Control of Emission of Organic Compounds, submitted by the Governor on December 15, 1995.

(i) Incorporation by reference.

(A) LAC, Title 33, Part III, Chapter 21, Section 2147, Limiting Volatile Organic Compound Emissions from Reactor Processes and Distillation Operations in the Synthetic Organic Chemical Manufacturing Industry, adopted in the Louisiana Register on April 20, 1995 (LR 21:380).

(B) LAC, Title 33, Part III, Chapter 21, Section 2149, Limiting Volatile Organic Compound Emissions from Batch Processing, adopted in the Louisiana Register on April 20, 1995 (LR 21:387).

(C) LAC, Title 33, Part III, Chapter 21, Section 2151, Limiting Volatile Organic Compound Emissions from Cleanup Solvent Processing, adopted in the Louisiana Register on April 20, 1995 (LR 21:391).

(ii) Additional material.

(A) Letter of negative declaration for wood furniture dated January 21, 1997, from the State of Louisiana Department of Environmental Quality.

3. Section 52.994 is amended by designating the existing text as paragraph (a) and adding paragraph (b) to read as follows:

§ 52.994 Conditional approvals.

* * * * *

(b) *Reasonable Available Control Technology for the Synthetic Organic Chemical Manufacturing Industry Batch Processing Source Category.* A letter dated June 17, 1997 from the Assistant Secretary of the Louisiana Department of Environmental Quality to the EPA Regional Administrator commits the State to make corrections in LAC 33.III.2149.A.2.b to restore the general single unit operation exemption to 500 pounds per year or less. The State commits to make the above rule change within one year from the **Federal Register** publication of the conditional approval of the batch processing Reasonable Available Control Technology rule.

[FR Doc. 97–31408 Filed 12–1–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 64, 70, and 71

[FRL–5928–5]

RIN 2060–AD18

Compliance Assurance Monitoring

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; availability of guidance document.

SUMMARY: On October 22, 1997 (62 FR 54900), EPA published a final Compliance Assurance Monitoring Rule (CAM). The final rule preamble described a Guidance Development Process in which the Agency would develop non-prescriptive examples of the types of monitoring that can be used to satisfy part 64 for various types of control devices and emissions units. In order to provide an opportunity for source owners or operators and other interested parties to submit suggestions, review drafts and generally clarify the part 64 requirements, a *Draft* CAM Technical Guidance Document is now available. The Agency emphasizes that the development of example monitoring approaches in this guidance document is intended to assist both regulated industry and permitting authorities to streamline permit review in those instances where a source owner or operator proposes monitoring based on one of the examples. These examples should not be considered as an implied limitation on the owner or operator's ability to propose a different approach that the owner or operator can demonstrate satisfies the part 64 requirements or on the permitting authority's authority to require additional monitoring. A final CAM Technical Guidance Document should be available by the end of March 1998.

DATES: Comments on the Draft CAM Technical Guidance Document should be received no later than January 5, 1998.

ADDRESSES: Comments should be sent to: Dan Bivins, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, MD–19, RTP, NC 27711, or to: Bivins.Dan@epamail.epa.gov

The Draft CAM Technical Guidance Document is available on U.S. Environmental Protection Agency's EMTIC Homepage on the Technology Transfer Network (via the Internet at ''http://ttnwww.rtpnc.epa.gov/html/emticwww/index.htm'', 24 hours a day, 7 days a week , except Monday, 8–12 a.m. EST).

FOR FURTHER INFORMATION CONTACT: Dan Bivins at (919) 541–5244.

Henry C. Thomas,

Acting Director, Office of Air Quality Planning and Standards.

[FR Doc. 97–31576 Filed 12–1–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180

[OPP–300589; FRL–5758–7]

Pyrimethanil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an import tolerance for residues of the fungicide 4,6-dimethyl-N-phenyl-2-pyrimidinamine expressed as pyrimethanil in or on the raw agricultural commodity (RAC) wine grapes at 5.0 ppm. AgrEvo USA Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170) requesting the tolerance.

DATES: This regulation becomes effective December 2, 1997. Objections and requests for hearings must be received by EPA on or before February 2, 1998.

ADDRESSEES: Written objections, and hearing requests identified by the docket control number, OPP–300589, must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, OPP–300589, must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All copies

of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300589]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Mary Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9354, e-mail: waller.mary@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 1, 1997 (62 FR 41379) (FRL–5732–4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) 21 U.S.C. 346a(e), announcing the filing of a pesticide tolerance petition (PP 4E4384) by AgrEvo USA Company, Little Falls Center One, 2711 Centerville Rd., Wilmington, DE 19808. The notice included a summary of the petition prepared by AgrEvo USA Company. There were no comments received in response to the notice of filing. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the fungicide 4,6-dimethyl-N-phenyl-2-pyrimidinamine expressed as pyrimethanil in or on the raw agricultural commodity wine grapes at 5.0 parts per million (ppm).

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines if the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure of the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is more commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA to pose a reasonable certainty of no harm. EPA generally uses the RfD to evaluate chronic risks posed by pesticide exposure. For shorter term risks, which could occur for residential uses of a pesticide, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor. The MOE is a measure of how close the exposure comes to the NOEL.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High-end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enactment of FQPA, this risk assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this reassessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However,

for cases in which high-end exposure can reasonably be expected from multiple sources (e.g., frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risks assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in ground water or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticide. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent crop treated estimates are derived from Federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. Review of this regional data allows EPA to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of pyrimethanil and to make the determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for pyrimethanil on wine grapes at 5.0 ppm. EPA's assessment of the dietary 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 below.

1. A battery of acute toxicity studies resulted in an acute oral LD_{50} = 4,149 milligrams/kilograms (mg/kg) (males) and 5,971 mg/kg (females); an acute dermal LD_{50} >5,000 mg/kg for both sexes; an acute inhalation LC_{50} >1.98 mg/L; slight eye irritation; no dermal irritation; and a finding that pyrimethanil is not a sensitizer.

2. A subchronic oral toxicity study in rats fed pyrimethanil at dose levels of 0, 80, 800, or 8,000 ppm for 13 weeks. Those doses were equivalent to daily intake of 0, 5.4, 54.5, 529.1 milligrams/kilograms/day (mg/kg/day) for males and 0, 6.8, 66.7, 625.9 mg/kg/day for females. A supplementary control and a high dose (8,000 ppm) group were similarly treated for 13 weeks then maintained off-dose for 28 days to investigate the reversibility of any findings. Treatment of pyrimethanil did not affect mortality, clinical signs, water intake, ophthalmology, hematology, blood chemistry, or macroscopic pathology.

Under the conditions of this study, the No Observed Effect Level (NOEL) was estimated to be 80 ppm (equivalent to a daily intake of 5.4 mg/kg/day for males and 6.8 mg/kg/day for females). The Lowest Observed Effect Level (LOEL) was estimated to be 800 ppm (54.5 mg/kg/day for males and 66.7 mg/kg/day for females). The LOEL is based on decreased body weight gains in females, changed coloration of urine specimens, and increased incidence of hypertrophy of centrilobular hepatocytes in males.

3. A subchronic oral toxicity in mice fed technical pyrimethanil at dose levels of 0, 80, 900, or 10,000 ppm for 13 weeks. Those doses were equivalent to 0, 12, 139, or 1,864 mg/kg/day for males and 0, 18, 203, or 2,545 mg/kg/day for females, respectively. There were no treatment-related effects in mortality, clinical signs, water intake, or hematological parameters.

The NOEL was estimated to be 900 ppm, equivalent to daily intake of 139 and 203 mg/kg/day for males and females, respectively. The LOEL was estimated to be 10,000 ppm, equivalent to daily intake of 1,864 and 2,545 mg/kg/day for males and females, respectively. The LOEL is based on decreased body weight gains, clinical chemistry data, necropsy, and histopathological findings.

4. A subchronic oral toxicity study in dogs dosed with technical pyrimethanil by gavage at dose levels of 0, 6, 80, or 1,000/800 mg/kg/day for 13 weeks. The highest dose was reduced from 1,000 mg/kg/day to 800 mg/kg on day 7 due to persistent vomiting seen in all dogs receiving 1,000 mg/kg. Concentrations of dosing suspension (0.5% (w/v) methyl cellulose in distilled water) were within ranges of 82.5% to 121.7% of nominal. There were no treatment related effects on mortality, organ weights, necropsy findings, histopathological, ophthalmoscopical, or hematological parameters.

Under the conditions of this study, the NOEL was estimated to be 6 mg/kg. The LOEL was estimated to be 80 mg/kg. The LOEL is based on the increased incidence of vomiting and diarrhea, salivation, cream coloration of feces, hypoactivity, and decreased water consumption.

5. A chronic oral toxicity study in dogs dosed with pyrimethanil by gavage at doses of 0, 2, 30, or 400/250 mg/kg/day for 12 months. Administration of the test material at 400 mg/kg/day caused a high incidence of vomiting/emesis during week 1 of the study. For this reason, the dose regimen was decreased to 250 mg/kg/day on day 8 of the study. At this dose (250 mg/kg) vomiting was decreased to about 1% in all animals.

Based on the results of this study, the NOEL is 30 mg/kg/day and the LOEL is 250 mg/kg/day, based on the decrease in body weight, food consumption, feed efficiency, and water consumption, reduced clotting times, and increases in white blood cells, (mainly neutrophils).

6. A carcinogenicity feeding study in mice fed technical pyrimethanil at dose levels of 0, 16 ppm (males 2.0, females 2.5 mg/kg/day), 160 ppm (males 20.0, females 24.9 mg/kg/day), or 1,600 ppm (males 210.9, females 253.8 mg/kg/day) for 80 weeks resulted in a dose-related increase in the percentage (24%, 38%, 40%, and 67% in control, low-, mid-, and high-dose males, respectively) of deaths occurring prior to week 56 in males but there was no dose-related adverse effect on survival in either sex and adequate numbers of mice (both sexes) were available at study termination.

Treated males displayed a higher incidence of urinary bladder distension at necropsy, and urogenital tract lesions were increased at the high-dose level compared to the control values. Since all urogenital tract tissues of the low- and mid-dose males were not examined, a dose-response cannot be determined. The NOEL for systemic effects can be set at 1,600 ppm (males 210.9, females 253.8 mg/kg/day), the highest dose tested (HDT). There was no increase in the incidence of any tumor type in either sex.

7. A combined chronic toxicity/carcinogenicity study in rats fed pyrimethanil at dose levels of 0, 32, 400, or 5,000 ppm for 52 weeks (interim kill) or 104 weeks (main study). Those doses were equivalent to daily intake of 0, 1.3, 17, or 221 mg/kg/day for males and 0, 1.8, 22, or 291 mg/kg/day for females.

At the interim kill (52 weeks), relative liver/body weight ratios of animals given 5,000 ppm were siginificantly higher than controls. Necropsy revealed dark thyroids in 5,000 ppm treated animals only. Microscopic pathology showed minimal to moderate hypertrophy of centrilobular hepatocytes in animals given 5,000 ppm. In the thyroid gland, at 5,000 ppm, there were higher incidences of minimal to slight colloid depletion and hypertrophy of the follicular epithelium in males and females. A single focus of follicular hyperplasia was seen in males only. There were minimal to moderate intra-epithelial depositions of brown pigment (lipofuscin).

At the terminal kill (104 weeks), at 5,000 ppm, an increase of absolute liver weight was observed in males only while increases of relative liver/body weight ratios were seen in both sexes. Non-neoplastic findings included minimal to slight hypertrophy of centrilobular hepatocyes. There were higher incidences of eosinophilic foci in the liver of males and females compared with controls. Minimal to moderate focal cystic degeneration of the liver was also observed in males and females. In the thyroid gland, colloid depletion and hypertrophy of the follicular epithelium was seen in males and females compared to controls. Depositions of intra-cytoplasmic brown pigment (lipofuscin) within the thyroid follicular epithelium were seen only in animals given 5,000 ppm (38/50 males and 47/50 females).

The only tissue showing a higher incidence of tumors than controls was the thyroid gland with benign follicular cell adenomas in both sexes. A pair-wise comparison for the incidence in high dose (5,000 ppm) treated males was not statistically higher than the control. The incidence in both sexes was higher than the historical control range. A positive trend of the incidence for both sexes was noted. In addition, thyroid follicular cell adenocarcinomas were seen in animals treated at 32 ppm (males) and 5,000 ppm (1 male only); however, the incidence was within the historical control range.

At 400 ppm, a statistically significant increase of serum GGT level in males only was observed at week 102. Increased absolute liver weight (the relative liver/body weight ratio was comparable to control) in males was reported in the terminal necropsy findings. However, these parameters are considered to be of no toxicological significance because no corresponding significant histopathological finding was seen.

No treatment-related significant effects were seen in animals given 32 ppm.

Under the condition of this study, the NOEL was estimated to be 400 ppm. (equivalent to 17 mg/kg/day for males and 22 mg/kg/day for females). The LOEL was estimated to be 5,000 ppm (equivalent to 221 mg/kg/day for males and 291 mg/kg/day for females). The LOEL was based on decreased body weight gains, increased serum cholesterol and GGT levels, increased relative liver/body weight ratios, necropsy, and histopathological findings.

8. An oral development toxicity study in rats gavaged with pyrimethanil suspensions (1% (w/v) aqueous methyl cellulose at doses of 0, 7, 85, or 1,000 mg/kg/day from gestation days 6 through 15. Maternal toxicity (hunched body posture, emaciation, and hair loss) were noted in high-dose animals. Treatment-related, statistically significant decreases in body weights and body weight gains were observed in high-dose animals. Except for statistically significant decreased in mean litter weight and mean fetal weight of high-dose animals, all other caesarian section data were comparable to control values. The maternal NOEL was 85 mg/kg/day and the LOEL was 1,000 mg/kg/day (limit dose), based on decreases in mean body weight, mean body weight gain, mean litter weight, and mean fetal weight. The developmental NOEL was 1,000 mg/kg/day (limit dose). The developmental LOEL was not established.

9. A developmental toxicity (teratology) study in rabbits gavaged with pyrimethanil at doses of 0, 7, 45, or 300 mg/kg/day on gestation day 7 through 19. At 7 mg/kd/day, no treatment-related maternal or developmental effects were observed. The maternal NOEL is 7 mg/kg/day and the maternal LOEL is 45 mg/kg/day based on the slight increase in the number of females with reduced production and size of fecal pellets. The developmental NOEL is 45 mg/kg/day and the LOEL is 300 mg/kg/day based on decreased fetal weight, increased incidence of fetal runts, increase in retarded ossification of fetal bones, increase in fetuses with 13 thoracic vertebrae, and 13 pairs of ribs.

10. A reproduction toxicity study in rats fed pyrimethanil at dose levels of 0, 32, 400, or 5,000 ppm (males: 0, 1.9, 23.1, or 294 mg/kg/day; females: 0, 2.2, 27.4, 343 mg/kg/day) during premating, gestation, and lactation periods. No treatment-related differences were noted in the necropsy findings of parental animals and their offspring. Treatment-related decreases in mean body weights were limited to high-dose parental animals and their offspring.

The NOEL for reproductive toxicity is 5,000 ppm (294 mg/kg/day, males; 343

mg/kg/day, females), the highest dose tested. The NOEL for developmental/systemic toxicity is 400 ppm (23.1 mg/kg/day, males; 343 mg/kg/day, females); the LOEL was established at 5,000 ppm (294 mg/kg/day, females), based on decreased pup body weights on lactation day 21.

11. Studies on gene mutation and other genotoxic effects: A bacterial mutation assay with *s. typhimurium*; a bacterial mutation assay with *E. Coli*; a mouse micronucleus assay; an *in vitro* metaphase chromosomal aberration assay (human lymphocytes); an *in vivo* unscheduled DNA synthesis assay (rats) showed no evidence of mutagenic activity.

12. A metabolism study showed that the majority (≈90%) of the administered dose of ^{14}C-pyrimethanil following 14 days of repeated oral exposure to unlabeled pyrimethanil (5/sex) at a dose level of 10 mg/kg was eliminated within 24 hours, and the major route of elimination was via the urine (≈72%). Approximately 17-18% of the dose was eliminated via feces. Radiolabeled pyrimethanil was detected only in the liver, kidney, and blood at study termination (24 hours post dose). The highest residue was displayed in the liver in both sexes. There was no significant sex difference. The overall recovery of radiolabeled pyrimethanil was ≈91%.

13. A metabolism study showed that the majority of a radiolabeled dose of pyrimethanil (≈97% low dose; 65% high dose) administered following single oral exposures of rats to dose levels of 11.89 or 800 mg/kg of pyrimethanil was eliminated within 24 hours, and the major route of elimination was via the urine (low dose 74%-76%; high dose 65%-67%). Approximately 21%-23% of the low dose and ≈15%-18% of the high dose was eliminated via the feces. The highest residues were displayed in the liver, kidney, thyroid, and blood at the high dose. The overall recovery of radiolabeled pyrimethanil following single-dose exposure was >94% at the high dose and >101% at the low dose. No sex differences were observed. Since tissue levels were measured at only one time point, no statement regarding bioaccumulation can be made.

14. A metabolism study in rats administered ^{14}C-pyrimethanil orally once a day over a period of 28 days (10 mg/kg), with periodic sacrifices at days 1, 3, 5, 8, 11, 17, 23, 28, and 32 for residue analysis of organs/tissues showed detectable levels of radiolabeled pyrimethanil in adrenals, blood, kidney, liver, spleen, and thyroid. Blood and liver displayed detectable levels of radiolabeled pyrimethanil after a single dose (24-hour sample). Four days after the last dose, detectable levels of radiolabeled pyrimethanil were found in the liver, kidney, and thyroids. It appeared that the levels in the blood, kidney, and thyroid continued to increase with increased exposure time, while the level in the adrenal appeared to reach a plateau, and levels in the liver appeared to decline.

B. Toxicological Endpoints

1. *Acute toxicity*. To assess acute dietary exposure, the Agency used a NOEL of 45 mg/kg/day and a LOEL of 300 mg/kg/day from a developmental toxicity study in rabbits for evaluating acute risk to females 13+, the subpopulation of concern.

2. *Chronic toxicity*. A RfD of 0.2 mg/kg was established based on a long-term rat toxicity study with a NOEL of 400 ppm and an uncertainty factor of 100.

3. *Carcinogenicity*. Pyrimethanil was classified as a Group C chemical - possible human carcinogen. The Agency's Carcinogenicity Peer Review Committee (CPRC) chose a non-linear approach (MOE) based on a NOEL of 17 mg/kg/day for increased incidences of thyroid tumors in rats. The MOE methodology was selected because of thyroid tumors associated with administration of pyrimethanil in the rat which may be due to a disruption in the thyroid-pituitary status.

4. *Toxicity endpoints for non-dietary exposure*. A toxicity endpoint for non-dietary exposure is not required as the Agency is only considering the import tolerance on wine grapes.

C. Exposure and Risks

1. *From food and feed uses*. This is the first tolerance for residues of pyrimethanil in or on a raw agricultural commodity. Risk assessments were conducted by EPA to assess dietary exposures and risks from pyrimethanil as follows:

i. *Acute dietary exposure and risk*. An acute dietary endpoint for females 13+ and the general public were assessed because of potential oral consumptions. For the subpopulation of concern, females 13+, the estimated acute Margin of Exposure (MOE) of 405 demonstrates no acute dietary concern.

ii. *Chronic exposure and risk*. The RfD used for the chronic dietary analysis was 0.20 mg/kg/day. A tolerance of 5.0 ppm in or on wine grapes was used. Using the tolerance level residue (5.0 ppm) and assuming that 100% of the crop is treated, the risk assessment resulted in use of less than 1% of the RfD for the general population and all 22 subgroups, including infants under 1 year and children under 13 years of age. No feed items are associated with wine grapes and therefore, secondary residues are not expected. In the best judgement of the Agency, the pyrimethanil chronic dietary risk does not exceed the level of concern.

2. *From drinking water*. Since this is an import tolerance and there are no U.S. registrations for this chemical, there are not risks associated with drinking water.

3. *From non-occupational non-dietary exposure*. As stated, this is an import tolerance and there are no U.S. registrations, therefore no non-occupational non-dietary exposure and risk are expected.

4. *Cumulative exposure to substances with common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical-specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues

can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether pyrimethanil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 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.

D. Aggregate Risks and Determinations of Safety for U.S. Population

1. *Chronic risk*. Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to pyrimethanil from food will utilize less than 1% of the RfD for the U.S. population and the 22 subgroups, including infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to pyrimethanil residues.

2. *Acute risk*. Acute dietary margins of exposure greater than 100 tend to cause no dietary concern. The estimated MOE value of 450 does not exceed the Agency's level of concern and therefore, EPA has a reasonable certainty that no harm will result from acute dietary exposure.

E. Aggregate Cancer Risk for the U.S. Population

This chemical has been classified as a Group C - chemical (possible human carcinogen) and a non-linear methodology (MOE) was applied for the estimation of human cancer risk. Cancer MOEs are estimated by dividing the carcinogenic NOEL of 17 mg/kg/day from the rat chronic feeding study by the chronic exposure (TMRC). The cancer MOE was estimated for the U.S. population as 40,380. The estimated MOE does not exceed the Agency's level of concern and therefore, EPA has a reasonable certainty that no harm will result from exposures to residues of pyrimethanil.

F. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children—i. In general*. In assessing the potential for additional sensitivity of infants and children to residues of pyrimethanil, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. The developmental and reproductive toxicity data base for pyrimethanil is considered to be complete. The data base includes an acceptable 2-generation reproduction study in rats and acceptable pre-natal developmental toxicity studies in rats and rabbits. The data did not suggest any additional sensitivity to the embryo or neonate following *in utero* or early post-natal exposure to pyrimethanil. The maternal NOEL was 85 mg/kg/day and the developmental NOEL was 1,000 mg/kg/day (highest dose tested) in the rat developmental toxicity study. In the developmental toxicity study in rabbits, the maternal NOEL was 7 mg/kg/day and the developmental NOEL was 45 mg/kg/day. Results from the 2-generation reproduction toxicity study in rats indicated a reproductive toxicity NOEL of 294 mg/kg/day for males and 343 mg/kg/day for females (highest dose tested). The developmental toxicity NOEL was established at 23.l mg/kg/day for males and 27.4 mg/kg/day for females. The developmental and reproductive NOEL are at least 1,000 fold higher than the RfD (0.2 mg/kg/day), and should be protective for infants and children. No additional safety factors are warranted.

2. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to pyrimethanil from food will utilize less than 1% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to pyrimethanil residues.

III. Other Considerations

A. Metabolism in Plants and Animals.

The metabolism in plants is adequately understood for the purposes of this use of pyrimethanil on wine grapes. The residue of regulatory concern is the parent compound only, pyrimethanil. Since it has been determined that secondary residues in livestock commodities are not likely to result from this use, metabolism of pyrimethanil in animals is not relevant to this requested use on wine grapes.

B. Analytical Enforcement Methodology

The method accepted by EPA for enforcement of pyrimethanil in wine grapes is AgrEvo USA's Method (R2/2) Analytical Method for the Determination of Residues of Pyrimethanil in Wine by HPLC (MRID # 433450-10). This method is available from the Docket under docket control number [OPP–300589] at the address stated above.

C. Magnitude of Residues.

Fifty-seven field trials consisting of different applications and concentrations of pyrimethanil were performed in Italy, Germany, South Africa, France, Spain, and Greece. HPLC/UV was the analytical method used for residue determination. Grape and wine samples were stored at -20 °C and 4 °C, respectively, until analysis. Maximum storage period was 9 months and 12 months for wine and grape samples, respectively. The storage period, as indicated by the storage stability data, is considered adequate for storage samples. Residues of pyrimethanil for grapes ranged from 0.74 to 4.14 ppm. The maximum value of 4.14 ppm was obtained after a maximum total application rate of 4 kg ai/Ha and a PHI of 26 days. Additionally, one study showed a maximum residue for grapes of 6.2 ppm (PHI = 0 days, Total application rate = 2.4 kg ai/Ha) and another maximum residue of 9.5 ppm (PHI = 26 days, Total application rate = 3.0 kg ai/Ha). However, most of the residue in wine grapes were less than 4.14 ppm. For

grape must, residues ranged from 0.41 to 1.3 ppm. For wine, residues ranged from <0.05 to 1.8 ppm.

A processing study was conducted in Fresno, California in which one application of pyrimethanil (40 SC) was made at a nominal rate of 1 kg ai/Ha at each of the following growth stages: flowering, grape closure, color change, and 21 days pre-harvest. Applications were made by airblast ground rig sprayer and all plots were harvested at normal harvest time.

Residues of pyrimethanil in whole grapes concentrated in all processed commodities produced from those grapes except juice. Raisins and juice are considered to be the only processed commodities. Raisin waste, wet and dry grape pomace are not considered processed commodities for the purposes of this petition in/on wine grapes. However, since this petition is for wine grapes and not for table grapes, a tolerance in/on raisins is not needed at this time. For future tolerance petitions in grapes grown for fresh consumption, a tolerance will be required for raisins.

D. Codex Considerations

There are no Mexican, Canadian, or Codex listings for residues of pyrimethanil; therefore, there are no harmonization issues.

IV. Conclusion

Therefore, the tolerance is established for pyrimethanil in or on wine grapes at 5.0 ppm.

V. Objections and Hearing Requests.

The new FFDCA section 408(g) provides essentially the same process for persons to ''Object'' to a tolerance regulation issued by EPA under the new section 408(e) and (1)(6) as was provided in the old section 408 and in section 409. However, the period of filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use its current procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by February 2, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number OPP–300589 (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at: opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et. seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section (408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility At (RFA) (5 U.S.C.601 *et. seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided

to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted 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 General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Parts 180

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

Dated: November 21, 1997.

Linda A. Travers,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371

b. Section § 180.518 is added to read as follows:

§ 180.518 Pyrimethanil; tolerances for residues.

(a) *General.* [Reserved]

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

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

(e) *Import.* Import tolerances are established for residues of the fungicide 4,6-dimethyl-N-phenyl-2-pyrimidinamine expressed as pyrimethanil in or on the following raw agricultural commodity:

Commodity	Parts per million
Wine grapes	5.0 ppm

[FR Doc. 97–31552 Filed 12-1-97; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 417

[HCFA–1911–IFC]

RIN 0938–AI35

Medicare+Choice Program; Collection of User Fees From Medicare+Choice Plans and Risk-Sharing Contractors

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final rule with request for comments.

SUMMARY: This interim final rule with a request for comments establishes the methodology that will be employed to assess fees applicable to Medicare risk-sharing contractors for fiscal year (FY) 1998. Under section 4002 of the Balanced Budget Act of 1997, these contractors must contribute their pro rata share of costs relating to beneficiary enrollment, dissemination of information, and certain counseling and assistance programs. The Medicare+Choice regulation to be published in June of 1998 will implement this requirement for Medicare+Choice plans.

DATES: *Effective Date:* These regulations are effective on January 1, 1998.

Comment Date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on February 2, 1998.

ADDRESSES: Mail an original and 3 copies of written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1911–IFC, P.O. Box 7517, Baltimore, MD 21207–5187.

If you prefer, you may deliver an original and 3 copies of your written comments to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Comments may also be submitted electronically to the following e-mail address: HCFA–1911–IFC@hcfa.gov. E-mail comments must include the full name and address of the sender, and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments.

Electronically submitted comments will be available for public inspection at the Independence Avenue address, below.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1911–IFC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Randy Ricktor, (410) 786–4632, Marty Abeln, (410) 786–1032.

SUPPLEMENTARY INFORMATION:

I. Background

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Public Law 105–33), added a new section 1857(e)(2) to the Social Security Act (the Act), that establishes a fee requirement that Medicare+Choice plans must contribute their pro rata share, as determined by the Secretary, of costs relating to enrollment and dissemination of information and certain counseling and assistance programs. Section 4002(b) of the BBA makes this requirement applicable to those managed care plans with risk sharing contracts under section 1876 of the Act. Any amounts collected are authorized to be appropriated only for the purpose of carrying out section 1851 of the Act (relating to enrollment and dissemination of information) and section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 103–66, OBRA 1990), relating to the health insurance counseling and assistance program.

For any Federal fiscal year (FY), the fees authorized under section 1857(e)(2)(B) of the Act are contingent upon enactment in an appropriations act of a provision specifying the aggregate amount of fees the Secretary is directed to collect in that fiscal year. The BBA fees collected during any FY are to be credited as offsetting collections. Under section 1857(e)(2)(D), the fees authorized under section 1857(e)(2)(B) are not to be established at any amount greater than the lesser of the estimated costs to be incurred by the Secretary in the FY in carrying out the activities described in sections 1851 of the Act and 4360 of the OBRA 1990; or $200 million in Federal fiscal year 1998; $150 million in fiscal year 1999; and $100 million in fiscal year 2000 and