V. Conclusion

Therefore, tolerances are established for residues of the insecticide, fenpropathrin, (alpha-cyano-3-phenoxy-benzyl 2,2,3,3-tetramethylcyclopropanecarboxylate), in or on almond, hulls at 4.5 ppm; cherry, sweet at 5.0 ppm; cherry, tart at 5.0 ppm; fruit, stone, crop group 12 (except cherry) at 1.4 ppm; nut, tree, crop group 14 at 0.10 ppm; avocado at 1.0 ppm; black sapote at 1.0 ppm; canistel at 1.0 ppm; maney sapote at 1.0 ppm; mango at 1.0 ppm; papaya at 1.0 ppm; sapodilla at 1.0 ppm; star apple at 1.0; caneberry, subgroup 13-07A at 12.0 ppm; olive at 5.0 ppm; and pistachio at 0.10 ppm. In addition, the Agency is deleting a time-limited tolerance on currant at 15 ppm which had an expiration date of 12/31/2008.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of 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). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: February 24, 2009.

Lois Rossi,

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.

■ 2. Section 180. 466 is amended by alphabetically adding the following commodities to the table in paragraph (a) and by removing the text in paragraph (b) and reserving the heading.

§ 180.466 Fenpropathrin; tolerances for residues.

* * * * *

Commodity	Parts per million
Almond, hulls	4.5
Avocado	1.0
* * *	* *
Caneberry subgroup 13-07A.	12
Canistel	1.0
* * *	* *
Cherry, sweet	5.0
Cherry, tart	5.0
* * *	* *
Fruit, stone, crop group 12, except cherry.	1.4
* * *	* *
Mango	1.0
* * *	* *
Nut, tree, crop group 14.	0.10
Olive	5.0
Papaya	1.0
* * *	* *
Pistachio	0.10
* * *	* *
Sapodilla	1.0
Sapote, black	1.0
Sapote, mamey	1.0
* * *	* *
Star apple	1.0

(b) *Section 18 emergency exemptions. [Reserved]*

* * * * *

[FR Doc. E9–6412 Filed 3–24–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–1202; FRL–8403–7]

Propiconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of propiconazole in or on beet, garden, roots at 0.30 ppm; beet, garden, tops at

5.5 ppm; cilantro, leaves at 13 ppm; parsley, fresh leaves at 13 ppm; parsley, dried leaves at 35 ppm; pineapple at 4.5 ppm; and pineapple, process residue at 7.0 ppm. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 25, 2009. Objections and requests for hearings must be received on or before May 26, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–1202. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr.*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–1202 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 as required by 40 CFR part 178 on or before May 26, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–1202, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of February 6, 2008 (73 FR 6964) (FRL– 8350–9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E7300) by the Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.343 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 compound in or on food commodities beet, garden, roots at 0.6 ppm; parsley, leaves at 13 ppm; parsley, dried leaves at 60 ppm; coriander, fresh at 13 ppm; vegetable, leaves of root and tuber, group 2 at 8.0 ppm; pineapple (post harvest) at 0.9 ppm; and turnip, roots at 0.2 ppm. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has corrected commodity definition, revised, deleted and/or modified tolerances petitioned for as follows:

- Revised the tolerance level (adjusted for 1x application rate) for beet, garden, roots from 0.6 to 0.30 ppm and established a tolerance for beet, garden, tops at 5.5 ppm,
- Revised the tolerance level for parsley, dried from 60 to 35 ppm,
- Revised the tolerance level for pineapple from 0.9 to 4.5 ppm, replacing existing pineapple tolerance of 0.1 ppm, and establish a tolerance for pineapple, process residue at 7.0 ppm,
- Corrected the commodity name from ''coriander, fresh'' to ''cilantro, leaves''.

At this time, the Agency is not making a decision on the proposed tolerance for vegetable, leaves of root and tuber, group 2 at 8.0 ppm, and the proposed tolerance for turnip, roots at 0.2 ppm. That aspect of the petition remains pending. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of 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) of FFDCA 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) of FFDCA 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....''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 for the petitioned-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 in or on food commodities: beet, garden, roots at 0.30 ppm; beet, garden, tops at 5.5 ppm, cilantro, leaves at 13 ppm; parsley, fresh at 13 ppm; parsley, dried at 35 ppm; pineapple at 4.5 ppm; and pineapple, process residue at 7.0 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

Propiconazole has low to moderate toxicity in experimental animals by the oral, dermal and inhalation routes. It is moderately irritating to the eyes, and minimally irritating to the skin. It is a dermal sensitizer. Propiconazole is readily absorbed by the rat skin with 40% absorption within 10 hours of dermal application.

The primary target organ for propiconazole toxicity in animals is the liver. Increased liver weights were seen in mice after subchronic or chronic oral exposures to propiconazole at doses >50 mg/kg/day. Liver lesions such as vacuolation of hepatocytes, ballooned liver cells, foci of enlarged hepatocytes, hypertrophy and necrosis are characteristic of propiconazole toxicity in rats and mice. Mice appear to be more susceptible to its toxicity than rats. Decreased body weight gain in experimental animals was seen in subchronic, chronic, developmental and reproductive studies. Dogs appeared to be more sensitive to the localized toxicity of propiconazole as manifested by stomach irritation at 6 mg/kg/day and above.

In rabbits, developmental toxicity occurred at a higher dose than the maternal toxic dose, while in rats, developmental toxicity occurred at lower doses than maternal toxic doses. Increased incidences of rudimentary ribs occurred in rat and rabbit fetuses. Increased cleft palate malformations were noted in two studies in rats. In one published study in rats developmental effects (incomplete ossification of the skull, caudal vertebrae and digits, extra rib (14^{th} rib) and missing sternebrae, malformations of the lung and kidneys) were reported at doses that were not maternally toxic.

In the 2–generation reproduction study in rats, offspring toxicity occurred at a higher dose than the parental toxic dose suggesting lower susceptibility of the offspring to the toxic doses of propiconazole in this study.

Propiconazole was negative for mutagenicity in the *in vitro* BALB/ C 3T3 cell transformation assay, bacterial reverse mutation assay, Chinese hamster bone marrow chromosomal aberration assay, unscheduled DNA synthesis studies in human fibroblasts and primary rat hepatocytes, mitotic gene conversion assay and the dominant lethal assay in mice. Hepatocellular proliferation studies in mice suggest that propiconazole induces cell proliferation followed by treatment-related hypertrophy in a manner similar to the known hypertrophic agent phenobarbital.

Propiconazole was carcinogenic to CD-1 male mice. Propiconazole was not carcinogenic to rats nor to female mice. The Agency classified propiconazole as Group C - possible human carcinogen and recommended that for the purpose of risk characterization the reference dose (RfD) approach be used for quantification of human risk. Propiconazole is not genotoxic and this fact, together with special mechanistic studies indicate that propiconazole is a threshold carcinogen. Propiconazole produced liver tumors in male mice only at a high dose that was toxic to the liver. At doses below the RfD liver toxicity is not expected, and therefore tumors are also not expected.

EPA has evaluated the available toxicity data and considered their 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. Specific information on the studies received and the nature of the adverse effects caused by propiconazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document: ''Propiconazole FQPA Human Health Risk Assessment for the Section 3 Registrations on Garden Beets, Turnips, Parsley, Cilantro and Pineapple.'' Petition No. 7E7300, dated September 30, 2008, page 21 in Docket ID number: EPA–HQ–OPP–2007–1202–0003.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which the NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the LOAEL or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/ safety factors (UFs) are used in conjunction with the POD to take into account 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. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the

margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for propiconazole used for human risk assessment can be found at *http://www.regulations.gov* in document: ''Propiconazole FQPA Human Health Risk Assessment for the Section 3 Registrations on Garden Beets, Turnips, Parsley, Cilantro and Pineapple.'' Petition No. 7E7300, dated September 30, 2008, page 21 in docket ID number EPA–HQ–OPP–2007–1202–0003.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to propiconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing propiconazole tolerances in (40 CFR 180.434). EPA assessed dietary exposures from propiconazole in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA conducted acute dietary analysis for propiconazole using tolerance level residues and 100 percent crop treated (PCT) for all existing and proposed uses.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA conducted chronic dietary analysis for propiconazole using tolerance level residues and 100 PCT for all existing and proposed uses.

iii. *Cancer*. As explained in this Unit, the chronic RfD is protective of propiconazole's cancer effects. For the purpose of assessing cancer risk under the chronic RfD, EPA used the same exposure estimates as discussed in Unit III.C.1.ii., chronic exposure.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for propiconazole. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for propiconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of propiconazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of propiconazole for acute exposures are estimated to be 55.8 parts per billion (ppb) for surface water and 0.64 ppb for ground water. The EECs for chronic exposures are estimated to be 21.6 ppb for surface water and 0.64 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID™). For acute dietary risk assessment, the peak water concentration value of 55.8 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the annual average concentration of 21.6 ppb was used to access the contribution to drinking 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 the following uses that could result in residential exposures: Turf, ornamentals, and antimicrobial uses in wood preservation treatments and paint. No new residential uses are associated with the petitioned-for tolerances. However, adults, adolesescents and toddlers may be exposed to propiconazole from currently registered uses. EPA assessed residential exposure using the following assumptions: Homeowners can be exposed to propiconazole through dermal and inhalation routes while applying home use products. All risk calculations were conducted using the maximum turf application rate (1.8 lb ai/acre). The anticipated use patterns and current labeling indicate three major residential exposure scenarios based on the types of equipment and techniques that can potentially be used to make propiconazole applications. The quantitative exposure/risk assessment developed for residential handlers is based on these scenarios:

- Mixer/Loader/applying liquids and wettable powder in water soluble packets via low pressure handwand.
- Mixer/Loader/applying liquids and wettable powder in water soluble packets via hose-end sprayer.
- Applying treated paint using airless sprayer and hose-end spray.

Residential handler exposure scenarios are considered to be short-term only due to the infrequent uses associated with homeowner products.

The existing residential use patterns result in post application dermal exposures to adults, and dermal and oral exposures to infants and children. These exposure scenarios are considered short term only, due to the fact that:

i. Post-application exposures were calculated using propiconazole as the parent compound;

ii. Compound specific turf transferable residue (TTR) data indicate that at the Indiana, California, and Pennsylvania test sites, average total propiconazole residues declined to below the minimum quantifiable limit (MQL) by 14, 10 and 8 days after treatment, respectively. These dissipation rates, combined with label specific use rates and frequency of use specifications, reinforce the hand to mouth short-term exposure scenario; and

iii. For short term exposure to children 1–2 years old, the driving factors for this risk assessment are hand to mouth, object to mouth, and dermal exposure. Soil ingestion is insignificant (margin of exposure (MOE) >300,000) compared to these factors, indicating that the post application scenario should be short term only. Although both residential and antimicrobial uses result in incidental oral and dermal exposure to children, the highest incidental oral and dermal exposure scenarios are from residential use on turf, which were used in the short term aggregate risk assessment.

In addition to using the EPA's Standard Operational Procedure (SOP) for residential assessment, the study

specific turf transferable residue (TTR) was used to estimate exposures. The EPA combined exposures resulting from separate post-application exposure scenarios when it is likely they can occur simultaneously based on the use-pattern and the behavior associated with the exposed population. The assumptions used for each of the scenarios separately are considered to account for potential high levels of exposure (i.e., time spent outdoors, dislodgeable residues) therefore, combining all these activities together is considered a very high end estimate of exposure.

Propiconazole is classified as a non-volatile chemical; therefore a residential inhalation post-application assessment was not assessed.

The only residential use scenario that will result in potential intermediate term exposure to propiconazole is post application exposure to children from wood treatment (antimicrobial use) from incidental oral and dermal contact activities. Propiconazole is used on many different types of wood including playground structures. EPA assessed the risk to children playing on propiconazole-treated structures using screening level assessment.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA 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.''

Propiconazole is a member of the triazole-containing class of pesticides. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events. In conazoles, however, a variable pattern of toxicological responses is found. Some include hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

Propiconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazolylalanine and triazolylacetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including propiconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazolylalanine, and triazolylacetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at *http://www.regulations.gov*, Docket Identification (ID) Number EPA–HQ–OPP–2005–0497. Also, see document: ''Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address Tolerance Petitions for Metconazole, Propiconazole, Prothioconazole, and Tetraconazole,'' dated November 8, 2008, Docket: EPA–HQ–OPP–2007–1202–0006.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The Agency concluded that there is low concern for pre- and/or postnatal toxicity resulting from exposure to propiconazole. In the developmental toxicity study in rabbits, the EPA determined that neither quantitative nor qualitative evidence of increased susceptibility of fetuses to *in utero* exposure to propiconazole was observed in this study. In the 2–generation reproduction study in rats, EPA determined that neither quantitative nor qualitative evidence of increased susceptibility of neonates (as compared to adults) to pre- and/or postnatal exposure to propiconazole was observed in this study. In the developmental rat study, however, quantitative susceptibility was evidenced as increased incidence of rudimentary ribs, unossified sternebrae, as well as increased incidence of shortened and absent renal papillae and increased cleft palate at 90 mg/kg/day, a dose lower than that evoking maternal toxicity (severe clinical toxicity at 300 mg/kg/day). nsidering the overall toxicity profile and the doses and endpoints selected for risk assessment for propiconazole, the EPA characterized the degree of concern for the effects observed in this study as low, noting that there is a clear no observed adverse effect level (NOAEL) and well-characterized dose response for the developmental effects observed. No residual uncertainties were identified. The NOAEL for developmental effects in this study (30 mg/kg/day) is used as the basis for the acute reference dose (aRfD) for the female 13–50 population subgroup as well as for short-term incidental oral, dermal and inhalation endpoints. For all other toxicity endpoints established for propiconazole, a NOAEL lower than this developmental NOAEL is used.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for propiconazole is complete except for immunotoxicity testing. EPA began requiring functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Since this requirement went into effect after the tolerance petition was submitted,

these studies are not yet available for propiconazole. In the absence of specific immunotoxicity studies, EPA has evaluated the available propiconazole toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. There was no evidence of adverse effects on the organs of the immune system at the LOAEL in any study propiconazole. In addition, propiconazole does not belong to a class of chemicals (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Based on the considerations in this Unit, EPA does not believe that conducting a special series 870.7800 immunotoxicity study will result in a point of departure less than the NOAEL of 10.0 mg/kg/day used in calculation the cPAD for propiconazole, and therefore, an additional database uncertainty factor is not needed to account for potential immunotoxicity.

ii. EPA also began requiring acute and subchronic neutotoxicity testing of all food and non-food use pesticides on December 26, 2007. An acute neurotoxicity study has been submitted to the Agency, but since the requirement for neurotoxicity testing went into effect after the tolerance petition was submitted, the subchronic neurotoxicity study is not yet available for propiconazole. In the absence of the subchronic neurotoxicity study, EPA has evaluated the available propiconazole toxicity data to determine whether an additional database uncertainty factor is needed to account for potential neurotoxicity after repeated exposures. With the exception of the developmental studies in the rat, there were no indications in any of the repeated dose studies that propiconazole is neurotoxic. In the developmental studies in the rat, there were some clinical signs of neurotoxicity at 300 mg/kg/day but not at lower doses. Based on the considerations in this Unit, EPA does not believe that conducting a series 870.6200b subchronic neurotoxicity study will result in a point of departure less than the NOAEL of 10 mg/kg/day used in calculation the cPAD for propiconazole, and therefore, an additional database uncertainty factor is not needed to account for potential neurotoxicity from repeated exposures. There is no indication in the developmental and reproduction studies, nor in the acute neurotoxicity study that a developmental neurotoxicity study should be required.

iii. There is no evidence that propiconazole results in increased susceptibility in *in utero* in rabbits in the rabbit prenatal developmental study or in young rats in the 2–generation reproduction study. Although quanititative susceptibility of the young was observed in the rat developmental study, there is low concern for the prenatal toxicity seen in this study for the reasons described in this Unit.

iv. There are no residual uncertainties identified in the exposure databases. Dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. The exposure databases (dietary food, drinking water, and residential) are complete and the risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern and does not underestimate the potential risk for infants and children. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to propiconazole in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by propiconazole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

Acute and chronic aggregate dietary (food and drinking water) exposure and risk assessments were conducted for parent propiconazole using the Dietary Exposure Evaluation Model DEEM-FCID™, Version 2.03 which use food consumption data from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994–1996 and 1998. This dietary assessment is for the parent propiconazole only. The common metabolites- triazole, triazolylalanine (TA), and triazolylacetic acid (TAA) are also residues of concern. Since these are common metabolites from several triazole pesticides, the risk assessment for triazoles was assessed separately. The updated risk assessment for triazole metabolites indicated that adding the new uses of propiconazole will not result in unacceptable risk to the triazole metabolites (see ''Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address Tolerance Petitions for Metconazole, Propiconazole, Prothioconazole, and Tetraconazole,'' dated November 8, 2008, ID Docket Number: EPA–HQ–OPP–2007–1202–0006.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to propiconazole will occupy 16% of the aPAD for all infants <1 year old the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to propiconazole from food and water will utilize 17% of the cPAD for children 1–2 years old the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of propiconazole is not expected.

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

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

An aggregated risk to toddlers from exposures to residential turf use including:

i. Hand-to-mouth activity,

ii. Object to mouth activity,

iii. Soil ingestion, and

iv. Turf-general high-contact activities

was evaluated and resulted in an aggregate MOE of 170 which is below the Agency's level of concern (MOE of 100 or less).

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential and antimicrobial exposures aggregated result in aggregate combined MOE of 160 resulting from all exposure

scenarios (oral and dermal). The highest incidental oral and dermal exposure scenarios are from residential use on turf, which were used in the short-term aggregate risk assessment. The short-term aggregate risk does not exceed the Agency's level of concern.

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

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

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures aggregated result in aggregate MOEs of 120 (exposure to Children 1–2 years old), which is below the Agency's level of concern (MOE of 100 or less). The only residential use scenario that will result in potential intermediate term exposure to propiconazole is post application exposure to children from wood treatment (antimicrobial use).

5. *Aggregate cancer risk for U.S. population*. The Agency considers the chronic aggregate risk assessment, making use of the cPAD, to be protective of the aggregate cancer risk. See Unit III.A.

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 or to infants and children from aggregate exposure to propiconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography (GC) method using flame ionization detection (Method AG-354) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for propiconazole in/on various raw agricultural commodities. In addition, both Canada and Mexico have established MRLs for propiconazole in/on various commodities. No Codex, Mexican, or Canadian MRLs have been established for any crop commodity associated with this petition.

C. Revisions to Petitioned-For Tolerances

Based upon review of available data supporting the petition, EPA revised the tolerance levels, added or deleted tolerances, or otherwise modified the petition as proposed in the notice of filing, as follows:

- Revised the tolerance level for beet, garden, roots from 0.6 to 0.30 ppm and established a tolerance for beet, garden, tops at 5.5 ppm, Adequate field trial residue data were submitted for garden beets at 1.5 times the proposed maximum treatment rate. Adjusting to the 1x rate, the Agency is setting a 0.30 ppm tolerance on garden beet roots and a 5.5 ppm tolerance on garden beet tops.
- Corrected the commodity name from ''coriander, fresh'' to ''cilantro, leaves'' based on the Agency's current crop naming guidelines,
- Revised the tolerance level for parsley, dried from 60 to 35 ppm. Available processing data show that propiconazole residues concentrate in parsley, dried (processing factor of 5.5). The highest average field trial (HAFT) value from field studies is 6.3 ppm. Multiplying the processing factor by the HAFT value indicates that a tolerance level of 35 is needed.
- Revised the proposed tolerance level for pineapple from 0.9 ppm to 4.5 ppm, replacing the existing pineapple tolerance of 0.1 ppm. The appropriate tolerance level for propiconzole in/on pineapple was calculated from HAFT values in a dataset of eighteen (18) samples from pineapple postharvest field trials using application rates within 25% of the maximum label use rate. These data indicate a propiconazole residue tolerance level for pineapple at 4.5 ppm is appropriate, and
- Established a tolerance for pineapple, process residue at 7.0 ppm. Propiconazole residues in pineapple process residue concentrate with a processing factor of 1.7. Multiplying the processing factor for pineapple by the HAFT value (3.6 ppm) indicates that a tolerance level of 7.0 ppm is needed.

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 food commodities: Beet, garden, roots at 0.30 ppm; beet, garden, tops at 5.5 ppm; cilantro, leaves at 4.5 ppm; parsley, fresh at 13 ppm; parsley, dried at 35 ppm; pineapple at 4.5 ppm; and pineapple, process residue at 7.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of 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). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10,

1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: February 27, 2009.

Daniel J. Rosenblatt,

Acting 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.

■ 2. Section 180.434 is amended by revising the tolerance for pineapple and by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§180.434 Propiconazole; tolerance for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Beet, garden, roots	0.30
Beet, garden, tops	5.5
* * * * *	
Cilantro, leaves	13
* * * * *	
Parsley, fresh leaves	13
Parsley, dried leaves	35
* * * * *	
Pineapple	4.5
Pineapple, process residue	7.0

* * * * *

[FR Doc. E9–6273 Filed 3–24–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0081; FRL–8404–4]

Thymol; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of thymol (as present in thyme oil) in or on food commodities when applied/used in/on public eating places, dairy processing equipment, and/or food processing equipment and utensils. Sensible Life Products submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of thymol.

DATES: This regulation is effective March 25, 2009. Objections and requests for hearings must be received on or before May 26, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0081. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Mark Hartman, Antimicrobials Division (7510P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0734; *hartman.mark@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person