Loreto, and Mulegé in the State of Baja California Sur; Bachiniva, Casas Grandes, Cuahutemoc, Guerrero, Namiquipa, and Nuevo Casas Grandes in the State of Chihuahua; and Altar, Atil, Bacum, Benito Juarez, Caborca, Cajeme, Carbo, Empalme, Etchojoa, Guaymas, Hermosillo, Huatabampo, Navajoa, Pitiquito, Plutarco Elías Calles, Puerto Penasco, San Luis Rio Colorado, San Miguel, and San Rio Muerto in the State of Sonora. Apples, apricots, grapefruit, oranges, peaches, persimmons, pomegranates, and tangerines may be imported from these areas without treatment for the pests named in this paragraph.

* * * * *

Done in Washington, DC, this 13th day of January 1999.

Joan M. Arnoldi,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99–1225 Filed 1–19–99; 8:45 am]

BILLING CODE 3410–34–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300770; FRL–6049–8]

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 in or on blueberries and raspberries. 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 blueberries and raspberries. This regulation establishes a maximum permissible level for residues of propiconazole in these food commodities 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 December 31, 1999.

DATES: This regulation is effective January 20, 1999. Objections and requests for hearings must be received by EPA on or before March 22, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300770], 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–300770], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300770]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Stephen Schaible, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9362, e-mail: schaible.stephen@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408 and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(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]-1H-1,2,4-triazole, and its metabolite determined as 2,4-dichlorobenzoic acid, in or on blueberries and raspberries at 1.0 part per million (ppm). These tolerances will expire and are revoked on December 31, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Findings

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

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

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

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will

result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such 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 Propiconazole on Blueberries and Raspberries and FFDCA Tolerances

Mummy berry (*Monilinia vaccinii-corymbosi*) is a fungal disease which causes damage to the fruit, flower and leaf of blueberries. The principal cause of significant yield reductions to wild blueberries is the destruction of flowers/flower clusters in the spring by the primary inoculum, though severe defoliation may also result in reduced berry size. Triflorine was the preferred fungicide for controlling this disease, but the use was voluntarily canceled by the registrant and only a limited amount of existing stock is available. Sulfur, ziram, neem oil, certain copper compounds, potassium salts of fatty acids, and chlorothalonil are all alternative fungicides registered for use on blueberries, but these are generally considered to provide unsuitable or unknown levels of performance. The only non-chemical control measure is the burning of fields to prune back vegetative growth; this practice is no longer considered environmentally acceptable and has been replaced by mowing, which does not reduce the fungal inoculum on the mummified berries. The Agency concluded that while it was unclear whether growers are expected to suffer ''significant'' economic losses in 1998 from this disease, they may incur significant economic losses in the 1999 growing season if the mummy berry disease intensifies without adequate control.

Yellow rust of raspberry is caused by a fungal pathogen, *Phragmidium rubi-idaei*. The pathogen is widespread in red raspberry fields in Oregon and Washington States, particularly in years when spring rains continue late. Historically, yellow rust has not been a problem. Under normal winter weather conditions of the Pacific Northwestern United States, teliospores of the pathogen are the sole survivor and they do not infect raspberry plants directly; urediniospores cause most damage to raspberry plants. However, last winter urediniospores also overwintered due to mild winter weather conditions. Urediniospores infected raspberry plants and disease symptoms were seen during early spring season. Urediniospores are the most damaging stage of yellow rust because they are normally produced in repeating cycles during summer months, but this spring they provided an immediate means to cause a rapid buildup of the pathogen, resulting in damage that caused this emergency. In addition, during the 1998 spring season the climatic conditions were very conducive for the disease development. The warm weather accompanied by rain caused the plants to break bud about 2–3 weeks earlier than normal. The moisture from dew and fog were sufficient to allow both spore germination and infection. All of these conditions contributed to the current emergency situation. EPA has authorized under FIFRA section 18 the use of propiconazole on blueberries for control of mummy berry disease (*Monilinia vacinii-corymbosi*) in Georgia, Maine and South Carolina and the use on raspberries for control of yellow rust (*Phragmidium rubi-idaei*) in Oregon and Washington. After having reviewed the 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 blueberries and raspberries. 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 exemption 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 tolerances will expire and are revoked on December 31, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on blueberries or raspberries after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. 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 blueberries or raspberries 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 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 Georgia, Maine, Oregon, South Carolina and Washington 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 the emergency exemptions for propiconazole, contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

III. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. 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 adversed effect level'' or ''NOAEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOAEL from the study with the lowest NOAEL 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% 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 NOAEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

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 NOAEL) 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 3 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/NOAEL 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 and its metabolites determined as 2,4-dichlorobenzoic acid on blueberries and raspberries at 1.0 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 used the developmental NOAEL of 30 mg/kg/day from a developmental toxicity study in rats. The lowest observed adversed effect level (LOAEL) 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 evaluates 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 used the developmental NOAEL of 30 mg/kg/day from the developmental toxicity study in rats. For short- and intermediate-term inhalation MOE calculations, EPA used the NOAEL of 92.8 mg/kg/day, the highest dose tested (HDT) from the 5-day inhalation toxicity study in rats. This risk assessment evaluates short- and intermediate-term risk to the population of concern, females 13 years and older.

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 NOAEL of 1.25 mg/kg/day taken from a one year feeding study in dogs. The effect seen at the LOAEL 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 has determined that the RfD approach for quantitation of human risk is appropriate. Therefore, the RfD noted above 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 and its metabolite determined as 2,4-dichlorobenzoic acid, in or on a variety of raw agricultural commodities. 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 one day or single exposure. The acute dietary (food only) risk assessment assumed tolerance level residues and one hundred percent 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 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 one hundred percent 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 one year, utilizes 20% of the RfD.

2. *From drinking water.* Available data suggest propiconazole is moderately persistent and moderately mobile to immobile in soil and aqueous environments. It has the potential to be transported with water, particularly in coarse-textured soils low in organic matter. Propiconazole's persistence indicates the potential to reach surface water with run-off or adsorbed to soil particles. There is no established Maximum Contaminant Level (MCL) for residues of propiconazole in drinking water. No health advisory levels for propiconazole in drinking water have been established.

The Agency has calculated drinking water levels of comparison (DWLOCs) for acute and chronic exposure to propiconazole in surface and groundwater. The DWLOCs are calculated by subtracting from the toxicity endpoint (acute or chronic) the respective acute or chronic dietary exposure attributable to food to obtain the acceptable exposure to propiconazole in drinking water. Default body weights (70 kg for males, 60 kg for females, and 10 kg for non-nursing infants < 1 year old) and default drinking water consumption estimates (2 L/day for adults, 1 L/day for non-nursing infants) are then used to calculate the actual DWLOCs. The DWLOC represents the concentration level in surface water or groundwater at which aggregate exposure to the chemical is not of concern.

Using Generic Expected Environmental Concentration (GENEEC) (surface water) and Screening Concentration in Ground Water (SCI-GROW) (groundwater) models, the Agency has calculated acute and chronic Tier I Estimated Environmental Concentrations (EECs) for propiconazole for use in human health risk assessments. These values represent the upper bound estimates of the concentrations of propiconazole that might be found in surface and ground water assuming the maximum application rate allowed on the label of the highest use pattern. The EECs from these models are compared to the DWLOCs to make the safety determination.

i. *Acute exposure and risk.* The subpopulation of concern for acute risk is females 13 years and older. Using the GENEEC model, the acute peak concentration in surface water was determined to be 110 parts per trillion (ppt). The Tier I SCI-GROW model predicted that groundwater concentrations of propiconazole are not likely to exceed 1.42 ppt. Assuming an adult female body weight of 60 kg and a drinking water consumption estimate of 2 L/day, the Agency calculated an acute DWLOC of 8,700 parts per billion (ppb). As even the upper bound concentrations of propiconazole are not expected to exceed 110 ppt in surface water or 1.42 ppt in groundwater, and this value is well below the acute DWLOC, the Agency concludes with reasonable certainty that acute exposure to propiconazole in drinking water is not of concern.

ii. *Chronic exposure and risk.* Using the GENEEC model, the Agency calculated a chronic concentration of propiconazole residues in surface water of 90 ppt. As described above, groundwater concentrations of propiconazole are not likely to exceed 1.42 ppt. Using the same body weight and drinking water consumption

estimates as those in the acute risk assessment, the DWLOCs for chronic exposure were calculated to be 420 ppb for the U.S. population, 430 ppb for males 13 years and older, 360 ppb for nursing females 13 years and older, and 100 ppb for infants and children. The estimated long-term concentrations of propiconazole in surface water and groundwater are well below any of these values, and the Agency concludes that chronic exposure to propiconazole in drinking water is not of concern. Since the RfD approach is recommended for quantification of cancer risk, the cancer and chronic DWLOCs are identical. Therefore the Agency also concludes that exposure is below the Agency's level of concern for cancer effects arising from chronic exposure to propiconazole in drinking water.

3. *From non-dietary exposure.* — i. Propiconazole is currently registered for residential use as a wood preservative and for residential lawn and turf uses as well as on ornamental plants. Under current OPP guidelines, these uses do not represent a chronic exposure scenario, but may constitute a short- and/or intermediate-term exposure scenario.

According to the acres-treated information available to the Agency on lawn and turf use, between 0.004% and 0.007% of all households nationally are treated with lawn products containing propiconazole as an active ingredient. Of those households which are treated, applications are mostly made by lawn care operators and landscapers instead of homeowners. It is therefore the Agency's best scientific judgement that potential residential exposure to propiconazole through the registered lawn and turf uses and use on ornamental plants is minimal. Based on this conclusion, risk assessments for these residential uses were not performed.

ii. *Short- and intermediate-term exposure and risk.* The Agency calculated exposure and risk from wood treatment use using recently developed methodologies for residential exposure assessment. These methodologies rely on high-end scenarios and the resulting exposure assessments should be considered conservative. If initial assessments using the assumptions in these methodologies indicate a potential concern, a more detailed exposure assessment, possibly incorporating chemical-specific or site-specific data, would be pursued. Because one of the variables used for assessing residential handlers exposure comes from the Pesticide Handlers Exposure Database (PHED), and is considered to be a central tendency value, resulting exposure and risk estimates are considered to be central tendency to high-end estimates. Using these assumptions, short-term dermal and inhalation MOEs from the wood treatment use were calculated to be 200 and 20,000, respectively. The Agency is generally not concerned with MOEs which exceed 100.

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

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

EPA does not have, at this time, available data to determine whether 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.* Using TMRC exposure assumptions, the Agency estimated the high-end exposure to females 13+ years, the population subgroup of concern, to be 0.01 mg/kg/day , which results in a dietary (food only) MOE of 3,000. Based on an adult female body weight of 60 kg and 2L consumption of water per day, the acute DWLOC for females 13 years and older is 8,700 ppb. The estimated peak concentration (acute) values of 110 ppt in surface water and 1.42 ppt in groundwater are lower than the acute DWLOC for females 13 years and older; therefore, the Agency concludes with reasonable certainty that the aggregate acute exposure to propiconazole residues in food and drinking water is not likely to 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 one year old (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. Based on body weight and drinking water consumption estimates discussed earlier, the chronic DWLOC for the U.S. population is 424 ppb, 430 ppb for males 13 years and older, and 360 ppb for females 13 years and older. The estimated chronic concentrations of 90 ppt in surface water and 1.42 ppt in groundwater are lower than these chronic DWLOCs. 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 exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

Short- and intermediate-term endpoints were identified for females 13 years and older, the subpopulation of concern. The aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus short- and intermediate-term residential uses.

When endpoints from multiple studies are selected from risk assessment, risks should only be aggregated if the endpoints (toxic effects) are the same or if the multiple residential exposure scenarios have a reasonable chance of occurring together. In this case the dermal and inhalation endpoints do not have the same toxic effects. Therefore the MOE dermal and MOE inhalation cannot be aggregated together. Furthermore, because exposure from residential wood preservative uses occurs mainly by the dermal route (dermal exposure = 0.15 mg/kg/day; inhalation exposure = 0.00047 mg/kg/day), exposure via inhalation was not considered in the calculation for risk from short- and intermediate-term aggregate exposure.

Using the Agency's interim guidance, short- and intermediate-term aggregate risk was calculated by considering short- and intermediate-term dermal exposure from residential uses, and chronic dietary exposure from food uses and drinking water. Because estimates for chronic exposure from drinking water are not available (only conservative estimates of environmental concentrations), the Agency calculated a short- and intermediate-term DWLOC by estimating the exposure level for drinking water which would result in an aggregate MOE of 100, given the known MOEs for food uses and residential exposure, and then deriving the DWLOC from this exposure value using the consumption and body weight assumptions discussed earlier. The short- and intermediate-term drinking water exposure was calculated to be 0.15 mg/kg/day. Using this value, the short- and intermediate-term DWLOC was calculated to be 4,500 ppb. Since chronic EECs are below this value, it is concluded that short- and intermediate-term aggregate risk does 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 used the RfD approach for quantitation of human risk. Therefore, the RfD is deemed protective of all chronic human health effects, including cancer; as aggregate chronic risk (discussed above) does not exceed the Agency's level of concern, there is a reasonable certainty that no harm will result from cancer effects arising from chronic aggregate exposure to propiconazole residues.

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

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

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the 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 MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* In the developmental toxicity study in rats, the maternal (systemic) NOAEL was 30 mg/kg/day. The maternal lowest observed adverse effect level (LOAEL) of 90 mg/kg/day was based on reduced body weight gain and rales in females. The developmental NOAEL was also 30 mg/kg/day. The developmental LOAEL 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) NOAEL was 100 mg/kg/day. The maternal LOAEL 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 NOAEL was 400 mg/kg/day (HDT), based upon the lack of developmental delays or alterations.

iii. *Reproductive toxicity study.* In the 2-generation reproductive toxicity study in rats, the parental (systemic) LOAEL 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 NOAEL for parental toxicity was not determined. The reproductive/developmental NOAEL was 25 mg/kg/day. The reproductive LOAEL of 125 mg/kg/day was based on decreased offspring survival of second generation (F_2) pups, and on decreased body weight throughout lactation, and an increase in the incidence of hepatic cellular swelling for both generations of offspring (F_1 and F_2 pups).

iv. *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. Propiconazole is not developmentally toxic in the rabbit. There is evidence in the 2-generation study that propiconazole is developmentally toxic in rats; however, toxicity in offspring occurred at doses toxic to the parents. 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.

v. *Conclusion.* Based on the above information, the Agency has concluded that a 100-fold safety factor is adequately protective of infants and children and that the 10-fold safety factor required by FQPA should be removed.

2. *Acute risk.* Toxicological effects applicable to the children/infants that

could be attributed to a single exposure (dose) were not observed in oral toxicity studies in rats and rabbits. Therefore, a dose and endpoint were not identified for acute dietary risk assessment for this population subgroup.

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 infants and 13% of the RfD for children aged 1 through 6. 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. Based on body weight and drinking water consumption estimates discussed earlier, the chronic DWLOC for infants and children is 100 ppb. The estimated chronic concentrations of 90 ppt in surface water and 1.42 ppt in groundwater are lower than this chronic DWLOC. Under current Agency criteria, the registered, non-dietary uses of propiconazole do not constitute a chronic exposure scenario. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from chronic aggregate exposure to propiconazole residues.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants is understood for the purposes of these section 18 emergency exemptions. The residues of concern are propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound (as specified in 40 CFR 180.434). As no animal feed items are associated with these requests, the nature of the residue in animals is not of concern.

B. Analytical Enforcement Methodology

Adequate methodology (Ciba-Geigy's Analytical Method AG-454) is available to enforce the established tolerances. This enforcement method for plants is a single moiety analytical method which detects residues as 2,4-dichlorobenzoic acid methyl ester and reports them as propiconazole equivalents. Separation and detection are performed by gas chromatography with electron capture detection. This analytical method has been validated by EPA's Analytical Chemistry Laboratory. Pending publication in PAM II, the analytical method is available from the Agency (IRSD/PIRIB)].

C. Magnitude of Residues

Residues of propiconazole and its regulated metabolites are not expected to exceed 1.0 ppm in/on blueberries and raspberries. Time-limited tolerances should be established at this level.

D. International Residue Limits

There are no CODEX, Canadian or Mexican Maximum Residue Limits (MRL) for propiconazole on blueberries or raspberries. Thus, harmonization of tolerances is not an issue for these tolerances.

E. Rotational Crop Restrictions

As blueberries and raspberries are not routinely rotated to other crops, rotational crop restrictions are not applicable.

VI. Conclusion

Therefore, tolerances are established for combined residues of propiconazole and its metabolite determined as 2,4-dichlorobenzoic acid in blueberries and raspberries at 1.0 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 as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by March 22, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this regulation. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Request for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300770] (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 Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C) Office of Pesticide Programs, Environmental Protection Agency, CM

#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 regulation, 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 record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

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

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

C. Executive Order 13084

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

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

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: December 30, 1998.

Robert A. Forrest,

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. In § 180.434, by alphabetically adding the following commodities to the table in paragraph (b) 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
* * * * *		
Blueberries	1.0	12/31/99
* * * * *		
Raspberries	1.0	12/31/99
* * * * *		

* * * * *

[FR Doc. 99–1255 Filed 1–19–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300763; FRL 6047–3]

RIN 2070–AB78

Fenpropathrin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

DATES: This regulation is effective January 20, 1999. Objections and requests for hearings must be received by EPA on or before March 22, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300763], 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–300763], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300763]. 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: Jacqueline Gwaltney, 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) 305–6792, e-mail: gwaltney.jackie@epamail.epa.gov.

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

I. Background and Statutory 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 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 tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.