requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

II. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in **ADDRESSES** at the beginning of this document

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300652]. No CBI should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

III. Regulatory Assessment Requirements

This final rule extends a time-limited tolerance that was previously extended by EPA under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). In addition, 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) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

Since this extension of an existing time-limited tolerance does 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. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

IV. 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 reportcontaining this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR part 180

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

Dated: May 21, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. In § 180.364, by revising paragraph (b) to read as follows:

§ 180.364 Glyphosate; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of the herbicide glyphosate, per se in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ revocation date
Cattle, kidney	4	2/29/00
Chickpeas	5	2/29/00
Goats, kidney	4	2/29/00
Horses, kidney ..	4	2/29/00
Lentils	5	2/29/00
Pea, hay	200	2/29/00
Pea, vines	60	2/29/00
Peas, dry	5	2/29/00
Sheep, kidney ...	4	2/29/00
Silage, hay	90	2/29/00

* * * * *

[FR Doc. 98–15327 Filed 6–9–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300662; FRL 5791–5]

RIN 2070–AB78

Fenbuconazole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of fenbuconazole and its metabolites in or on blueberries. 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 blueberries in several States. This regulation establishes a maximum permissible level for residues of fenbuconazole in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on December 31, 1999.

DATES: This regulation is effective June 10, 1998. Objections and requests for hearings must be received by EPA on or before August 10, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300662], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300662], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300662]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Daniel Rosenblatt, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9375; e-mail: rosenblatt.dan@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for the fungicide fenbuconazole and its metabolites, in or on blueberries at 1.0 part per million (ppm). This tolerance will expire and is revoked on December 31, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL 5572–9).

New 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 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 FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

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.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Fenbuconazole on Blueberries and FFDCA Tolerances

Mummy berry disease *Monilinia vaccinii-corymbosi* is a plant disease which causes a variety of leaf, flower, and fruit damage. Of special concern for blueberry producers are the blighted flower clusters on blueberry bushes and mummified fruit that the disease will produce. Yield loss projections suggest that mummy berry disease may produce losses of 25–50% of the blueberry crop. In addition, the mummified fruit will serve as the inoculum for subsequent outbreaks of mummy berry disease so it is important to gain control over the pest in order to avert future problem outbreaks.

In past growing seasons, blueberry growers typically used triforine to control mummy berry disease. However, triforine was voluntarily canceled by its manufacturer. Now that triforine pesticides have been canceled, there do not appear to be any registered pesticidal or cultural measures that growers can use. Therefore, EPA concurs that the pressures presented by mummy berry disease on blueberry growers represent an urgent and non-routine situation and has authorized under FIFRA section 18 the use of fenbuconazole on blueberries to numerous States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of fenbuconazole in or on blueberries. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary

tolerance under FFDCA section 408(l)(6) would be consistent with the new 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 under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on blueberries 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 fenbuconazole meets EPA's registration requirements for use on blueberries 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 fenbuconazole 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 those authorized under section 18 to use this pesticide on this crop without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for fenbuconazole, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregateexposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1–day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (females 13 years and older) was not regionally based.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of fenbuconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of fenbuconazole and its metabolites on blueberries at 1.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by fenbuconazole are discussed below.

1. *Acute toxicity.* For the purposes of the acute dietary risk assessment, EPA assessments are based on an acute RfD of 0.3 milligrams/kilogram/day (mg/kg/day). This figure is derived from developmental toxicity data from laboratory animals where the NOEL was determined to be 30 mg/kg/day. The observed effect was a decrease in the number of live fetuses at the Lowest Effect Level (LEL) of 75 mg/kg/day and an uncertainty factor of 100. EPA determined that an additional safety factor of 3x for the protection of infants and children was appropriate. Therefore, the FQPA acute allowable risk is 0.1 mg/kg/day.

2. *Short - and intermediate - term toxicity.* No dermal or systemic toxicity endpoints were identified for this exposure duration. Therefore, a risk assessment is not needed.

3. *Chronic toxicity.* EPA has established the RfD for fenbuconazole at 0.03 mg/kg/day. This RfD is based on a chronic toxicity study in the rat with a NOEL of 3.03/4.02 in males/females. The NOEL is based on decreased body weight gains (females), hepatocellular enlargement and vaculation (females), increases in thyroid weight (both sexes) and histopathological lesions in the thyroid glands (males), at the LEL of 30.62/43.04 mg/kg/day in males/females. For the population subgroup of infants and children an uncertainty factor of 300 was used. The FQPA chronic allowable risk is 0.01 mg/kg/day for infants, children, and females 13 years and older.

4. *Carcinogenicity.* Using its Guidelines for Carcinogen Risk Assessment, EPA has classified fenbuconazole as a Group C (possible human carcinogen) chemical. EPA believes it is appropriate to use the Q_1^* approach of 3.59×10^{-3} $(mg/kg/day)^{-1}$.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.480) for the use of fenbuconazole and its metabolites, in or on a variety of raw agricultural commodities. Time-limited tolerances have been established for residues of fenbuconazole, alpha-2-(4-chlorophenyl)-ethyl-alpha-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites, cis-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H* 1,2,4-triazole-1-ylmethyl-2-3*H*-furanone, expressed as fenbuconazole in or on commodities ranging from 0.1 ppm in pecans to 2.0 ppm in the stone fruit crop group. Risk assessments were conducted by EPA to assess dietary exposures and risks from fenbuconazole as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. In conducting an acute dietary risk assessment for fenbuconazole, EPA has made conservative assumptions which result in an overestimate of human dietary exposure. The acute dietary (food only) risk assessment used TMRC. The resulting high-end exposure estimate is 0.015 mg/kg/day. This exposure level utilizes 15% of the dietary (food only) FQPA acute allowable risk for females 13+ years. Refinement using anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis would result in lower acute dietary exposure estimates.

ii. *Chronic exposure and risk.* The chronic dietary risk assessment is partially refined. Tolerance level residues were assumed for all commodities, including stone fruits. Percent crop treated data were used for

stone fruits only and 100% crop-treated data were used for all other commodities. The existing tolerances for fenbuconazole plus exposures connected with the section 18 on blueberries result in an anticipated residue contribution (ARC) that is equivalent to 3% of the RfD for non-nursing infants (<1 year old), the highest exposed subpopulation.

2. *From drinking water.* There are no established Maximum Contaminant Level for residues of fenbuconazole in drinking water and no health advisory levels for fenbuconazole in drinking water have been established.

Fenbuconazole is moderately persistent and slightly mobile to immobile in soil. Because of its adsorption to soil, the potential for fenbuconazole to leach to ground water appears to be slight. However, the potential to contaminate ground water may be greater at vulnerable sites, where soils are low in organic matter and where ground water is relatively close to the surface. The long half-lives of aerobic soil and terrestrial field dissipation indicate that when fenbuconazole is applied over multiple growing seasons, soil residue accumulation may result. These residues may be available for rotational crop uptake or may be transported with sediments during runoff events.

For the purposes of EPA's water screening assessments, it is assumed that adult males weigh 70 kg, adult females 60 kg, and children 10 kg. Average consumption is assumed to be 2 liters/day for adults and 1 liter/day for children.

EPA performed a ground water assessment with its ground water screening tool to establish an estimated environmental concentration (EEC). The Tier I estimate projected that the concentration of fenbuconazole in drinking water from ground water sources is not likely to exceed an acute and chronic EEC of 0.019 µg/l for ground and aerial applications.

A Tier I drinking water assessment of fenbuconazole was also conducted for surface water. The EECs are generated for high exposure agricultural scenarios and correspond to a stagnant pond with no outlet that receives pesticide loading from an adjacent 100% cropped, 100% treated field. As such, these computer generated EECs represent conservative screening levels for ponds and lakes and are thought to represent an overestimate of the actual EEC. The peak EEC projection for surface water involved aerial applications. The acute peak EEC was 4.27 µg/l. The chronic 56–day EEC was 2.29 µg/l. Because the surface water EECs appear to be higher, EPA used these worst case calculations in its dietary risk assessment.

i. *Acute exposure and risk.* EPA calculated the acute risks from drinking water for fenbuconazole based on dietary (food) exposure and the default assumptions mentioned above. To calculate the acute drinking water level of concern (DWLOC), the acute dietary food exposure estimate is subtracted from the acute RfD.

The calculations were based on the following: the acute RfD for fenbuconazole is 0.3 mg/kg/day; the FQPA acute allowable risk is 0.1 mg/kg/day based on an uncertainty factor of 3. If the acute food exposure estimate (0.015 mg/kg/day) is subtracted from the FQPA acute allowable risk (0.1 mg/kg/day) the result is the maximum acute water exposure which is 0.085 mg/kg/day or 2,600 parts per billion (ppb).

The peak EEC (acute) value is 4.27 ppb, based on aerial application of fenbuconazole. This figure is significantly lower that the DWLOC of 2,600 ppb. Therefore, EPA concludes with reasonable certainty that the acute exposure to fenbuconazole in drinking water is less than the level of concern.

ii. *Chronic exposure and risk.* To calculate the chronic DWLOC, the chronic dietary food exposure is subtracted from the RfD. Chronic DWLOCs were calculated for various subpopulations ranging from 1,050 ppb for the U.S. population to 92 ppb for infants and children (non-nursing < 1 year). The computer model suggested that the chronic EEC for fenbuconazole is 2.29 ppb for aerial applications of the pesticide. Since the EEC is less than the DWLOC, EPA concludes that there is reasonable certainty that chronic exposure is less than the level of concern.

EPA calculated the cancer risk associated with fenbuconazole and drinking water. To calculate the DWLOC for cancer, the chronic dietary food exposure was subtracted from the negligible risk standard (1×10^{-6}) divided by the Q_1^* (0.00359 mg/kg/day). EPA's drinking water level of concern from cancer is 5.4 ppb for the U.S. population. This compares to the level of 2.29 ppb from the conservative computer model EPA used to estimate exposures. Since the DWLOC is higher than the calculated EEC of 2.29 ppb, EPA concludes with reasonable certainty that exposure to fenbuconazole in drinking water does not pose a level of concern with respect to cancer risks.

3. *From non-dietary exposure.* Fenbuconazole is not currently registered for any residential or non-food use sites. Therefore, a discussion of the toxicity endpoints for non-dietary exposure and a risk assessment for these uses is not germane to this review.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether fenbuconazole 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, fenbuconazole 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 fenbuconazole has a common mechanism of toxicity with other substances.

C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* For the population subgroup of concern, females 13 years and older, EPA used the TMRC approach and calculated that exposure would utilize 15% of the RfD. EPA generally has no concerns for exposures below 100% of the acute RfD. In addition, for acute exposures associated with drinking water, EPA has concluded that the level of concern is 2,600 ppb. The EEC value is 4.27 ppb. This leads EPA to conclude that acute exposure to fenbuconazole does not pose a level of concern.

2. *Chronic risk.* Using ARC exposure assumptions, EPA has concluded that aggregate exposure to fenbuconazole from food will utilize less than 1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants where 3% of the RfD is utilized. A full discussion of the risks associated with exposure to infants and children is presented below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA's level of concern from chronic exposure to drinking water is 1,050 ppb for the U.S. population. The EEC for aerial application is projected to be 2.29 ppb. Therefore, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to fenbuconazole residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term endpoints were not identified for fenbuconazole. Therefore, an aggregate risk assessment was not conducted for these endpoints. Furthermore, fenbuconazole has no residential uses.

D. Aggregate Cancer Risk for U.S. Population

Fenbuconazole has been classified as a Group C Carcinogen with a Q_1^* of 3.59 x 10^{-3} (0.00359 mg/kg/day). The Q^* approach was used for risk assessments involving carcinogenic effects. Using partially refined exposure estimates, the cancer risk estimate for the U.S. population is 3.25 x 10^{-7}. For exposures connected with drinking water, EPA's level of concern is 5.4 ppb. EPA projects that the EEC for fenbuconazole is 2.29 ppb. Therefore, EPA concludes with reasonable certainty that exposure to fenbuconazole does not exceed the level of concern for cancer risks.

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

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

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In the developmental toxicity study in rats, the maternal (systemic) NOEL was 30 mg/kg/day, based on decreases in body weight and body weight gain at the LOEL of 75 mg/kg/day. The developmental (fetal) NOEL was 30 mg/kg/day, based on an increase in post implantation loss and a significant decrease in the number of live fetuses per dam at the LOEL of 75 mg/kg/day. In the developmental toxicity study in rabbits, the maternal (systemic) NOEL was 10 mg/kg/day, based on decreased body weight gain at the LOEL of 30 mg/kg/day. The developmental (pup) NOEL was 30 mg/kg/day, based on increased resorptions at the LOEL of 60 mg/kg/day.

iii. *Reproductive toxicity study.* In the 2-generation reproductive study in rats, the paternal (systemic) NOEL was 4 mg/kg/day, based on decreased body weight and food consumption, increased number of dams not delivering viable or delivering nonviable offspring, and increases in adrenal and thyroid weights at the LOEL of 40 mg/kg/day. The reproductive (pup) NOEL was 40 mg/kg/day, the highest dose tested (HDT).

iv. *Pre- and post-natal sensitivity.* The toxicological data base for evaluating pre-and post-natal toxicity for fenbuconazole is complete with respect to EPA's current data requirements. Based on the developmental and reproductive toxicity studies there is not adequate evidence to completely remove the FQPA 10x factor. There is some evidence suggestive of increased susceptibility in developing offspring. An increase in post implantation loss and a significant decrease in the number of live fetuses per dam in rats in the presence of effects on maternal weight gain may be indicative of increased susceptibility in the fetus. However, the increased incidence does not appear to be very great at 75 mg/kg/day for either effect. Similarly, in rabbits there are reported resorptions at 60 mg/kg/day and effects on maternal weight gain at 30 mg/kg/day. Therefore, EPA determined that the 10x factor required by FQPA for protection of infants and children from exposure to fenbuconazole should be reduced to 3x.

The retention of the 3x factor for this risk assessment does not result in exposure values which exceed EPA's level of concern. This action should not pose an unacceptable aggregate risk to infants and children.

2. *Acute risk.* Toxicological effects relevant to infants and children that could be attributed to a single exposure (dose) were not observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits. A dose and endpoint was not identified. Therefore, an aggregate risk assessment is not required for this subpopulation.

3. *Chronic risk.* Using ARC exposure assumptions, EPA has concluded that aggregate exposure to fenbuconazole from food will utilize 3% of the RfD for non-nursing infants less than 1 year old to less than 1% for children 1–6 years old. EPA generally has no concern for exposures below 100% of the RfD

because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA's level of concern for chronic exposure to infants and children through drinking water is 92 ppb. EPA's water exposure model suggests that aerial application could result in an EEC of 2.29 ppb. Therefore, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to fenbuconazole residues.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue of fenbuconazole for this action is adequately understood. The residue of concern is fenbuconazole (alpha-[2-4-chlorophenyl)-ethyl]alpha-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites, cis-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanoneandtrans-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone, expressed as fenbuconazole as specified in 40 CFR 180.480.

No livestock feed items are associated with this request. Thus, the nature of the residue in livestock is not of concern.

B. Analytical Enforcement Methodology

Analytical methodology is available to enforce the tolerances forfenbuconazole.

C. Magnitude of Residues

Residues of fenbuconazole and its regulated metabolites are not expected to exceed 1.0 ppm in/on blueberries. Secondary residues are not expected as no livestock feed items are associated with this use.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican maximum residue limits (MRLs) for fenbuconazole on blueberries.

E. Rotational Crop Restrictions

Blueberries are not rotated. Rotational crop restrictions are not germane to this action.

VI. Conclusion

Therefore, the tolerance is established for residues of fenbuconazole (alpha-[2-4-chlorophenyl)-ethyl]alpha-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites, cis-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone and trans-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H* 1,2,4-triazole-1-ylmethyl-2-3*H*-furanone, expressed as fenbuconazole in blueberries at 1.0 ppm.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by August 10, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300662] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior

consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established under FFDCA section 408 (l)(6), such as the [tolerance] in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted 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 General Accounting Office prior to publication of this rule in today's **Federal Register**. This 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: May 20, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. Section 180.480 is amended by adding a heading to paragraph (a); by designating the text in paragraph (a) as paragraph (a)(1); by redesignating paragraph (b) as paragraph (a)(2) and amending it to revise the phrase ''paragraph (a) of this section'' to read ''paragraph (a)(1) of this section''; by adding a new paragraph (b); and by adding and reserving with headings paragraphs (c) and (d) to read as follows:

§ 180.480 Fenbuconazole; tolerances for residues.

(a) *General.* (1) * * *

(2) * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for fenbuconazole (alpha-[2-4-chlorophenyl)-ethyl]alpha-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites, cis-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone and trans-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H* 1,2,4-triazole-1-ylmethyl-2-3*H*-furanone, expressed as fenbuconazole in or on blueberries in connection with use of the pesticide under a section 18 exemption granted by EPA. The time-limited tolerance will expire on the date specified in the following table.

Commodity	Parts per million	Expiration/ revocation date
Blueberries	1.0	12/31/99

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

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

[FR Doc. 98–15173 Filed 6–9–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300657; FRL–5789–8]
RIN 2070–AB78

Clopyralid; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule extends a time-limited tolerance for residues of the herbicide clopyralid in or on canola at 3 part per million (ppm) for an additional one and one-half–year period, to January 31, 2000. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on canola. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (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.

DATES: This regulation becomes effective June 10, 1998. Objections and requests for hearings must be received by EPA, on or before August 10, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP–300657, must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, OPP–300657, must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Follow the instructions in Unit II. of this preamble. No Confidential Business Information (CBI) should be submitted through e-mail.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 272, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)–308–9364; e-mail: pemberton.libby@epamail.epa.gov.