supported by the brief statement in Unit I. of this preamble. 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 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: March 2, 1999.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

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

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

2. Section 180.1183 is revised to read as follows:

§ 180.1183 Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene) and the genetic material necessary for it's production; Exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biological plant pesticide Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene) and the genetic material necessary for its production.

[FR Doc. 99–6176 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300810; FRL–6068–4]

RIN 2070–AB78

Propiconazole; Establishment of Time-Limited Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole, and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in or on corn, peanuts and pineapples. Novartis Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire on December 31, 2000.

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

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300810], 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–300810, 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–300810]. 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: Mary L. Waller, 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. 249, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9354, waller.mary@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 20, 1998 (63 FR 64498) (FRL–6042–1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) announcing the filing of pesticide petitions (PP) for tolerances by Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. This notice included a summary of the petitions prepared by Novartis Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.434 be amended by establishing time-limited tolerances for combined residues of the fungicide propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound on corn, fodder at 12 parts per million (ppm); corn, forage at 12 ppm; corn, grain at 0.1 ppm; corn, sweet (kernels plus cobs with husks removed) at 0.1 ppm; peanuts at 0.2 ppm; peanuts, hay at 20 ppm; pineapple at 0.1 ppm and pineapple, fodder at 0.1 ppm. These proposed tolerances will expire on December 31, 2000 and will replace previously established tolerances which expired on December 31, 1998.

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 propiconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound on corn, fodder at 12 parts per million (ppm); corn, forage at 12 ppm; corn, grain at 0.1 ppm; corn, sweet (kernels plus cobs with husks removed) at 0.1 ppm; peanuts at 0.2 ppm; peanuts, hay at 20 ppm; pineapple at 0.1 ppm and pineapple, fodder at 0.1 ppm. 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 propiconazole are discussed in this unit.

1. Acute toxicity data were as follows: acute oral LD_{50} = 1,517 m/kg (toxicity category III); acute dermal LD_{50} > 4,000 mg/kg (toxicity category III); acute inhalation LC_{50} = 1.26 mg/L; primary eye irritation - clear by 72 hours (toxicity category III); primary skin irritation - slight irritation (toxicity category IV); and dermal sensitization - negative.

2. A developmental toxicity study with rats which were gavaged with doses of 0, 30, 90 or 360/300 mg/kg/day. The developmental no observed adverse effect level (NOAEL) was 30 mg/kg/day. Evidence of developmental toxicity observed at the 90 mg/kg/day level lowest observed adverse effect level (LOAEL) included statistically significant increased incidence of unossified sternebrae, and nominally increased rudimentary ribs, and shortened or absent renal papillae. The maternal NOAEL was 30 mg/kg/day and the maternal LOAEL was 90 mg/kg/day based on reduced body weight gain and occurrence of rales in 1/24 females.

3. A developmental toxicity study with rabbits which were gavaged with doses of 0, 30, 90, or 180 mg/kg/day with no evidence of maternal or developmental toxicity observed under the conditions of the study.

4. A developmental toxicity study with rabbits which were gavaged with doses of 0, 100, 250, or 400 mg/kg/day on gestation days 7 through 19 with no developmental toxicity observed under the conditions of the study. The maternal NOAEL was 100 mg/kg/day and the maternal LOAEL was 250 mg/kg/day based on decreased food consumption, weight gain, and an increase in the number of resorptions at the higher dose levels. The developmental NOAEL was 400 mg/kg/day.

5. A 2-generation reproduction study with rats fed diets containing 0, 1, 100, 500 or 2,500 ppm showed no reproductive effects under the conditions of the study. The developmental NOAEL was 500 ppm (equivalent to 25 mg/kg/day), and the developmental LOAEL was 2,500 ppm (equivalent to 125 mg/kg/day) based on decreased offspring survival, body weight depression, and increased incidence of hepatic lesions in rats. The parental NOAEL was 100 ppm (equivalent to 5 mg/kg/day) and the parental LOAEL was 500 ppm (equivalent to 25 mg/kg/day) based on increased incidence of hepatic cell change.

6. A 1–year feeding study with dogs fed diets containing 0, 5, 50, or 250 ppm with a NOAEL of 50 ppm (equivalent to 1.25 mg/kg/day). The LOAEL was 250 ppm (equivalent to 6.25 mg/kg/day based on mild irritation of stomach mucosa.

7. A 2–year chronic feeding/carcinogenicity study with rats fed diets containing 0, 100, 500, or 2,500 ppm with a systemic NOAEL of 100 ppm (equivalent to 5 mg/kg/day) based on hepatocyte changes in males at the 500 ppm level and in both sexes at the 2,500 ppm level. There were no carcinogenic effects observed under the conditions of the study.

8. A 2–year chronic feeding/carcinogenicity study with mice fed diets containing 0, 100, 500, or 2,500 ppm with a systemic NOAEL of 100 ppm (equivalent to 15 mg/kg/day) based on decreased body weight, and increased liver lesions and liver weight in males. There was a statistically significant increase in combined adenomas and carcinomas of the liver in male mice at the 2,500 ppm level (equivalent to 375 mg/kg/day).

9. A battery of mutagenicity studies to determine the potential of propiconazole to induce gene mutation, chromosomal aberrations, and other genotoxic effects were all negative.

B. Toxicological Endpoints

1. *Acute toxicity*. The acute reference dose (RfD) is 0.3 mg/kg/day based on the NOAEL of 30 mg/kg/day from a developmental toxicity study in rats and using an uncertainty factor (UF) of 100.

2. *Short- and intermediate-term toxicity*. For short- and intermediate-term dermal margin of exposure (MOE) calculations, the developmental NOAEL of 30 mg/kg/day from a developmental toxicity study in rats was selected. For short- and intermediate-term inhalation MOE calculations the NOAEL of 92.8 mg/kg/day (0.5 mg/L), the highest dose tested, from a 5–day inhalation toxicity study was selected.

3. *Chronic toxicity*. EPA has established the RfD for propiconazole at 0.013 milligrams/kilogram/day (mg/kg/day). This RfD is based on a 1–year feeding study in dogs with a NOAEL of 1.25 mg/kg/day and an uncertainty factor of 100. The LOAEL of 6.25 mg/kg/day was based on mild irritation of the gastric mucosa.

4. *Carcinogenicity*. Propiconazole has been classified as a Group C, ''possible human carcinogen'', chemical. The Cancer Peer Review Committee recommended using the RfD approach for quantification of human risk.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.434) for the combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound, in or on a variety of raw agricultural commodities. Among these tolerances are stone fruits, various grain crops, grass, bananas, celery, mushrooms and pecans. Tolerances have also been established for meat, milk, poultry and eggs. Risk assessments were conducted by EPA to assess dietary exposure from propiconazole as follows:

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on

such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

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 population subgroup; 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.

Percent of crop treated estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. Typically, a range of estimates are supplied and the upper end of this range is assumed for 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. Regional consumption information and consumption information for significant population subgroups is taken into account through EPA's computer-based model for evaluating the exposure of significant population subgroups 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 propiconazole may be applied in a particular area.

The Agency used percent of crop treated (PCT) information as follows: The percent crop treated data used in the risk estimates for propiconazole for the crops for which tolerances are being established are: corn, 6%; pineapples, 100%; and peanuts, 1%. Percent crop treated data was used in determinations for several crops for which tolerances are already established (pecans, peaches, rice, rye and wheat).

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. The acute dietary (food only) risk assessment used the theoretical maximum residue contribution (TMRC), individual food consumption data as reported in the USDA Nationwide Food Consumption Survey (NFCS) which accumulates exposure to propiconazole from each commodity, and the assumption that 100% of the crops were treated with propiconazole. This risk assessment used high-end exposure estimates and should be viewed as a conservative risk assessment which overestimates the risk. The acute dietary exposure for the only population subgroup of concern, females 13 years and older, used 3.3% of the acute RfD of 0.3 mg/kg/day. The acute dietary risk (food only) does not exceed the Agency's level of concern.

ii. *Chronic exposure and risk*. The chronic dietary risk assessment used the RfD of 0.013 mg/kg/day. EPA used data from the USDA NFCS, and made partial refinements to the exposure assumptions. Tolerance level residues were used for corn, pineapples and peanuts. Percent of crop treated estimates were made for corn (6%), pineapple (100%) and peanuts (1%). For some of the other crops included in the analysis, anticipated residue levels and percent crop treated estimates were used. The existing propiconazole tolerances (published and pending, including tolerances for emergency exemptions) resulted in exposure estimates that are equivalent to the following percentages of the RfD: U.S. population (48 states), 7%; non-nursing infants less than 1 year old, 20%; children 1-6 years old, 13%; children 7-12 years old, 9%; all other subgroups, 6-9%. EPA generally has no concern for exposures below 100% of the chronic RfD (when the FQPA factor has been removed) because this RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Therefore, the chronic dietary risk (food only) does not exceed the Agency's level of concern.

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 propiconazole, modeling data were used to estimate surface water concentrations because very limited surface water monitoring data were available. EPA does not use these model estimates to quantify risk. Currently, EPA uses drinking water levels of comparison (DWLOCs) to estimate 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 population subgroups. EPA believes model estimates to be overestimations of concentrations of propiconazole expected in drinking water. Propiconazole is moderately persistent and moderately mobile to immobile in soil and aqueous environments. It has the potential to be transported with water, particularly in coarse-textured soils low in organic matter. Propiconazole's persistence indicates the potential to reach surface water with run-off or adsorb to soil particles. There is no established Maximum Contaminant Level for residues of propiconazole in drinking water. No health advisory levels for propiconazole in drinking water have been established.

i. *Acute exposure and risk*. The acute DWLOC is 8,700 µg/L for the only population subgroup of concern, females 13 years old or older. The estimated environmental concentration (EEC) in surface water (0.11 µg/L, peak value) is much lower than EPA's DWLOC of 8,700 µg/L for the population subgroup, females 13 years old or older. Therefore, EPA concludes with reasonable certainty that exposure to propiconazole in drinking water will result in no harm.

ii. *Chronic exposure and risk*. The chronic DWLOC is 100 µg/L for the population subgroup with the lowest chronic DWLOC (non-nursing infants < 1 year old). The lowest chronic DWLOC is substantially higher than the Generic Expected Environmental Concentration (GENEEC) 56-day EEC of 0.09 µg/L. Therefore, EPA concludes with reasonable certainty that exposure of propiconazole in drinking water is less than EPA's level of concern.

3. *From non-dietary exposure.* Propiconazole is currently registered for use on the following residential non-food sites: wood preservative. Under current Agency guidelines, this use does not present an acute or chronic exposure scenario, but may constitute a short- and/or intermediate-term dermal and inhalation exposure scenario for applicators. The Agency calculated short- and intermediate-term dermal and inhalation margins of exposure (MOEs) of 200 and 200,000 respectively for the wood preservative use of propiconazole. MOEs above 100 do not exceed the Agency's level of concern. For post application exposure, the Agency determined that propiconazole is volatile and not readily aerosolized. Therefore, post-application exposure from contact with treated wood is expected to be minimal and the Agency determined that a risk assessment for post-application exposure is 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 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 propiconazole 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, propiconazole 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 propiconazole 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.* The acute dietary (food only) risk does not exceed the Agency's level of concern. Using the TMRC, the population subgroup of concern, females 13 years old and older, utilizes 3.3% of the dietary (food only) acute RfD . For drinking water, the acute DWLOC for this population subgroup is 8,700 µg/L which is substantially higher that the peak EEC of 0.11 µg/L. Therefore, the risk from acute aggregate exposure to propiconazole does not exceed the Agency's level of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to propiconazole from food will utilize 7% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to propiconazole in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to propiconazole residues.

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 short- and intermediate-term dermal and inhalation exposure from residential uses. The dermal and inhalation endpoints used for estimating short- and intermediate-term exposure via the two routes of exposure measured different toxic effects. Therefore, the dermal margin of exposure (MOE) and the inhalation MOE should not be aggregated. For residential uses, dermal exposure of applicators was considered to be the driving factor in the short- and intermediate-term risk assessment, and the contribution of inhalation exposure to the short- and intermediate-term risk assessment was negligible (inhalation MOE = 200,000). Therefore, the inhalation exposure was not calculated in the aggregate short-and intermediate-term risk assessment. The aggregate short- and intermediate-term risk assessment estimated the dietary MOE to be 33,000, the dermal MOE to be 200 and the DWLOC to be 4,500 µg/L which is higher than the EEC of 0.09 µg/L. Therefore, the short- and intermediate-term aggregate risk does not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population.* EPA classified propiconazole as a Group C, possible human carcinogen and determined that the RfD approach be used to estimate the carcinogenic risk to humans. Risk concerns for carcinogenicity due to long-term consumption of propiconazole residues are adequately addressed by the aggregate chronic exposure analysis using the chronic RfD. Therefore, EPA concludes that there is reasonable certainty that no harm will result from aggregate exposure to propiconazole residue.

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 propiconazole.

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 propiconazole, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure 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.

ii. *Pre- and post-natal sensitivity.* The pre- and post-natal toxicology data base for propiconazole is complete with respect to current FQPA-relevant toxicological data requirements. Propiconazole is not developmentally toxic in the rabbit. There is evidence that propiconazole is developmentally toxic in the rat at doses that are toxic to the parents. In the developmental toxicity study in rats, the toxicity noted

at the maternal LOAEL of 90 mg/kg/day consisted of rales and decreased weight gain on gestation days 6–8 whereas the toxicity noted at the developmental LOAEL of 90 mg/kg/day consisted of statistically significant increased incidences of unossified sternebrae, and nominally increased incidences of rudimentary ribs and shortened or absent renal papillae. Where fetotoxic effects occur at the maternally toxic dose levels, they generally are of less concern than those occurring at non-maternally toxic dose levels because of the influence of toxicity in the mothers on the fetal toxicity expressed. However, where the fetal effects are judged to be qualitatively more severe than the effects in the maternal animals, there may be greater sensitivity in the fetus and thus of greater concern. Here, the effects in the fetus (delayed development) were not judged to be more sever than the effects in the maternal animals (decreased weight gain).

iii. *Conclusion*. There is a complete toxicity database for propiconazole and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures. Based on the completeness of the data base and the lack of any data indicating increased pre- or post-natal sensitivity, EPA concludes that an additional safety factor is not necessary to protect the safety of infants and children.

2. *Acute risk*. The available studies suggest the only acute risk infants and children face from propiconazole is through exposure to the developing fetus as a result of exposure to the mother. As shown in Unit II. D.1. of this preamble, the acute risk to the developing fetus from this exposure is not above the Agency's level of concern.

3. *Chronic risk*. Using the conservative exposure assumptions described in this unit, EPA has concluded that aggregate exposure to propiconazole from food will utilize 50% of the RfD for infants and children. 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 propiconazole in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to propiconazole residues.

4. *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 propiconazole residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residues in plants and animals is adequately understood. The residues of concern are propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (GC/ECD) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, 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, (703) 305–5229.

C. Magnitude of Residues

The currently established time-limited tolerances for corn, peanuts, and pineapple commodities are appropriate for these crops.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits (MRL) for propiconazole on corn, peanuts, or pineapple. Thus, harmonization of tolerances is not an issue for the extension of these tolerances.

E. Rotational Crop Restrictions

Soybeans may be planted as a double crop following a cereal crop which has been treated with propiconazole. Crops intended for food, grazing, or any component of animal feed or bedding may not be rotated within 105 days of propiconazole application unless the crop appears on the product label.

IV. Conclusion

Therefore, the time-limited tolerances are extended for combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2- yl]methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound on corn, fodder at 12 ppm; corn, forage at 12 ppm; corn, grain at 0.1 ppm; corn, sweet (kernels, plus cobs with husks removed) at 0.1 ppm; peanuts at 0.2 ppm; peanuts, hay at 20 ppm; pineapple at 0.1 ppm and pineapple, fodder at 0.1 ppm. These tolerances will expire on December 31, 2000 and will replace previously established tolerances which expired on December 31, 1998. These tolerances are time-limited because the Agency has not completed the review of a modified carcinogenicity study in mice which required testing at a mid-dose level. This study was requested to confirm or supplement findings in an Agency reviewed carcinogenicity study in mice in which testing was conducted at low and high dose levels.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA 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 May 17, 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 ''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) or a request for a fee waiver. 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–300810] (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 time-limited tolerances 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 specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances 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

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: March 4, 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. 321(q), 346a and 371.

§ 180.434 [Amended]

2. In § 180.434, in the table to paragraph (a), by changing the expiration dates for corn, fodder; corn, forage; corn, grain; corn, sweet (kernels plus cobs with husks removed); peanuts; peanuts, hay; pineapple; and pineapple, fodder, to read ''12/31/00''.

[FR Doc. 99–6388 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300804; FRL–6063–9]

RIN 2070–AB78

Pendimethalin; Extension of Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for the combined residues of the herbicide pendimethalin and its metabolites in or on fresh mint hay and mint oil at 0.1 and 5.0 parts per million (ppm), respectively, for an additional 1-year period. These tolerances will expire and are revoked on May 31, 2000. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on mint. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act 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 FIFRA section 18.

DATES: This regulation becomes effective March 17, 1999. Objections and requests for hearings must be received by EPA, on or before May 17, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300804], 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–300804], 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–300804]. 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: Stephen Schaible, 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. 271, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–308–9362, schaible.stephen@epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of May 23, 1997 (62 FR 28355) (FRL–5718–5), which announced that on its own initiative under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) it established time-limited tolerances for the combined residues of pendimethalin and its metabolites in or on fresh mint hay and mint oil at 0.1 ppm and 5.0 ppm, respectively, with an expiration date of May 31, 1998. EPA extended the expiration date of these tolerances to May 31, 1999 in a **Federal Register** notice published March 4, 1998 (63 FR 10545–10547) (FRL–5772–9). EPA established the tolerances because 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 FIFRA section 18. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of pendimethalin on mint for this year growing season due to the continued emergency situation for Idaho, Oregon and Washington mint