

Surface Water Screening Models. Presentation to the FIFRA SAP, May 27, 1999.

6. US EPA. Office of Pesticide Programs. 1997. Standard Operating Procedures (SOPs) for Residential Exposure Assessments (Draft December 19, 1997).

7. US EPA Office of Pesticide Programs. 2001. Science Advisory Council for Exposure (ExpoSAC) Policy 12: Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessments. February 2001.

8. US EPA Office of Pesticide Programs. 2002a. ExpoSAC Policy 13: Postapplication Exposure Assessment for Children from Pet Treatments. January 2002.

9. US EPA Office of Pesticide Programs. 2002b. Office of Pesticide Programs' Policy on the Determination of the Appropriate FQPA Safety Factor(s) for Use in Tolerance Assessment. Available at <http://www.epa.gov/oppfead1/trac/science/determ.pdf>.

10. US EPA Office of Pesticide Programs. 2002c. Carbaryl: Updated Toxicology Chapter for RED. May 24, 2002. See docket ID EPA-HQ-OPP-2002-0138.

11. US EPA Office of Pesticide Programs. 2000b. The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorous and Carbamate Pesticides (August 18, 2000).

12. US EPA. Office of Research and Development. 2000. Benchmark Dose Technical Guidance Document. Draft report. Risk Assessment Forum, Office of Research and Development, U.S. Environmental Protection Agency. Washington, DC. EPA/630/R-00/001.

13. FIFRA Science Advisory Panel. 2002. Methods Used to Conduct a Preliminary Cumulative Risk Assessment for Organophosphate Pesticides. Final Report from the FIFRA Scientific Advisory Panel Meeting of February 5-7, 2002 (Report dated March 19, 2002). FIFRA Scientific Advisory Panel, Office of Science Coordination and Policy, Office of Prevention, Pesticides and Toxic Substances, U.S. Environmental Protection Agency. Washington, DC. SAP Report 2002-01.

14. FIFRA Science Advisory Panel. 2005a. Final report on N-Methyl Carbamate Cumulative Risk Assessment: Pilot Cumulative Analysis. Final Report from the FIFRA Scientific Advisory Panel Meeting of February, 2005 (Report dated September 2, 1998). Available at: <http://www.epa.gov/scipoly/sap/2005/february/minutes.pdf>.

15. FIFRA Science Advisory Panel. 2005b. Final report on Preliminary N-

Methyl Carbamate Cumulative Risk Assessment. Final Report from the FIFRA Scientific Advisory Panel Meeting of July 29-30, 2005 (Report dated September -, 2005). Available at: <http://www.epa.gov/scipoly/sap/2005/august/minutes.pdf>.

16. US EPA Office of Pesticide Programs. 2004. Interim Reregistration Eligibility Decision for Carbaryl. (October 22, 2004).

17. US EPA Office of Pesticide Programs. March 9, 2005 letter to Peg Cherney, Bayer Crop Science, Final Cancellation Order for Carbaryl Liquid Broadcast Application to Lawns/Turf; EPA Registration Numbers 264-324, 264-325, and 264-328.

18. US EPA Office of Pesticide Programs. 2007. Office of Prevention, Pesticides and Toxic Substances, EPA, Reregistration Eligibility Decision for Carbaryl (September 24, 2007).

19. BayerCropScience, Comments of BayerCropScience on the Petition to Revoke or Modify Tolerances Established for Carbaryl. May 31, 2005.

20. US EPA Office of Pesticide Programs. 2007. Carbaryl Refined Drinking Water Time Series Simulations Using Regional PCAs (March 13, 2007).

21. UP3 2007. Pesticides in Urban Surface Water. Urban Uses Trends Annual Report, available at http://www.up3project.org/documents/Final_UP3_Use_Report_2007.pdf.

22. USEPA Office of Pesticide Programs. Report of the FIFRA SAP Meeting held April 30 to May 1, 2002. A Set of Scientific Issues Being Considered by the EPA regarding CARES model review. June 13, 2002. EPA SAP 2002-02.

23. US EPA. Office of Research and Development. 2007. Report on Comparative Cholinesterase Study of Carbaryl May 7, 2007).

24. US EPA Office of Pesticide Programs. 2007. Carbaryl: Updated Endpoint Selection for Single Chemical Risk Assessment (June 29, 2007).

25. Padilla S, Setzer W, Marshall RS, et al. 2007. Time Course of cholinesterase inhibition in adult rats treated acutely with carbaryl, carbofuran, formetanate, methomyl, methiocarb, oxamyl, or propoxur. *Toxicology and Applied Pharmacology* 219: 202-209.

26. US EPA Office of Pesticide Programs. 2007. Carbaryl: Review of in vitro Dermal Absorption Study (MRID 47151902). June 28, 2007.

27. US EPA Office of Pesticide Programs. 2007. Carbaryl: Revisions to Residential Exposure and Risk Assessment. June 29, 2007.

28. US EPA Office of Pesticide Programs. 1999. Overview of Issues

Related to the Standard Operating Procedures for Residential Exposure Assessment. Presented to the FIFRA SAP on September 21, 1999.

29. US EPA Office of Pesticide Programs. 2007. Revised N-methyl Carbamate Cumulative Risk Assessment. September 24, 2007. (EPA-HQ-OPP-2007-0935-0003).

30. Freeman, N. C. G., Jimenez, M., Reed, K. J., Gurunathan, S., Edwards, R. D., & Liou, P. J. 2001. Quantitative Analysis of Children's Microactivity Patterns: The Minnesota Children's Pesticide Exposure Study. *Journal of Exposure Analysis and Environmental Epidemiology*. 11(6): 501-509.

31. Geno PW, Camann DE, Harding, HJ, Villalobos K, Lewis RG. 1995. Handwipe Sampling and Analysis Procedure for the Measurement of Dermal Contact with Pesticides. *Arch Environ Contam Toxicol*. 30:132-138.

32. Fenske R. and C. Lu. 1994. Determination of Handwash Removal Efficiency: Incomplete Removal of the Pesticide Chlorpyrifos from Skin by Standard Handwash Techniques. *American Industrial Hygiene Association Journal*. 55(5): 425-432.

33. Wester RC, and Maibach HI. 1989. Dermal Decontamination and Percutaneous Absorption. In: *Percutaneous Absorption*. 2nd ed. R. Bronaugh and H.I. Maibach, editors. New York: Marcel Dekker, pp 335-342.

List of Subjects in 40 CFR Part 180

Environmental protection, Carbaryl, Pesticides and pest.

Dated: September 30, 2008.

Debra Edwards,

Director, Office of Pesticide Programs.

[FR Doc. E8-25693 Filed 10-28-08; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0609; FRL-8384-7]

Pyrimethanil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the tolerances in the 40 CFR 180.518 for residues of the fungicide, pyrimethanil, 4,6-dimethyl-N-phenyl-2-pyrimidinamine, in or on pome fruit crop group 11, establishes tolerances for the residues of pyrimethanil in or on apple wet pomace, and amends the tolerances for residues of pyrimethanil

and its metabolites in or on milk, kidney of cattle, goat, horse and sheep. Pace International, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 29, 2008. Objections and requests for hearings must be received on or before December 29, 2008, 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-2008-0609. 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: Tamue L. Gibson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-9096; e-mail address: gibson.tamue@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 pilot e-CFR site 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-2008-0609 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 December 29, 2008.

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-2008-0609, 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 August 13, 2008 (73 FR 47164) (FRL-8377-9), 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 7F7250) by Pace International, LLC, 5661 Branch Road, Wapato, WA 98951. The petition requested that 40 CFR 180.518 be amended by increasing tolerances for residues of the fungicide pyrimethanil, 4,6-dimethyl-N-phenyl-2-pyrimidinamine, in or on pome fruit crop group, namely apples, crabapple, loquat, mayhaw, pear, including oriental pear, and quince to 14 parts per million (ppm), and pome fruit wet pomace to 56 ppm. The petitioner also proposed to increase the tolerances for the combined residues of the fungicide pyrimethanil, [4,6-dimethyl-N-phenyl-2-pyrimidinamine] and its metabolite 4-[4,6-dimethyl-2-(pyrimidinyl)amino]phenol in or on kidney of cattle, goat, horse, and sheep to 0.6 ppm, and to increase the tolerances for the combined residues of the fungicide pyrimethanil, 4, 6-dimethyl-N-phenyl-2-pyrimidinamine and its metabolite 4,6-dimethyl-2-(phenylamino)-5-pyrimidinol in milk to 0.06 ppm. That notice referenced a summary of the petition prepared by Pace International, LLC, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA’s response to these comments is discussed in Unit IV.C.

Pace International is seeking a tolerance increase for pyrimethanil to support the use of thermofogging as a viable method of application. It is generally recognized that thermofogging may result in variable residues dependent on a wide range of factors, and field studies on apples have demonstrated residue levels of pyrimethanil up to 9.47 ppm, which is greater than the existing pome fruit tolerance.

Based upon review of the data supporting the petition, EPA is establishing a lower tolerance for pome

fruit wet pomace and milk and a higher tolerance for kidney of cattle, goat, horse, and sheep than were proposed. The reason for these changes is 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 increased tolerances for residues of the fungicide pyrimethanil, 4,6-dimethyl-*N*-phenyl-2-pyrimidinamine, in or on pome fruit group 11 at 14 ppm, apple, wet pomace at 40 ppm, cattle, goat, horse and sheep, kidney at 2.5 ppm and milk at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Pyrimethanil is of low acute toxicity by the oral, inhalation, and dermal routes. It is slightly irritating to the eyes and non-irritating to the skin in rabbit studies. Pyrimethanil is not a dermal sensitizer. Subchronic and chronic

repeated oral toxicity studies in rats, mice, and dogs primarily resulted in decreased body weight and body-weight gains, often accompanied by decreased food consumption. The major target organs in rats and mice were the liver and thyroid. In subchronic studies in rats and mice, liver toxicity was manifested as increased absolute and relative body weights. Histopathological changes in the liver were primarily associated with increased evidence of hypertrophy in centrilobular hepatocytes. In a subchronic toxicity study in mice, increases in absolute thyroid weight were observed, associated with exfoliative necrosis and pigmentation of follicular cells. In a subchronic toxicity study in rats, thyroid effects were manifested as an increased incidence and severity of follicular epithelial hypertrophy and follicular epithelial brown pigment. There was no quantitative or qualitative evidence of increased susceptibility following prenatal exposure (in rats and rabbits), or postnatal exposure (in rats). There were no effects on fertility or reproduction in the 2-generation reproduction study in rats.

No signs of neurotoxicity were evident at doses up to 392 milligrams/kilograms/day (mg/kg/day) in the subchronic neurotoxicity study in rats. No evidence of neuropathology was seen in neurotoxicity studies, subchronic or chronic studies in mice, rats, and dogs.

In a carcinogenicity study in mice, there was no increase in the incidence of any tumor types in either sex. In a carcinogenicity study in rats, the thyroid was the only tissue showing a higher incidence of tumors than those seen in the control group. In this study, benign follicular cell adenomas were seen in both sexes. A pair-wise comparison of the incidence in the high-dose treated males was not statistically significant when compared to the control group, while the high-dose females were determined to be statistically significant. EPA classified pyrimethanil as a Group C- possible human carcinogen; EPA is using a threshold or MOE approach to estimate cancer risk to humans based on its conclusion that the thyroid tumors associated with administration of pyrimethanil in Sprague-Dawley rats are likely to be due to a disruption in the thyroid-pituitary status. The mode of action for thyroid carcinogens such as pyrimethanil is a threshold effect that is well understood by the Agency. There is no concern for mutagenicity resulting from exposures to pyrimethanil.

In a 90-day oral toxicity study with rats, a slight decrease in thymus weight

was observed at 529 mg/kg/day (highest dose tested; (HDT)). There were no histopathological findings noted in the thymus. There were no effects on the thymus in the chronic carcinogenicity study in rats at doses up to and including 221 mg/kg/day HDT. Therefore, decreases in thymus weight in the 90-day study are considered equivocal and not a trigger for immunotoxicity study.

Specific information on the studies received and the nature of the adverse effects caused by pyrimethanil, [4,6-dimethyl-*N*-phenyl-2-pyrimidinamine] 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 *Pyrimethanil. Application for Amended Section 3 Registration of Xedathane A for Postharvest Use on Pome Fruits by Thermafog Application. Human-Health Risk Assessment*, page 17 in docket ID number EPA-HQ-OPP-2008-0609.

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 no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (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-term, 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 pyrimethanil used for human risk assessment can be found at <http://www.regulations.gov> in document *Pyrimethanil. Application for Amended Section 3 Registration of Xedathane A for Postharvest Use on Pome Fruits by Thermafog Application*, page 17 in docket ID number EPA-HQ-OPP-2008-0609.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyrimethanil, EPA considered exposure under the petitioned-for tolerances as well as all existing pyrimethanil tolerances in (40 CFR 180.518). EPA assessed dietary exposures from pyrimethanil 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 Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance-level residues, 100% crop treated (PCT), default processing factors as necessary, and empirical processing factors for orange and apple juice.

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 assumed tolerance-level residues, 100 PCT, default processing factors as necessary, and empirical processing factors for orange and apple juice.

iii. *Cancer.* The Agency has classified pyrimethanil as a Group C carcinogen based on thyroid follicular cell tumors in both sexes of the 2-year rat study. A non-linear approach was used to assess cancer risk using 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 residues and PCT information in the dietary assessment for pyrimethanil. Tolerance level residues and 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 pyrimethanil in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyrimethanil. 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 drinking water concentrations (EDWCs) of pyrimethanil and its major metabolite (2-amino-4,6-dimethylpyrimidine) for acute exposures are estimated to be 37.8 parts per billion (ppb) for surface water and 4.8 ppb for ground water and for chronic exposures are estimated to be 5.1 ppb for surface water and 4.8 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 37.8 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 5.1 ppb was used to assess 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).

Pyrimethanil is not registered for any specific use patterns that would result in residential exposure.

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.”

EPA has not found pyrimethanil to share a common mechanism of toxicity with any other substances, and pyrimethanil does not appear to

produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyrimethanil does not have 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 EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

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.* Based on the results in developmental toxicity studies in rats and rabbits, there is no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure to pyrimethanil. There were no effects on fertility or reproduction in the 2-generation reproduction study in rats. In a 90-day oral toxicity study with rats, a slight decrease in thymus weight was observed at 529 mg/kg/day HDT. There were no histopathological findings noted in the thymus. There were no effects on thymus in the chronic carcinogenicity study in rats at doses up to and including 221 mg/kg/day HDT. Therefore, decreases in thymus weight in the 90-day study are considered equivocal and not a trigger for an immunotoxicity study. Since an immunotoxicity study is now a data requirement in the revised 40 CFR part 158, it will be required as a condition of registration. However, a database uncertainty factor is not warranted since the effects (decreased thymus weight) were seen only in the 90-day study and not in a chronic study and the decrease in thymus weight was not associated with any histopathological finding. In addition, the current NOAEL of 17 mg/kg/day selected for cRFD would be protective of any potential immunotoxicity seen at a dose level of 529 mg/kg/day.

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

i. The toxicity database for pyrimethanil is adequate. EPA classified the submitted subchronic neurotoxicity study as unacceptable because it was not conducted at doses up to 1,000 mg/kg/day (limit-dose). Nonetheless, EPA determined that no additional data is needed on neurotoxicity because, given that no signs of neurotoxicity were evident at doses up to 392 mg/kg/day in the subchronic neurotoxicity study in rats and no evidence of neuropathology was seen in neurotoxicity studies, subchronic or chronic studies in mice, rats, and dogs, the results of a repeat study are not likely to impact the current endpoints used for risk assessment. EPA began requiring functional immunotoxicity testing (series 870.7800) of all food and non-food use pesticides on December 26, 2007. These studies are not yet available for pyrimethanil. In the absence of specific immunotoxicity studies, EPA has evaluated the available toxicity data for pyrimethanil and determined that an additional database uncertainty factor is not needed to account for potential immunotoxicity. In a 90-day oral toxicity study with rats, a slight decrease in thymus weight was observed at 529 mg/kg/day HDT. There were no histopathological findings noted in the thymus and a NOAEL of 54.5 mg/kg/day was established. There were no effects on thymus in the chronic carcinogenicity study in rats at doses up to and including 221 mg/kg/day HDT. Therefore, decreases in thymus weight in the 90-day study are considered equivocal and not a trigger for an immunotoxicity study. Since an immunotoxicity study is now a data requirement in the revised 40 CFR part 158, it will be required as a condition of registration. However, a database uncertainty factor is not warranted since the effects (decreased thymus weight) were seen only in the 90-day study and not in a chronic study, the effects were only seen at a relatively high dose, and the decrease in thymus weight was not associated with any histopathological finding.

ii. Based on the weight of evidence, a developmental neurotoxicity study is not required for pyrimethanil since there is no evidence of neuropathology and no neurotoxic signs up to 392 mg/kg/day in a subchronic neurotoxicity study in rats where the only evidence of neurotoxicity occurs after an acute dose level (1,000 mg/kg) much higher than

the doses used to establish endpoints for risk assessment.

iii. There is no evidence that pyrimethanil results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessment utilizes tolerance-level residues and 100 PCT for all proposed/established commodities. By using these assumptions, the acute and chronic exposures/risks will not be underestimated. The dietary drinking water assessment utilizes water concentration values generated by models and associated modeling parameters which are designed to provide conservative, health-protective, high-end estimates of water concentrations which will not likely be exceeded. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyrimethanil in drinking water.

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.

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 pyrimethanil will occupy 33% 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 pyrimethanil from food and water will utilize 59% of the cPAD for (children 1-2 years old) the population group receiving the greatest

exposure and 12% of the aPAD for the U.S. population as a whole. There are no residential uses for pyrimethanil.

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). Pyrimethanil is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to pyrimethanil through food and water and will not be greater than the chronic aggregate risk.

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).

Pyrimethanil is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to pyrimethanil through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* A separate cancer dietary assessment was not conducted for pyrimethanil as the chronic assessment is considered protective for carcinogenic effects. Based upon chronic food plus water exposure of the general U.S. population, the MOE for cancer assessment is 830. For threshold cancer effects where the mode of action is well understood, like thyroid carcinogens such as pyrimethanil, the MOE that indicates a reasonable certainty of no harm would be 100 or greater (representing 2 factors of 10 for inter-species and intra-species extrapolation). Therefore, the aggregate cancer risk does not exceed the Agency's level of concern.

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 pyrimethanil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, high performance liquid chromatography and liquid chromatography-mass spectrometry (HPLC and LC-MS/MS) are available to enforce the tolerance expression. The method may be required from: Chief, Analytical Chemistry Branch,

Environmental Science Center, 701 Mapes Rd., Ft. Mead, MD 20755-5350; telephone number: (410) 305-2905; e-mail address; residuemethods@epa.gov.

B. International Residue Limits

Codex maximum residue limits (MRLs) have been established for pyrimethanil *per se* in or on plant commodities. Codex MRLs have also been established for milk in terms of the sum of pyrimethanil and 2-anilino-4,6-dimethylpyrimidin-5-ol, expressed as pyrimethanil, and for livestock tissues (excluding poultry) as the sum of pyrimethanil and 2-(4-hydroxyanilino)-4,6-dimethylpyrimidine, expressed as pyrimethanil. Codex MRLs are listed for pome fruit at 7 ppm (postharvest), milk at 0.05 ppm, dry apple pomace at 40 ppm, and edible offal at 0.1 ppm. Except for apple pomace and milk, harmonization is not feasible at this time, presumably due to differences in good agricultural practices.

A Canadian MRL for pome fruit is established at 3 ppm. There are no Mexican MRLs established for residues of pyrimethanil on the crops associated with this tolerance petition.

C. Response to Comments

One comment was received from an anonymous commenter objecting to increasing the tolerances. The comments contained no scientific data or evidence to rebut the Agency's conclusions that there is reasonable certainty that no harm will result from aggregate exposure to pyrimethanil.

D. Revisions to Petitioned-For Tolerances

Based upon review of the dietary exposure levels and the residue data from an available ruminant feeding study, the existing pyrimethanil tolerances have been reassessed and the Agency has determined that the tolerances for residues in cattle, goat, horse, and sheep kidney should be increased to 2.5 ppm and the tolerance for residues in milk should be lowered to 0.05 ppm. Additionally, the apple, wet pomace residue tolerance should be lowered to 40 ppm.

V. Conclusion

Therefore, tolerances are amended to increase the residues of the fungicide, pyrimethanil, 4,6-dimethyl-N-phenyl-2-pyrimidinamine, in or on pome fruit group 11 at 14 ppm, apple, wet pomace at 40 ppm, cattle, goat, horse and sheep, kidney at 2.5 ppm and milk at 0.05 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: October 9, 2008.

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 180.518 is amended by revising the following entries in the table in paragraphs (a)(1), (a)(2), and (a)(3) to read as follows:

§ 180.518 Pyrimethanil; tolerances for residues.

(a) * * *
(1) * * *

Commodity	Parts per million
* * *	* *
Apple, wet pomace	40
* * *	* *
Fruit, pome, group 11 (pre-harvest and post-harvest)	14
* * *	* *

(2) * * *

Commodity	Parts per million
* * *	* *
Cattle, kidney	2.5
* * *	* *
Goat, kidney	2.5
* * *	* *
Horse, kidney	2.5
* * *	* *
Sheep, kidney	2.5
* * *	* *

(3) * * *

Commodity	Parts per million
Milk	0.05
* * * * *	

[FR Doc. E8-25676 Filed 10-28-08; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 271 and 272

[EPA-R06-RCRA-2008-0144; FRL-8727-3]

Texas: Final Authorization of State-Initiated Changes and Incorporation by Reference of State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: During a review of Texas' regulations, the EPA identified a variety of State-initiated changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). We have determined that these changes are minor and satisfy all requirements needed to qualify for Final authorization and are authorizing the State-initiated changes through this Immediate Final action. In addition, today's document corrects technical errors made in the August 18, 1999 and June 14, 2005 **Federal Register** authorization documents for Texas.

The Solid Waste Disposal Act, as amended, commonly referred to as the Resource Conservation and Recovery Act (RCRA), allows the Environmental Protection Agency (EPA) to authorize States to operate their hazardous waste management programs in lieu of the Federal program. The EPA uses the regulations entitled "Approved State Hazardous Waste Management Programs" to provide notice of the authorization status of State programs and to incorporate by reference those provisions of the State statutes and regulations that will be subject to the

EPA's inspection and enforcement. The rule codifies in the regulations the prior approval of Texas' hazardous waste management program and incorporates by reference authorized provisions of the State's statutes and regulations.

DATES: This regulation is effective December 29, 2008, unless the EPA receives adverse written comment on the codification of the Texas authorized RCRA program by the close of business November 28, 2008. If the EPA receives such comments, it will publish a timely withdrawal of this immediate final rule in the **Federal Register** informing the public that this rule will not take effect. The incorporation by reference of authorized provisions in the Texas statutes and regulations contained in this rule is approved by the Director of the Federal Register as of December 29, 2008 in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R06-RCRA-2008-0144 by one of the following methods:

1. *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.
2. *E-mail:* patterson.alima@epa.gov or Banks.Julia@epa.gov.
3. *Mail:* Alima Patterson, Region 6, Regional Authorization Coordinator, or Julia Banks, Codification Coordinator, State/Tribal Oversight Section (6PD-O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733.
4. *Hand Delivery or Courier:* Deliver your comments to Alima Patterson, Region 6, Regional Authorization Coordinator, or Julia Banks, Codification Coordinator, State/Tribal Oversight Section (6PD-O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733.

Instructions: Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov>, or e-mail. The Federal <http://www.regulations.gov> Web site is an "anonymous access" system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to the EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your

name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. You can view and copy the documents that form the basis for this authorization and codification and associated publicly available materials from 8:30 a.m. to 4 p.m. Monday through Friday at the following location: EPA, Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733, phone number (214) 665-6444. Interested persons wanting to examine these documents should make an appointment with the office at least two weeks in advance.

FOR FURTHER INFORMATION CONTACT:

Alima Patterson, Region 6 Regional Authorization Coordinator, or Julia Banks, Codification Coordinator, State/Tribal Oversight Section (6PD-O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733, Phone number: (214) 665-8533, and e-mail address patterson.alima@epa.gov or Banks.Julia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Authorization of State-Initiated Changes

A. Why are Revisions to State Programs Necessary?

States which have received Final authorization from the EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal hazardous waste program. As the Federal program changes, the States must change their programs and ask the EPA to authorize the changes. Changes to State hazardous waste programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to the EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 268, 270, 273 and 279. States can also initiate their own changes to their hazardous waste program and these changes must then be authorized.

B. What Decisions Have We Made in This Rule?

We conclude that Texas' revisions to its authorized program meet all of the