will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

V. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: April 3, 2001.

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), 346(a) and 371.

§ 180.368 [Amended]

2. In § 180.368, amend the table in paragraph (b) by revising the date under the heading ''Expiration/revocation date'' for ''tomato paste,'' ''tomato puree,'' and ''tomatoes'' to read ''6/30/02.''

[FR Doc. 01–9365 Filed 4–17–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301115; FRL–6778–1]

RIN 2070–AB78

Propiconazole; 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]-1H-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. Syngenta Crop Protection, Inc., formerly known as 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 March 30, 2004.

DATES: This regulation is effective April 18, 2001. Objections and requests for hearings, identified by docket control number OPP–301115, must be received by EPA on or before June 18, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301115 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9354; and e-mail address: *waller.mary@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr—00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301115. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of December 6, 2000 (65 FR 235) (FRL–6537–7), 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) (Public Law 104–170) announcing the filing of a pesticide petition (8F3654 and 8F3674) for tolerances by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. This notice included a summary of the petition prepared by Syngenta 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 tolerances for combined residues of the fungicide propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent, in or on corn, field, stover at 12 parts per million (ppm); corn, field, forage at 12 ppm; corn, field, grain at 0.1 ppm; corn, sweet, kernel plus cob with husks removed at 0.1 ppm; pineapple at 0.1 ppm; pineapple, fodder at 0.1 ppm (8F3674); peanut at 0.2 ppm; and peanut, hay at 20 ppm (8F3654). These proposed tolerances will expire on March 30, 2004 and will replace previously established tolerances which expired on December 31, 2000.

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).

III. 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 and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound on corn, field, stover at 12 parts per million (ppm); corn, field, forage at 12 ppm; corn, field, grain at 0.1 ppm; corn, sweet, kernel plus cob with husks removed at 0.1 ppm; pineapple at 0.1 ppm; pineapple, fodder at 0.1 ppm; peanut at 0.2 ppm; and peanut, hay at 20 ppm. EPA's assessment of 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 propiconazole are discussed in the following section.

1. Acute toxicity data were as follows: acute oral LD_{50} = 1,517 mg/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 effects level (NOAEL) was 30 mg/kg/day. Evidence of developmental toxicity observed at 90 mg/kg/day, the lowest observed adverse effect level (LOAEL) included increased incidence of unossified sternebrae, 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 two-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

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for propiconazole is discussed below.

1. *Acute toxicity*. The acute 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 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. The level of concern is 100.

3. *Chronic toxicity*. EPA has established the RfD for propiconazole at 0.013 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 UF 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 RfD approach for quantification of human risk was used. Since the RfD approach used the same endpoint to assess chronic toxicity, the chronic risk assessment addresses both the cancer risk as well as chronic effects.

C. Exposure Assessment

1. *Dietary exposure 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]-1H-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 exposures from propiconazole in food as follows:

i. *Acute exposure*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Risk Exposure System was used for calculating acute dietary exposure. This analysis evaluated the individual food consumption as reported by respondents in the USDA 1977–1978 Nationwide Food Consumption Survey (NFCS) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: The acute dietary (food only) risk assessment used the Theoretical Maximum Residue Contribution (TMRC). Percent Crop Treated (PCT) data and anticipated residue values were not used. 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*. In conducting this chronic dietary risk assessment the Dietary Risk Exposure System was used. This analysis evaluated the individual food consumption as reported by respondents in the USDA 1977–1978 NFSC and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Anticipated residues and percent crop treated data were used for various commodities.

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. Anticipated residue levels were used for the following crops: pecans; bananas; plantains; barley; eggs; milk and milk-by-products; poultry, beef, goat, sheep, swine and by-products; rice, rye, wheat and by-products. Percent of crop treated estimates were made for corn (6%), pineapple (100%) and peanuts (1%). 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.

iii. *Cancer*. A quantitative risk assessment using a cancer endpoint was not performed since the RfD approach was identical to the chronic assessement. The chronic risk assessment is adequately protective for cancer risk as well as other chronic effects.

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: Condition 1, 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; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, 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 crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information as follows: Percent crop treated data was used for the following crops: corn (6%), peanuts (1%), pecans (47%), fresh peaches (13%), barley (2%), rice (25%), rye and wheat (1%) and corn and peanut oil (1%). It was assumed that propiconazole was used on 100% of the pineapple crop.

The Agency believes that the three conditions previously discussed have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for propiconazole in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of propiconazole.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW (Screening concentration in ground water), which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporates an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water

exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to propiconazole they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the estimated environmental concentrations (EECs) of propiconazole for acute exposures are estimated to be .11 parts per billion (ppb) for surface water and .0014 ppb for ground water. The EECs for chronic exposures are estimated to be .09 ppb for surface water and .0014 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Propiconazole is currently registered for use on the following residential non-dietary site: preservative for wood. The risk assessment was conducted using the following residential exposure assumptions: 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 a 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. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. 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 prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity*. The pre- and post-natal toxicology database 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.

iii. *Conclusion*. There is a complete toxicity database for propiconazole and exposure data are complete or are estimated based on data that reasonably account for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because, in cases, where fetotoxic effects occur at the maternally toxic dose levels, the effects 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 severe than the effects in the maternal animals (decreased weight gain).

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

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

When EECs for surface water and groundwater are less than the calculated DWLOCs, EPA's Office of Pesticide Programs (OPP) concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable

data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to propiconazole will occupy 3.3% of the aPAD for females 13 years and older, the only population subgroup of concern. In addition, there is potential for acute dietary exposure to propiconazole in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to propiconazole from food will utilize 7% of the cPAD for the U.S. population, 20% of the cPAD for non-nursing infants < 1 year old and 13% of the cPAD for children 1–6 years old. Based the use pattern, chronic residential exposure to residues of propiconazole is not expected. In addition, there is potential for chronic dietary exposure to propiconazole in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 1:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PROPICONAZOLE

Population subgroup	cPAD mg/kg/day	% cPAD (food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	.009	7	.09	.0014	420
Non-nursing infants < 1 year	.0026	20	.09	.0014	100
Children 1–6 years	.0017	13	.09	.0014	> 100

3. *Short- and/or intermediate-term risk*. Short- and/or intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Propiconazole is currently registered for use that could result in short- and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short- and intermediate-term exposures for propiconazole.

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in an aggregate MOE of 200. This aggregate MOE does not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of propiconazole in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short- and intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR SHORT- AND INTERMEDIATE-TERM EXPOSURE TO PROPICONAZOLE

Population subgroup	Aggregate MOE (food + residential)	Aggregate level of concern (LOC)	Surface water EEC (ppb)	Ground water EEC (ppb)	Short-term DWLOC (ppb)
Females 13 years and older	200	100	.09	.0014	4,500

5. *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.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example - gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

International CODEX values are established for almond, animal products, bananas, barley, coffee, eggs, grapes, mango, meat, milk, oat, peanut-whole, peanut grains, pecans, rape, rye, stone fruit, sugar cane, sugar beets, sugar beet tops, and wheat. The U.S. residue definition includes both propiconazole and metabolites determined as 2,4-dichlorobenzoic acid (DCBA), and the CODEX definition is for propiconazole, per se, i.e. parent only. This difference results in unique tolerance expressions (0.1 ppm for peanuts) with the U.S. definition resulting in the higher tolerance levels (0.2 ppm for peanuts). EPA includes the metabolite in its assessment because it also raises hazard concerns.

C. Conditions

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.

V. Conclusion

Therefore, tolerances are established for combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound, in or on corn, field, stover at 12 ppm; corn, field, forage at 12 ppm; corn, field, grain at 0.1 ppm; corn, sweet, kernel plus cob with husks removed at 0.1 ppm; pineapple at 0.1 ppm; pineapple, fodder at 0.1 ppm; peanut at 0.2 ppm; and peanut, hay at 20 ppm. These tolerances will expire on March 30, 2004 and will replace previously established tolerances which expired on December 31, 2000. These tolerances are time-limited because the Agency requested a modified carcinogenicity study in mice conducted at a mid-dose level to confirm or supplement findings in an Agency reviewed carcinogenicity study in mice conducted at low and high dose levels. Although the Agency has completed the review of the mid-dose level carcinogenicity study, the Agency has not yet reevaluated the data as a whole and the cancer classification.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301115 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before June 18, 2001.

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

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301115, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the

Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under 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 OMB review or any other Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.''‘‘ Policies that have federalism implications'' is defined in the Executive Order to include regulations that have'' substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

For these same reasons, the Agency has determined that this rule does not have any tribal implications as described in Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications. Policies that have tribal implications is defined in the Executive Order to include regulations that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

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

List of Subjects in 40 CFR Part 180

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

Dated: April 2, 2001.

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), 346(a) and 371.

2. Section 180.434 is amended by revising the section heading, and in the table to paragraph (a) by removing the entries for corn, forage; and corn, grain; by adding an entry for corn, field, stover; corn, field, forage; corn, field, grain; and by revising the entries for corn, sweet, kernel plus cob with husks removed; peanuts; peanuts, hay; pineapple; and pineapple, fodder, to read as follows:

§ 180.434 Propiconazole; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million	Expiration Date
* * * * *		
Corn, field, forage	12	3/30/04
Corn, field, grain ...	0.1	3/30/04
Corn, field, stover	12	3/30/04
Corn, sweet (kernel plus cob with husks removed)	0.1	3/30/04
* * * * *		
Peanut	0.2	3/30/04
Peanut, hay	20	3/30/04
* * * * *		
Pineapple	0.1	3/30/04
Pineapple, fodder ..	0.1	3/30/04
* * * * *		

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[FR Doc. 01–9366 Filed 4–17–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301116; FRL–6778–5]

RIN 2070–AB78

Flumioxazin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerances for residues of flumioxazin in or on soybean seed and peanuts. Valent U.S.A. Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective April 18, 2001. Objections and requests for hearings, identified by docket control number OPP–301116, must be received by EPA on or before June 18, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please