's ability to catch more king mackerel than present trip limits allow and preventing fishermen from reaping the socio-economic benefits derived from this increase in catch.

As this action allows fishermen to increase their harvest of king mackerel from 50 fish per day to 75 fish per day in or from the EEZ of the Florida east coast subzone, the AA finds that it relieves a restriction and may go into effect on its effective date pursuant to 5 U.S.C. 553(d)(1). This action is taken under 50 CFR 622.43(a) and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*