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 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 tolerances and exemptions that are established under FFDCA section 408(l)(6), such as the tolerance/exemption 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 acations published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the 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: January 20, 1999.

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 § 180.507, paragraph (b) by alphabetically inserting the following commodity to the table to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ RevocationDate
* *	*	* *
Strawberries	10.0	7/30/00
* *	*	* *

* * * * *

[FR Doc. 99–2206 Filed 1–28–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300776; FRL–6054–3]

RIN 2070–AB78

Fenbuconazole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of Fenbuconazole and its metabolites RH-9129 and RH-9130, expressed as the parent fenbuconazole in or on grapefruit and livestock commodities . 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 grapefruit. This regulation establishes maximum permissible levels for residues of fenbuconazole in these food and feed commodities 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 tolerances will expire and are revoked on June 30, 2000.

DATES: This regulation is effective January 29, 1999. Objections and requests for hearings must be received by EPA on or before March 30, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300776], 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–300776], 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 (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–300776]. 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: Andrea Beard, 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: CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9356, e-mail: beard.andrea@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 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 combined residues of the fungicide fenbuconazole and its metabolites RH-9129 and RH-9130, expressed as the parent fenbuconazole, in or on whole grapefruit at 0.5 part per million (ppm), at 4.0 ppm in/on dried grapefruit, at 35 ppm in/on grapefruit oil; and at 0.1 ppm in/on meat and meat by-products of cattle, goats, hogs, horses, and sheep. These tolerances will expire and are revoked on June 30, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerances 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 tolerances 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 Grapefruit and FFDCA Tolerances

The Florida Department of Agriculture and Consumer Services has requested an exemption for the use of fenbuconazole on grapefruit for control of the disease, greasy spot (*Mycosphaerella citri*). Greasy spot disease has become a problem in Florida because of high relative humidity (nearly 100%) and higher temperatures for prolonged periods. The disease affects all citrus varieties and can be a more serious problem on grapefruit, due to its low resistance. The applicant asserts that this pathogen has developed resistance to a registered alternative, while other alternatives have limited efficacy and can cause damage to the fruit, causing them to be downgraded to juice grade. A recent drop in grapefruit prices have exacerbated this situation, and significant economic losses are predicted without the requested fungicide. EPA has authorized under FIFRA section 18 the use of fenbuconazole on grapefruit for control of greasy spot (*Mycosphaerella citri*) in Florida. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of fenbuconazole in or on grapefruit and livestock commodities. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on June 30, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on grapefruit and animal commodities 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 levels that were authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

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

III. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the Final Rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997)(FRL–5754–7) .

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action EPA has sufficient data to assess the hazards of fenbuconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of fenbuconazole and its metabolites RH-9129 and RH-9130, expressed as the parent fenbuconazole on whole grapefruit at 0.5 ppm, at 4.0 ppm in/on dried grapefruit, at 35 ppm in/on grapefruit oil; and at 0.1 ppm in/on meat and meat by-products of cattle, goats, hogs, horses, and sheep. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances 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 reference dose (RfD) of 0.3 milligrams/kilogram/day (mg/kg/day). This figure is derived from the No Observed Adversed Effect Level (NOAEL) of 30 mg/kg/day from the developmental toxicity study in rats, and an uncertainty factor of 100. The observed effect was a decrease in the number of live fetuses at the Lowest Effect Level (LEL) of 75 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 chronic RfD for fenbuconazole at 0.03 mg/kg/day. This RfD is based on a chronic toxicity study in the rat with a NOAEL of 3.03/4.02 mg/kg/day in males/females, and an uncertainty factor of 100. The NOAEL 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.

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 for determination of risk, and has calculated a Q^{1*} 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 combined residues or residues of fenbuconazole and its metabolites RH-9129 and RH-9130, expressed as the parent fenbuconazole, 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. An acute dietary risk assessment for fenbuconazole is only needed for the population subgroup, females 13+ years (yrs.) old, as the effect was increased resorptions and decreased live fetuses. The acute dietary risk assessment used the Theoretical Maximum Residue Contribution (TMRC, tolerance level residues and 100% crop treated); the tolerances used for grapefruit and animal commodities are the levels given above. The Novigen Dietary Exposure Evaluation Model (DEEM) analysis was used and this analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals conducted in 1989 through 1992. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure. Resulting exposure values (at the 99th percentile) and percentage of the acute RfD are shown below. Values for the 99th percentile are considered to be conservative as OPP policy dictates exposure estimates from as low as the 95th percentile may be utilized for risk estimates from acute DEEM runs. Thus,

these results are viewed as conservative estimates, and refinement using anticipated residue values and percent crop treated information, in conjunction with a Monte Carlo analysis, would result in lower estimates of acute dietary exposure and risk. The resulting high-end exposure estimates (food only, 99.9 percentiles) ranges from 0.0072 to 0.015 mg/kg/day for the population subgroups females 13+ yrs. old (nursing), and females 13 - 19 yrs. old (not pregnant or nursing), respectively. The percentages of the acute RfD utilized by these exposure levels, for these two subgroups are 2.3 and 5.0%, respectively.

ii. *Chronic exposure and risk.* The chronic dietary risk assessment is partially refined. Additional refinement would incorporate percent crop treated and anticipated residues for all commodities, and would result in lower exposure estimates. Again, the Novigen DEEM analysis was used, as described above. 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 grapefruit result in an anticipated residue contribution (ARC) that is equivalent to 3.1% of the RfD for non-nursing infants <1 yr. old, the highest exposed subpopulation. Exposure for all other population subgroups was at a level below this. iii. Cancer Risk. Fenbuconazole is classified as a Group C Carcinogen, with a Q_1* of 3.59 x 10^{-3} $(mg/kg/day)^{-1}$. Using the partially refined exposure estimates described above under Chronic exposure and risk, the cancer risk estimate for the U.S. Population is calculated to be 8.3 x 10^{-7}.

2. *From drinking water.* There is no established Maximum Contaminant Level or Health Advisory Levels for imidacloprid in drinking water. To date, there are no validated modeling approaches for reliably predicting pesticide levels in drinking water. The Agency uses models designed for use for ecological assessment, which are not ideal tools for use in drinking water risk assessment, as they could overestimate actual drinking water concentrations.

Thus, these models are considered a coarse screening tool for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern. For surface water, the Agency used PRZM1 (Pesticide Root Zone Model - simulates the transport of a pesticide off the agricultural field) and EXAMS (EXposure Analysis Modeling System - simulates fate and transport of a pesticide in surface water) models which are used to produce estimates of pesticide concentrations in a farm pond. For ground water the Agency used SCI-GROW (Screening Concentration In GROund Water) model to estimate the concentration of imidacloprid residues in ground water. SCI-GROW is a prototype model for estimating ''worst case' ground water concentrations of pesticides. This model assumes that the pesticide is applied at its maximum rate in areas where the ground water is particularly vulnerable to contamination. SCI-GROW is biased in that studies where the pesticide is not detected in ground water are not included in the data set. Thus, it is not expected that SCI-GROW estimates would be exceeded. In the absence of monitoring data for pesticides, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimated environmental concentrations (EECs) of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption, and body weights. Different populations will have different DWLOCs. DWLOCs are used in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. DWLOC values are not regulatory standards for drinking water. Since DWLOCs address total aggregate exposure to imidacloprid they are further discussed in the aggregate risk sections below.

i. *Acute exposure and risk.* EPA used estimated concentrations of imidacloprid in surface and ground water for acute exposure analysis of 6.7 and 0.03 g/L parts per billion (ppb), respectively. Since the ground water estimate is much less than that for surface water, only the surface water estimated maximum concentration of 6.7 ppb was used for comparison to the DWLOCs. The acute DWLOC was calculated for the segment of the population subgroup of concern with the highest food exposure, females 13 - 19 yrs. old (not pregnant or nursing). This DWLOC was calculated to be 8,600 ppb.

ii. *Chronic exposure and risk.* Since the estimated concentration for chronic exposure to ground water (0.03 ppb) was much less than that for surface water (3.6 ppb), EPA used the surface water estimate for chronic exposure analysis as a worst case estimation. The chronic DWLOCs were calculated for the population subgroup with the highest food exposure, Non-Hispanic (other than black or white). These DWLOCs were calculated to be 1,000 ppb for males and 890 ppb for females.

3. *From non-dietary exposure.* Fenbuconazole is not currently registered for use on any residential non-food 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.''

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. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the Final Rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk.* For the population subgroups of concern, females 13+ yrs. old (nursing), and females 13 - 19 yrs. old (not pregnant or nursing), the percentages of the acute RfD utilized by these exposure levels, for these two subgroups are 2.3 and 5.0%, respectively. 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 DWLOC is 8,600 ppb. The EEC value is 6.7 ppb. This leads EPA to conclude that acute exposure to fenbuconazole is within acceptable limits, and there is reasonable certainty of no harm.

2. *Chronic risk.* Using the ARC exposure assumptions described above,

EPA has concluded that aggregate exposure to fenbuconazole from food will utilize <1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is 3.1% of the chronic RfD for non-nursing infants <1 yr. old, which is further discussed below. For the rest of the population subgroups, the RfD utilized is <1 - 2.5%. Based upon dietary (food only) exposure, the chronic DWLOCs were calculated for the population subgroup with the highest food exposure, Non-Hispanic (other than black or white). These DWLOCs were calculated to be 1,000 ppb for males and 890 ppb for females. Using the rough screening models described above for ground and surface water, the EEC was estimated at 3.6 ppb, significantly less than the calculated DWLOCs. 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. Despite the potential for exposure to fenbuconazole in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

3. *Short- and intermediate-term risk.* Short- and intermediate-term endpoints were not identified; additionally, fenbuconazole has no residential uses. Thus short- and intermediate-term aggregate risk assessments are not required.

4. *Aggregate cancer risk for U.S. population*. The existing tolerance plus this proposed tolerance for this exemption result in a cancer risk estimate of 8.3×10^{-7} for the overall U.S. population. The risk from the time-limited tolerances with section 18s (blueberries, grapefruit, meat, and meat by-products) was not amortized. This is sometimes done to account for the temporary nature of the section 18 use. Based on this level, and the level considered to be acceptable for cancer risk, and incorporating the usual default values for body weight and drinking water consumption, a DWLOC was calculated of 1.6 ppb for the U.S. Population. This is compared to the EEC, as derived from the rough screening models (described above) of 3.6 ppb. EPA policy is that a factor of 3 will be applied to these model values to determine whether a DWLOC has been exceeded. If the model value is <3 times the DWLOC, the pesticide is considered to have passed the screen and no further assessment is needed. In this case, the model value of 3.6 ppb is less than three times the DWLOC (3 x 1.6 = 4.8 ppb), and thus EPA concludes with reasonable certainty that residues of fenbuconazole in drinking water, considered along with other sources of chronic exposure, will not result in unacceptable levels of aggregate cancer risk estimates. EPA also notes that the chronic food exposure estimate is only partially refined, and further refinement of this exposure would result in lower risk estimates.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to fenbuconazole residues.

D. 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 two-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 margin of exposure (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) NOAEL was 30 mg/kg/day, based on decreases in body weight and body weight gain at the lowest observed effectlevel (LOEL) of 75 mg/kg/day. The developmental (fetal) NOAEL 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) NOAEL was 10 mg/kg/day, based on decreased body weight gain at the LOEL of 30 mg/kg/day. The developmental (pup) NOAEL 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 maternal (systemic) NOAEL 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) NOAEL 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. EPA has determined that the studies indicated no increased susceptibility of rats or rabbits to in utero and/or postnatal exposure to fenbuconazole. In the prenatal developmental toxicity studies in rats and rabbits, and the 2-generation reproduction study in rats, toxicity to the fetuses and offspring, when observed, occurred at equivalent or higher doses and was not judged to be more severe than toxic effects on the maternal and parental animals. Based on the developmental and reproductive toxicity studies, EPA scientists concluded that the FQPA 10x uncertainty factor may be removed.

v. *Conclusion*. There is a complete toxicity database for fenbuconazole and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

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 the exposure assumptions described above, EPA has concluded that aggregate exposure to fenbuconazole from food will utilize 3.1% of the RfD for the most highly exposed subgroup for infants and children, non-nursing infants <1 yr. 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. Despite the potential for exposure to fenbuconazole in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk.* Short- and intermediate-term endpoints were not identified; additionally, fenbuconazole has no residential uses. Thus short- and intermediate-term aggregate risk assessments are not required.

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

IV. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue of fenbuconazole in plants and livestock is adequately understood, for this action. 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 (also known as RH-9129 and RH-9130,respectively), expressed as fenbuconazole as specified in 40 CFR 180.480.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with a nitrogen phosphorus detector) is available to enforce the tolerance expression. The method has not yet appeared in the Pesticide Analytical Manual II, but may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

C. Magnitude of Residues

Residues of fenbuconazole and its regulated metabolites are not expected to exceed 0.5 ppm in/on whole grapefruit, 4.0 ppm in dried citrus pulp, and 35 ppm in citrus oil. Grapefruit pulp is not a poultry feed, but may be fed to other livestock. Therefore, residues are not expected to exceed 0.01 ppm in or on meat and meat by-products of cattle, goats, hogs, horses, and sheep.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican maximum residue limits (MRLs) for fenbuconazole on grapefruit or livestock commodities. Thus, harmonization is not an issue for this use.

E. Rotational Crop Restrictions

Grapefruit is not rotated to other crops, and therefore, rotational crop restrictions are not germane to this action.

V. Conclusion

Therefore, the tolerance is established for combined residues of fenbuconazole and its metabolites RH-9129 and RH-9130, expressed as the parent fenbuconazole in grapefruit at 0.5 ppm, in grapefruit pulp, dried, at 4.0 ppm, in grapefruit oil at 35 ppm, and in meat and meat by-products of cattle, goats, hogs, horses, and sheep at 0.01 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation 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 March 30, 1999, 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 un der the ''ADDRESSES'' section (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). EPA is authorized to wave 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 tolerance objection fee waivers, contact James Tompkins, 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. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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.

VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300776] (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, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

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

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit 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 record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes time-limited tolerances under FFDCA section 408(l)(6). 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 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 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.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the 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: January 20, 1999.

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 § 180.480, paragraph (b) by alphabetically inserting the following commodities to the table to read as follows:

§ 180.480 Fenbuconazole; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ Revocation Date
* * * * * * *		
Cattle, fat	0.01	6/30/00
Cattle, mbyp	0.01	6/30/00
Cattle, meat	0.01	6/30/00
Goats, fat	0.01	6/30/00
Goats, mbyp	0.01	6/30/00
Goats, meat	0.01	6/30/00
Grapefruit	0.5	6/30/00
Grapefruit pulp, dried.	4.0	6/30/00
Grapefruit oil	35	6/30/00
Hogs, fat	0.01	6/30/00
Hogs, mbyp	0.01	6/30/00
Hogs, meat	0.01	6/30/00
Horses, fat	0.01	6/30/00
Horses, mbyp	0.01	6/30/00
Horses, meat	0.01	6/30/00
* * * * * * *		
Sheep, fat	0.01	6/30/00
Sheep, mbyp	0.01	6/30/00
Sheep, meat	0.01	6/30/00
* * * * * * *		

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[FR Doc. 99–2207 Filed 1–28–99; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300780; FRL–6056–2]

RIN 2070–AB78

Lambda-cyhalothrin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for the combined residues of lambda-cyhalothrin and its epimer in or on flax, barley, canola, and sugarcane. 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 flax, barley, canola, and sugarcane. This regulation establishes maximum permissible levels for residues of lambda-cyhalothrin in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and are revoked on December 31, 2000.

DATES: This regulation is effective January 29, 1999. Objections and requests for hearings must be received by EPA on or before March 30, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300780], 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–300780], 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@epa.gov. Copies of electronic 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 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300780]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, 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, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9367, e-mail: ertman.andrew@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408 and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), is establishing a tolerances for the combined residues of the insecticide lambda-cyhalothrin and its epimer, in or on flax seed at 0.1 parts per million (ppm), barley bran at 0.2 ppm, barley grain at 0.05 ppm, barley hay at 2.0 ppm, barley straw at 2.0 ppm, canola seed at 0.1 ppm and sugarcane at 0.03 ppm. These tolerances will expire and are revoked on December 31, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Findings

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 in this preeamble 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