entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D, of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, the Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted on by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

D. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

E. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 19, 1997. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: April 30, 1997.

Philip G. Millam,

Acting Regional Administrator.

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

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401–7671q.

Subpart MM—Oregon

2. Section 52.1970 is amended by adding paragraph (c)(121) to read as follows:

§ 52.1970 Identification of plan.

* * * * *

(c) * * *

(121) On April 7, 1997, the Director of the Oregon Department of Environmental Quality (ODEQ) submitted a Reasonably Available Control Technology (RACT) determination for VOC emissions from PCC Structurals, Inc., Large Parts Campus, at 4600 SE Harney Drive, Portland, Oregon.

(i) Incorporation by reference.

(A) The letter dated April 7, 1997, from the Director of ODEQ submitting a SIP revision for a RACT determination contained in PCC Structurals, Inc.'s Oregon Title V Operating Permit for VOC emissions, consisting of permit #26–1867, expiration date 4–1–2000, effective date April 4, 1997. Only conditions 19, 20, and 21 in PCC Structurals' Addendum No. 2 to permit #26–1867 are incorporated into the SIP.

[FR Doc. 97–16114 Filed 6–19–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300506; FRL–5725–7]

RIN 2070–AB78

Tebuconazole; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the fungicide tebuconazole in or on barley grain, barley hay, barley straw, wheat hay, wheat straw, pistachios, milk, and meat byproducts of cattle, goats, hogs, horses, poultry and sheep in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act. These tolerances will expire and are revoked on June 30, 1998.

DATES: This regulation becomes effective June 20, 1997. Objections and requests for hearings must be received by EPA on or before August 19, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300506], 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–300506], must be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), 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. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk

may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300506]. 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: Stephen Schaible, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: Second Floor, Crystal Mall #2, Rm. 267, 1921 Jefferson Davis Highway, Arlington, VA 22202. (703) 308–9362, e-mail: schaible.stephen@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for the 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 barley grain at 2.0 parts per million (ppm), barley hay at 20 ppm, barley straw at 20 ppm, wheat hay at 15 ppm, wheat straw at 2.0 ppm, and pistachios at 1.0 ppm; the currently established tolerance of 0.05 ppm for wheat grain is adequate to cover any residues in wheat grain expected from these section 18 uses. EPA is 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 (HGW 2061), hereafter referred to in this document as tebuconazole, in milk at 0.1 ppm and in meat byproducts of cattle, goats, hogs, horses, poultry and sheep at 0.2 ppm. These tolerances will expire and are revoked on June 30, 1998. After June 30, 1998, EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the FFDCA, 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under section 408 with a new safety standard and new procedures. These activities are described below 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 CFR 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 tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemptions for Tebuconazole on Barley, Pistachios, and Wheat and FFDCA Tolerances

On April 16, 1997, the Louisiana Department of Agriculture and Forestry availed of itself the authority to declare the existence of a crisis situation within its state, thereby authorizing use under FIFRA section 18 of tebuconazole on wheat to control rust. On April 21 and April 25, the Mississippi Department of Agriculture and Commerce and the Arkansas State Plant Board, respectively, followed suit by declaring crisis situations within their states for the same pest. Unusually wet and cool weather this year are to blame for this disease outbreak. Triadimefon is registered for use on wheat, but existing stocks have been depleted; other registered alternatives, including tebuconazole, do not allow application at a sufficiently late stage to control rust. These emergency exemptions allow application later in the growth stage of wheat than is currently specified on the existing label. The Washington Department of Agriculture has requested a specific exemption for the use of tebuconazole on wheat to control stripe rust; a similar situation exists in which application of registered alternatives is not allowed at the later growth stages needed to control the disease. The Oregon, Washington and Idaho Departments of Agriculture have requested specific exemptions for the use of tebuconazole on barley to control rust, and North Dakota and Minnesota have requested use of this chemical on this crop to control head blight. The California Environmental Protection Agency, Department of Pesticide Regulation, has requested a specific exemption for the use of tebuconazole on pistachios to control late blight. After having reviewed these submissions, EPA concurs that emergency conditions exist for these states.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of tebuconazole in or on wheat, barley, and pistachios, as well as potential risks presented by secondary residues in milk and meat byproducts of cattle, goats, hogs, horses, poultry and sheep. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. These tolerances will permit the marketing of these commodities treated in accordance with the provisions of the section 18 emergency exemptions. Consistent with the need to

move quickly on these emergency exemptions in order to address urgent non-routine situations and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on June 30, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on these commodities after that date will not be unlawful, provided the pesticide is applied in a manner that is lawful under FIFRA. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether tebuconazole meets EPA's registration requirements for use on barley, wheat, or pistachios or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of tebuconazole by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any States other than those listed above to use this pesticide on these crops under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding these emergency exemptions for tebuconazole, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

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

A. Toxicity

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

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This hundredfold margin of exposure is based on the same rationale as the hundredfold uncertainty factor.

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

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

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

Short-term risk results from exposure to the pesticide for a period of 1 to 7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1 to 7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

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

similar to the short-term risk assessment.

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

B. Aggregate Exposure

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

Percent of crop treated estimates are derived from Federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-nursing infants < 1 year old) was not regionally based.

IV. 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 these actions. Tebuconazole is already registered by EPA for numerous food uses. For the purpose of these emergency exemptions, EPA has sufficient data to assess the hazards of tebuconazole and to make a determination on aggregate exposure, consistent with 408(b)(2), for time-limited tolerances for residues of tebuconazole on barley grain at 2.0 ppm, barley hay at 20 ppm, barley straw at 20 ppm, wheat hay at 15 ppm, wheat straw at 2.0 ppm, pistachios at 1.0 ppm, milk at 0.1 ppm, and meat byproducts of cattle, goats, hogs, horses, poultry and sheep at 0.2 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by tebuconazole are discussed below.

1. *Acute toxicity.* For acute dietary risk assessment, OPP recommended use of the developmental NOEL of 10 mg/kg/day from the developmental toxicity study in mice. Effects observed at the lowest observed effect level (LOEL) of 30 mg/kg/day are an increased number of runts and fetuses with malformations of the skull, brain, and spinal cord. The population subgroup of concern for this acute dietary risk assessment is females (13+ years).

2. *Short- and intermediate-term toxicity.* OPP has determined that short- and intermediate-term inhalation risk assessments and short-term dermal risk assessments are appropriate for non-occupational, non-dietary routes of exposure. OPP recommends that the NOEL of 1,000 mg/kg/day, taken from the dermal developmental toxicity study in mice, be used for the short-term dermal MOE calculations. This NOEL was the highest dose tested in the study. For short- and intermediate-term inhalation MOE calculations, OPP recommends using the NOEL of 0.0106 mg/L/day (1.75 mg/kg/day), based on liver toxicity and piloerection at the LOEL of 0.1558 mg/L/day (25.7 mg/kg/day) in the 3–week inhalation rat toxicity study.

3. *Chronic toxicity.* The RfD of 0.03 mg/kg/day was established based on the NOEL of 2.96 mg/kg/day from a 1–year dog feeding study. Adrenal effects (fatty change and hypertrophy) were observed at the LOEL of 4.39 mg/kg/day. An Uncertainty Factor (UP) of 100 was applied to account for both interspecies and intraspecies variability.

4. *Carcinogenicity.* OPP's Cancer Peer Review Committee (CPRC) has determined that tebuconazole is a Group C (possible human carcinogen) chemical, based on mouse liver tumors in both sexes (adenomas and carcinomas in males and carcinomas in females) at 280 mg/kg/day, the highest dose tested. OPP recommends using the RfD approach for quantification of human risk. Therefore, the RfD is deemed protective of all chronic human health effects, including cancer.

B. Aggregate Exposure

Tolerances have been established (40 CFR 180.474) for parent tebuconazole (*alpha*-[2-(4-chlorophenyl)-ethyl]-*alpha*-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol), in or on a variety of raw agricultural commodities at levels ranging from 0.05 ppm in barley, oat and wheat grain to 4.0 ppm in cherries and peanut hulls. Time-limited tolerances for wheat commodities are based on residue data provided with the section 18 submission; time-limited tolerances for barley commodities are based on residue data submitted with tolerance petition PP#9F3724; and the time-limited tolerance for pistachios is based on residue data submitted with tolerance petition PP#3F4222. Time-limited 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 (HGW 2061) will be established to address potential secondary residues of tebuconazole in milk and meat byproducts of cattle, goats, hogs, horses, poultry and sheep.

For the purpose of assessing potential chronic dietary exposure from tebuconazole, EPA assumed tolerance level residues and 100% of crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for major identifiable subgroups of consumers,

including infants and children, from the proposed and existing food uses of tebuconazole. These same assumptions were made in assessing acute dietary exposure as well.

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

There are no groundwater data for tebuconazole available in OPP's One-Liner Data Base. No Maximum Concentration Level and no Health Advisory Level has been established for residues of tebuconazole in drinking water.

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause exposure from tebuconazole to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with tebuconazole in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

Tebuconazole is not currently registered for indoor or outdoor residential use. Thus, no non-dietary, non-occupational exposure is expected.

C. Cumulative Exposure to Substances With Common Mechanism of Toxicity

Tebuconazole is a member of the triazole class of systemic fungicides (The Pesticide Book, 4th ed., 1994). Other triazoles include bitertanol, cyproconazole, diclobutrazole, difenoconazole, diniconazole, fenbuconazole, flusilazole, hexaconazole, myclobutanil, penconazole, propiconazole, tetraconazole, triadimefon, and triadimenol.

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

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether 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.

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

1. *Acute risk.* EPA has concluded that for the population subgroup of concern, females (13+ years), acute aggregate exposure to tebuconazole from existing and proposed food uses will result in an MOE of 1,000. Despite the potential for exposure to tebuconazole in drinking water, EPA does not expect the aggregate exposure to exceed the level of concern for acute dietary exposure. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to tebuconazole residues.

2. *Chronic risk.* EPA has concluded that aggregate exposure to tebuconazole from food will utilize 6% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants less than 1 year old (discussed below). EPA generally has no concern for exposures below 100 percent 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, EPA does not expect the aggregate exposure to exceed 100% of the RfD. 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

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, rabbit, and mouse and a 2-

generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

The pre- and post-natal toxicology data base for tebuconazole is complete with respect to current toxicological data requirements. The data base does not indicate a potential for increased sensitivity from pre- and post-natal exposure.

From the rat developmental study, the maternal NOEL was 30 mg/kg/day, based on increased liver weight at the LOEL of 60 mg/kg/day. The developmental NOEL was 30 mg/kg/day, based on delayed ossification and supernumerary ribs at the developmental LOEL of 60 mg/kg/day. In the rabbit developmental study, the maternal NOEL was 30 mg/kg/day, based on decreased weight gain and food consumption at the maternal LOEL of 100 mg/kg/day. The developmental NOEL was 30 mg/kg/day, based on increased resorptions due to post-implantation loss at the developmental LOEL of 100 mg/kg/day. The maternal NOEL in the mouse study was 10 mg/kg/day, with reduced hematocrit occurring at the maternal LOEL of 30 mg/kg/day in the oral developmental toxicity study. The developmental NOEL was 10 mg/kg/day, with effects at the LOEL of 30 mg/kg/day being an increased number of runts, and fetuses with malformations of the skull, brain and spinal cord.

In the 2–generation rat reproduction study, the parental NOEL was 15 mg/kg/day, based on decreased body weight and increased spleen weight at the LOEL of 50 mg/kg/day. The reproductive NOEL was 15 mg/kg/day, with decreased body weight of neonates being the effect at the LOEL of 50 mg/kg/day.

FDCA 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 database 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 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 margin of exposure and uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold margin of exposure/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 margin of exposure/safety factor.

Neither the rat, rabbit, and mouse developmental studies nor the rat reproduction study seem to demonstrate any special pre- or post-natal sensitivity for infants and children, since the NOELs and LOELs were the same for both parental and pup toxicity in all of these studies. This demonstrates that developmental or reproductive toxicity to pups occurs only in the presence of maternal effects. EPA therefore concludes that reliable data support use of the standard hundredfold uncertainty factor and that an additional safety factor is not needed to protect infants and children.

1. *Acute risk.* The acute dietary MOE for females (13+ years), the subpopulation of concern for developmental toxicity, is 1,000. Generally, MOEs of greater than 100 are of no concern to the Agency. Despite the potential for exposure to tebuconazole in drinking water, EPA does not expect the aggregate exposure to infants or children to exceed the level of concern for acute dietary exposure. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to tebuconazole residues.

2. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to tebuconazole from food will utilize 32% of the RfD for non-nursing infants and 14% of the RfD for children 1 through 6 years old. EPA generally has no concern for exposures below 100 percent 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, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from chronic aggregate exposure to tebuconazole residues.

V. Other Considerations

The nature of tebuconazole residues in plants and animals is adequately understood. The residue of concern in plants is tebuconazole *per se*. In ruminants and poultry, the residue of concern is the parent compound and its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol metabolite (HGW 2061). Adequate enforcement methodology is available to enforce the tolerance expressions. For the pistachio, barley and wheat tolerances, a gas chromatographic method is available with the Agency, associated with PP#9F3724; for the meat byproduct and milk tolerances, a gas chromatographic method for determining residues of tebuconazole and its metabolite HGW 2061 is available with the Agency, also associated with PP#9F3724. Residues of tebuconazole per se are not expected to exceed 2.0 ppm in/on barley grain, 20 ppm in/on barley hay, 20 ppm in/on barley straw, 15 ppm in/on wheat hay, 2.0 ppm in/on wheat straw, and 1.0 ppm in/on pistachios as a result of these section 18 uses. Combined residues of tebuconazole and its metabolite HGW 2061 are not expected to exceed 0.1 ppm in/on milk, and 0.2 ppm in/on meat byproducts of cattle, goats, hogs, horses, poultry and sheep as a result of these section 18 uses.

Codex maximum residue limits (MRLs) exist for residues of tebuconazole *per se* in/on barley grain at 0.2 ppm; barley straw and dry fodder at 10 ppm; wheat grain at 0.05 ppm; wheat straw and dry fodder at 10 ppm; milk (cattle) at 0.01 ppm; cattle edible offal at 0.05 ppm; and chicken edible offal at 0.05 ppm. These Codex MRLs are not in harmony with those of the United States with respect to: (a) the tolerance expression for animal commodities; (b) the definitions of the tolerated commodities; and, (c) the tolerance levels. These disparities can not be harmonized for purposes of these section 18 actions.

OPP suggests that, once permanent tolerances and section 3 registrations are established for the uses on barley and wheat, the registrant consider providing all relevant studies to Codex in order that Codex MRLs may be amended to accommodate U.S. use needs.

There is no Canadian MRL established for use of tebuconazole on barley. There is a Mexican MRL of 0.2 ppm for residues of tebuconazole *per se* in/on barley (grain); the use pattern of these section 18s does not permit harmonization to that tolerance level.

There is a Canadian MRL established for tebuconazole on ''wheat seed'' at 0.1 ppm. There is no Mexican MRL.

There are no Codex, Canadian or Mexican MRLs for residues of tebuconazole in or on pistachios. International harmonization is not an issue for this section 18 use.

VI. Conclusion

Therefore, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of tebuconazole in or on barley grain at 2.0 ppm, barley hay at 20 ppm, barley straw at 20 ppm, wheat hay at 15 ppm, wheat straw at 2.0 ppm, and pistachios at 1.0 ppm. 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 (HGW 2061) in milk at 0.1 ppm and in meat byproducts of cattle, goats, hogs, horses, poultry and sheep at 0.2 ppm. These tolerances will expire and are revoked on June 30, 1998.

VII. 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 August 19, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as 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.

VIII. Public Docket

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP–300506] (including comments and data submitted electronically as described below). 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 official rulemaking record is located at the Virginia address in **ADDRESSES** at the beginning of this document.

Electronic comments can 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. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number [OPP–300506]. Electronic comments on this rule may be filed online at many Federal Depository Libraries.

IX. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950) (May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **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: June 9, 1997.

James Jones,

Acting 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. Section 180.474 is amended as follows:

i. The section heading is revised to read as set forth below.

ii. The existing text is designated as paragraph (a) ''General''.

iii. Paragraphs (b), (c), and (d) are added as follows:

§ 180.474 Tebuconazole; tolerances for residues.

(a) *General.* * * *

* * * * *

(b) *Section 18 emergency exemptions*—(1) *Use on grains, hay and other plant products.* Time-limited tolerances are established for residues of the fungicide tebuconazole (*alpha*-[2-(4-chlorophenyl)-ethyl]-*alpha*-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Barley, grain	2.0	June 30, 1998
Barley, hay	20.0	Do.
Barley, straw	20.0	Do.
Pistachios	1.0	Do.
Wheat, hay	15.0	Do.
Wheat, straw	2.0	Do.

(2) *Use on meat and meat byproducts.* Time-limited 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 (HGW 2061) in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Milk	0.1	June 30, 1998
Cattle, meat byproducts	0.2	Do.
Goats, meat byproducts	0.2	Do.
Hogs, meat byproducts	0.2	Do.
Horses, meat byproducts	0.2	Do.
Poultry, meat byproducts	0.2	Do.
Sheep, meat byproducts	0.2	Do.

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

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

[FR Doc. 97–16216 Filed 6–19–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300348; FRL–5718–7]

RIN 2070–AC78

Terbacil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the herbicide, terbacil in or on the raw agricultural commodities watermelons in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of terbacil on watermelons in Delaware, Maryland, and Virginia. This regulation establishes maximum permissible levels for residues of terbacil on watermelons pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. This tolerance will expire and is revoked on May 31, 1998.

DATES: This regulation becomes effective June 20, 1997. Objections and requests for hearings must be received by EPA on August 19, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, ''OPP–300348,'' 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–300348,'' should be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), 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. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number ''OPP–300348.'' 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: Virginia Dietrich, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location,