Procedural Requirements

This final rule does not meet the criteria for a ''significant regulatory action'' pursuant to Executive Order 12866. The notice and public comment procedures requirements of the Administrative Procedure Act are inapplicable, pursuant to 5 U.S.C. 553(a)(2).

As no notice of proposed rulemaking was required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601, *et seq*.) do not apply.

There are no collections of information contained in this final rule. Therefore, the Paperwork Reduction Act does not apply.

List of Subjects in 31 CFR Part 357

Bonds, Electronic funds transfer, Federal Reserve System, Government securities, Incorporation by reference, Securities.

For the reasons set forth in the preamble, Title 31, Chapter II, Subchapter B, Part 357 is amended as follows:

PART 357—REGULATIONS GOVERNING BOOK-ENTRY TREASURY BONDS, NOTES AND BILLS

1. The authority citation for Part 357 continues to read as follows:

Authority: 31 U.S.C. chapter 31; 5 U.S.C. 301; 12 U.S.C. 391.

Appendix B to Part 357—[Amended]

2. Appendix B to part 357 is amended by redesignating the second footnote 9 through footnote 17 as footnote 10 through 18.

3. Appendix B to part 357 is further amended in the Section-by-Section Analysis for § 357.11(b), in the third paragraph, by revising the fourth sentence and redesignated footnote 11 to read as follows:

Appendix B to Part 357—TRADES Commentary

* * * * *

Section-by-Section Analysis

* * * * *

Section 357.11—Law Governing Other Interests

* * * * *

(b) *Limited Scope of Federal Preemption*

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* * * Treasury has determined that the versions of Article 8 passed by 30 [11] states that have enacted Article 8 meet this standard. * * *

Dated: July 17, 1997.

Gerald Murphy,

Fiscal Assistant Secretary.

[FR Doc. 97–21405 Filed 8–12–97; 8:45 am]

BILLING CODE 4810–39–W

[11] Alabama, Alaska, Arizona, Arkansas, California, Colorado, District of Columbia, Idaho, Illinois, Iowa, Indiana, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, Mississippi, Nebraska, New Mexico, Oklahoma, Oregon, Pennsylvania, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wyoming.

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD08–97–024]

RIN 2115–AE46

Special Local Regulations; Steubenville Regatta, Steubenville, Ohio

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: This notice implements the special local regulations of 33 CFR 100.201, ''Annual marine events within the Second Coast Guard District'' for the ''Steubenville Regatta.'' 33 CFR 100.201 (Table One, No. 35). In 1996, the Second Coast Guard District was disestablished, and the Eighth District boundaries were expanded to include the prior Second District area of responsibility. The Eighth District Commander now exercises authority over the combined geographical region. 61 FR 29958 (June 13, 1996). This event will be held in Steubenville, Ohio at Ohio River mile 65.0–67.0 from August 15–17, 1997. Implementation of section 33 CFR 100.201 (Table One, No. 35) is necessary to provide for the safety of life on navigable waters during the event.

EFFECTIVE DATES: Section 33 CFR 100.201 (Table One, No. 35) is effective on the following dates/times:

8 a.m. until 11 p.m. on August 15, 1997
8 a.m. until 11 p.m. on August 16, 1997
8 a.m. until 11 p.m. on August 17, 1997

FOR FURTHER INFORMATION CONTACT: LT T.J. Ferring, Marine Safety Office, Pittsburgh, PA, Tel: (412) 644–5808.

SUPPLEMENTARY INFORMATION: The Steubenville Regatta is an annual river festival sponsored by the Steubenville Regatta and Racing Association, Inc. These special local regulations permit the Coast Guard to control vessel traffic in order to ensure the safety of spectators and participants. Spectators will be able to view the event from areas designated by the sponsor. Non-participating vessels will be able to transit the area during breaks between scheduled events.

Dated: July 29, 1997.

T.W. Josiah,

Rear Admiral, U.S. Coast Guard Commander, Eighth Coast Guard District.

[FR Doc. 97–21358 Filed 8–12–97; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300525; FRL–5735–2]

RIN 2070–AB78

Propiconazole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA) in or on grain sorghum, grain; grain sorghum, stover; and sorghum aspirated grain fractions . This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on grain sorghum. This regulation establishes maximum permissible levels for residues of propiconazole 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 tolerances will expire and are revoked on July 31, 1998.

DATES: This regulation is effective August 13, 1997. Objections and requests for hearings must be received by EPA on or before October 14, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300525], 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–300525], must also 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–300525]. 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 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9362, 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 combined residues of the fungicide propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA), in or on grain sorghum, grain at 0.2 parts per million (ppm); grain sorghum, stover at 1.5 ppm; and sorghum aspirated grain fractions at 20 ppm . These tolerances will expire and are revoked on July 31, 1998. After July 31, 1998, EPA will publish a document in the **Federal Register** to remove the revoked tolerances 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 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 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 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 tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Propiconazole on Grain Sorghum and FFDCA Tolerances

Sorghum ergot (*Claviceps africana*) is a new disease to grain sorghum in the United States. It was detected on sorghum in the Rio Grande Valley of Texas in February and March of 1997. The fungus infects unfertilized flower ovaries, with the resulting fungal growth eventually producing a sticky fluid known as honeydew. In sorghum grown for hybrid seed production, the disease reduces seed yield by decreasing the availability of viable pollen. In sorghum grown for grain, the disease lowers grain yield and quality, makes threshing difficult, and reduces seed germination. Currently there are no products registered for sorghum which are effective in controlling ergot, nor are there feasible alternative control practices. Efficacy data from Brazil show that the triazole group of fungicides was most successful at controlling the disease; based on limited data submitted by the registrant, propiconazole appears effective against sorghum ergot. EPA has authorized under FIFRA section 18 the use of propiconazole on grain sorghum for control of sorghum ergot in Illinois, Kansas, Nebraska, New Mexico, Oklahoma, and Texas. 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 propiconazole in or on grain sorghum commodities. 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. Consistent with the need to move quickly on the emergency exemptions in order to address an urgent non-routine situation 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 tolerance will expire and are revoked on July 31, 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 grain sorghum, grain; grain sorghum, stover; and sorghum aspirated grain fractions after that date will not be unlawful, provided the pesticide is applied in a manner that was 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 propiconazole meets EPA's registration requirements for use on grain sorghum or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of propiconazole by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Illinois, Kansas, Nebraska, New Mexico, Oklahoma, and Texas to use this pesticide on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for propiconazole, 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 MOE 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 MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

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

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

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since 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 1-7 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% 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 less than 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 this action, EPA has sufficient data to assess the hazards of propiconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA) on grain sorghum, grain at 0.2 ppm; grain sorghum, stover at 1.5 ppm; and sorghum aspirated grain fractions at 20 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the 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 propiconazole are discussed below.

1. *Acute toxicity*. For acute dietary risk assessment, EPA recommends use of the developmental NOEL of 30 mg/kg/day from a developmental toxicity study in rats. The LEL of 90 mg/kg/day was based on the increased incidence of unossified sternebrae, rudimentary ribs, and shortened or absent renal papillae. This risk assessment will evaluate acute dietary risk to the population of concern, females 13 years and older.

2. *Short - and intermediate - term toxicity.* For short- and intermediate-term dermal MOE calculations, EPA recommends use of the developmental NOEL of 30 mg/kg/day from the developmental toxicity study in rats. For short- and intermediate-term inhalation MOE calculations, EPA recommends use of the NOEL of 92.8 mg/kg/day, the highest dose tested (HDT) from the 5-day inhalation toxicity study in rats.

3. *Chronic toxicity*. EPA has established the RfD for propiconazole at 0.013 milligrams/kilogram/day (mg/kg/day). This RfD is based on a NOEL of 1.25 mg/kg/day taken from a 1–year feeding study in dogs. The effect seen at the LEL of 6.25 mg/kg/day is mild irritation of the gastric mucosa. An uncertainty factor of 100 was added to take into account interspecies and intraspecies variation.

4. *Carcinogenicity*. Propiconazole has been classified as a Group C, ''possible human carcinogen,'' chemical by the Agency. EPA recommends using the RfD approach for quantitation of human risk. Therefore, the RfD is deemed protective of all chronic human health effects, including cancer.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.434) for the combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA), in or on a variety of raw agricultural commodities. Secondary residues in animal commodities are not expected to exceed existing tolerances as a result of the proposed use. Risk assessments were conducted by EPA to assess dietary exposures and risks from propiconazole 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. The acute dietary (food only) risk assessment assumed tolerance level residues and 100% crop treated. The resulting high-end exposure estimate of 0.01 mg/kg/day, which results in a dietary (food only) MOE of 3,000 for females 13+ years old, should be viewed as conservative; refinement using anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis would result in a lower acute dietary exposure estimate.

ii. *Chronic exposure and risk*. For the purpose of assessing chronic dietary exposure from propiconazole, EPA assumed anticipated residues and percent of crop treated refinements for many of the existing uses to estimate the Anticipated Residue Contribution (ARC) from existing and proposed uses. While more refined than TMRC exposure estimates, the assumptions of tolerance level residues and 100% of crop treated for the proposed use and numerous existing uses still result in overestimation of exposure. Based on the above assumptions, chronic dietary exposure to the U.S. population represents 7% of the RfD. Dietary exposure to the subgroup most highly exposed, non-nursing infants less than 1 year, utilizes 20% of the RfD.

2. *From drinking water.* Review of terrestrial field dissipation data indicates that propiconazole is persistent and leaches into groundwater. There is no established Maximum Contaminant Level (MCL) for residues of propiconazole in drinking water. No drinking water health advisory levels have been established for propiconazole.

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 propiconazole 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 propiconazole 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.

3. *From non-dietary exposure.* Propiconazole is currently registered for use on the following residential non-food sites: a preservative treatment for finished wood (window moldings, fences, etc.), and for ornamental turf and lawns. While EPA does not consider that these types of outdoor residential uses constitute a chronic residential exposure scenario, EPA acknowledges that there may be short- and intermediate-term, non-occupational exposure scenarios. Toxicological endpoints have been identified for short- and intermediate-term risk assessment. However, no acceptable, reliable data to assess these potential risks are available at this time. Given the time-limited nature of this request, the need to make emergency exemption decisions quickly, and the significant scientific uncertainty at this time about how to aggregate non-occupational exposure with dietary exposure, the Agency will make the safety determination for these tolerances based on those factors which it can reasonably integrate into a risk assessment. What limited data are available to the Agency suggest that residential use of propiconazole by homeowners is quite limited.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Propiconazole is a member of the triazole class of pesticides. Other triazoles include bitertanol, cyproconazole, diclobutrazole, difenoconazole, diniconazole, fenbuconazole, flusilazole, hexaconazole, myclobutanil, penconazole, tebuconazole, 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 commonmechanism 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 propiconazole 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, propiconazole 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 propiconazole has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* For the population subgroup of concern, females 13+ years and older, the calculated MOE is 3,000. The Agency acknowledges the potential for exposure to propiconazole in drinking water, but does not expect that exposure would result in an aggregate MOE (food plus water) that would exceed the Agency's level of concern for acute dietary exposure.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to propiconazole from food will utilize 7% 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 (discussed below). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to propiconazole in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to propiconazole residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate risk estimates take into account exposure from chronic dietary food and water (considered to be a background exposure level) plus potential indoor and outdoor residential exposures. Based on the large acute dietary MOE for the subgroup of concern (3,000 for females 13+), the small percentage of the RfD occupied for the U.S. population (7%), and the minimal non-dietary exposure, in our best scientific

judgment, the short- and intermediate-term aggregate risk from exposure to propiconazole will not exceed the Agency's level of concern.

D. Aggregate Cancer Risk for U.S. Population

Propiconazole has been classified as a Group C, ''possible human carcinogen,'' chemical by the Agency. EPA recommends using the RfD approach for quantification of human risk. Human health risk concerns due to long-term exposure to propiconazole residues are adequately addressed by the aggregate chronic exposure analysis using the RfD.

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

1. *Safety factor for infants and children*— a. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of propiconazole, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-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 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 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 hundredfold safety factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold safety 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.

b. *Developmental toxicity studies*. In the developmental toxicity study in rats, the maternal (systemic) NOEL was 30 mg/kg/day. The maternal LEL of 90 mg/kg/day was based on reduced body weight gain and rales in females. The developmental NOEL was also 30 mg/kg/day. The developmental LEL of 90 mg/kg/day was based on the increased incidence of unossified sternebrae, rudimentary ribs, and shortened or absent renal papillae. In the rabbit developmental toxicity study, the maternal (systemic) NOEL was 100 mg/kg/day. The maternal LEL of 250 mg/kg/day was based on decreased food consumption and body weight gain. There was also an increased incidence of abortion at 400 mg/kg/day. The developmental NOEL was 400 mg/kg/day (HDT), based upon the lack of developmental delays or alterations.

c. *Reproductive toxicity study*. From the 2-generation reproductive toxicity study in rats, the parental (systemic) LEL of 5 mg/kg/day (lowest dose tested) was based on the increased incidence of hepatic ''clear-cell change'' at all dose levels; additionally, at 25 and 125 mg/kg/day, decreased body weights, decreased food consumption, and/or an increased incidence of hepatic cellular swelling were observed. A NOEL for parental toxicity was not determined. The reproductive/ developmental NOEL was 25 mg/kg/day. The reproductive LEL of 125 mg/kg/day was based on decreased offspring survival of second generation (F2) pups, and on decreased body weight throughout lactation, and an increase in the incidence of hepatic cellular swelling for both generations of offspring (F1 and F2 pups).

d. *Pre- and post-natal sensitivity*. The pre- and post-natal toxicology data base for propiconazole is complete with respect to current toxicological data requirements. There are no pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation rat reproductive study. Based on the developmental and reproductive toxicity studies discussed above, for propiconazole there does not appear to be an extra sensitivity for pre- or post-natal effects.

EPA notes developmental toxicity NOELs of 30 mg/kg/day in rats and 400 mg/kg/day (HDT) in rabbits. Developmental toxicity was observed in rats at 90 mg/kg/day; these effects occurred in the presence of maternal toxicity. The significant developmental effects in the rat study required an acute dietary risk assessment for females 13+ years of age. The calculated MOE of 3,000 demonstrated that the developmental risks were below HED's level of concern. In rabbits, no developmental delays or alterations were noted; however, increased abortions were observed at the maternally toxic dose of 400 mg/kg/day. The developmental NOELs are more than 24- and 320-fold higher in rats and rabbits, respectively, than the NOEL of 1.25 mg/kg/day from the 1-year feeding study in dogs, which is the basis of the RfD.

e. *Conclusion*. EPA concludes that reliable data support use of the standard hundredfold uncertainty factor and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk*. The calculated acute dietary (food only) MOE for females 13+ years old (accounts for both maternal and fetal exposure) is 3,000. This MOE calculation was based on the developmental NOEL in rats of 30 mg/kg/day. This risk assessment assumed 100% crop treated and tolerance level residues on all treated crops consumed, resulting in a significant over-estimate of dietary exposure. The Agency does not expect any significant exposure from the residential use of propiconazole. Despite the potential for exposure to propiconazole in drinking water, EPA does not expect the acute aggregate exposure to exceed our level of concern. The large acute dietary MOE calculated for females 13+ years old provides assurance that there is a reasonable certainty of no harm for both females 13+ years and the pre-natal development of infants.

3. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to propiconazole from food will utilize 20% of the RfD for non-nursing infants less than 1 year old and 13% of the RfD for children 1 through 6 years old. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to propiconazole in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to propiconazole residues.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants and animals is adequately understood. The residues of concern are propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole), and its metabolites determined as 2,4-

dichlorobenzoic acid (DCBA) and expressed as parent compound as specified in 40 CFR 180.434 .

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. Analytical methodologies for the determination of propiconazole and its metabolites in plant and animal commodities (Ciba-Geigy Analytical Methods AG-454 and AG-517, respectively) have been successfully validated by the Agency's Analytical Chemistry Laboratory and have been approved for publication in PAM II for enforcement purposes. These methods have not as of this time appeared in PAM II, but a copy of the methods may be obtained from the Information Resources and Services Division of OPP, at the address provided above.

C. Magnitude of Residues

Residues of propiconazole are not expected to exceed 0.2 ppm in grain sorghum, grain or 1.5 ppm in grain sorghum, stover as a result of the proposed section 18 use. Residues are not expected to exceed 20 ppm on sorghum aspirated grain fractions based on the expected tolerance level for grain sorghum grain, 0.2 ppm, and the maximum concentration factor, of 100x, for sorghum aspirated grain fractions.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican maximum residue limits for propiconazole on sorghum; therefore, international harmonization is not an issue for this action.

E. Rotational Crop Restrictions

Do not rotate to any crop intended for food, grazing, or any component of animal feed or bedding within 105 days of product application, unless the crop appears on the product label.

VI. Conclusion

Therefore, tolerances are established for combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole, and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA) in grain sorghum, grain at 0.2 ppm; grain sorghum, stover at 1.5 ppm; and sorghum aspirated grain fractions at 20 ppm.

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 October 14, 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 Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300525] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

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

IX. Regulatory Assessment Requirements

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

X. Submission to Congress and the General Accounting Office

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

List of Subjects in 40 CFR Part 180

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

Dated: August 5, 1997.

Peter Caulkins,

Acting Director, Registration Divison, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.434, in the table to paragraph (b), by removing the entries for ''grain sorghum,'' and ''grain sorghum stover,'' and by adding entries for ''sorghum, aspirated grain fractions,'' ''sorghum, grain, grain,'' and ''sorghum, grain, stover,'' to read as follows:

§ 180.434 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
* *	* * *	
Sorghum, aspirated grain fractions	20	July 31, 1998
Sorghum, grain, grain	0.2	July 31, 1998
Sorghum, grain, stover	1.5	July 31, 1998

* * * * *

[FR Doc. 97–21145 Filed 8–12–97; 8:45 am]
BILLING CODE 6560–50–F

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA–7670]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the **Federal Register**.

EFFECTIVE DATES: The effective date of each community's suspension is the third date (''Susp.'') listed in the third column of the following tables.

ADDRESSES: If you wish to determine whether a particular community was suspended on the suspension date, contact the appropriate FEMA Regional Office or the NFIP servicing contractor.

FOR FURTHER INFORMATION CONTACT: Robert F. Shea Jr., Division Director, Program Implementation Division, Mitigation Directorate, 500 C Street, SW., Room 417, Washington, DC 20472, (202) 646–3619.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the National Flood Insurance Program, 42 U.S.C. 4001 *et seq.*, unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59 *et seq.* Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

In addition, the Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM if one has been published, is indicated in the fourth column of the table. No direct Federal financial