the NESHAPs on these non-trust lands within the 1873 Survey Area.''

III. Correction

In the December 1, 1998, direct final rule and delegation of authority for the three local air pollution control agencies in Washington, there were several minor typographical errors in the EPA Action section of the preamble, in the Delegation of Specific Standards subsection. Beginning on page 66054, in the issue of Tuesday, December 1, 1998, make the following corrections:

On page 66056, in the second column, in the last paragraph, in the eighth line; in the third column, in the first line under the table; and on page 66057, in the first column, in the last paragraph, in the eleventh line, ''63.6(I)(1)'' should read ''63.6(i)(1)''. On page 66056 in footnote number three, in the first line, ''112(I)(1) and (3)'' should read, ''112(i)(1) and (3)''. On page 66057, in the first column, in the last paragraph, in the eighteenth line, ''(63.7(e)(2)(I))'' should read, ''(63.7(e)(2)(i))'.

List of Subjects

40 CFR Part 61

Environmental protection, Air pollution control, Arsenic, Asbestos, Benzene, Beryllium, Hazardous substances, Mercury, Reporting and recordkeeping requirements, Vinyl Chloride.

40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated: February 1, 1999.

Chuck Clarke,

Regional Administrator, Region X.

[FR Doc. 99–3526 Filed 2–16–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300789; FRL 6059–7]

RIN 2070–AB78

Fenbuconazole; Reestablishment of Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for combined residues of fenbuconazole [alpha-(2-(4-chlorophenyl)-ethyl)-alpha-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites [cis-and trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone] of fenbuconazole in or on stone fruits (except plums and prunes) at 2.0 ppm, pecans at 0.1 ppm and bananas at 0.3 ppm. The Rohm and Haas Company requested these tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170). The tolerances will expire on December 31, 2001.

DATES: This regulation is effective February 17, 1999. Objections and requests for hearings must be received by EPA on or before April 19, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300789], 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–300789], 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. 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 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300789]. 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: Cynthia Giles-Parker, 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. 247, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–7740; e-mail: cynthia giles-parker@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 7, 1998; (63 FR 67476) (FRL 6047–2), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP) for tolerance by The Rohm and Haas Company, 100 Independence Mall West, Philadelphia, PA 19106–2399. This notice included a summary of the petition prepared by The Rohm and Haas Company, the registrant. There were no comments received in response to the notice of filing. The petition requested that 40 CFR 180.480 be amended by establishing time-limited tolerances for combined residues of the fungicide fenbuconazole, [alpha-(2-(4-chlorophenyl)-ethyl)-alpha-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites [cis-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 stone fruits (except plums and prunes), 2.0 ppm; pecans, 0.1 ppm; bananas, 0.3 ppm part per million (ppm). The existing time-limited tolerances expired December 31, 1998. The reestablishment of these time-limited tolerances will expire on December 31, 2001. Time-limited tolerances are being reestablished due to a chemistry data gap for storage stability in other raw agricultural commodities. However, based on apparent storage stability, EPA believes that the existing data support reestablishment of time-limited tolerances to December 31, 2001.

I. Background and Statutory Findings

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.''

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).

II. 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, [alpha-(2-(4-chlorophenyl)-ethyl)-alpha-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites [cis-and trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone]] and to make a determination on aggregate exposure, consistent with section 408(b)(2), for reestablishment of time-limited tolerances for combined residues of Fenbuconazole, [alpha-(2-(4-chlorophenyl)-ethyl)-alpha-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites [cis-and trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*1,2,4-triazole-1-ylmethyl)-2-3H-furanone]] on stone fruit (except plums and prunes), 2.0 ppm; pecans, 0.1 ppm; and bananas, 0.3 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 in this unit.

1. A rat acute oral study with an LD_{50} greater than 2 grams (g)/kilogram (kg).

2. A 13-week rat feeding study with a no-observed-adverse-effect-level (NOAEL) of 20 ppm (1.3 milligrams(mg)/kg/day males and 1.5 mg/kg/day females) and a lowest-observed-adverse-effect-level (LOAEL) of 80 ppm (5.1 mg/ kg/day males and 6.3 mg/kg/day females), based on hepatotoxicity.

3. A 3-month mouse feeding study with a NOAEL of 20 ppm (3.8 mg/kg/day males and 5.7 mg/kg/day females) and a LOAEL of 60 ppm (11.1 mg/kg/day males and 17.6 mg/kg/day females) based on hepatotoxicity.

4. A 3-month dog feeding study with a NOAEL of 100 ppm (3.3 mg/kg/ day males and 3.5 mg/kg/day females) and LOAEL of 400 ppm (13.3 mg/kg/ day males and 14.0 mg/kg/day females), based on hepatocellular hypertrophy.

5. A 21-day rabbit dermal study with a NOAEL greater than 1,000 mg/ kg/day (limit dose).

6. A 78-week dietary carcinogenicity study in mice with a NOAEL of 1.43 mg/kg/day and a LOAEL of 28.6 mg/kg/day (males) and 92.9 mg/kg/day (females) based on hepatocellular enlargement and a greater incidence and severity of hepatocellular vacuolation. There was evidence of carcinogenicity based on the occurrence of increased trend for malignant liver tumors in males and an increase in benign and malignant liver tumors in females.

7. A 24-month rat chronic feeding/carcinogenicity study with a NOAEL of 40 ppm (3.03 mg/kg/day for females and 4.02 mg/kg/day for males) for systemic effects and a LOAEL of 800 ppm (30.62 mg/kg/day for males and 43.07 mg/kg/day for females) based on decreases in body weight gains and hepatocellular enlargement and vacuolization in females, and thyroid weight and histopathological changes in both sexes. There was evidence of carcinogenicity based on the increased occurrence of thyroid follicular cell benign and malignant tumors in males.

8. A 24-month male rat chronic feeding/carcinogenicity study with a NOAEL of 800 ppm (30.41 mg/kg/day) and a LOAEL of 1,600 ppm (63.94 mg/kg/ day) based on increased liver and thyroid weights and lesions. There was evidence of carcinogenicity based on the increased occurrence of thyroid follicular cell benign and malignant tumors.

9. A 1-year dog chronic feeding study with a NOAEL of 150 ppm (3.75 mg/kg/day). The LOAEL is based on decreases in body weight gain and increased liver weight, at 1,200 ppm (30 mg/kg/day).

10. A 2-generation reproduction study in rats with a parental (systemic) and reproductive NOAEL of 4 mg/kg/day (80 ppm) and a LOAEL of 40 mg/kg/day (800 ppm), 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/parathyroid weights.

11. A developmental toxicity study in rabbits with a maternal NOAEL of 10 mg/kg/day, and a developmental NOAEL of 30 mg/kg/day, and a maternal LOAEL of 60 mg/kg/day due to only 1/19 (5) of the pregnant does producing a viable fetus and no developmental LOAEL (greater than 30 mg/kg/day).

12. A developmental toxicity study in rats with a maternal NOAEL and developmental NOAEL of 30 mg/kg/day and an LOAEL of 75 mg/kg/day due to decrease in maternal body weight compared to controls and increase in early and late resorption with a decrease in number of live fetuses per dam.

13. No evidence of gene mutation was observed in a test for induction of gene mutation at the HGPRT locus in Chinese hamster ovary cells. No increase in the number of cells with aberrations or observations per cell were noted in an in vivo cytogenetics assay using bone marrow from treated rats. No increase in unscheduled DNA synthesis in rat primary hepatocyte study was observed.

14. A rat metabolism study showed that radiolabeled fenbuconazole is rapidly absorbed, distributed, and excreted following oral administration in rats. Biliary excretion data indicated that systemic absorption of fenbuconazole was high for all dosing groups. The feces was the major route of excretion. Tissue distribution and bioaccumulation of fenbuconazole appeared to be minimal.

B. Toxicological Endpoints

1. *Acute toxicity*. For an acute dietary risk assessment a Reference Dose (acute RfD) of 0.3 mg/kg/day was established for females 13+ years, the population subgroup of concern, based on the developmental toxicity study in the rat with a NOAEL of 30 mg/kg/day based on an increase in post implantation loss with a significant decrease in the number of live fetuses per dam at the LOAEL of 75 mg/kg/day and an uncertainty factor of 100. EPA determined that the 10X factor required by FQPA for protection of infants and children from exposure to fenbuconazole should be removed since:

i. The toxicology data base is complete.

ii. There is no indication of increased susceptibility of rats or rabbit fetuses to in utero and/or postnatal exposure in the developmental and reproductive toxicity studies.

iii. Dietary (food) exposure estimates are slightly refined (using limited %CT data for stone fruit) but likely result in

an overestimate of the actual dietary exposure.

iv. Models are used for ground and surface source drinking water exposure assessments resulting in estimates that are upper-bound concentrations.

v. There are currently no registered residential uses for fenbuconazole and therefore, this type of exposure to infants and children is not expected.

2. *Short - and intermediate - term toxicity*. Short- and intermediate-term endpoints were not identified; therefore, an aggregate risk assessment was not done for these endpoints. Furthermore, fenbuconazole has no residential uses.

3. *Chronic toxicity*. The Reference Dose (chronic RfD) of 0.03 mg/kg/day was re-affirmed by the Hazard Identification Assessment Review Committee (HIARC) based on the chronic toxicity study in the rat with a NOAEL of 3.03/4.02 mg/kg/day in males/females based on decreased body weight gains (females), hepatocellular enlargement and vacuolation (females), increases in thyroid weight (both sexes) and histopathological lesions in the thyroid glands (males), at the LOAEL of 30.62/43.04 mg/kg/day in males/females and an uncertainty factor of 100.

4. *Carcinogenicity*. The Health Effects Division Carcinogenicity Peer Review Committee has concluded that the available data provide limited evidence of the carcinogenicity of fenbuconazole in mice and rats and has classified fenbuconazole as a Group C (possible human carcinogen with limited evidence of carcinogenicity in animals) in accordance with Agency guidelines, published in the **Federal Register** in 1986 (51 FR 33992, Sept. 24, 1986) and recommended that for the purpose of risk characterization a low-dose extrapolation model applied to the experimental animal tumor data should be used for quantification for human risk (Q1*). This decision was based on the induction of thyroid follicular cell adenomas and/or combined adenomas-carcinomas in male rats in two studies, both by pair-wise comparison with controls and by trend analysis. The studies were combined for the purpose of deriving the Q1*. The Q1* for fenbuconazole is 3.59 x 10^{-3} (mg/kg/day)$^{-1}$ in human equivalents.

C. Exposures and Risks

1. *From food and feed uses*. Time-limited tolerances have been established (40 CFR 180.480) for the combined residues of fenbuconazole, [alpha-(2-(4-chlorophenyl)-ethyl)-alpha-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites [cis-and trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone]] in/on stone fruits (except plums prunes), bananas (banana pulp), pecans, and blueberries. Risk assessments were conducted by EPA assessing dietary exposures 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 1-day or single exposure. In conducting this acute dietary risk assessment, very conservative assumptions were used which resulted in an overestimate of human dietary exposure. The following assumptions have been made: 100% of the crops are treated and residues will be at the tolerance levels. These assumptions result in a conservative risk estimate; refinement using anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis would result in a lower acute dietary exposure estimate. Thus, in making a safety determination for these tolerances, the Agency is taking into account this conservative exposure assessment.

The Novigen Dietary Exposure Evaluation Model (DEEM) system was used for this acute dietary exposure analysis. The 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.

The acute dietary (food only) risk assessment used Theoretical Maximum Residue Contribution (TMRC). The resulting high-end exposure estimate for females, ≧ 13 years old ranges from 0.0072 to 0.015 mg/kg/day for the population subgroup females, ≧ 13 years old (nursing), and females, 13 to 19 years old (not pregnant or nursing), respectively . These exposure levels utilize 2.3% to 5.0% of the Acute RfD, respectively.

ii. *Chronic exposure and risk*. In conducting this chronic dietary risk assessment, the Agency has made a partially refined exposure estimate. Tolerance level residues were assumed for all commodities, including stone fruits. Percent crop treated data were used for stone fruits and 100% crop treated data were assumed for all other commodities. The percent crop treated data for stone fruits were based upon a production cap. For additional refinement, incorporation of percent crop treated and anticipated residues for all commodities would result in lower exposure estimates. The Novigen DEEM system was used for this chronic dietary exposure analysis. The 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 dietary exposure.

The existing fenbuconazole tolerances (published, pending, and including the necessary section 18 tolerance(s)) result in an anticipated residue contribution (ARC) that is equivalent to the following percentages of the chronic RfD: U.S. population (48 States), < 1%; all infants (< 1 year old), 2.5%; nursing Infants (< 1 year old), 1.1%; non-nursing infants, 3.1%; children (1–6 years old), 1.5%; children (7–12 years old) < 1.0%; non-hispanic (other than black or white), 1.0%; seniors 1.0%.

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

Fenbuconazole is classified as a group C carcinogen (Q1*=.00359 (mg/kg/day). Using the partially refined exposure estimates described above, the cancer risk estimate for the U.S. population (48 states) is 8.3 x 10^{-7}.

2. *From drinking water*. In the absence of reliable, available monitoring data, EPA uses models to estimate concentrations of pesticides in ground and surface water. For fenbuconazole, modeling was used to estimate surface water concentrations because of very limited surface water monitoring data. However, EPA does not use these model estimates to quantify risk. Currently, EPA uses drinking water levels of comparison (DWLOC's) as a surrogate to capture risk associated with exposure to pesticides in drinking water. A DWLOC is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide from food, water and residential uses. A DWLOC will vary depending on the residue level in foods, the toxicity endpoint and with drinking water consumption patterns and body weights for specific subpopulations. EPA believes model estimates to be overestimates of concentrations of fenbuconazole expected in drinking water.

Fenbuconazole is moderately persistent to 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 (i.e. where soils are low in organic matter and where ground water is relatively close to the surface). The long half-lives of the aerobic soil and terrestrial field dissipation studies 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. 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.

i. *Acute exposure and risk*. Acute DWLOC for drinking water were calculated using the default body weights and drinking water consumption figures. Based on an adult female body weight of 60 kg and 2L consumption of water per day, level of comparison from acute exposure estimates for females 13 years and older, is 8,600 ppb. The peak EEC (acute) value of 6.7 ppb for aerial application is lower than, the acute DWLOCs for females 13 years and older (8,600 ppb).

ii. *Chronic exposure and risk*. Based on the chronic dietary (food) exposure and using default body weights and water consumption figures, chronic drinking water levels of comparison (DWLOC) for drinking water were calculated. The level of comparison from chronic exposure estimates for males is 1,000 ppb, 890 ppb for females and 290 ppb for infants and children. The chronic EEC, GENEEC 56-day, value of 3.6 ppb for aerial application is lower than, the chronic DWLOCs for males 1,000 ppb, females 890 ppb, and infants and children 290 ppb.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: That the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent of crop treated as required by the section 408(b)(2)(F), EPA may require registrants to submit data on percent of crop treated.

The Agency used percent crop treated (PCT) information as follows: Percent crop treated data were used only for stone fruits, in conducting the chronic risk assessment. For all other commodities it was assumed that 100% of the crop would be treated. The Agency believes that the three conditions listed in Units II, C1 i-iii of this preamble have been met. With respect to Unit II, C1 i of this preamble, percent of crop treated estimates are derived from federal and private market survey data, which are reliable and have a valid basis. The assumption is that stone fruit residues (except plums and prunes) are at the tolerance level and the limitation of production of the only fenbuconazole product registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use on stone fruit to 28,500 pounds of active ingredient per year (calculated to be equivalent to treating 12.812f the total U.S. acreage of apricots, cherries, nectarines, and peaches per year). 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 the percentage of the food treated is not likely to be an underestimated. As to Units II, C1ii, and iii of this preamble, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which fenbuconazole may be applied in a particular area.

3. *From non-dietary exposure*. Currently fenbuconazole has no registered residential non-food sites uses. No dermal or systemic toxicity was observed in the short- or intermediate term studies. Therefore, no endpoints were established and a risk assessment for residential non-dietary exposure was not needed.

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 considers ''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 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).

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

1. *Acute risk*. Toxicological effects applicable to population subgroups other than females 13 years old or older that could be attributed to a single exposure (dose) were not observed in oral toxicity studies in rats and rabbits. Therefore, a dose and endpoint was not identified for acute dietary risk assessment for these population groups.

The population subgroup of concern for acute risk is females, 13 years and older. The acute dietary (food only) risk assessment used TMRC. The resulting high-end exposure estimates (food only) for females, ≧ 13 years old, ranges from 0.0072 to 0.015 mg/kg/day for the population subgroups females, ≧13 years old (nursing), and females, 13 to 19 years old (not pregnant or nursing), respectively. These exposure levels utilize 2.3% to 5.0% of the Acute RfD, respectively. Based on the acute dietary (food only) exposure, acute DWLOCs were calculated. To calculate the acute DWLOCs, the acute dietary food exposure (from the DEEM analysis) was subtracted from the Acute RfD to give the maximum allowable exposure level for drinking water. DWLOCs were then calculated using default body weights

and drinking water consumption figures. The estimated peak concentration of fenbuconazole in surface water (6.7 µg/L) is less than the level of comparison for fenbuconazole in drinking water as a contribution to acute aggregate exposure (8.6×10^3 µg/L). Therefore, taking into account the registered uses and uses proposed, it is concluded with reasonable certainty that residues of fenbuconazole in drinking water (when considered along with other sources of acute exposure for which the Agency has reliable data) would not result in unacceptable levels of acute aggregate human health risk estimates for females, 13 years old and older, at this time.

The Agency generally has no concern for exposures below 100% of the acute RfD (when the FQPA Safety Factor has been removed, as is the case for fenbuconazole) because the acute RfD represents the level at or below which a single daily exposure will not pose appreciable risks to human health. The acute aggregate exposure is not expected to exceed 100% of the acute RfD for the subpopulation of concern (females 13 years and older). It is concluded that there is a reasonable certainty that no harm will result to females (13 years and older) from acute aggregate exposure to fenbuconazole residues.

2. *Chronic risk*. Using the conservative ARC exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, it was determined that chronic dietary exposure to fenbuconazole from food will utilize from <1.0% to 1.0% of the chronic RfD for the population subgroups which include adults (U.S. population (48 States) and non-hispanics (other than black or white), respectively). Based on the chronic dietary (food only) exposure, chronic (non-cancer) DWLOCs were calculated. To calculate the chronic DWLOCs, the chronic dietary food exposure (from the DEEM analysis) was subtracted from the chronic RfD to give the maximum allowable exposure level for drinking water. DWLOCs were then calculated using the default body weights and drinking water consumption figures. The estimated 56-day concentration of fenbuconazole in surface water (3.6 µg/L) is less than the levels of comparison for fenbuconazole in drinking water as a contribution to chronic aggregate exposure (1.0×10^3 µg/L and 8.9×10^2 µg/L for males and females, respectively). Therefore, taking into account the registered uses and uses proposed, it is concluded with reasonable certainty that residues of fenbuconazole in drinking water (when considered along with other sources of chronic exposure for which there is reliable data) would not result in unacceptable levels of chronic aggregate human health risk estimates for adult population subgroups.

The Agency generally has no concern for exposures below 100% of the chronic RfD (when the FQPA Safety Factor has been removed, as is the case for fenbuconazole) because the chronic RfD represents the level at or below which average daily life-time exposure will not pose appreciable risks to human health. Despite the potential for exposure to fenbuconazole in drinking water, the chronic aggregate exposure is not expected to exceed 100% of the chronic RfD for population subgroups which include adults.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Short- and intermediate-term endpoints were not identified; therefore, an aggregate risk assessment was not done for these endpoints. Furthermore, fenbuconazole has no residential uses.

4. *Aggregate cancer risk for U.S. population*. Fenbuconazole has been classified as a Group C Carcinogen with a Q_1^* of 3.59×10^{-3} (0.00359 (mg/kg/day)$^{-1}$).

The existing fenbuconazole tolerances (published, pending, and including the necessary section 18 tolerance(s)) result in a cancer risk estimate of 8.3×10^{-7} for the U.S. population (48 States). Based on the cancer dietary (food only) exposure and using default body weights and water consumption figures, a cancer DWLOC was calculated. To calculate the cancer DWLOC, the negligible risk level (1×10^{-6}) is divided by the Q_1^* to give the maximum allowable exposure (food plus water). The chronic food exposure was subtracted from the maximum allowable exposure (from the DEEM analysis) to give the maximum allowable exposure level for drinking water. The DWLOC was then calculated using the default body weight and drinking water consumption figure. The estimated 56–day concentration of fenbuconazole in surface water (3.6 µg/L) is less than three times the level of comparison ($3 \times 1.6 = 4.8$ µg/L) for fenbuconazole in drinking water as a contribution to chronic (cancer) aggregate exposure. Therefore, taking into account the registered uses and uses proposed, it is concluded with reasonable certainty that residues of fenbuconazole in drinking water (when considered along with other sources of chronic (cancer) exposure for which there is reliable data) would not result in unacceptable levels of cancer aggregate human health risk estimates for the U.S. population (48 States). The chronic food exposure estimate is partially refined. Further refinement of the food exposure would result in a lower exposure estimate and result in a higher DWLOC.

The Agency generally has no concern for exposures that result in a cancer risk estimate below 1×10^{-6}. Despite the potential for exposure to fenbuconazole in drinking water, the Agency does not expect the chronic (cancer) aggregate exposure to exceed 1×10^{-6} for the U.S. population (48 States). It is concluded that there is a reasonable certainty that no harm will result to the U.S. population (48 States) from chronic aggregate exposure to fenbuconazole residues.

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 residues of fenbuconazole.

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 as well as a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing fetus 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 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.

The Agency has determined that the FQPA Safety Factor (for enhanced sensitivity of infants and children as required by the Food Quality Protection Act of 1996) should be removed for this active ingredient.

ii. *Developmental toxicity studies*—a. *Rats*. 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 LOAEL 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 LOAEL of 75 mg/kg/day.

b. *Rabbits*. In the developmental toxicity study in rabbits, the maternal (systemic) NOAEL was 10 mg/kg/day, based on decreased body weight gain at the LOAEL of 30 mg/kg/day. The developmental (pup) NOAEL was 30 mg/kg/day, based on increased resorptions at the LOAEL of 60 mg/kg/day.

iii. *Reproductive toxicity study—Rats*. In the 2–generation reproductive toxicity study in rats, the parental (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 LOAEL of 40 mg/kg/day. The reproductive (pup) NOAEL was 40 mg/kg/day, the highest dose tested.

iv. *Pre- and post-natal sensitivity*. The toxicological data base for evaluating pre- and post-natal toxicity for fenbuconazole is complete with respect to current data requirements. Based on the developmental and reproductive toxicity studies there is no increased susceptibility of rats or rabbits to in utero and/or postnatal exposure to fenbuconazole. In the developmental toxicity studies in rats and rabbits as well as the 2–generation reproduction study in rats, toxicity to the fetuses/offspring, when observed, occurred at equivalent or higher doses and was not judged to be more severe than in the maternal/parental animals.

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. EPA determined that it was safe for infants and children to remove the FQPA safety factor sine:

i. The toxicology data base is complete.

ii. There is not indication of increased susceptibility of rats or rabbit fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity studies.

iii. Dietary (food) exposure estimates are slightly refined (using limited %CT data for stone fruit) but likely result in an overestimate of the actual dietary exposure.

iv. EFED models are used for ground and surface source drinking water exposure assessments resulting in estimates that are upper-bound concentrations.

v. There are currently no registered residential uses for fenbuconazole and therefore, this type of exposure to infants and children is not expected.

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, this subpopulation is not expected to face any appreciable acute risk.

3. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that chronic exposure to fenbuconazole from food will utilize 3.1% for non-nursing infants less than 1 year old, 2.5% for all infants (<1 year old), 1.5% for children (1–6 years old), 1.1% for nursing infants (<1 year old), 1% for non-hispanic (other than black or white), 1% for seniors (>55 years old) and <1% for children (7–12 years old) of the chronic RfD. 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. Base on chronic dietary exposure, a chronic (non-cancer) drinking water level of comparison (DWLOC) was calculated to be 2.9 x 10 for non-nursing infants (<1 year old). The estimated 56–day concentration of fenbuconazole in surface water (3.6 µg/L) is less than the Agency's levels of comparison for fenbuconazole in drinking water as a contribution to chronic aggregate exposure (1.0×10^3 µg/L and 8.9×10^2 µg/L for males and females, respectively). It is concluded with reasonable certainty that residues of fenbuconazole in drinking water (when considered along with other sources of chronic exposure data) would not result in unacceptable levels of chronic aggregate human health risk estimates for the population subgroups.

4. *Short- or intermediate-term risk*. There are no residential uses. No short and intermediate term aggregate exposure end points were identified, therefore EPA concluded that fenbuconazole did not pose a short or intermediate term risk.

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.

III. Other Considerations

A. Metabolism In Plants and Animals

1. The nature of the residue in plants 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-and trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone], as specified in 40 CFR 180.480.

2. As no livestock feed items are associated with this request, the nature of the residue in livestock is not of concern.

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. This method involves extraction of parent and metabolites into solvent followed by concentration, clean up, separation by GC, and detection with a nitrogen phosphorus detector. This method was submitted for inclusion in PAM II. The method 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, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703–305–5229).

C. Magnitude of Residues

Fenbuconazole, [alpha-(2-(4-chlorophenyl)-ethyl)-alpha-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites [cis-and trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone] expressed as fenbuconazole are not expected to exceed the tolerance levels. Tolerances levels in/on bananas are based on the highest residues resulting from applications to both bagged and unbagged bananas. Additional crop field trial data submitted as a condition of registration support reestablishment of time-limited tolerance for whole bananas. These data showed that level for residues in banana

pulp was exceeded in these field trials. Based on field data, EPA is not reestablishing a separate tolerance on banana pulp.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits (MRL) for fenbuconazole on pecans, bananas and the crop group stone fruit (except prunes and plums).

E. Rotational Crop Restrictions

Rotational crop restrictions are not applicable since pecans, bananas and stone fruit (except prunes and plums), are not routinely rotated.

IV. Conclusion

Therefore the time-limited tolerances are reestablished and amended for combined residues of fenbuconazole, [alpha-(2-(4-chlorophenyl)-ethyl)-alpha-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites [cis- and trans-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone] in or on [stone fruits (except plums and prunes) at 2.0 ppm, pecans at 0.1 ppm and bananas at 0.3] ppm.

V. 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 April 19, 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 under 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 regulation. 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 waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding 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, Crystal Mall #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.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300789] (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. Objections and hearing requests may be sent by e-mail directly to EPA at: opp-docket@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.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408(d) of the FFDCA 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 specficed 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 tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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 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 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. VIII. Submission to Congress and the Comptroller General.

VIII. Submission of Report to Congress and 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 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: February 2, 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, by revising paragraph (a)(1) to read as follows:

§ 180.480 Fenbuconazole; tolerances for residues.

(a) *General.* (1) Time-limited tolerances, to expire on December 31, 2001, are reestablished for combined residues of the fungicide 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 the following raw agricultural commodities:

Commodity	Parts per million	Expiration/ revocation date
Bananas (whole fruit) ...	0.3	12/31/01
Pecans	0.1	12/31/01
Stone fruit crop group (except plums and prunes)	2.0	12/31/01

* * * * *

[FR Doc. 99–3519 Filed 2–16–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300769; FRL–6049–9]

RIN 2070–AB78

Cinnamaldehyde; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the biochemical cinnamaldehyde in or on all food commodities when applied as a broad spectrum fungicide/insecticide/algaecide in accordance with good agricultural practices. The Interregional Research Project No. 4 (IR-4) submitted a petition to EPA on behalf of Proguard, Inc., under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) requesting the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of cinnamaldehyde. The Agency also removes the mushroom- specific