45. Section 21.344 is amended by revising the authority citation to read as follows:

§ 21.344 Facility offering training or rehabilitation services.

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(Authority: 38 U.S.C. 3110)

46. Section 21.390 is amended by revising paragraph (c) to read as follows:

§ 21.390 Rehabilitation research and special projects.

* * * * *

(c) *Research by Vocational Rehabilitation and Counseling (VR&C) staff members.* VA will encourage research by VR&C staff members. This research will address problems affecting service delivery, initiation and continuation in rehabilitation programs, and other areas directly affecting the quality of VR&C services to veterans.

(Authority: 38 U.S.C. 3119(a))

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47. Section 21.410 is revised to read as follows:

§ 21.410 Delegation of authority.

The Secretary delegates authority to the Under Secretary for Benefits to make findings and decisions under 38 U.S.C. chapter 31 and regulations, precedents, and instructions that affect vocational rehabilitation services for disabled veterans. The Under Secretary for Benefits may further delegate this authority to supervisory and non-supervisory Vocational Rehabilitation and Counseling staff members.

(Authority: 38 U.S.C. 512(a))

48. In § 21.430, paragraph (c) is amended by revising the heading and introductory text; and the authority citation is revised to read as follows:

§ 21.430 Accountability for authorization and payment of training and rehabilitation services.

* * * * *

(c) *Vocational Rehabilitation and Counseling (VR&C) Officer's review of program costs.* The VR&C Officer will review the program costs for the services in paragraphs (c)(1) through (c)(3) of this section if the case manager's program cost estimate for a calendar year exceeds $25,000. The VR&C Officer may not delegate this responsibility. The case manager will neither sign a rehabilitation plan nor authorize expenditures before the VR&C Officer approves the program costs. The services subject to this review are:

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(Authority: 38 U.S.C. 3115(b)(4))

[FR Doc. 97–9022 Filed 4–10–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300474; FRL–5600–5]

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 or on the raw agricultural commodities almonds and cranberries 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 almonds in California and cranberries in Wisconsin. This regulation establishes maximum permissible levels for residues of propiconazole in these foods pursuant to section 408(l)(6) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation becomes effective April 11, 1997. Objections and requests for hearings must be received by EPA on or before June 10, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300474], 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–300474], 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. 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–300474]. 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, DC 20460. Office location, telephone number, and e-mail: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202. (703) 308-6418, e-mail: odiott.olga@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, 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 pesticide propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole) in or on almond nutmeats at 0.1 part per million (ppm), in or on almond hulls at 2.5 ppm, and in or on cranberries at 1.0 ppm.

I. Background and Statutory Authority

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

New section 408(b)(2)(A)(i) 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 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) 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(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.

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 Exemptions for Propiconazole on Almonds and on Cranberries and FFDCA Tolerances

The California EPA Department of Pesticide Regulation availed itself of the authority to declare the existence of a crisis situation within the state on February 3, 1997, thereby authorizing use under FIFRA Section 18 of propiconazole on almonds to control anthracnose (*Colletotrichum acutatum*). California has also requested a specific exemption for this use of propiconazole. California stated that an emergency situation was present due to persistent and extended periods of rainfall during 1991 to 1995, which caused anthracnose levels to reach epidemic proportions in the northern and central almond growing areas of the state. California also stated that the causal organism is relatively insensitive to registered pesticides and that significant production and revenue losses are expected to occur without the availability of propiconazole. After having reviewed their submission, EPA concurs that an emergency condition exists.

The Wisconsin Department of Agriculture, Trade and Consumer Protection have requested a specific exemption for the use of propiconazole on cranberries to control cottonball disease. Production and distribution of triforine (Funginex), the only fungicide registered for control of cottonball disease, has been discontinued by its manufacturer. Most growers depleted their supplies of Funginex during the 1996 growing season. Wisconsin states that the lack of a fungicide to control cottonball disease can have devastating effects on cranberry growers' production and revenue. After having reviewed their submission, EPA concurs that an emergency condition exists.

As part of its assessment, EPA assessed the potential risks presented by residues of propiconazole in or on almonds nutmeats, in or on almond hulls, and in or on cranberries. 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 almonds and cranberries 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 for in section 408(l)(6). Although these tolerances will expire as intended in the table, under FFDCA section 408(l)(5), residues of propiconazole not in excess of the amount specified in the tolerances remaining in or on almonds 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 exemption. 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 almonds and cranberries, or whether permanent tolerances for propiconazole for these commodities 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 California and Wisconsin to use this product 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 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 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 relationships. 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% 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 Assessments, Cumulative Risk Discussion, 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 registered by EPA for use on pecans for control of scab, and on stone fruits for control of brown rot. At this time EPA is not in possession of a registration application for propiconazole on almonds or on cranberries. 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 the time-limited tolerances for residues of propiconazole in or on almond nutmeats at 0.1 part per million (ppm), in or on almond hulls at 2.5 ppm, and in or on cranberries at 1.0 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, the Office of Pesticide Programs (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 lowest effect level (LEL) of 6.25 mg/kg/day was based on mild irritation of the gastric mucosa.

2. *Acute toxicity.* Based on the available acute toxicity data, 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 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.

3. *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.

4. *Carcinogenicity.* 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. Aggregate Exposure

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).

Tolerances have been established (40 CFR 180.434) for the combined residues of propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-trizole) and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA) and expressed as parent compound, in or on certain raw agricultural commodities ranging from 0.05 ppm in milk to 60 ppm in grass (seed screenings). For purposes of these Section 18 uses, the nature of the residue in plants and animals is adequately understood. Almond hulls (proposed tolerance, 2.5 ppm) is not fed to poultry or swine, but can be fed up to 10% of the diet of beef and dairy cattle. This is a negligible contribution, comparatively speaking, and is not expected to increase the daily dietary burden to livestock. Secondary residues in animal commodities are not expected to exceed existing tolerances as a result of these Section 18 uses.

1. *Chronic exposure.* Given the emergency nature of these requests for the use of propiconazole and the

resulting need for a timely analysis and risk assessment, the chronic dietary (food only) risk assessment was partially refined using anticipated residue levels and percent crop-treated values for selected commodities. Further refinement using anticipated residue levels and percent crop-treated values for all commodities would result in lower dietary exposure estimates.

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 consumption of 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.

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.

Based on the nature of the outdoor and indoor residential uses of propiconazole, OPP has concluded that a chronic residential exposure scenario does not exist for outdoor residential use. A chronic residential exposure scenario may exist for indoor residential use. The indoor residential use (window moldings) will be assumed to account for 5% of the total aggregate chronic risk until additional data are provided. This value is considered conservative and protective of the public health. The aggregate chronic risk is equal to the sum of the chronic risk from food + water + residential (indoor and outdoor) uses. In the best scientific judgment of OPP, this aggregate chronic risk for propiconazole does not exceed our level of concern.

2. *Acute 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 aggregate acute risk (food and water) from the currently registered, and this proposed Section 18 uses of propiconazole, do not exceed our level of concern. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, 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 from acute aggregate exposure.

3. *Short- and intermediate-term aggregate risk assessment.* Short- and intermediate-term aggregate risk estimates take into account exposure from chronic dietary food and water (considered to be a background exposure level) plus potential indoor and outdoor residential exposures.

Considering the nature of the outdoor residential uses, OPP 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. The chronic food and water exposure estimates for the aggregate short- and intermediate-term risk assessments are considered conservative for the reasons mentioned above.

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.

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.

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 EPA has not assumed that propiconazole has a common mechanism of toxicity with other substances.

D. Determination of Safety for U.S. Population

1. *Chronic risk.* Using the conservative exposure assumptions described above, taking into account 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% 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 from drinking water and indoor uses, 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.

2. *Acute risk.* For the population subgroup of concern, females 13+ years (accounts for both maternal and fetal exposure), the calculated Margins of Exposure (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.

3. *Short- and intermediate-term risk.* For propiconazole, EPA does not have concerns for short- and intermediate-term dietary exposure because of the very high values calculated for the MOE. The calculated MOE value is 37,000 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.

E. 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 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.

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; LDT). 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 increased pre- or post-natal sensitivity to infants and children (that infants and children might be more sensitive than adults) to propiconazole exposure.

1. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that the percent of the RfD that will be utilized by exposure to residues of propiconazole ranges from 8% for children 7 - 12 years old, up to 20% for non-nursing infants (the most highly exposed population subgroup). Despite the potential for exposure to propiconazole from drinking water and indoor uses, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Therefore, taking into account the completeness and reliability of the toxicity data and the conservative exposure assessment, 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.* 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.

3. *Short- and 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 12,000 was calculated. The large MOE calculated for non- nursing 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.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (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 exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. EPA believes that reliable data support using the standard margin of exposure (usually 100x for combined inter- and intra-species variability) and not the additional tenfold margin of exposure when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin of exposure. Based on current toxicological data requirements, the database for propiconazole relative to pre- (provided by rat and rabbit developmental studies) and post-natal (provided by the rat reproduction study) toxicity is complete.

Further, as noted above, the acute dietary MOE for children 13+ years is 3,000. This large MOE demonstrates that the prenatal exposure to infants is not a toxicological concern at this time, and the additional uncertainty factor is not needed to protect the safety of infants and children.

The acute dietary risk assessment used tolerance level residues and 100% crop-treated information. Further refinement using anticipated residue levels and percent crop-treated values would result in a lower dietary exposure estimate.

The chronic dietary risk assessment was partially refined using anticipated residue levels and percent crop-treated values for selected commodities. This risk estimate should be viewed as conservative; further refinement using anticipated residue levels and percent crop-treated values for all commodities included in the analysis would result in lower dietary exposure estimates. Therefore, EPA concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to propiconazole residues.

V. Other Considerations

The metabolism of propiconazole in plants and animals is adequately understood for the purposes of these tolerance actions. There is a Codex maximum residue level (MRL) of 0.05 ppm for residues of propiconazole in/on almonds. The Section 18 tolerance on almond nut meats is proposed at 0.1 ppm and that on almond hulls at 2.5 ppm. The available field trial data on almonds do not support harmonization with the Codex MRL of 0.05 ppm because they indicate that residues used under the use patterns approved for the emergency exemption could exceed 0.05 ppm. There are no Canadian or Mexican levels established for residues of propiconazole on almonds. There are no Mexican, Canadian, or Codex MRLs established for residues of propiconazole on cranberries. 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, but have not yet appeared in PAM II. In the interim, a copy of the methods is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm 1128, 1921 Jefferson Davis Hwy., Arlington, VA, 703-305-5805.

VI. Conclusion

Therefore, time-limited tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of propiconazole in or on almond nutmeats at 0.1 part per million (ppm), in or on almond hulls at 2.5 ppm and in on or cranberries 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 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 June 10, 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 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–300474]. 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), 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.

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. 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 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:April 4, 1997.

Penelope A. Fenner-Crisp,

Acting 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. By revising § 180.434 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.

(a) *General.* Tolerances are established for the combined residues of the fungicide 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in or on the following commodities:

Commodity	Parts per million	Expiration Date
Apricots	1.0	None
Bananas	0.2	None
Barley, grain	0.1	None
Barley, straw	1.5	None
Cattle, fat	0.1	None
Cattle, kidney	2.0	None
Cattle, liver	2.0	None
Cattle, mbyp (except kidney and liver)	0.1	None
Cattle, meat	0.1	None
Celery	5.0	None
Corn, fodder	12	December 31, 1998
Corn, forage	12	December 31, 1998
Corn, grain	0.1	December 31, 1998
Corn, sweet (kernels, plus cobs with husks removed)	0.1	December 31, 1998
Eggs	0.1	None
Goats, fat	0.1	None
Goats, kidney	2.0	None
Goats, liver	2.0	None
Goats, mbyp (except kidney and liver)	0.1	None
Goats, meat	0.1	None
Grass, forage	0.5	None
Grass, hay (straw)	40	None
Grass, seed screenings	60	None
Hogs, fat	0.1	None
Hogs, kidney	2.0	None
Hogs, liver	2.0	None
Hogs, mbyp (except kidney and liver)	0.1	None
Hogs meat	0.1	None
Horses, fat	0.1	None
Horses, kidney	2.0	None
Horses, liver	2.0	None
Horses, mbyp (except kidney and liver)	0.1	None
Horses, meat	0.1	None
Milk	0.05	None
Mushrooms	0.1	None
Nectarines	1.0	None
Oats, forage	10.0	None
Oats, grain	0.1	None
Oats, hay	30.0	None
Oats, straw	1.0	None
Peaches	1.0	None
Peanuts	0.2	December 31, 1998
Peanuts, hay	20.0	December 31, 1998
Peanuts, hulls	1.0	December 31, 1998
Pecans	0.1	None
Pineapple	0.1	December 31, 1998
Pineapple, fodder	0.1	December 31, 1998
Plums	1.0	None
Poultry, fat	0.1	None
Poultry, kidney	0.2	None
Poultry, liver	0.2	None
Poultry, mbyp (except kidney and liver)	0.1	None
Poultry, meat	0.1	None
Prunes, fresh	1.0	None
Rice, grain	0.1	None
Rice, straw	3.0	None
Rye, grain	0.1	None
Rye, straw	1.5	None
Sheep, fat	0.1	None
Sheep, kidney	2.0	None
Sheep, liver	2.0	None
Sheep, mbyp (except kidney and liver)	0.1	None
Sheep, meat	0.1	None
Stonefruit group	1.0	None
Wheat, grain	0.1	None
Wheat, straw	1.5	None

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established permitting the combined residues of 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA.

Residues in these commodities not in excess of the established tolerances resulting from the uses described in this paragraph remaining after expiration of the time-limited tolerances will not be considered to be actionable if the pesticide is applied during the term of and in accordance with the provisions of this paragraph. The tolerances are specified in the following table. These tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration/ Revocation Date
Almond hull ...	2.5	July 31, 1998
Almond nut meats	0.1	July 31, 1998
Cranberries ...	41.0	July 31, 1998
Grain sorghum	0.1	October 31, 1998
Grain sorghum stover	1.5	October 31, 1998

(c) *Tolerances with regional registrations.* A tolerance with regional registration, as defined in § 180.1(n), is established for residues of 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound, in or on the following commodities:

Commodity	Parts per million
Mint, tops (leaves and stems) ..	0.3
Wild rice	0.5

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

[FR Doc. 97–9371 Filed 4–10–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300463; FRL–5597–3]

RIN No. 2070–AB78

Phosphinothricin Acetyltransferase and the Genetic Material Necessary for Its Production in All Plants; Exemption From the Requirement of a Tolerance On All Raw Agricultural Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of the plant-pesticide inert ingredients Phosphinothricin Acetyltransferase (PAT) and the genetic material necessary for its production in all plants when used as plant-pesticides in or on all raw agricultural commodities (RACs). Dekalb Genetics Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of l996 (FQPA) requesting the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of this plant-pesticides in or on all RACS.

EFFECTIVE DATE: This regulation becomes effective on April 11, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300463], may 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 should be identified by the docket control number and 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 copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway., Arlington, VA. A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically to the OPP 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 in 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–300463]. 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. Additional information on electronic submissions can be found in Unit VIII. of this preamble.

FOR FURTHER INFORMATION CONTACT: By mail: Mike Mendelsohn, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, U. S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 5th Floor CS, 2800 Crystal Drive, Arlington, VA 22202, (703)–308–8715); email: mendelsohn.mike@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 24, 1996 (62 FR 3682)(FRL–5380–2), EPA issued a notice pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d) announcing the filing of a pesticide petition for an exemption from the requirement for a tolerance by Dekalb Genetics Corporation (Dekalb), 3100 Sycamore Road, Dekalb, IL 60115. The notice contained a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the FQPA (Pub. L. 104–170). The petition requested that an exemption from the requirement of a tolerance be established for the plant-pesticides PAT and the genetic material necessary for its production in plants in or on all raw agricultural commodities (RACS). There were no comments or requests for referral to an advisory committee received in response to the notice of filing. The data submitted in the petition and other relevant material have been evaluated. The toxicology and other data listed below were considered in support of this exemption from the requirement of a tolerance.

I. Toxicological Profile

The data submitted regarding potential health effects of PAT include information on the characterization of the expressed protein in corn, the acute oral toxicity of PAT, and *in vitro* digestibility studies of the protein. The results of these studies were determined applicable to evaluate human risk and the validity, completeness, and reliability of the available data from the studies were considered.

The acute oral toxicity test of bacterially-derived PAT protein showed no test substance related deaths at a dose of 2,500 milligrams per kilogram (mg/kg). Residue chemistry data were not required for a human health effects assessment of the subject plant-pesticide inert ingredients because of the lack of mammalian toxicity. Both (1) available information concerning the dietary