40 CFR Part 180

[OPP–300441; FRL–5572–9]

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 fungicide propiconazole in or on the raw agricultural commodity sorghum in connection with EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of propiconazole on sorghum in Texas. This regulation establishes maximum permissible levels for residues of propiconazole in this food 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 be revoked automatically without further action by EPA on October 31, 1998.

DATES: This regulation becomes effective November 13, 1996. This regulation expires and is revoked automatically without further action by EPA on October 31, 1998. Objections and requests for hearings must be received by EPA on or before January 13, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300441], 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–300441], must also be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP–300441]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Stephen Schaible, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–8337, e-mail: schaible.stephen@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for residues of the fungicide propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole, in or on grain sorghum at 0.1 part per million (ppm) and grain sorghum stover at 1.5 ppm. These tolerances will expire and be revoked automatically without further action by EPA on October 31, 1998.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures.

New section 408(b)(2)(A)(i) 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, 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 408(b)(2)(D) specifies factors EPA is to consider in establishing a tolerance. Section 408(b)(3) requires EPA to determine that there is a practical method for detecting and measuring levels of the pesticide chemical residue in or on food and that the tolerance be set at a level at or above the limit of detection of the designated method. Section 408(b)(4) requires EPA to determine whether a maximum residue level has been established for the pesticide chemical by the Codex Alimentarius Commission. If so, and EPA does not propose to adopt that level, EPA must publish for public comment a notice explaining the reasons for departing from the Codex level. Section 408(c) governs EPA's establishment of exemptions from the requirement for a tolerance using the same safety standard as section 408(B)(2)(A) and incorporating the provisions of section 408(b)(2)(C) and (D).

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. Generally, these regulations allow a State or Federal agency to apply for an exemption to allow use of a pesticide for which that pesticide is not registered to alleviate an emergency condition. The regulations set forth information requirements, procedures, and standards for EPA's approval or denial of such exemptions.

Prior to FQPA, when EPA granted an emergency exemption under section 18 in connection with use of a pesticide that could result in residues of the pesticide chemical in or on food, EPA did not establish a tolerance or exemption from the requirement for a tolerance under FFDCA. Rather, EPA advised the Food and Drug Administration (FDA) of the emergency exemption and of the level of residues that EPA concluded would be present in or on affected foods as a result of the

emergency use. However, new section 408(l)(6) 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. Section 408(l)(6) also requires EPA to promulgate regulations by August 3, 1997, governing the establishment of tolerances and exemptions under section 408(l)(6) and requires that the regulations be consistent with section 408(b)(2) and (c)(2) and FIFRA section 18.

Section 408(e) gives EPA general authority to establish tolerances and exemptions from the requirement for a tolerance through notice and comment rulemaking procedures upon EPA's initiative. Section 408(l)(6) allows EPA to establish tolerances or exemptions from the requirement for a tolerance, in connection with EPA's granting of FIFRA section 18 emergency exemptions, without providing notice or a period for public comment. Thus, consistent with the need to act expeditiously on requests for emergency exemptions under FIFRA, EPA can establish such tolerances or exemptions under the authority of section 408(e) and (l)(6) without notice and comment rulemaking. The other procedures set out in section 408(e) and (g) are applicable to these tolerances and exemptions. Tolerances and exemptions issued under section 408(l)(6) must be consistent with the safety standards in section 408(b)(2) and (c)(2), respectively, that are applicable to all tolerances and exemptions under section 408, and with FIFRA section 18. Section 408(l)(6) specifies that such tolerances and exemptions must have an expiration date but does not specify how EPA is to set such an expiration date.

In light of FQPA, EPA is engaged in an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will generally delay the review of food use applications, particularly those involving exposure to children. However, recognizing the importance of FIFRA section 18 emergency exemptions and their time sensitive nature, EPA will continue to process section 18 applications for food uses which clearly are emergencies and which clearly are consistent with the new FFDCA section 408 safety standard and with FIFRA section 18. EPA will issue a notice in the Federal Register soon summarizing the requirements of FQPA, indicating how EPA intends to meet those requirements, and describing actions necessary to assure that EPA complies with the law. EPA intends to promulgate the procedural rule required under section 408(l)(6) by August 3, 1997, but EPA also intends to continue to grant appropriate section 18 emergency exemptions and issue the associated tolerances and exemptions in the interim pending promulgation of that rule. EPA also intends to issue interim guidance to States and others on how EPA will implement section 18 of FIFRA and section 408(l)(6) in the near future.

EPA intends to address how it will provide an expiration date for section 408(l)(6) tolerances and exemptions in the general procedural rule to be promulgated by August 3, 1997. In the interim, EPA has decided to proceed as follows. Section 408(l)(5) specifies that, if a tolerance or exemption from the requirement for a tolerance for a pesticide chemical residue in or on a food has been revoked under section 408, food containing the residue is not unsafe (and thus subject to action by FDA as ''adulterated'') if ''the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful'' under FIFRA and ''the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance. . . .'' Taking section 408(l)(5) and (6) together, EPA has concluded that the best way to effect an ''expiration date'' during this interim period for a tolerance or exemption established in connection with EPA's grant of a FIFRA section 18 emergency exemption is to specify that the tolerance or exemption will expire and be revoked automatically, without further action by EPA, as of a specified date. That date will generally be approximately 1 year from the date of issuance of the emergency exemption. Under section 408(l)(5), food that contains residues of the pesticide chemical as a result of lawful use under the terms of the section 18 emergency exemption, and at levels that are authorized at the time of that application or use under the tolerance or exemption that was established under section 408(l)(6) in connection with the section 18 action, would remain lawful after the tolerance or exemption is automatically revoked. EPA believes that handling the section 18-related tolerances and exemptions in this manner will allow EPA to respond promptly to emergency conditions during this interim period and will ensure that food containing pesticide residues as a result of use under an emergency exemption will not be considered ''adulterated.''

In deciding to continue to act on section 18 emergency exemptions and to issue the associated tolerances and exemptions early in the process of FQPA implementation, EPA recognizes that it will be necessary to make decisions about the new FFDCA section 408, including the new safety standard. In establishing section 18-related tolerances and exemptions during this interim period before EPA issues the section 408(l)(6) procedural regulation and before EPA makes its broad policy decisions concerning the interpretation and implementation of the new section 408, EPA does not intend to set precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Rather, these early section 18 tolerance and exemption decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further rulemaking and policy development. EPA intends to act on section 18-related tolerances and exemptions that clearly qualify under the new law.

II. Emergency Exemption for Propiconazole on Sorghum and FFDCA Tolerances

On September 4, 1996, the Texas Department of Agriculture availed of itself the authority to declare the existence of a crisis situation within the state, thereby authorizing use under FIFRA section 18 of propiconazole on sorghum for control of northern leaf blight. Texas stated that unusually wet weather conditions this summer have resulted in an increase of this disease above normally occurring levels. It is estimated that as much as 90% of all the world's grain sorghum grown for seed production is grown in the requested site of this section 18 application. Due to the high market prices for grain sorghum, acreage has increased this last year and reserves of certified seed for planting have been exhausted. If northern leaf blight significantly reduces yield and seed quality of the sorghum grown for seed in this area, there may not be enough available seed for planting in the 1997 season. This could result in an economic disaster affecting grain sorghum producers everywhere.

As part of its assessment of this crisis declaration, EPA assessed the potential risks presented by residues of propiconazole in or on sorghum. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided to grant the section 18

exemptions only after concluding that the necessary tolerances under FFDCA section 408(l)(6) would clearly be consistent with the new safety standard and with FIFRA section 18. These tolerances for propiconazole will permit the marketing of sorghum treated in accordance with the provisions of the section 18 emergency exemptions. Consistent with the need to move quickly on the emergency exemptions 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 be revoked automatically without further action by EPA on October 31, 1998, under FFDCA section 408(l)(5), residues of propiconazole not in excess of the amounts specified in the tolerances remaining in or on sorghum after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, the emergency exemptions. 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 the requirements for registration under FIFRA section 3 for use on sorghum, or whether a permanent tolerance for propiconazole for sorghum would be appropriate. This action by EPA does not serve as a basis for registration of propiconazole by a State for special local needs under FIFRA section 24(c). Nor does this action serve as the basis for any State other than Texas to use this product 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 percent or less of the RfD) is generally considered by EPA to pose a reasonable certainty of no harm.

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

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, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water. 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 percent of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

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. Propiconazole is already registered by EPA for use on apricots, bananas, barley, celery, corn, grass, nectarines, peaches, peanuts, pecans, pineapple, plums, rice, rye, wheat, and wild rice (see 40 CFR 180.434 for specific tolerances). Tolerances exist for meat, milk, poultry and eggs to address the potential for secondary residues resulting from the use of treated commodities as feed. Secondary residues in animal commodities from this section 18 use, resulting from the use of grain sorghum stover as feed, are not expected to exceed existing tolerances. At this time, EPA is not in possession of a registration application for propiconazole on sorghum. However, based on information submitted to the Agency, 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 a time-limited tolerance for residues of propiconazole on grain sorghum at 0.1 ppm and grain sorghum stover at 1.5 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

1. *Chronic toxicity*. Based on the available chronic toxicity data, EPA has established the RfD for propiconazole at 0.013 milligrams(mg)/kilogram(kg)/day. This RfD is based on a 1 year dog

feeding study with a NOEL of 1.25 mg/kg/day and an uncertainty factor of 100. The uncertainty factor of 100 was applied to account for inter-species extrapolation (10) and intra-species variability (10). Mild irritation of the gastric mucosa was the effect observed at the lowest effect level (LEL) of 6.2 mg/kg/day.

2. *Acute toxicity*. Agency toxicologists have recommended that the developmental NOEL of 30 mg/kg/day from the rat developmental toxicity study be used for acute dietary risk calculations. The LEL of 90 mg/kg/day is based on the increased incidence of unossified sternebrae, rudimentary ribs, and shortened or absent renal papillae. The population of concern for this risk assessment is females 13+ years old.

3. *Carcinogenicity*. Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), EPA has classified propiconazole as Group ''C'' for carcinogenicity (possible human carcinogen). The Cancer Peer Review Committee recommended the RfD approach for quantitation of human risk. Therefore, the RfD is deemed protective of all chronic human health effects, including cancer.

B. Aggregate Exposure

Tolerances have been established (40 CFR 180.434) for the residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent compound) in or on various raw agricultural commodities ranging from 0.05 ppm in milk to 60.0 ppm in grass seed screenings.

1. *Chronic exposure*. For the purpose of assessing chronic dietary exposure from propiconazole, EPA assumed anticipated residue and percent of crop treated refinements to estimate the Anticipated Residue Contribution (ARC) from the proposed and existing food uses of propiconazole. The use of anticipated residues and/or percent of crop treated data for several of the existing food uses in this analysis results in a more refined estimate of exposure than the TMRC.

Other potential sources of exposure of the general population to residues of pesticides are residues in drinking water and exposure from non-occupational sources. Review of terrestrial field dissipation data by the Environmental Fate and Effects Division indicates that propiconazole is persistent and leaches into groundwater (Pesticides in Groundwater Database (EPA 734-12-92-001, September 1992). There is no established Maximum Concentration Level for residues of propiconazole in drinking water. No drinking water health advisory levels have been established for propiconazole.

The Agency does not have available data to perform a quantitative drinking water risk assessment for propiconazole at this time. Previous experience with more persistent and mobile pesticides for which there have been available data to perform quantitative risk assessments have demonstrated that drinking water exposure is typically a small percentage of the total exposure when compared to the total dietary exposure. This observation holds even for pesticides detected in wells and drinking water at levels nearing or exceeding established MCLs. Based on this experience and the OPP's best scientific judgement, EPA concludes that it is not likely that the potential exposure from residues of propiconazole in drinking water added to the current dietary exposure will result in an exposure which exceeds the RfD.

Propiconazole is currently registered for residential use as a preservative treatment for wood and for lawn and ornamental uses. At this time, the Agency does not have reliable data which would allow quantitative incorporation of risk from these uses into a human health risk assessment.

Of residential uses, EPA believes that the lawn use poses the greatest potential for chronic exposure. According to lawn care usage data, there is no reported usage by homeowners. Two sources report 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 would represent between 0.004% to 0.007% of all households nationally. This calculation does not include propiconazole use on golf courses.

2. *Acute exposure*. In assessing acute dietary exposure for propiconazole, EPA assumed tolerance level residues, 100 percent crop treated, and individual, single-day consumption information for ''females, 13+ years old'', the population of concern.

EPA has not estimated non-occupational exposures other than dietary for propiconazole. Though the Agency acknowledges that there may be short-term residential or drinking water exposure scenarios, no acceptable reliable data to assess these potential risks are available at this time. Propiconazole is registered for residential uses. While dietary and residential scenarios could possibly occur in a single day, propiconazole would rarely be present on both the food eaten and the lawn on that single day. Even assuming this were the case, it is yet more unlikely that residues would be present at tolerance level on all food eaten that day for which propiconazole tolerances exist, as is assumed in the acute dietary risk analysis, and on the lawn that same day. Because the acute dietary exposure estimate assumes tolerance level residues and 100% crop treated for all crops evaluated it is a large over-estimate of exposure and it is considered to be protective of any acute exposure scenario.

At this time, the Agency has not made a determination that propiconazole and other substances that may have a common mode of toxicity would have cumulative effects. For purposes of this tolerance only, the Agency is considering only the potential risks of propiconazole in its aggregate exposure.

C. Determination of Safety for U.S. Population

1. *Chronic risk*. Based on the completeness and reliability of the toxicity data, EPA has concluded that dietary exposure to propiconazole will utilize 6% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100 percent of the RfD. Acceptable, reliable data are not available to quantitatively assess risk from drinking water. However, EPA concludes that there is a reasonable certainty that no harm to the U.S. population will result from aggregate exposure to propiconazole residues.

2. *Acute risk*. For the population subgroup of concern, females 13+ years old, the calculated Margin Of Exposure (MOE) value is 3000. This MOE does not exceed the Agency's level of concern for acute dietary exposure.

D. Determination of Safety for Infants and Children

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-year reproductive toxicity study in rats. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproductive toxicity studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

Based on current toxicological data requirements, the data base for propiconazole relative to pre- and post-natal toxicity is complete. EPA notes developmental toxicity NOELs of 30 mg/kg/day in rats and 400 mg/kg/day

(HDT) in rabbits. Developmental toxicity was observed in rats at 90 mg/kg/day; these effects occurred in the presence of maternal toxicity. In rabbits, no developmental delays or alterations were noted; 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 the 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 the rat, the reproductive/developmental toxicity NOEL of 25 mg/kg/day was greater than the parental (systemic) toxicity NOEL (<5 mg/kg/day; LDT). EPA notes that 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 (F2) pups, and on decreased body weight throughout lactation, and an increase in the incidence of hepatic cellular swelling for both generations of offspring (F1 and F2 pups). Because these reproductive effects occurred in the presence of parental (systemic) toxicity, these data do not suggest an increased post-natal sensitivity to children and infants (that infants and children might be more sensitive than adults) to propiconazole exposure.

1. *Chronic risk*. Based on ARC exposure estimates, EPA has concluded that the percentage of the RfD that will be utilized by dietary exposure to residues of propiconazole ranges from 8% for children 7-12 years old, up to 20% for non-nursing infants.

FFDCA section 408 provides that EPA shall apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety is appropriate. Based on current toxicological data requirements, the data base for propiconazole relative to pre- and post-natal toxicity is complete. As mentioned above, because reproductive effects occurred in the presence of parental (systemic) toxicity, these data do not suggest an increased post-natal sensitivity of children and infants to propiconazole exposure, and therefore an additional safety factor was not applied.

The ARC value for the most highly exposed infant and children subgroup (non-nursing infants <1 year old) occupies 20 percent of the RfD. This calculation assumes anticipated residue and percent of crop treated refinements for some commodities. Acceptable, reliable data are not available to quantitatively assess risk to this subgroup from drinking water. However, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to propiconazole residues.

2. *Acute risk*. At present, the acute dietary MOE for females 13+ years old is 3000. This MOE calculation was based on the developmental NOEL of 30 mg/kg/day from the rat study. This risk assessment assumed 100% crop treated with tolerance level residues on all treated crops consumed, resulting in a significant over-estimate of dietary exposure. The large acute dietary MOE calculated for females 13+ years old provides assurance that there is a reasonable certainty of no harm for both females 13+ years and the pre-natal development of infants.

V. Other Considerations

The nature of the residue in plants and animals is adequately understood for this tolerance. There are no Codex maximum residue levels established for residues of propiconazole on sorghum. Adequate enforcement methodology, GC/ECD, is available to enforce the tolerance expression. Analytical methodologies for the determination of propiconazole and its metabolites in plant and animal commodities (Ciba-Geigy Analytical Methods AG-454 and AG-517, respectively) have been successfully validated by the Agency's Analytical Chemistry Laboratory and have been approved for publication in PAM II for enforcement purposes. These methods have not as of this time appeared in PAM II, but a copy of the methods may be obtained from the Public Response and Program Resources Branch at the location listed under the ADDRESSES unit.

VI. Conclusion

Therefore, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of propiconazole in grain sorghum at 0.1 ppm and grain sorghum stover at 1.5 ppm. These tolerances will expire and be automatically revoked without further action by EPA on October 31, 1998.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by January 13, 1997 file written objections to any aspect of this regulation (including the automatic 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 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 number [OPP–300441]. 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 Response and Program Resources Branch, Field Operations 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), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines ''a significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

This action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), entitled *Enhancing the Intergovernmental Partnership,* or special consideration 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.

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by 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) of the APA as amended.

List of Subjects in 40 CFR Part 180

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

Dated: October 31, 1996.

Daniel M. Barolo,

Director, 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 adding a new paragraph (d) 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.

* * * * *

(d) Time-limited tolerances are established for residues of the fungicide propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances are specified in the following table. Each tolerance expires and is automatically revoked on the date specified in the table without further action by EPA.

Commodity	Parts per million	Expiration/ revocation date
Grain sorghum	0.1	October 31, 1998
Grain sorghum stover	1.5	October 31, 1998

[FR Doc. 96–29020 Filed 11–12–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 431

Administration for Children and Families

45 CFR Part 205

RIN 0970–AB32

Medicaid and Aid to Families With Dependent Children; Certain Provisions of the National Voter Registration Act of 1993

AGENCIES: Administration for Children and Families (ACF), and Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: These final rules would remove certain regulatory restrictions that conflict with implementation of the National Voter Registration Act of 1993 (NVRA), Pub. L. 103–31. The NVRA provisions will make it easier for individuals to vote in elections for Federal office.

EFFECTIVE DATE: November 13, 1996.

FOR FURTHER INFORMATION CONTACT: AFDC: Mr. Mack A. Storrs, ACF/OFA 5th floor, 370 L'Enfant Promenade SW., Washington, DC 20447, telephone (202) 401–9289.

Medicaid: Mr. Marinos T. Svolos, 7500 Security Boulevard, Baltimore, Maryland, 21244–1850, telephone (410) 786–4582.

SUPPLEMENTARY INFORMATION:

Background

The NVRA contains three provisions which will make it easier for individuals to register to vote in elections for Federal office. These include: (1) The simultaneous application for or renewal of drivers licenses and voter registration (the motor voter part of the bill); (2) the adoption and use of a ''mail'' application form for voter registration;