treatment, or examination, compensation will be payable for such additional disability.

(**Authority:** 38 U.S.C. 1151)

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§§ 3.361 through 3.363 [Removed]

2. Sections 3.361 through 3.363 are removed.

§ 3.800 [Amended]

3. The introductory text to § 3.800 is removed.

[FR Doc. 99–432 Filed 1–7–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300768; FRL 6050–5]

RIN 2070–AB78

Tebuconazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tebuconazole in or on grapes, grass forage, grass hay, grass seed screenings, grass straw, milk, meat by-products of cattle, goats, horses and sheep. Bayer Corporation requested these tolerances under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective January 8, 1999. Objections and requests for hearings must be received by EPA on or before March 9, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300768], 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–300768], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #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 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300768]. 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 February 2, 1997, (62 FR 16590) (5F4577) and of March 5, 1997, (62 FR 10047) (6F4669), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of pesticide petitions (PP) for tolerances by Bayer Corporation, 8400 Hawthorne Road, Kansas City, MO, 64120–0013 (amended in a letter from Bayer Corporation to EPA dated September 18, 1998). These notices included summaries of the petitions prepared by Bayer Corporation, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.474 be amended by establishing tolerances for residues of the fungicide, tebuconazole (alpha-[2-(4-chlorophenyl)-ethyl]-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol) in or on grapes at 5 parts per million (ppm), grass forage at 8 ppm, grass hay at 25 ppm, grass seed screenings at 55 ppm, grass straw at 30 ppm, and by establishing tolerances for the combined residues of tebuconazole and its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol metabolite (HWG 2061), hereafter referred to in this document as tebuconazole, in milk at 0.1 ppm, and meat by-products of cattle, horses, goats and sheep at 0.2 ppm.

I. Risk Assessment and Statutory Findings

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

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

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 tebuconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of tebuconazole in or on grapes, grass forage, grass hay, grass seed screenings, grass straw, milk, meat by-products of cattle, horses, goats and sheep. 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 tebuconazole is discussed below.

1. *Acute toxicity*. Tebuconazole exhibits moderate toxicity. The rat acute oral LD_{50} = 3,933 milligram/kilogram (mg/kg) (category III); the rabbit acute dermal LD_{50}>5,000 mg/kg (category IV); and the rat acute inhalation LC_{50}>0.371 milligram/Liter (mg/L) (category II). Technical tebuconazole was slightly irritating to the eye (category III) and was not a skin irritant (category IV) in rabbits. Tebuconazole was not a dermal sensitizer.

2. *Subchronic toxicity*—i. In a 90–day oral feeding study, rats were administered technical tebuconazole at levels of 0, 100, 400, or 1,600 ppm (0, 8, 34.8, or 171.7 mg/kg/day for males or 0, 10.8, 46.5, or 235.2 mg/kg/day for females). In males, the no observed adverse effect level (NOAEL) was 34.8 mg/kg/day and the lowest observed adverse effect level (LOAEL) was 171.7 mg/kg/day based on decreased body weight and decreased body weight gain, adrenal vacuolation and spleen hemosiderosis. In females, the NOAEL was 10.8 mg/kg/day and the LOAEL of 46.5 mg/kg/day was based on adrenal vacuolation.

ii. In a 90–day oral feeding study, Beagle dogs were administered technical tebuconazole at levels of 0, 200, 1,000, or 5,000 ppm (0, 74, 368, or 1,749 mg/kg/day for males or 0, 73, 352, or 1,725 mg/kg/day for females). In females, the NOAEL was 73 mg/kg/day and the LOAEL was 352 mg/kg/day based on decreased body weight and decreased body weight gain, decreased food consumption and increased liver *N*-demethylase activity. At the highest dose tested (HDT), lens opacity was seen in all males and in one female and cataracts were seen in three females.

iii. In a 21–day dermal toxicity study, rabbits were exposed dermally to technical tebuconazole 5 days a week at doses of 0, 50, 250, or 1,000 mg/kg/day. No significant systemic effects were seen. The systemic NOAEL > 1,000 mg/kg/day.

iv. In a 21–day inhalation toxicity study, rats were exposed to technical tebuconazole (15 exposures – 6 hours/day for 3 weeks) at airborne concentrations of 0, 0.0012, 0.0106, or 0.1558 mg/L/day. The NOAEL was 0.0106 mg/L/day and the LOAEL was 0.1558 mg/L/day based on piloerection and induction of liver *N*-demethylase.

3. *Chronic toxicity*—i. In a 2–year combined chronic feeding/carcinogenicity study, rats were administered technical tebuconazole at levels of 0, 100, 300, or 1,000 ppm (0, 5.3, 15.9, or 55 mg/kg/day for males or 0, 7.4, 22.8, or 86.3 mg/kg/day for females). In males, the NOAEL was 5.3 mg/kg/day and the LOAEL was 15.9 mg/kg/day based on C-cell hyperplasia in the thyroid gland. In females, the NOAEL was 7.4 mg/kg/day and the LOAEL was 22.8 mg/kg/day based on body weight depression, decreased hemoglobin, hematocrit, mean corpuscular volume and mean corpuscular hemoglobin concentration and increased liver microsomal enzymes. No evidence of carcinogenicity was found at the levels tested.

ii. In a 1–year chronic feeding study, Beagle dogs were administered technical tebuconazole at levels of 0, 40, 200, or 1,000 (weeks 1–39) and 2,000 ppm (weeks 40–52) (0, 1, 5 or 25/50 mg/kg/day for males and females). The NOAEL was 1 mg/kg/day and the LOAEL was 5 mg/kg/day based on ocular lesions (lenticular and corneal opacity) and hepatic toxicity (changes in the appearance of the liver and increased siderosis).

iii. In a 1–year chronic feeding study, Beagle dogs were administered technical tebuconazole at levels of 0, 100, or 150 ppm (0, 3.0, or 4.4 mg/kg/day for males or 0, 3.0 or 4.5 mg/kg/day for females). The NOAEL was 3.0 mg/kg/day and the LOAEL was 4.4 mg/kg/day based on adrenal affects in both sexes. In males there was hypertrophy of adrenal zona fasciculata cells amounting to 4/4 at 150 ppm and to 0/4 at 100 ppm and in controls. Other adrenal findings in males included fatty changes in the zona glomerulosa (3/4) and lipid hyperplasia in the cortex (2/4) at 150 ppm vs. (1/4) for both effects at 100 ppm and control dogs. In females there was hypertrophy of zona fasciculata cells of the adrenal amounting to 4/4 at 150 ppm and to 0/4 at 100 ppm and 1/4 in controls. Fatty changes in the zona glomerulosa of the female adrenal amounted to 2/4 at 150 ppm and to 1/4 at 100 ppm and in controls.

4. *Carcinogenicity*. In a 91–week carcinogenicity study, mice were administered technical tebuconazole at levels of 0, 500, or 1,500 ppm (0, 84.9, or 279 mg/kg/day for males or 0, 103.1, or 365.5 mg/kg/day for females). Neoplastic histopathology consisted of statistically significant increased incidences of hepatocellular neoplasms; adenomas (35.4%) and carcinomas (20.8%) at 1,500 ppm in males and carcinomas (26.1%) at 1,500 ppm in females. Statistically significant decreased body weights and increased food consumption were reported that were consistent with decreased food efficiency at 500 and 1,500 ppm in males and at 1,500 ppm in females. Clinical chemistry values (dose-dependent increases in plasma GOT, GPT and Alkaline Phosphatase) for both sexes were consistent with hepatotoxic effects at both 500 and 1,500 ppm. Relative liver weight increases reached statistical significance at both 500 and 1,500 ppm in males and at 1,500 ppm in females. Non-neoplastic histopathology included dose-dependent increases in hepatic pancinar fine fatty vacuolation, statistically significant at 500 and 1,500 ppm in males and at 1,500 ppm in females. Other histopathology included significant oval cell proliferation in both sexes and dose-dependent ovarian atrophy that was statistically significant at 500 and 1,500 ppm. The Maximum Tolerated Dose (MTD) was achieved at or around 500 ppm.

5. *Developmental toxicity*—i. In a developmental toxicity study, pregnant female rats were gavaged with technical tebuconazole at levels of 0, 30, 60, or 120 mg/kg/day between days 6 and 15 of gestation. The maternal NOAEL was 30 mg/kg/day and the maternal LOAEL was 60 mg/kg/day based on increased absolute and relative liver weights. The developmental NOAEL was 30 mg/kg/day and the developmental LOAEL was 60 mg/kg/day based on delayed ossification of thoracic, cervical and sacral vertebrae, sternum and limbs plus an increase in supernumerary ribs.

ii. In a developmental toxicity study, pregnant female rabbits were gavaged with technical tebuconazole at levels of 0, 10, 30, or 100 mg/kg/day between days 6 and 18 of gestation. The maternal NOAEL was 30 mg/kg/day and the maternal LOAEL was 100 mg/kg/day based on minimal depression of body weight gains and food consumption. The developmental NOAEL was 30 mg/kg/day and the developmental LOAEL was 100 mg/kg/day based on increased postimplantation losses, malformations in 8 fetuses out of 5 litters (including peromelia in 5 fetuses/4 litters; palatoschisis in 1 fetus/1 litter), hydrocephalus and delayed ossification.

iii. In a developmental toxicity study, pregnant female mice were gavaged with technical tebuconazole at levels of 0, 10, 30, or 100 mg/kg/day between days 6 and 15 of gestation (part 1 of study) or at levels of 0, 10, 20, 30, or 100 mg/kg/day between days 6 and 15 of gestation (part 2 of study). The maternal NOAEL was 10 mg/kg/day and the maternal LOAEL was 20 mg/kg/day. Maternal toxicity (hepatocellular vacuolation and elevations in AST, ALP and alkaline phosphatase) occurred at

all dose levels but was minimal at 10 mg/kg/day. Reduction in mean corpuscular volume in parallel with reduced hematocrit occurred at doses greater than or equal to 20 mg/kg/day. The liver was the target organ. The developomental NOAEL was 10 mg/kg/day and the developmental LOAEL was 30 mg/kg/day based on an increase in the number of runts.

iv. In a developmental toxicity study, pregnant female mice were administered dermal doses of technical tebuconazole applied at levels of 0, 100, 300, or 1,000 mg/kg/day between days 6 and 15 of gestation. Equivocal maternal toxicity was observed 1,000 mg/kg/day.The maternal NOAEL was ≈ 1,000 mg/kg/day. The developmental NOAEL was 1,000 mg/kg/day.

v. In a 2–generation reproduction study, rats were fed technical tebuconazole at levels of 0, 100, 300, or 1,000 ppm, (0, 5, 15, or 50 mg/kg/day, males and females). The parental maternal NOAEL was 15 mg/kg/day and the parental LOAEL was 50 mg/kg/day based on depressed body weights, increased spleen hemosiderosis and decreased liver and kidney weights. The reproductive NOAEL was 15 mg/kg/day and the reproductive LOAEL of 50 mg/kg/day based on decreased pup body weights from birth through 3 – 4 weeks.

6. *Mutagenicity*. An Ames test with *Salmonella sp*., a mouse micronucleus assay, a sister chromatid exchange assay with Chinese hamster ovary cells, and an unscheduled DNA synthesis assay with rat hepatocytes provided no evidence of mutagenicity.

7. *Dermal penetration*. Radio-labeled technical tebuconazole in ethanol was applied dermally to rats in doses of 0.604, 5.85, 52.4, or 547 micrograms per square centimeter (µg/cm^2). The percent of dose absorbed after 24 hours amounted to 27.77, 27.06, 23.01, and 6.38% of the applied dose, respectively. The amount which remained on the application site after soap and water wash increased with the dose and amounted at 24 hours to 24.7, 24.4, 32.02, and 53.11% of the above applied doses, respectively. The percent of the dose absorbed after 8 hours was 49.9% at the dose of 0.604 µg/cm^2. The ethanol used as a solvent may have led to an overestimate of absorption.

8. *Neurotoxicity*. No acute or subchronic neurotoxicity studies are available for tebuconazole. In a battery of subchronic and chronic studies, there were no indications of treatment-related effects on the central or peripheral nervous system of experimental animals. In the prenatal developmental toxicity studies, however, several effects on the fetal nervous system were noted. These effects included alterations in the development of the fetal nervous system in mice (increased malformations of the brain and spinal column, and exencephaly), in rats (anophthalmia), and in rabbits (neural tubule defects characterized as meningocoele and spina bifida, and hydrocephalus).

9. *General metabolism*. Rats were gavaged with 1 or 20 mg/kg radio-labeled technical tebuconazole. 98.1 % of the oral dose was absorbed. Within 72 hours of dosing, over 87% of the dose was excreted in urine and feces. At sacrifice (72 hours post dosing), total residue (-GI tract) amounted to 0.63% of the dose. A total of 10 compounds were identified in the excreta. A large fraction of the identified metabolites corresponded to successive oxidations steps of a methyl group of the test material. At 20 mg/kg, changes in detoxication patterns may be occurring.

B. Toxicological Endpoints

1. *Acute toxicity*. EPA selected the NOAEL of 10 mg/kg/day from a developmental toxicity study in mice based on an increased incidence of runts observed at the LOAEL of 30 mg/kg/day. The population subgroups of concern are females (13+ years), infants, and children. An Uncertainty Factor of 100 was used to account for inter-species extrapolation and intra-species variability. On this basis, the acute Reference dose (RfD) for tebuconazole was calculated to be 0.10 mg/kg/day. EPA determined that a 10 x FQPA safety factor is applicable to the subpopulations females (13+ years), as well as infants and children because the effects seen were developmental, the severity of observed effects and the effects are presumed to occur following ''acute'' exposures. A dose and toxicity endpoint were not identified for the general population.

2. *Short - and intermediate - term toxicity*. No short - intermediate - or long-term dermal toxicity endpoints were identified. For short - intermediate - and long-term inhalation toxicity, the NOAEL of 0.0106 mg/L/day from the 21–day rat inhalation toxicity study was selected for risk assessment. The LOAEL of 0.1558 mg/L/day was based on induction of liver microsomal enzymes and piloerection.

3. *Chronic toxicity*. EPA established the RfD for tebuconazole at 0.03 mg/kg/day. The RfD is based on a 1–year feeding study in dogs in which the NOAEL was 3.0 mg/kg/day and the LOAEL was 4.4 mg/kg/day based on histopathological changes in the adrenal gland. An Uncertainty Factor of 100 was used to account for inter-species extrapolation and intra-species variability.

4. *Carcinogenicity*. EPA concluded that tebuconazole should be classified as a Group C - possible human carcinogen and determined that the RfD approach be used to estimate human risk. A statistically significant increase in the incidence of hepatocellular adenomas, carcinomas and combined adenoma/carcinomas was observed in male mice at the highest dose tested; a statistically significant increase in the incidence of hepatocellular carcinomas and combined adenomas/carcinomas was observed in female mice at the highest dose tested; and tebuconazole was determined to be structurally related to at least six other triazole fungicides that also produce hepatocellular tumors in male and/or female mice.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances are established under 40 CFR §180.474(a) for residues of the fungicide tebuconazole in or on bananas at 0.05 ppm, barley forage, hay and straw at 0.10, barley grain at 0.05 ppm, cherries at 4.0 ppm, oat forage, hay and straw at 0.10 ppm, oat grain at 0.05 ppm, peaches (includes nectarines) at 1.0 ppm, peanuts at 0.1 ppm, peanut hulls at 4.0 ppm, wheat forage, hay, and straw at 0.10 ppm, and wheat grain at 0.05 ppm. Time-limited tolerances for section 18 emergency exemptions are established under 40 CFR §180.474(b)(1) for residues of the fungicide tebuconazole in or on barley grain at 2.0 ppm, barley hay and straw at 20 ppm; pistachios at 1.0 ppm, wheat hay at 15 ppm, and wheat straw at 2.0 ppm. Time-limited tolerances for section 18 emergency exemptions are established under 40 CFR §180.474(b)(2) for residues of the fungicide tebuconazole in or on milk at 0.1 ppm; cattle, goats, hogs, horses, poultry, and sheep meat byproducts at 0.2 ppm. Risk assessments were conducted by EPA to assess dietary exposures from tebuconazole as follows.

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by

section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The acute dietary (food only) risk assessment used a highly refined Monte Carlo analysis based on the following assumptions: percent crop treated data were used for all commodities; maximum residue levels from crop field trials for single serving commodities such as bananas and peaches were utilized; average residue levels from crop field trials were used for blended commodities such as fruit juices, grains and oils; anticipated residue levels for ruminant commodities were calculated using a livestock diet constructed from anticipated residue levels for livestock feed items. Application of the 10 x safety factor to the Acute RfD of 0.10 mg/kg/day results in an acceptable acute dietary risk of 10% or less of the Acute RfD for the following subpopulations of concern: 8.5% for children (1 to 6 years); 7.4% for non-nursing infants (<1 year); 7% for all infants (<1 year); 6.7% for nursing infants (<1 year); and 3.3% for children (7 to 12 years) and females (13+ years). Application of the 10 x safety factor to the Acute RfD results in an acceptable acute dietary exposure of 10% or less of the Acute RfD.

ii. *Chronic exposure and risk.* The chronic dietary (food only) risk assessment used the RfD of 0.03 mg/kg/day. EPA used the Dietary Exposure Evaluation Model (DEEM) which utilized data from the USDA 1989–91 Continuing Survey of Food Intake by Individuals (CSFII). The risk assessment is very conservative and uses the Theoretical Maximum Residue Concentration (TMRC) which assumes that 100% of all treated food and/or feed commodities having tebuconazole tolerances will contain tebuconazole residues at the tolerance level. EPA generally has no concern for exposures below 100% of the chronic RfD (when the FQPA factor has been removed) because this RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The Agency has estimated that chronic dietary exposure to tebuconazole from food only will utilize 12% of the chronic RfD for the population subgroup, U.S. Population, and the maximum percent of the chronic RfD (41%) is utilized by children (1–6 years).

2. *From drinking water.* There are no monitoring data for residues of tebuconazole in ground water. No health advisory levels or Maximum Contaminant Levels for residues of tebuconazole in drinking water have been established. Tebuconazole is persistent and relatively immobile in water.

The Agency used the Screening Concentration in Ground Water (SCI-GROW) screening model to determine the Estimated Environmental Concentration (EEC) of 0.3 µg/L of tebuconazole in ground water for both chronic and acute analysis. SCI-GROW is an empirical model based upon actual ground water monitoring data collected from the registration of a number of pesticides that serve as benchmarks for the model. SCI-GROW provides realistic estimates of pesticide concentrations in shallow, highly vulnerable ground water sites (i.e., sites with sand soils and depth to ground water of 10 to 20 feet). EPA compares drinking water levels of concern (DWLOC) directly with the SCI-GROW model values.

The Agency used the Generic Estimated Environmental Concentration (GENEEC) screening model to determine the surface water acute EEC of 14 µg/L (peak) and the surface water chronic EEC of 10 µg/L (avg 56–day concentration). GENEEC is used to estimate pesticide concentrations in surface water for up to 56 days after a single runoff event. GENEEC provides an upper-bound concentration value and can substantially overestimate (by a ≤ 3-fold factor) true pesticide concentrations in drinking water. EPA applies a factor of 3 to GENEEC model values when determining whether or not a level of concern has been exceeded. If the GENEEC model value is ≤ 3 times the DWLOC, the pesticide is considered to have passed the screen and no further assessment is needed.

i. *Acute exposure and risk.* The acute DWLOC is 200 µg/L for females (13+ years old) and 14 µg/L for infants/children. The EEC's for acute analysis of water are 0.3 µg/L (ground water) and 14 µg/L (surface water). EPA does not expect the acute aggregate exposure to exceed 10% of the acute RfD. Therefore, EPA concludes with reasonable certainty that no harm will result to the subpopulations of concern, females (13+ years old), or infants and children from aggregate exposure to residues of tebuconazole.

ii. *Chronic exposure and risk.* The chronic DWLOC is 910 µg/L for the U.S. population, 720 µg/L for females (13+ years, nursing), and 190 µg/L for infants/children. The EEC's for chronic analysis of water are 0.3 µg/L (ground water) and 10 µg/L (surface water). EPA does not expect the chronic aggregate exposure to exceed 100% of the chronic RfD. Therefore, EPA concludes with reasonable certainty that no harm will result from chronic (non-cancer) aggregate exposure to tebuconazole residues.

3. *From non-dietary exposure.* Tebuconazole is currently registered for use on the following residential non-food sites: the formulation of wood-based composite products, wood products for in-ground contact, plastics, exterior paints, glues and adhesives. Exposure via incidental ingestion (by children) and inhalation are not a concern for these products which are used outdoors. No paints or other end-use products containing tebuconazole are available for interior use. Thus, no risk is expected for residential nonfood sites.

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.''

EPA does not have, at this time, available data to determine whether tebuconazole 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, tebuconazole 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 tebuconazole has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the Final Rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk.* Application of the 10x safety factor for enhanced susceptibility of infants and children to the Acute RfD of 0.1 mg/kg/day results in an acceptable acute dietary exposure of 10% or less of the Acute RfD for the subpopulations of concern, females (13+ years), infants and children. The acute

DWLOC for females (13+ years) is 200 µg/L and for infants/children is 14 µg/L. These values are higher than the SCI-GROW EEC value of 0.3 µg/L for ground water and the GENEEC acute EEC of 14 µg/L for surface water (peak value) when divided by three. Therefore, EPA concludes with reasonable certainty that the potential risks from aggregate acute exposure (food & water) would not exceed the Agency's level of concern.

2. *Chronic risk*. Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to tebuconazole from food will utilize 12% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children 1–6 years old, as discussed below. 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. Despite the potential for exposure to tebuconazole in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is reasonable certainty that no harm will result from aggregate exposure to tebuconazole residues.

3. *Aggregate cancer risk for U.S. population*. EPA classified tebuconazole as a Group C - possible human carcinogen and determined that the RfD approach be used to estimate the carcinogenic risk to humans. Risk concerns for carcinogenicity due to long-term consumption of tebuconazole residues are adequately addressed by the aggregate chronic exposure analysis using the chronic RfD. Therefore, EPA concludes that there is reasonable certainty that no harm will result from aggregate exposure to tebuconazole residues.

4. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to tebuconazole residues.

E. 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 tebuconazole, EPA considered data from developmental toxicity studies in mice, rats, rabbits 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 maternal pesticide exposure during gestation. 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 ecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Pre- and post-natal sensitivity*. Pre-natal developmental toxicity studies indicated several effects on the fetal nervous system. These effects included alterations in the development of the fetal nervous system in mice (increased malformations of the brain and spinal column, and exencephaly), in rats (anophthalmia), and in rabbits (neural tubule defects characterized as meningocoele and spina bifida, and hydrocephalus). On the basis of comparable developmental and maternal NOAEL's and LOAEL's, EPA determined that there was no indication of increased sensitivity of the offspring of mice, rats, or rabbits to pre-natal or post-matal exposure to tebuconazole. However, EPA does note that there is increased sensitivity in the pups based on the more severe developmental effects observed at the developmental LOAEL's and at higher doses as compared to the maternal effects observed at the maternal LOAEL's and at higher doses. EPA also notes that tebuconazole is structurally related to several other triazole fungicides which have demonstrated a developmental LOAEL below the maternal LOAEL in rats and/or rabbits.

iii. *Conclusion*. EPA determined that based on the observed fetal nervous system effects and the fact that data on several other structurally related triazole fungicides indicate neurotoxic effects, a developmental neurotoxicity study will be required. Otherwise, there is a complete toxicity database for tebuconazole and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10x safety factor be retained because of the increased sensitivity of pups as demonstrated by the severity of the observed developmental effects, evidence of alterations in the development of the fetal nervous system, the structural relationship of tebuconazole to several other triazole fungicides which have been shown to cause developmental effects, and the fact that a developmental neurotoxicity study will be required.

2. *Acute risk*. EPA determined that the 10x factor to account for enhanced sensitivity of infants and children be retained . Application of the 10x safety factor to the Acute RfD of 0.10 mg/kg/day results in an acceptable acute dietary risk of 10% or less of the Acute RfD for the following subpopulations of concern: 8.5% for children (1 to 6 years); 7.4% for non-nursing infants (<1 year); 7% for all infants (<1 year); 6.7% for nursing infants (<1 year); and 3.3% for children (7 to 12 years) and females (13+ years). EPA concludes with reasonable certainty that the potential risks from aggregate acute exposure (food & water) would not exceed the Agency's level of concern.

3. *Chronic risk*. Using the exposure assumptions described above, EPA has concluded that the highest aggregate exposure to tebuconazole from food will utilize 41% of the RfD for children (1–6 years). 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. Despite the potential for exposure to tebuconazole in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

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

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants and animals is adequately understood. The residue of concern in plants is tebuconazole. The residues of concern in animals are the parent compound, tebuconazole, and its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol metabolite. Tolerances on animal commodities milk at 0.1 ppm, and meat by-products of cattle, horses, goats and sheep at 0.2 ppm are required in conjunction with this use.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin

Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703–305–5229).

C. Magnitude of Residues

EPA has concluded that residue data submitted in support of the tolerances for grapes at 5 ppm, grass forage at 8 ppm, grass hay at 25 ppm, grass seed screenings at 55 ppm, grass straw at 30 ppm, milk at 0.1 ppm, and meat by-products of cattle, horses, goats and sheep at 0.2 ppm indicate that the tolerances requested by the petitioner are adequate.

D. International Residue Limits

There are no established Codex, Canadian, or Mexican MRLs established for tebuconazole. A Codex MRL is proposed for residues of tebuconazole in or on grapes at 2.0 ppm. There are no proposed MRLs for tebuconazole in or on grapes in Canada and Mexico. Tolerance compatibility problems do not exist with respect to Mexico or Canada, but do exist with respect to the Codex MRL. The submitted residue data support a U.S. tolerance level of 5.0 ppm for tebuconazole in/on grapes, and it is not possible to harmonize the proposed tolerance for residues of tebuconazole in or on grapes with Codex. The higher residues in the U.S. may be due to different agricultural practices and/or climatic conditions.

E. Rotational Crop Restrictions

Rotational crop restrictions are not required as rotation to other crops in conjunction with the production of grapes and grass grown for seed is not considered significant.

IV. Conclusion

Therefore, the tolerances are established for residues of tebuconazole in or on grapes at 5 ppm, grass forage at 8 ppm, grass hay at 25 ppm, grass seed screenings at 55 ppm, grass straw at 30 ppm, and tolerances are established for the combined residues of tebuconazole, and its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol metabolite in milk at 0.1 ppm, and meat by-products of cattle, horses, goats and sheep at 0.2 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 new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for 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 those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by March 9, 1999, 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. 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 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 Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300768] (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 119 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

A. Certain Acts and Executive Orders

This final rule establishes tolerances 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 tolerances 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. Nevertheless, the Agency has 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.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This 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: December 21, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180 — [AMENDED]

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

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

2. In §180.474, in paragraph (a), by designating the text after the heading as paragraph (a)(1) and alphabetically adding the following commodities to the table and by adding a new paragraph (a)(2) to read as follows:

§180.474 Tebuconazole; tolerances for residues.

(a)(1) * * *

Commodity	Parts per million
* * * * *	
Grapes	5.0
Grass, forage	8.0
Grass, hay	25.0
Grass, seed screenings.	55.0
Grass, straw	30.0
* * * * *	

(a)(2) Tolerances are established for the combined residues of the fungicide, tebuconazole and its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol metabolite.

Commodity	Parts per million
Cattle, mbyp	0.2
Goats, mbyp	0.2
Horses, mbyp	0.2
Milk	0.1
Sheep, mbyp	0.2

* * * * *

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