IV. 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 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: May 17, 1999.

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. 321(q), 346a and 371.

§180.425 [Amended]

2. In §180.425, by amending the table in paragraph (b) by revising the date ''5/30/99'' to read ''5/30/01''.

[FR Doc. 99–13193 Filed 5–25–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300855; FRL–6079–1]

RIN 2070–AB78

Tebuconazole; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of tebuconazole in or on garlic. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on garlic. This regulation establishes a maximum permissible level for residues of tebuconazole in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on June 30, 2000.

DATES: This regulation is effective May 26, 1999. Objections and requests for hearings must be received by EPA on or before July 26, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300855], 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–300855], 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@epa.gov. Copies of electronic 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 electronic objections and hearing requests must be identified by the docket control number [OPP–300855]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Stephen Schaible, 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: Rm. 271, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–308–9362; e-mail: schaible.stephen@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408 and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), is establishing a tolerance for residues of the fungicide tebuconazole, in or on garlic at 0.1 part per million (ppm). This tolerance will expire and is revoked on June 30, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Findings

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described in this preamble and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

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 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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Tebuconazole on Garlic and FFDCA Tolerances

While garlic rust is usually a disease of minor concern in California, it appeared as a serious pest problem in several garlic growing areas of the state in the 1997–98 growing season. The mild winter that year allowed the pathogen to survive the winter and cause infection early in the season. No fungicide is specifically registered for control of rust on garlic. The fungicides registered for use on garlic are not effective at controlling the disease under high pest pressure. Data presented by the state indicate that tebuconazole is highly effective at controlling the disease. EPA has authorized under FIFRA section 18 the use of tebuconazole on garlic for control of garlic rust in California. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of tebuconazole in or on garlic. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on June 30, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on garlic after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether tebuconazole meets EPA's registration requirements for use on garlic or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of tebuconazole by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than California to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for tebuconazole, contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

III. Aggregate Risk Assessment and Determination of Safety

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) .

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 a time-limited tolerance for residues of tebuconazole on garlic at 0.1 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 tebuconazole are discussed in this unit.

B. Toxicological Endpoint

1. *Acute toxicity*. The acute reference dose (RfD) of 0.1 milligrams/kilogram/day (mg/kg/day) for tebuconazole was established based on a developmental toxicity study in mice with a no observed adverse effect level (NOAEL) of 10 mg/kg/day for developmental toxicity. At the lowest observed adverse effect level (LOAEL) of 30 mg/kg/day, an increased incidence of runts (fetuses weighing less than 1.3 gram) were observed. An uncertainty factor of 100 was applied to the NOAEL to calculate the acute RfD of 0.1 mg/kg/day. EPA has determined that the 10x factor to account for enhanced susceptibility of infants and children (as required by FQPA) should be retained. This determination is based on the results of the developmental toxicity study in mice used to establish the acute RfD, other developmental toxicity studies in mice, rats and rabbits and the structural relationship of tebuconazole to several other triazole pesticides which also have been shown to induce developmental toxicity in rats and/or rabbits. For acute dietary exposure, EPA determined that the 10x safety factor is applicable to the subpopulations females (13+ years), as well as infants and children because the effects seen were developmental and are presumed to occur following ''acute'' exposures. For subpopulations other than females (13+ years), infants and children, a toxicological endpoint was not identified. 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 (food plus water) of 10% or less of the acute RfD.

2. *Short-and intermediate-term toxicity*. Toxicological endpoints for short- or intermediate-term dermal toxicity were not identified. Adverse systemic effects were not observed in dermal developmental toxicity studies in mice or rats at the limit dose of 1,000

mg/kg/day or in a 21-day dermal toxicity study in rabbits at the limit dose of 1,000 mg/kg/day. Therefore, risk assessments for short- or intermediate-term dermal exposure were not conducted.

A NOAEL of 0.0106 mg/liter/day (equivalent to 2.9 mg/kg/day) was identified as the toxicological endpoint for short- and intermediate-term (and chronic) inhalation toxicity based on a 21-day inhalation toxicity study in rats. At the LOAEL of 0.1558 mg/liter/day, piloerection and increased liver O-demethylase and N-demethylase activity were observed in both males and females. EPA determined that the 10x safety factor to account for enhanced susceptibility of infants and children (as required by FQPA) is not applicable for inhalation toxicity for the currently registered residential exposures to tebuconazole. A Margin of Exposure (MOE) of 100 or more for short- or intermediate-term non-dietary risk is acceptable for all subpopulations.

3. *Chronic toxicity*. EPA has established the RfD for tebuconazole at 0.03 (mg/kg/day). This RfD is based on a 1-year chronic feeding study in dogs in which the NOAEL was 100 ppm (2.96 mg/kg/day in males and 2.94 mg/kg/day in females) and the LOAEL was 150 ppm (4.39 mg/kg/day in males and 4.45 mg/kg/day in females), based on histopathological changes in the adrenal gland (hypertrophy of the zona fasciculata and fatty changes in the zona glomerulosa in both sexes and lipid hyperplasia in the cortex in males). An uncertainty factor of 100 was used to account for inter-species extrapolation and intra-species variability. EPA determined that the 10x factor for enhanced susceptibility of infants and children (as required by FQPA) is not applicable for chronic dietary exposure. The developmental effects which contributed to the decision to retain the 10x factor for acute dietary exposure are considered to be acute effects; maternal effects in those same studies were minimal. Additionally, the NOAEL on which the RfD is based is the lowest NOAEL in the toxicology data base for this chemical. A chronic dietary exposure (food plus water) of 100% or less of the chronic RfD is acceptable for all subpopulations.

4. *Carcinogenicity*. Tebuconazole is classified as a Group C (possible human) carcinogen. This decision was primarily based on results in a 91-week carcinogenicity study in mice in which the following effects were observed:

1. A statistically significant increase in the incidence of hepatocellular adenomas, carcinomas and combined adenomas/carcinomas in male mice at the highest dose tested (279 mg/kg/day).

2. A statistically significant increase in the incidence of hepatocellular carcinomas and combined adenomas/carcinomas in female mice at the highest dose tested (366 mg/kg/day). In addition, tebuconazole is structurally related to several other triazole pesticides that produce similar liver tumors in mice. For the purpose of carcinogenic risk assessment, the RfD methodology is used to estimate human risk.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.474) for the residues of tebuconazole, in or on a variety of raw agricultural commodities. Tolerances have been established for milk and meat byproducts in connection with use of tebuconazole under a previous section 18. Risk assessments were conducted by EPA to assess dietary exposures and risks from tebuconazole as follows:

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 1-day or single exposure. An acute dietary endpoint of concern was identified for subpopulations females (13+ years), as well as infants and children.

An acute dietary (food only) probablistic risk analysis submitted in conjunction with another action was used to estimate acute dietary risk. The following assumptions were utilized in the Monte Carlo analysis:

1. Percent crop treated (PCT) data were used for all commodities.

2. Maximum residue levels from crop field trials for single serving commodities such as bananas and peaches were utilized.

3. Average residue levels from crop field trials were used for blended commodities such as fruit juices, grains and oils.

4. Anticipated residue levels for ruminant commodities were calculated using a livestock diet constructed using anticipated residue levels for livestock feed items. This analysis is considered to be highly refined. This analysis was run with 2,000 iterations. The results of the Monte Carlo analysis indicate that the percent of acute RfD for all children and infants subgroups as well as females 13+ years old are all below 10% of the RfD nursing infants (<1 year), 7%; non-nursing infants (<1 year), 7%; children (1 to 6 years) 9%, children (7 to 12 years) 3%; all infants (<1 year), 7%; females (13 years plus), 3%.

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.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: That the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

PCT refinements were assumed for all commodities evaluated in the probablistic risk assessment. For published uses, PCT data were based on information obtained from the registrant and were derived from Doane Marketing Research and USDA National Agricultural Statistics Service (NASS). For those commodities being requested under section 18, total U.S. acreage treated under section 18 was aggregated for each crop and compared to total acreage grown in the U.S. to derive a national PCT estimate.

The Agency believes that the three conditions, discussed in section 408 (b)(2)(F) concerning the Agency's responsibilities in assessing acute dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. 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 the PCT, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. The regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which tebuconazole may be applied in a particular area.

ii. *Chronic exposure and risk*. The Agency conducted a chronic dietary exposure analysis and risk assessment. The analysis evaluated individual food consumption as reported by respondents in the USDA 1977–78 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to the chemical for each commodity. In conducting the chronic dietary risk assessment, the Agency made the very conservative assumption that 100% of every commodity evaluated will contain residues and those residues will be at tolerance level; this assumption results in an overestimation of human dietary exposure. Thus, in making a safety determination for this time-limited tolerance, the Agency is taking into account this conservative exposure assessment.

The existing tebuconazole tolerances published, pending, and including the necessary section 18 tolerance(s) result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to percentages of the RfD below 100% for all subgroups i.e., U.S. population, 11% and non-nursing infants (<1 year old), the most highly exposed subgroup, 37%.

2. *From drinking water*. Based on present data available to the Agency, tebuconazole is persistent and relatively immobile. There are no established Maximum Contaminant Level or health advisory levels for residues of tebuconazole in drinking water. Monitoring data for residues of tebuconazole in surface and ground water are not available. Tebuconazole is not included in the Pesticides in Ground Water Database (US EPA, 1992), and it was not an analyte in the National Pesticide Survey (US EPA, 1990).

EPA estimated exposure for tebuconazole for both surface and ground water based on available modeling. Environmental concentrations for surface water were estimated using modeling from Generic Estimated Environmental Concentration (GENEEC). For surface water, the maximum concentrations were used for acute risk calculations, the annual means (1–10 years) for chronic risk calculations. Current Agency policy allows that a factor of 3 be applied 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 drinking water level of comparison (DWLOC), the pesticide is considered to have passed the screen. Acute and chronic ground water concentrations were estimated using the Screening Concentration in Ground Water (SCI-GROW) model. For the purposes of the screening level assessment, the maximum and average annual concentrations in ground water are not believed to vary significantly. DWLOCs will be compared directly to SCI-GROW values.

i. *Acute exposure and risk*. DWLOCs were calculated for acute exposures to tebuconazole in surface and ground water for females 13+ years old and children (1–6 years old). Relative to an acute toxicity endpoint, the acute dietary food exposure (from the probablistic analysis) was subtracted from the ratio of the acute NOAEL to the appropriate percentage acute RfD to obtain the acceptable acute exposure to tebuconazole in drinking water. DWLOCs were then calculated from this acceptable exposure using default body weights (60 kg for females and 10 kg for children) and drinking water consumption figures (2 liters for females 1 liter for children). Based on these calculations EPA's DWLOC for acute dietary risk is 14 parts per billion (ppb) for children (1-6 years old) and 200 ppb for females 13+ years old.

Maximum concentrations of tebuconazole in surface and ground water are estimated to be 14 ppb and 0.3 ppb, respectively. The maximum estimated concentrations of tebuconazole in surface and ground water do not exceed EPA's levels of concern for acute exposure in drinking water for the females 13+ and children.

ii. *Chronic exposure and risk*. EPA has calculated DWLOCs for chronic exposures to tebuconazole in surface and ground water. To calculate the DWLOC for chronic exposures relative to a chronic toxicity endpoint, the chronic dietary food exposure was subtracted from the chronic RfD (0.03 mg/kg/day) to obtain the acceptable chronic exposure to tebuconazole in drinking water. DWLOCs were then calculated from this exposure using default body weights (70 kg for U.S. population, 60 kg for females 10 kg for children) and drinking water consumption figures (2 liters U.S. population females 1 liter children). Based on these calculations EPA's DWLOCs for chronic risk are 950 ppb for the U.S. population, 780 ppb for females and 190 ppb for non-nursing infants (<1 year old).

Estimated annual average concentrations of tebuconazole in surface water and ground water are 10 ppb and 0.3 ppb, respectively. The estimated annual average concentrations of tebuconazole in surface and ground water are less than EPA's levels of concern for chronic exposure in drinking water.

3. *From non-dietary exposure*. No short- or intermediate-term dermal toxicological endpoints were identified. Tebuconazole's registered residential uses are for the formulation of wood-based composite products, wood products for in-ground contact, plastics, exterior paints, glues and adhesives. Currently, the only residential end-use products on the market are for exterior treated wood use. 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. Accordingly, residential exposure is not expected at this time.

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 more 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*. A toxicological endpoint was identified for acute dietary risk assessments for subpopulations females (13+ years), infants and children. The 10x safety factor for enhanced susceptibility of infants and children as required by FQPA is applicable for all of these subgroups. Therefore, 10% or less of the acute RfD of 0.1 mg/kg/day results in an acceptable acute dietary exposure (food plus water).

An acute dietary (food only) probablistic risk analysis resulted in 3% of the acute RfD utilized for females (13+ years). The maximum estimated concentrations of tebuconazole in surface and ground water do not exceed EPA's levels of concern for acute exposure in drinking water for the females 13+. Currently the only residential end-use products on the market are for exterior treated wood use. 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. Accordingly residential exposure is not expected with these uses. Therefore, EPA concludes with reasonable certainty that residues of tebuconazole do not contribute significantly to the aggregate acute risk at the present time.

2. *Chronic risk*. Using the TMRC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to tebuconazole from food will utilize 11% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants (< 1 yr.), 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. Estimated environmental concentrations of tebuconazole in surface water and ground water do not exceed chronic DWLOCs calculated by the Agency; therefore, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

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

No short- or intermediate-term dermal toxicological endpoints were identified. Also, no residential exposure is expected from the current residential uses. Thus, no risk assessments were conducted for residential exposure. Therefore, EPA concludes with reasonable certainty that tebuconazole does not contribute significantly to the aggregate shortand intermediate-term risk at the present time.

4. *Aggregate cancer risk for U.S. population*. Tebuconazole is classified as a Group C (possible human) carcinogen. Since, for the purpose of carcinogenic risk assessment the Reference Dose (RfD) methodology was used, the discussion for chronic risk (11% of RfD utilized) above applies to cancer risk as well. Therefore, EPA concludes with reasonable certainty that tebuconazole does not contribute significantly to the aggregate cancer risk at the present time.

5. *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 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 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 and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species 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. *Developmental toxicity studies*. In two associated oral developmental toxicity studies in mice, the maternal NOAEL was 10 mg/kg/day and the LOAEL was 20 mg/kg/day, based on decreased hematocrit and effects in the liver. The developmental toxicity NOAEL was 10 mg/kg/day and the LOAEL was 30 mg/kg/day, based on increased numbers of runts (fetuses weighing less than 1.3 gram). In addition, at 100 mg/kg/day, frank malformations in the skull, brain and spinal column and a reduced rate of ossification in the cranium were observed. In a dermal developmental toxicity study in mice, no toxicologically significant maternal toxicity or developmental toxicity was observed at the limit dose of 1,000 mg/kg/day.

In an oral developmental toxicity study in rats, the maternal NOAEL was 30 mg/kg/day and the LOAEL was 60 mg/kg/day, based on increased liver weight. The developmental toxicity NOAEL was 30 mg/kg/day and the LOAEL was 60 mg/kg/day, based on delayed ossification of several bones and increased numbers of fetuses with supernumerary ribs. In addition, at 120 mg/kg/day, increased resorptions, decreased fetal body weights and frank malformations in two fetuses (missing tail, agnatha, microtomia and anophthalmia) were observed. In a dermal developmental toxicity study in rats, no toxicologically significant maternal toxicity or developmental toxicity was observed at the limit dose of 1,000 mg/kg/day.

In an oral developmental toxicity study in rabbits, the maternal NOAEL was 30 mg/kg/day and the LOAEL was 100 mg/kg/day, based on decreased body weight gain and decreased food consumption during the dosing period. The developmental toxicity NOAEL was 30 mg/kg/day and the LOAEL was 100 mg/kg/day, based on increased postimplantation loss, increased frank malformations, hydrocephalus and delayed ossification of bones. In another oral developmental toxicity study in rabbits, the maternal NOAEL was <10

mg/kg/day and the LOAEL was 10 mg/kg/day, based on increased incidences of single cell necrosis (minimal severity) in liver cells. The maternal NOAEL from this study was not used to determine the acute RfD because single cell necrosis was not considered to result from a single exposure. The developmental toxicity NOAEL was 30 mg/kg/day and the LOAEL was 100 mg/kg/day, based on increased postimplantation loss, decreased fetal body weights, increased percentage of fetuses with abnormalities (including runts, hemidiaphragm, limb abnormalities and neural tube defects characterized as meningocoele and spina bifida) and delayed ossification of bones.

iii. *Reproductive toxicity study*. In a 2-generation reproduction study in rats, the parental (systemic) toxicity NOAEL was 15 mg/kg/day and the LOAEL was 50 mg/kg/day, based on loss of hair, decreased body weights, decreased food consumption, increased severity of spleen hemosiderosis and decreased liver and kidney weights. For offspring toxicity, the NOAEL was 15 mg/kg/day and the LOAEL was 50 mg/kg/day, based on decreased pup body weights from birth through weeks 3–4 in all litter groups.

iv. *Pre-and postnatal sensitivity*. The above studies meet the standard toxicology data requirements, as required for a food-use chemical, in 40 CFR part 158. However, after evaluation of the findings in these studies, particularly with respect to effects on the fetal nervous system, together with a consideration of neurotoxic effects observed in several other developmental toxicity studies on structurally related triazole pesticides, the Agency requested a postnatal developmental neurotoxicity study in rats (Guideline 83–6) be conducted. The EPA notes effects on the nervous system of fetuses in studies on tebuconazole occurred only at doses of 100 mg/kg/day or higher—i.e., at doses at least ten-fold higher than the developmental toxicity NOAEL (10 mg/kg/day) to be used for the assessment of acute dietary risk.

On the basis of comparative NOAELs and LOAELs, it was determined there was no indication of increased susceptibility of the offspring of mice, rats or rabbits resulting from prenatal and/or postnatal exposure to tebuconazole. However, the maternal effects observed in the developmental toxicity studies at the LOAEL were of minimal concern and did not increase substantially in severity at higher doses, whereas the developmental effects at the LOAEL were pronounced and at higher doses were quite severe (including frank malformations) in mice (at 100 mg/kg/day), rats (at 120 mg/kg/day) and rabbits (at 100 mg/kg/day). Based on a consideration of all the above findings, the Agency retained the 10x factor for enhanced susceptibility to infants and children. The 10x factor is applicable to acute dietary exposures for the subpopulations females (13+ years), infants and children. The 10x factor for enhanced sensitivity of infants and children is not applicable to chronic exposure analysis.

v. *Conclusion*. There is a complete toxicity data base for tebuconazole and exposure data are complete or estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk*. An acute dietary (food only) probablistic risk analysis resulted in the following percentages for the acute RfD: nursing infants (<1 year), 7%; non-nursing infants (<1 year), 7%; children (1 to 6 years) 9%, children (7 to 12 years) 3%; and all infants (<1 year), 7%. The maximum estimated concentrations of tebuconazole in surface and ground water do not exceed EPA's levels of concern for acute exposure in drinking water for children. Currently, the only residential end-use products on the market are for exterior treated wood use. 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. Accordingly residential exposure is not expected with these uses. Therefore, EPA concludes with reasonable certainty that residues of tebuconazole do not contribute significantly to the aggregate acute risk at the present.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to tebuconazole from food will utilize up to 37% 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. As stated above, residential exposure to tebuconazole is not expected for the currently registered uses. Estimated environmental concentrations of tebuconazole in surface water and ground water do not exceed chronic DWLOCs calculated by the Agency; therefore, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. As stated above, residential exposure to tebuconazole is not expected for the currently registered uses.

5. *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.

IV. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants is understood based on metabolism studies in grapes, wheat and peanuts. For the purpose of this section 18 only, the nature of the residue in garlic is considered to be adequately understood. The residue of concern in plants is tebuconazole *per se*.

B. Analytical Enforcement Methodology

Method 101341, a GC/NPD method, is adequate to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, 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, (703) 305–5229.

C. Magnitude of Residues

No residue data were provided for garlic. Residue data were translated from dry bulb onion data generated in Mexico. Based on these data, residues of tebuconazole are not expected to exceed 0.1 ppm on garlic as a result of the proposed section 18 use.

D. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) for residues of tebuconazole in/on garlic. International harmonization is thus not an issue for this time-limited tolerance.

E. Rotational Crop Restrictions

A plant back interval of 120 days after last application for crops not listed on the label is required.

V. Conclusion

Therefore, the tolerance is established for residues of tebuconazole in garlic at 0.1 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation 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 July 26, 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 under the ''ADDRESSES'' section (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). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, 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: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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.

VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300855] (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.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit 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 record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408 of the FFDCA. 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(l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. 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.

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 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.

IX. 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 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: May 12, 1999.

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. 321(q), 346a and 371.

2. In §180.474, by alphabetically adding the following commodity ''garlic'' to the table in paragraph (b) to read as follows:

§180.474 Tebuconazole; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ Revocation Date
* * *	*	*
Garlic	0.1	6/30/00
* * *	*	*

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[FR Doc. 99–12935 Filed 5–25–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR PART 180

[OPP–30116; FRL–6056–6]

RIN 2070–AB78

Pesticide Tolerance Processing Fees

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule increases fees charged for processing tolerance petitions for pesticides under the Federal Food, Drug, and Cosmetic Act (FFDCA). The change in fees reflects a 3.68 percent cost of living and locality pay increase for civilian Federal General Schedule (GS) employees working in the Washington, DC and Baltimore, MD metropolitan area in 1999.

This rule does not, however, reflect the requirements in the Food Quality Protection Act of 1996 (FQPA), which states that the Agency shall collect tolerance fees that, in the aggregate, will cover all costs associated with processing tolerance actions. The amendments to the tolerance fee schedule to meet the FQPA requirement will be addressed in a seperate rulemaking, the proposal for which is expected shortly.

EFFECTIVE DATE: June 25, 1999.

FOR FURTHER INFORMATION CONTACT: About this rule contact Ed Setren, Resources Management Staff (7501C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460, telephone: (703) 305–5927, fax: (703) 305–5060, e-mail: setren.edward@epa.gov. For further technical information about tolerance petitions and individual fees contact: Sonya Brooks, Resources Management Staff (7501C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, telephone: (703) 308–6423, fax: (703) 305–5060, e-mail: brooks.sonya@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this rule apply to me?

This rule may directly affect any person who might petition the Agency for new tolerances, hold a pesticide registration with existing tolerances, or anyone who is interested in obtaining or retaining a tolerance in the absence of a registration. This group can include pesticide manufacturers or formulators, companies that manufacture inert ingredients, importers of food, grower groups, or any person who seeks a tolerance. The vast majority of potentially affected categories and entities may include, but are not limited to: