intended to be opened or activated in a manner that exposes the contents to human contact. Products that qualify for this exemption must fully comply with all other CRP effectiveness, compatibility, and durability standards as well as all other requirements of 40 CFR part 157. CRP certification for products relying on this exemption must specify that the package does not comply with the senior and younger adult effectiveness specifications per this exemption. This exemption becomes effective on June 13, 1997 and expires on June 13, 2002.

List of Subjects in 40 CFR Part 157

Administrative practice and procedure, Infants and children, Packaging and containers, Pesticides and pest, Reporting and recordkeeping requirements.

Dated: June 4, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–15565 Filed 6–12–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300494; FRL–5718–8]

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 the pesticide propiconazole in on or the raw agricultural commodities dry beans, dry bean forage and dry bean hay in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of propiconazole on dry beans in Minnesota, North Dakota, Nebraska, Colorado and Kansas. These tolerances will expire and are revoked on December 31, 1998.

DATES: This regulation becomes effective June 13, 1997. Objections and requests for hearings must be received by EPA on or before August 12, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300494], 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 document control number, [OPP–300494], 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. Such 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–300494]. 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: Olga Odiott, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. Office location, telephone number, and e-mail: Sixth Floor, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. (703) 308-9363, e-mail: odiott.olga@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for the combined residues of the pesticide propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole)and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA) and expressed as parent compound, in or on dry beans at 0.5 part per million (ppm), in or on dry bean forage at 8.0 ppm, and in or on dry bean hay at 8.0 ppm. These tolerances will expire and be revoked by EPA on December 31, 1998. After December 31, 1998, EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) was signed into law August 3, 1996. FQPA amends both the 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.* Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 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 a 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 Dry Beans and FFDCA Tolerances

The Applicants stated that *Uromyces appendiculatus*, the causal organism of the bean rust, has the potential to erupt in epidemic proportions. Due to the heavy precipitations during the winter in the Midwest and high rust buildup during previous years, the ideal environmental conditions are present for rapid development of the disease. The pathogen is capable of mutating and although resistance has been traditionally bred into bean varieties, the available cultivars are susceptible to the new races of the rust. The registered pesticides are protectant fungicides and must be applied before infection occurs. When disease pressure is high, effective control is difficult to attain with these pesticides unless all the growers in the region begin a calendar base spray program. Propiconazole is a curative fungicide and because of its post-infection activity allows an integrated pest management approach with applications made only at the first signs of infection. Propiconazole is also an antisporulant and thereby can reduce inoculum production. EPA has authorized under FIFRA section 18 the use of propiconazole on dry beans for control of rust (*Uromyces appendiculatus*). After having reviewed their 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 dry beans. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. These tolerances will permit the marketing of dry beans treated in accordance with the provisions of the section 18 emergency exemption. 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, 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 dry beans, dry bean forage, and dry bean hay after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, section 18 of 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.

EPA has not made any decisions about whether propiconazole meets EPA's registration requirements for use on dry beans or whether permanent tolerances for this use would be appropriate. These tolerances do not 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 Minnesota, North Dakota, Nebraska, Colorado, and Kansas 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. For many of these 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% 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 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 NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

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. 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.

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.

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.* Based on the available acute toxicity data, the Office of Pesticide Programs (OPP) has determined that the NOEL of 30 mg/kg/day from a developmental toxicity study in rats should be used to assess risks from acute toxicity. The developmental lowest effect level (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 evaluates acute dietary risk to females 13+ years.

2. *Short- and intermediate-term toxicity.* Based on the available data, OPP has determined that a NOEL of 30 mg/kg/day from a developmental toxicity study in rats should be used to assess risks from short- and intermediate-term dermal toxicity. At the developmental LEL of 90 mg/kg/day, there were increased incidences of unossified sternebrae, rudimentary ribs, and shortened or absent renal papillae. For short- and intermediate-term inhalation toxicity, OPP has determined that a NOEL of 92.8 mg/kg/day (0.5 mg/L), the highest dose tested from a 5-day inhalation toxicity study in rats should be used to assess risks for occupational and residential exposure scenarios.

3. *Chronic risk.* Based on the available chronic toxicity data, OPP has established the RfD for propiconazole at 0.013 mg/kg/day. The RfD is based on a one-year feeding study in dogs with a NOEL of 1.25 mg/kg/day and an uncertainty factor (UF) of 100. The LEL of 6.25 mg/kg/day was based on mild irritation of the gastric mucosa.

4. *Cancer risk.* Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), EPA has classified propiconazole as a Group C, ''possible human carcinogen'', chemical. The OPP Carcinogenicity Peer Review Committee (CPRC) recommended using the RfD approach for quantification of human risk.

B. Exposures and Risks

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

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]-1H-1,2,4-triazole)and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA) and expresed as parent compound, in or on a variety of raw agricultural commodities at levels ranging from 0.05 ppm in milk to 60 ppm in grass (seed screenings). Risk assessments were conducted by EPA to assess dietary exposures and risks from propiconazole as follows:

i. *Acute risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure.

The acute dietary (food only) risk assessment used tolerance level residues and 100% crop-treated information. Thus, the acute dietary risk estimate is an over-estimate of exposure and it is considered to be protective of any acute exposure scenario. In the best scientific judgment of OPP, the acute dietary risk from the currently registered, and this proposed Section 18 uses of propiconazole, do not exceed our level of concern. For the population subgroup of concern, females 13+ years, a MOE value of 3,000 was calculated. Further refinement using anticipated residue values and percent crop-treated data would result in lower acute dietary risk estimates.

ii. *Chronic risk.* The chronic dietary risk assessment was partially refined using anticipated residue levels and percent crop-treated values for selected commodities. The population subgroup with the largest percentage of the RfD occupied is non-nursing infants less than 1 year old, at 20% of the RfD. This risk estimate should be viewed as conservative; further refinement using anticipated residue levels and percent crop-treated values for all commodities would result in lower dietary exposure estimates.

iii. *Cancer risk.* Based on the OPP Carcinogenicity Peer Review Committee's (CPRC) recommendation that the RfD approach be used to assess cancer risk, a quantitative cancer risk assessment was not performed. Human health risk concerns due to long-term exposure to propiconazole residues are adequately addressed by the aggregate chronic exposure analysis using the RfD.

2. *From drinking water.* Based on available studies used in EPA's assessment of environmental risk, propiconazole is soluble in water but relatively immobile in most soils and fairly persistent in the environment. No Maximum Concentration Level has been established for residues of propiconazole in drinking water. No Health Advisory Levels for propiconazole in drinking water have been established.

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 tolerances 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 tolerances are granted.

3. *From non-dietary exposure.* Propiconazole is registered for residential usage as a preservative for finished wood (fences, window moldings) and for ornamental turf/lawns. Lawn care usage data available to the Agency indicates that there is no reported usage of propiconazole products by homeowners. Two sources reported usage by lawn care operators and landscapers. Based on acres treated information, between 3,850 to 6,725 households are estimated to be potentially treated with propiconazole. This represents between 0.004% to 0.007% of all households nationally.

i. *Acute risk.* EPA generally will not include residential or other non-dietary exposure as a component of the acute exposure assessment. Theoretically, it is also possible that a residential, or other non-dietary, exposure could be combined with the acute total dietary exposure from food and water. However, the Agency does not believe that aggregating multiple exposure to large amounts of pesticide residues in the residential environment via multiple products and routes for a one day exposure is a reasonably probable event. It is highly unlikely that, in one day, an individual would have multiple high-end exposures to the same pesticide by treating their lawn and garden, treating their house via crack and crevice application, swimming in a pool, and be maximally exposed in the food and water consumed. Additionally, the concept of an acute exposure as a single exposure does not allow for including post-application exposures, in which residues decline over a period of days after application. Therefore, the Agency believes that residential exposures are more appropriately included in the short-term exposure scenario discussed below.

ii. *Chronic risk.* Based on the nature of the outdoor and indoor residential uses of propiconazole, the Agency has concluded that a chronic residential exposure scenario does not exist.

iii. *Short- and intermediate-term risk.* Considering the nature of the outdoor residential uses, the Agency has concluded that a short- to intermediate-term outdoor residential exposure scenario could exist. The contribution from indoor residential inhalation exposure resulting from propiconazole-treated window moldings to the short- and intermediate-term aggregate risk would be negligible, and has not been included in this risk characterization.

In the absence of data, and until further data are provided, risks from residential uses will be assumed to account for 10% (5% each for outdoor and indoor residential usage) of the total allowable aggregate short- and intermediate-term risk. OPP considers this estimate of total aggregate short- and intermediate-term exposure as conservative and protective of the public health. In the best scientific judgment of OPP, the shortand intermediate-term aggregate risks from the currently registered, and the proposed Section 18 uses of propiconazole, do not exceed our level of concern.

C. 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.

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

1. *Acute risk.* For the population subgroup of concern, females 13+ and older (accounts for both maternal and fetal exposure), the calculated MOE

value is 3,000. This MOE value does not exceed the Agency's level of concern for acute dietary exposure. Despite the potential for exposure to propiconazole from drinking water EPA concludes that the aggregate acute risk from the currently registered uses of propiconazole does not exceed the Agency's level of concern.

2. *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. For propiconazole, EPA does not have concerns for short- and intermediate-term dietary exposure because of the very high values calculated for the MOEs. The calculated MOE value is 34,000 for the U.S. population. Despite the potential for exposure to propiconazole from drinking water EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to propiconazole residues.

3. *Chronic risk.* Using the conservative 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. 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.

4. *Cancer risk.* Based on the OPP Carcinogenicity Peer Review Committee's (CPRC) recommendation that the RfD approach be used to assess cancer risk, a quantitative cancer risk assessment was not performed. 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

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.

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 pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

1. *Developmental toxicity studies.*—i. *Rat.* 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.

ii. *Rabbit.* 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.

2. *Reproductive toxicity study (rat).* From the 2-generation reproductive toxicity study in rats, the parental (systemic) LEL of 5 mg/kg/day, the lowest dose tested (LET), 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 (F.) pups, on decreased body weight throughout lactation, and on an increase in the incidence of hepatic cellular swelling for both generations of offspring (F1 and F. pups).

3. *Pre- and post-natal sensitivity.* The developmental toxicity NOELs were 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. 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.

In the two-generation reproductive toxicity study in rats, the reproductive (pup) toxicity NOEL of 25 mg/kg/day was greater than the parental (systemic) toxicity NOEL (<5 mg/kg/day; LET). The NOEL of 25 mg/kg/day for reproductive (pup) toxicity was 20-fold higher than the NOEL of 1.25 mg/kg/day from the 1-year feeding study in dogs, which is the basis of the RfD. The reproductive (pup) LEL of 125 mg/kg/day was based on decreased offspring survival of second generation (F.) pups, and on decreased body weight throughout lactation, and an increase in the incidence of hepatic cellular swelling for both generations of offspring (F. and F. pups). Because these reproductive effects occurred in the presence of parental (systemic) toxicity, these data do not suggest increased pre- or post-natal sensitivity to infants and children (that infants and children might be more sensitive than adults) to propiconazole exposure.

4. *Acute risk.* For the population subgroup of concern, females 13+ years, an MOE value of 3,000 was calculated using the high end exposure value of 0.01 mg/kg/day. Tolerance level residues and 100% crop-treated information were used in conducting the analysis. Thus, this acute dietary risk estimate is considered conservative. The large acute dietary MOE calculated for females 13+ years old provides assurance that there is a reasonable certainty of no harm from aggregate exposures to females 13+ years and the pre-natal development of infants.

5. *Short- or intermediate-term risk.* For the most highly exposed population subgroup (non-nursing infants less than

1 year old), a short- and intermediate-term MOE of 11,000 was calculated. The large MOE calculated for nonnursing infants provides assurance that there is a reasonable certainty of no harm for infants and children from short- and intermediate-term aggregate exposures to propiconazole residues.

6. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that the percent of the RfD that will be utilized by aggregate exposure to residues propiconazole from food ranges from 8% for nursing infants, up to 20% for non-nursing infants (the most highly exposed population subgroup). 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

1. *Metabolism in plants and animals*. The metabolism of propiconazole in plants and animals is adequately understood for the purposes of these tolerance actions. The residues of concern are propiconazole (1-[[2-(2,4-dichloro-phenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole), and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA) and expressed as parent compound as per 40 CFR 180.434.

2. *Analytical enforcement methodology*. There are practical analytical methods for detecting and measuring levels of propiconazole in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances. EPA has provided information on these method to FDA. These methods have been approved for publication in PAM II for enforcement purposes.

3. *Magnitude of residues*. Residues of propiconazole are not expected to exceed 0.5 ppm in/on dry beans (seed), 8.0 ppm in/on dry bean forage, and 8.0 ppm in/on dry bean hay as a result of these Section 18 uses. Time-limited tolerances should be established at these levels. Secondary residues in animal commodities are not expected to exceed existing tolerances as a result of these Section 18 uses.

4. *International residue limits*. There are no Codex, Canadian, or Mexican international residue limits established for use of propiconazole on dry beans.

VI. Conclusion

Therefore, tolerances in connection with the FIFRA section 18 emergency exemptions are established for the combined residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA) and expressed as parent compound, in or on dry beans at 0.5 ppm, in or on dry bean forage at 8.0 ppm, and in or on dry bean hay at 8.0 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 issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by August 12, 1997, file written objections to any aspect of this regulation (including the revocation provision) 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

A record has been established for this rulemaking under docket control number [OPP–300494]. A public version of this record, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 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.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing requests, 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. The official rulemaking record is the paper record maintained at the address in **ADDRESSES** at the beginning of this document.

IX. Regulatory Assessment Requirements

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

specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

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

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104-121, 110 Stat. 847), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: May 28, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.434, paragraph (b) is amended by alphabetically adding the tolerances to the table 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
* * * *	*	*
Dry bean forage	8.0	December 31, 1998
Dry bean hay	8.0	December 31, 1998
Dry beans	0.5	December 31, 1998
* * * *	*	*

* * * * *

[FR Doc. 97–15373 Filed 6–12–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300497; FRL–5718–6]

RIN 2070-AC78

Azoxystrobin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the fungicide azoxystrobin in or on the raw agricultural commodities rice and rice straw and hulls, liver of cattle, hog, goat, horse, sheep, and poultry; meat and fat of cattle, goat, horse, sheep, poultry, and swine; kidney and milk of cattle; and eggs in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of azoxystrobin on rice in Mississippi. This regulation establishes maximum permissible levels for residues of azoxystrobin on the commodities listed above pursuant to section 408(l)(6) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on May 30, 1999.

DATES: This regulation becomes effective June 13, 1997. Objections and requests for hearings must be received by EPA on August 12, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP–300497, 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 document control number, OPP–300497, should 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–300497. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Virginia Dietrich, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Document Processing Desk, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 308–9359, e-mail: dietrich.virginia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, pursuant to section 408(e) and (l)(6) of