(NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective September 27, 2004.

K. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 25, 2004. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: August 3, 2004.

Wayne Nastri,

Regional Administrator, Region IX.

■ Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(316)(i)(F) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(316) * * *

(i) * * *

(F) Antelope Valley Air Quality Management District.

(*1*) Rule 1113, adopted on March 18, 2003.

* * * * *

[FR Doc. 04–19523 Filed 8–25–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0195; FRL–7371–2]

Pyrimethanil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances as follows: For residues of pyrimethanil, 4,6-dimethyl-*N*-phenyl-2-pyrimidinamine, in or on almond; almond, hulls; apple, wet pomace; banana; citrus oil; fruit, citrus, group 10 (post-harvest); fruit, pome, group 11 (pre-harvest and post-harvest); fruit, stone (except cherry), group 12; grape; grape, raisin; onion, dry bulb; onion, green; pistachio; strawberry; tomato; and vegetable, tuberous and corm, subgroup 1C; for residues of pyrimethanil and its metabolite, 4-[4,6-dimethyl-2-pyrimidinyl)amino]phenol in or on cattle, fat; cattle, kidney; cattle, meat; cattle meat-by-products (except kidney); goat, fat; goat, kidney; goat, meat; goat meat-by-products (except kidney); horse, fat; horse, kidney; horse, meat; horse, meat-by-products (except kidney); sheep, fat; sheep, kidney; sheep, meat; and sheep, meat-by-products (except kidney); and for residues of pyrimethanil and its metabolite 4,6-dimethyl-2-(phenylamino)-5-pyrimidinol in milk. Bayer Crop Science and Janssen Pharmaceutica, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 26, 2004. Objections and requests for hearings must be received on or before October 25, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket ID number OPP–2004–0195. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9354; e-mail address: *waller.mary@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 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers;

greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.

• Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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. 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 and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of February 14, 2003 (68 FR 7548) (FRL–7289–1), and March 5, 2003 (68 FR 10458) (FRL–7291–2), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 2F6480, 2F6439, and 9E6054) by Janssen Pharmaceutica Inc., Plant and Material Protection Division, 1125 Trenton-Harbouton Road, Titusville, NJ 08560, and Bayer Crop Science, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. These notices included a summary of the petitions prepared by Janseen Pharmaceutica Inc., and Bayer Crop Science, the registrants. There were no comments received in response to these notices of filing.

The petitions requested that 40 CFR 180.518 be amended by establishing tolerances for residues of the fungicide pyrimethanil, 4,6-dimethyl-*N*-phenyl-2-pyrimidinamine, in or on citrus fruits (calamondin, citrus citron, citrus hybrids, grapefruit, kumquat, lemon, lime, mandarin, sour and sweet oranges, pummelo and satsuma mandarin) at 6 parts per million (ppm); pome fruit (apples, pears, oriental pears, crabapples, loquats, mayhaws, and quince) wet pomace at 12 ppm; and pome fruit (apples, pears, oriental pears, crabapples, loquats, mayhaws, and quince) at 3 ppm 2F6480; tree nut, nutmeat, group at 0.25 ppm; tree nut, hulls, group at 12 ppm; fruit, pome, group at 0.20 ppm; apple, wet pomace at 0.75 ppm; fruit, stone, group at 3.0 ppm; grape at 3.0 ppm; grape, dry pomace at 20 ppm,; grape, wet pomace at 7.0 ppm; grape, raisen waste at 50 ppm; grape, raisin at 5.0 ppm; vegetable, bulb, group at 2.0 ppm; vegetable, tuberous and corm, subgroup at 0.05 ppm; strawberry at 3.0 ppm; tomato at 0.50 ppm; wheat, rotational at 0.05 ppm; cattle, meat at 0.1 ppm; cattle, meat-by-products at 0.1 ppm; and milk at 0.03 ppm 2F6439;, and banana at 0.10 ppm 9E6054.

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. * * *''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances November 26, 1997 (62 FR 62961) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for tolerances as follows: (1) For residues of pyrimethanil on almond at 0.20 ppm; almond, hulls at 12 ppm; apple, wet pomace at 12 ppm; banana at 0.10 ppm; citrus oil at 150 ppm; fruit, citrus, group 10 (post-harvest) at 10 ppm; fruit, pome, group 11 (pre-harvest and post-harvest) at 3.0 ppm; fruit, stone (except cherry), group 12 at 3.0 ppm; grape at 5.0 ppm; grape, raisin at 8.0 ppm; onion, dry bulb at 0.10 ppm; onion, green at 2.0 ppm; pistachio at 0.20 ppm; strawberry at 3.0 ppm; tomato at 0.50 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.05 ppm; (2) for residues of pyrimethanil and its metabolite, 4-[4,6-dimethyl-2-pyrimidinyl)amino]phenol on cattle, fat at 0.01 ppm; cattle, kidney at 0.30 ppm; cattle, meat at 0.01 ppm; cattle, meat-by-products (except kidney) at 0.01 ppm; goat, fat at 0.01 ppm; goat, kidney at 0.30 ppm; goat, meat at 0.01 ppm; goat, meat-by-products (except kidney) at 0.01 ppm; horse, fat at 0.01 ppm; horse, kidney at 0.30 ppm; horse, meat at 0.01 ppm; horse, meat-by-products (except kidney) at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, kidney at 0.30 ppm; sheep, meat at 0.01 ppm; and sheep, meat-by-products (except kidney) at 0.01 ppm; and (3) for residues of pyrimethanil and its metabolite, 4,[6-dimethyl-2-(phenyl]amino)-5-pyrimidinol in milk at 0.03 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by pyrimethanil are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity-rodents (rat)	NOAEL = 54.5 milligrams/kilogram/day (mg/kg/day) male (M), 66.7 mg/kg/day female (F) LOAEL = 529.1 mg/kg/day M, 625.9 mg/kg/day F decreased body weights (20%), body weight gain (30%), food consumption, brown urine, increased urinary protein; decreased absolute heart, adrenal, spleen, thymus weights; increased relative liver kidney, gonad weights, liver, thyroid hypertrophy
870.3100	90–Day oral toxicity-rodents (mouse)	NOAEL = 139 mg/kg/day M, 203 mg/kg/day F LOAEL = 1,864 mg/kg/day M, 2,545 mg/kg/day F based on decreased body-weight gain (7–12%); increased cholesterol, bilirubin F/M, dark thyroids, increased relative liver weights, kidney, thyroid, bladder histopathology
870.3150	90–Day oral toxicity-non-rodents	NOAEL = 80 mg/kg/day LOAEL = 1,000/800 mg/kg/day based on decreased water consumption, vomiting, diarrhea, salivation, hypoactivity
870.3700	Prenatal developmental-rodents	*Maternal* NOAEL = 85 mg/kg/day *Maternal* LOAEL = 1,000 mg/kg/day based on decreased body weight, and body weight gain *Developmental* NOAEL = 85 mg/kg/day *Developmental* LOAEL = 1,000 mg/kg/day based on decrease in mean litter weight and mean fetal weight
870.3700	Prenatal developmental-nonrodents	*Maternal* NOAEL = 45 mg/kg/day *Maternal* LOAEL = 300 mg/kg/day based on deaths, decreased body weights, body weight gain, food consumption, production and size of fecal pellets *Developmental* NOAEL = 45 mg/kg/day *Developmental* LOAEL = 300 mg/kg/day based on death, decreased body weight, body weight gain, food consumption, production and size of fecal pellets; decreased fetal weight, increased fetal runts, retarded ossification, 13 thoracic vertebrae and pairs of ribs
870.3800	2-Generation reproduction and fertility effects (rats)	*Parental/systemic* NOAEL = 23.1 mg/kg/day M, 27.4 mg/kg/day F *Parental/systemic* LOAEL = 294 mg/kg/day M, 343 mg/kg/day F based on decreased body weight (11–13%), and body weight gain (11–17%) *Reproductive* NOAEL = 294/343 mg/kg/day *Reproductive* *Offspring* NOAEL = 23.1 mg/kg/day M, 27.4 mg/kg/day F *Offspring* LOAEL = 294 mg/kg/day based on decreased pup body weights on PND 21
870.4100	Chronic toxicity - dogs	NOAEL = 30 mg/kg/day LOAEL = 250 mg/kg/day based on decreased body weight, food and water consumption, food efficiency, increased neutrophils, decreased clotting time
870.4200	Carcinogenicity mice	NOAEL = 210.9 mg/kg/day M, 253.8 mg/kg/day F No toxicologically significant effects were found
870.4300	Combined Chronic/carcinogenicity (rats)	NOAEL = 17 mg/kg/day M, 22 mg/kg/day F LOAEL = 221 mg/kg/day M, 291 mg/kg/day F based on decreased body-weight gain (5–15% M, 15–45% F) 10–15% at 6 months; increased serum cholesterol, gamma glutamyl transferase, relative liver weights; liver, thyroid histopathology increased thyroid adenomas
870.5100	Gene mutation	There was no evidence of induced mutant colonies over background
870.5300	Cytogenetics	There was no clear evidence of biologically significant induction of mutant colonies over background
870.5375	Chromosome aberration	There was no evidence of chromosome aberrations induced over background

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.5395	Mammalian erythrocyte micronucleus test in mice	There was no statistically significant increase in the frequency of micronucleated polychromatic erythrocytes in mouse bone marrow at any dose or harvest time
870.5550	Unscheduled DNA synthesis in mammalian culture	Negative in inducing unscheduled DNA synthesis in rat hepatocytes as a result of *in vivo* gastric intubation
870.6200	Acute neurotoxicity screening battery (rat)	NOAEL = 100 mg/kg/day M, 100 mg/kg/day F LOAEL = 1,000 mg/kg/day M, 1,000 mg/kg/day F based on decreased motor activity, ataxia, and decreased body temperature in both sexes, decreased hind limb grip strength in males, and increased dilated pupils in females on Day 1
870.6200	Subchronic neurotoxicity screening battery (rat)	NOAEL = 44.3 mg/kg/day F LOAEL = 429.9 mg/kg/day F, greater than 391.9 mg/kg/day M based on decreased body weight (8%), body weight gain (21%), food consumpton (9–15%) F. No effects in males

B. Toxicological Endpoints

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

Three other types of safety or UFs may be used: ''Traditional UF'' the ''special FQPA safety factor; '' and the ''default FQPA safety factor.'' By the term ''traditional UF'' EPA is referring to those additional UFs used prior to FQPA passage to account for data base deficiencies. These traditional UFs have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional UF or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional UFs deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for pyrimethanil used for human risk assessment is shown in the following Table 2.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYRIMETHANIL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-50 years of age)	NOAEL = 45 mg/kg/day UF = 100 Acute RfD = 0.45 mg/kg/day	Special FQPA SF = 1 aPAD = aRfD ÷ Special FQPA SF = 0.45 mg/kg/day	Developmental toxicity - rabbit LOAEL = 300 mg/kg/day based on increased in fetuses with 13 thoracic vertebrae and 13 pairs of ribs

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYRIMETHANIL FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (general population including infants and children)	NOAEL = 100 mg/kg/day UF = 100 aRfD = 1 mg/kg/day	Special FQPA SF = 1 aPAD = aRfD ÷ Special FQPA SF = 1 mg/kg/day	Acute neurotoxicity - rat LOAEL = 1,000 mg/kg/day based on decreased motor activity, ataxia, decreased body temperature, hind lim grip strength, and dilated pupils
Chronic dietary (All populations)	NOAEL= 17 mg/kg/day UF = 100 Chronic RfD = 0.17 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD ÷ Special FQPA SF = 0.17 mg/kg/day	Chronic toxicity - rat LOAEL = 221 mg/kg/day based on decreased body-weight gains, increased serum cholesterol and GGT, increased relative liver/body-weight ratios, necropsy and histopathological findings in the liver and thyroid
Cancer (oral, dermal, inhalation)			Pyrimethanil was classified as a Group C carcinogen based on thyroid follicular cell tumors in both sexes of the 2–year rat study (NOAEL = 17 mg/kg/day). The Agency's Cancer Peer Review Committee recommended a threshold or Margin of Exposure (MOE) approach because the thyroid tumors associated with administration of pyrimethanil in Sprague-Dawley rats may be due to a disruption in the thyroid-pituitary status.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.518) for the residues of pyrimethanil, in or on imported wine grapes. Risk assessments were conducted by EPA to assess dietary exposures from pyrimethanil plus the metabolites, 4-[4,6-dimethyl-2-pyrimidinyl)amino]phenol and 4,6-dimethyl-2-(phenylamino)-5-pyrimidinol, in food as follows:

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

In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM™-FCID), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: The acute analysis assumed tolerance level residues, 100% crop treated, and DEEM™ (ver. 7.76) default processing factors for all proposed commodities. Percent crop treated (PCT) data and anticipated residues were not used.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the DEEM software with the FCID, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic analyses assumed tolerance level residues for ruminant tissues and milk and was refined through the use of average crop field trial residues for all crops. Conservative projected PCT estimates were used.

iii. *Cancer.* In conducting the cancer dietary risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The cancer risk assessment used the MOE methodology (MOE equals NOAEL (17 mg/kg/day) divided by chronic exposure). The following assumptions were made for the cancer exposure assessment: The cancer analyses assumed tolerance level residues for ruminant tissues and milk and was refined through the use of average crop field trial residues for all crops. Conservative projected percent crop treated estimates were used.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of FFDCA, EPA will issue a Data-Call-In for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to

contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group, and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used projected PCT (PPCT) information for the following crops: almonds, apples (field use), grapes, onions, pear (field use), peach/stone fruit, potatoes, strawberries, tomatoes, post harvest pome fruit, and post-havest citrus. A 100% crop treated estimate was assumed for bananas, tuberous and corm vegetables (excluding potatoes), milk, meat and meat-by-products. These PPCT values are based on projected market share information. The registrants provided the Agency with their anticipated market share projections. The Agency estimated market share projections by comparing the efficacy spectrum of the registered alternatives to the efficacy spectrum of pyrimethanil. In conducting its risk assessment, the Agency utilized EPA-derived estimates. As to Condition 1, the Agency believes that this approach is conservative and will overestimate the potential risk. To further ensure the reliability of these data, as a condition of registration, the registrant will be required to provide annual reports on the market penetration and market share of pyrimethanil for each of the registered crops. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which pyrimethanil may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for pyrimethanil and its major metabolite, 2-amino-4,6-dimethylpyrimidine in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of pyrimethanil and 2-amino-4,6-dimethylpyrimidine. Pyrimethanil is expected to have low mobility in the environment, and 2-amino-4,6,-dimethylpyrimidine is expected to be moderately mobile and more persistent in the environment.

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

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a percent referance dose (%RfD) or percent population adjusted dose (%PAD). Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to pyrimethanil and 2-amino-4,6-dimethylpyrimidine they are further discussed in the aggregate risk sections in Unit III.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of pyrimethanil and 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. The EECs for chronic exposures are estimated to be 5.1 ppb for surface water and 4.8 ppb for ground water. All EECs were adjusted for regional percent cropped area and all EECs were developed using the strawberry use pattern which represents the worst case scenario (highest single and seasonal application rates).

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 use on any sites 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pyrimethanil and 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 not assumed that pyrimethanil has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's OPP concerning

common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety (MOS) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data that a different MOS will be safe for infants and children. MOS are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using UFs (safety) in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. EPA determined that there are no residual concerns for pyrimethanil for prenatal and postnatal toxicologically based on the following:

- There is no evidence of qualitative or quantitative increased susceptibility following prenatal or postnatal exposures.
- There are no concerns or residual uncertainties for prenatal and/or postnatal toxicity following exposure to pyrimethanil.
- Because a decrease in thyroid hormones may cause neurotoxicity in the young exposed prior to birth or early in life, the Agency considered the possible need for a comparative thyroid assay and reviewed the evidence for thyroid toxicity in the data base. The Agency concluded that a comparative thyroid assay in young and adult rats is not required.
- Based on the weight-of-evidence presented, the Agency concluded that a developmental neurotoxicity study is not required for pyrimethanil since there is no evidence of neuropathology and no neurotoxic signs up to 400 mg/kg/day in a subchronic neurotoxicity study in rats; the only evidence of neurotoxicity occurs after an acute dose level (1,000 mg/kg) much higher than those used to establish endpoints for risk assessment (100 mg/kg for acute exposures; approximately 20 mg/kg/day for repeated exposures), the 1,000 mg/kg/day dose is also higher than the doses tested or than those used in the reproduction study, which had a high dose of 343 mg/kg/day.
- The Agency noted, as seen in the CPRC report, that the effects on the thyroid-pituitary status were associated with the large increase in uridine diphosphate glucuronosyl transferases seen in the 14–day dietary rat study. The effects seen in the thyroid and the liver, while treatment-related, are not severe in nature; in each of these studies there is a wide dose spread (approxiamately 10–fold difference between NOAELs and LOAELs) which provides a measure of protection for any potential effects reflecting increased sensitivity or susceptibility in offspring. Additionally, the endpoints selected for risk assessment will cover any concern for thyroid or liver effects seen at higher doses.
- The Agency has a complete database on rat thyroid tumors. The mode of action in thyroid tumors in rats is well understood.

3. *Conclusion*. There is a complete toxicity data base for pyrimethanil and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA factor is removed because of the completeness of the data base and the lack of concern for prenatal and postnatal toxicity. EPA concluded that reliable data shows an additional safety factor of 10X is not needed for the protection of infants and children.

E. Aggregate Risks and Determination of Safety

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

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

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to pyrimethanil plus the metabolites, 4-[4,6-dimethyl-2-pyrimidinyl)amino]phenol and 4,6-dimethyl-2-(phenylamino)-5-pyrimidinol will occupy 10% of the aPAD for the U.S. population, 16% of the aPAD for females 13-49 years old, 15% of the aPAD for all infants less than 1 year old, and 31% of the aPAD for children 1-2 years old. In addition, there is potential for acute dietary exposure to pyrimethanil and 2-amino-4, 6-dimethylpyrimidine in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO PYRIMETHANIL PLUS THE METABOLITES, 4-[4,6-DIMETHYL-2-PYRIMIDINYL)AMINO]PHENOL AND 4,6-DIMETHYL-2-(PHENYLAMINO)-5-PYRIMIDINOL

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
General U.S. population	1	10	37.8	4.8	31,000
All infants less than (1 year old)	1	15	37.8	4.8	8,500
Children (1-2 years old)	1	31	37.8	4.8	6,900
Females (13-49 years old)	0.45	16	37.8	4.8	33,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pyrimethanil plus the metabolites, 4-[4,6-dimethyl-2-pyrimidinyl)amino]phenol and 4,6-dimethyl-2-(phenylamino)-5-pyrimidinol from food will utilize 1% of the cPAD for the U.S. population, 4.5% of the cPAD for all infants less than 1 year old, less than 1% of the cPAD for females 13-49 years old and 5.3% of the cPAD for children 1-2 years old. There are no residential uses for pyrimethanil that result in chronic residential exposure to pyrimethanil. Based on the use pattern, chronic residential exposure to residues of pyrimethanil is not expected. In addition, there is potential for chronic dietary exposure to pyrimethanil and 2-amino-4,6-dimethylpyrimidine in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4.

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO PYRIMETHANIL PLUS THE METABOLITES, 4-[4,6-DIMETHYL-2- PYRIMIDINYL)AMINO]PHENOL AND 4,6-DIMETHYL-2-(PHENYLAMINO)-5- PYRIMIDINOL

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.17	1	5.1	4.8	5,900
All infants less than (1 year old)	0.17	4.5	5.1	4.8	1,600
Females (13-49 years old)	0.17	less than 1	5.1	4.8	5,100
Children (1-2 years)	0.17	5.3	5.1	4.8	1,600

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

Pyrimethanil is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

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

Pyrimethanil is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Pyrimethanil was classified as a Group C chemical (possible human carcinogen) and a non-linear methodology MOE was applied for the estimation of human cancer risk. The chronic dietary food analyses resulted in MOEs for the U.S. population of greater than 9,000. The estimated cancer aggregate MOE for the U.S. population is 9,200.

Generally, for threshold cancer effects where the mode of action is well understood, like thyroid carcinogens such as pyrimethanil, the general margin of exposure that indicates a reasonable certainty of no harm would be 100 (representing 2 factors of 10 for inter-species and intra-species extrapolation). The question of an acceptable MOE for threshold cancer effects is a relatively recent issue; however, given that the MOE here is 9,200, there is no question that this margin demonstrates that there is a reasonable certainty of no harm from cancer effects resulting from exposure to pyrimethanil.

EPA has asked for an additional cancer study in the mouse because even at the highest dose tested there were no adverse effects. Given the dose levels used in the first mouse cancer study, EPA does not expect that even if the second study was positive it would result in a cancer risk estimate any higher than the current risk estimate. For example, the NOAEL and LOAEL from the 2 year combined chronic/carcinogenicity study in rats are 17 mg/kg/day and 221mg/kg/day, respectively. The NOAEL (highest dose tested) from the first mouse cancer study was 210 mg/kg/day which is comparable to the LOAEL of 221 mg/kg/day in rat.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to pyrimethanil plus the metabolites, 4-[4,6-dimethyl-2-pyrimidinyl)amino]phenol and 4,6-dimethyl-2-(phenylamino)-5-pyrimidinol residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies (gas chromatography/mass spectrometry

(GS/MS) and high performance liquid chromatography/ultraviolet (HPLC-UV)) are 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

There are no established or proposed CODEX or Mexican maximum residue limits (MRL). There is an established Canadian MRL for residues on grapes which is consistent with the recommended tolerance for grapes in this rule.

C. Conditions

1. Plantback intervals will be required for all crops other than those with registered uses.
2. Additional clarifying data will be required for Guideline 860.1300 Nature of the Residue - Livestock and 860.1380 Storage Stability.
3. A carcinogenicity study-mice (Guideline 870.4200(b) will be required because the high dose in the existing study was judged to be inadequate for assessing the carcinogenic potential of pyrimethanil.

V. Conclusion

Therefore, tolerances are established (1) for residues of pyrimethanil on almond at 0.20 ppm; almond, hulls at 12 ppm; apple, wet pomace at 12 ppm; banana at 0.10 ppm; citrus oil at 150 ppm; fruit, citrus, group 10 (post-harvest) at 10 ppm; fruit, pome, group 11 (pre-harvest and post-harvest) at 3.0 ppm; fruit, stone (except cherry), group 12 at 3.0 ppm; grape at 5.0 ppm; grape, raisin at 8.0 ppm; onion, dry bulb at 0.10 ppm; onion, green at 2.0 ppm; pistachio at 0.20 ppm; strawberry at 3.0 ppm; tomato at 0.50 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.05 ppm; (2) for residues of pyrimethanil and its metabolite 4-[4,6-dimethyl-2-pyrimidinyl)amino]phenol on cattle, fat at 0.01 ppm; cattle, kidney at 0.30 ppm; cattle, meat at 0.01 ppm; cattle, meat-by-products (except kidney) at 0.01 ppm; goat, fat at 0.01 ppm; goat, kidney at 0.30 ppm; goat, meat at 0.01 ppm; goat, meat-by-products (except kidney) at 0.01 ppm; horse, fat at 0.01 ppm; horse, kidney at 0.30 ppm; horse, meat at 0.01 ppm; horse, meat-by-products (except kidney) at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, kidney at 0.30 ppm; sheep, meat at 0.01 ppm; and sheep, meat-by-products (except kidney) at 0.01 ppm; and (3) for residues of pyrimethanil and its metabolite 4,6-dimethyl-2-(phenylamino)-5-pyrimidinol in milk at 0.03 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0195 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 25, 2004.

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

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0195, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 rule has

been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.''''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: August 13, 2004.

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 adding text to paragraph (a), and by removing paragraph (e). Paragraph (a) reads as follows:

§ 180.518 Pyrimethanil; tolerances for residues.

(a) *General.* (1) Tolerances are established for the residues of the fungicide pyrimethanil 4,6-dimethyl-*N*-phenyl-2-pyrimidinamine in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond	0.20
Almond, hulls	12
Apple, wet pomace	12
Banana	0.10
Citrus oil	150
Fruit, citrus, group 10 (post-harvest)	10
Fruit, pome, group 11 (pre-harvest and post-harvest)	3.0
Fruit, stone (except cherry), group 12	3.0
Grape	5.0
Grape, raisin	8.0
Onion, dry bulb	0.10
Onion, green	2.0
Pistachio	0.20
Strawberry	3.0

Commodity	Parts per million
Tomato	0.50
Vegetable, tuberous and corm, subgroup 1C	0.05

(2) Tolerances are established 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 the following commodities:

Commodity	Parts per million
Cattle, fat	0.01
Cattle, kidney	0.30
Cattle, meat	0.01
Cattle, mbyp (except kidney)	0.01
Goat, fat	0.01
Goat, kidney	0.30
Goat, meat	0.01
Goat, mbyp (except kidney)	0.01
Horse, fat	0.01
Horse, kidney	0.30
Horse, meat	0.01
Horse, mbyp (except kidney)	0.01
Sheep, fat	0.01
Sheep, kidney	0.30
Sheep, meat	0.01
Sheep, mbyp (except kidney)	0.01

(3) Tolerances are established 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 or on the following commodity:

Commodity	Parts per million
Milk	0.03

* * * * *

[FR Doc. 04–19525 Filed 8–25–04; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[WC Docket No. 03–225; FCC 04–182]

Default Compensation Rate for Dial-Around Calls From Payphones Increased to $.494

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: By this document, the Commission approves an increase from $.24 to $.494 in the default compensation rate for dial-around calls from payphones. This is the first increase in the dial-around default rate in over five years. The intended effect of this order is to ensure the widespread deployment of payphones and to provide fair compensation to payphone service providers.

DATES: Effective September 27, 2004.

ADDRESSES: All filings must be sent to the Commission's Secretary, Marlene H. Dortch, Office of the Secretary, Federal Communications Commission, Room TW–A325, 445 Twelfth Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Jon Stover, Wireline Competition Bureau, Pricing Policy Division, (202) 418–0390.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order (Order), adopted on August 12, 2004. The complete text of this Order is available for public inspection Monday through Thursday from 8 a.m. to 4:30 p.m. and Friday from 8 a.m. to 11:30 a.m. in the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, Room CY–A257, 445 Twelfth Street, SW., Washington, DC 20554. The complete text is available also on the Commission's Internet site at *http://www.fcc.gov*. Alternative formats are available to persons with disabilities by contacting Brian Millin at (202) 418–7426 or TTY (202) 418–7365. The complete text of the Order may be purchased from the Commission's duplicating contractor, Best Copy and Printing Inc., Room CY–B402, 445 Twelfth Street, SW., Washington, DC 20554, telephone 202–488–5300, facsimile 202–488–5563 or e-mail at *FCC@BCPIweb.com*.

Synopsis of Final Rule

1. The Order approves an increase from $.24 to $.494 in the payphone dial-around default rate based on cost evidence submitted by the American Public Communications Council (APCC), the RBOC Payphone Coalition (BellSouth Public Communications, Inc., SBC Communications, Inc., and the Verizon telephone companies) and numerous interexchange (long-distance) carriers. The new rate of $.494 ensures that all payphone service providers (PSPs) are fairly compensated for each and every completed call as mandated by 47 U.S.C. 276.

2. According to cost studies submitted by APCC and the RBOC Payphone Coalition and the Commission's analysis of those cost studies, per-payphone costs have not changed dramatically since 1998, but falling call volumes at payphones have caused a major increase in per-call costs at marginal payphones. Thus, the Commission concluded that