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This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Allison Engine Company, P.O. Box 420, Speed Code P–40A, Indianapolis, IN 46206–0420; telephone (317) 230–2720, fax (317) 230–3381. Copies may be inspected at the FAA, New England Region, Office of the Assistant Chief Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective on December 3, 1997.

Issued in Burlington, Massachusetts, on November 10, 1997.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300559; FRL 5753–5]

RIN 2070–AB78

Fenarimol; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of fenarimol in or on filberts. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on filberts. This regulation establishes a maximum permissible level for residues of fenarimol in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on December 31, 1998.

DATES: This regulation is effective November 18, 1997. Objections and requests for hearings must be received by EPA on or before January 20, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300559], 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–300559], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 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 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300559]. 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 (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 268, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9363; e-mail: odiott.olga@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the fungicide fenarimol, in or on filberts at 0.02 part per million (ppm). This tolerance will expire and is revoked on December 31, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

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

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

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

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Fenarimol on Filberts and FFDCA Tolerances

The state of Oregon availed itself of the authority to declare a crisis exemption to use fenarimol for control of the Eastern filbert blight *Anisogramma anomala* in hazelnuts filberts. A. *Anomala* is a fungus with a long life cycle. A major infection center was discovered east of Portland, Oregon in 1986, and recent surveys have detected the disease scattered through the northern production areas of the Willamette Valley. Without controls the disease renders an orchard unproductive within 4 years of infection. Since Oregon produces 98% of the hazelnuts in the United States the entire U.S. production is at risk. EPA has authorized under FIFRA section 18 the use of fenarimol on filberts for control of the Eastern filbert blight in Oregon. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of fenarimol in or on filberts. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on filberts after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether fenarimol meets EPA's registration requirements for use on filberts or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of fenarimol by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Oregon to use this pesticide on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for fenarimol, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an

uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

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

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

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

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup non-nursing infants < 1 year old was not regionally based.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of fenarimol and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of fenarimol on filberts at 0.02 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by fenarimol are discussed below.

1. *Acute toxicity*. The Agency determined that the NOEL of 13 mg/kg/day, based on hydronephrosis at the lowest effect level (LEL) of 35 mg/kg/day, from a developmental study in rats should be used to assess acute dietary risks from residues of fenarimol. This risk assessment will evaluate risk to females 13+ years old, the population subgroup of concern.

2. *Short - and intermediate - term toxicity.* The Agency determined that the NOEL of 13 mg/kg/day from the rat developmental study should be used to assess risks from short- and intermediate-term exposures to residues of fenarimol. At the LEL of 35 mg/kg/day, there was hydronephrosis.

3. *Chronic toxicity*. EPA has established the RfD for fenarimol at 0.065 milligrams/kilogram/day (mg/kg/day). This RfD is based on a 2–year rat feeding study with a NOEL of 6.5 mg/kg/day and an uncertainty factor of 100 based on fatty change in the liver at the LEL of 13 mg/kg/day.

4. *Carcinogenicity*. The Agency's Carcinogenicity Peer Review Committee (CPRC) has classified fenarimol as a Group E (non-carcinogenic in humans) chemical.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.421) for the residues of fenarimol (alpha-(2 chlorophenyl)-alpha-(4-chlorophenyl)-5-pyrimidinemethanol), in or on a variety of raw agricultural commodities at levels ranging from 0.003 ppm in milk to 0.1 ppm in apples, pears and pecans. Tolerances have also been established for residues of fenarimol and its metabolites (alpha-(2-chlorophenyl)-alpha-(4-chlorophenyl)-1,4-dihydro-5-pyrimidinemethanol, and 5-[2-chlorophenyl)-(4-chlorophenyl)methyl]-3,4-dihydro-4-pyrimidinol measured as the total of fenarimol and 5-[(2-chlorophenyl)-(4-chlorophenyl)methyl]-3,4-dihydro-4-pyrimidine (calculated as fenarimol)) ranging from 1.0 ppm for cherries to 0.02 ppm for grapes. For this Section 18 only, the Agency determined that the residue of concern in filberts is parent fenarimol. Risk assessments were conducted by EPA to assess dietary exposures and risks from fenarimol as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The acute dietary (food only) risk assessment used TMRC estimates. The resulting high-end exposure estimate of 0.01 mg/kg/day results in a dietary (food only) MOE of 1300 for females 13+ years. This MOE should be viewed as a conservative risk estimate. Refinement of the risk assessment using anticipated residue values and percent crop-treated data would result in a lower acute dietary risk estimate.

ii. *Chronic exposure and risk.* For the chronic dietary (food only) risk assessment, the Agency assumed that 100% of filberts and all other commodities having fenarimol tolerances will contain fenarimol residues and those residues would be at the tolerance level. These assumptions result in an over estimate of human dietary exposure. Thus, in making a safety determination for this tolerance, HED is taking into account this conservative exposure assessment. The existing fenarimol tolerances (published and pending, and including the necessary Section 18 tolerance) result in a TMRC that is equivalent to percentages of the RfD that range from 1% for the U.S. population to 3% for non-nursing infants < 1 year old.

2. *From drinking water.* Based on available data used in EPA's assessment of environmental risk, fenarimol is not expected to leach to groundwater. Information on its persistence is inconclusive. There is no information on the persistence/mobility of fenarimol metabolites/degradates. There are no established Maximum Contaminant Levels for residues of fenarimol in drinking water and no Health Advisory Levels for this active ingredient in drinking water have been issued.

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause fenarimol to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with fenarimol in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *From non-dietary exposure.* Fenarimol is currently registered for use on the following residential non-food sites: ornamentals, turf and lawns. There are no indoor residential uses for fenarimol. Based on the nature of the outdoor residential uses, the EPA concludes that chronic residential exposure scenarios do not exist for fenarimol. Short and/or intermediate term exposure scenarios may exist. However, the Agency currently lacks sufficient residential-related exposure data to complete a comprehensive residential risk assessment for many pesticides, including fenarimol.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific

policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

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

EPA does not have, at this time, available data to determine whether fenarimol has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that fenarimol has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* For the population subgroup of concern, females 13+ years, the Agency estimated an MOE value of 1300 for the acute aggregate dietary (food only) risk from exposures to fenarimol residues. Despite the potential for exposure to fenarimol in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed the Agency's level of concern.

2. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to fenarimol from food will utilize 1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants < 1 year old. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to fenarimol in drinking water, 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 fenarimol residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Based on the registered uses of fenarimol short and/or intermediate term exposure scenarios may exist. However, the Agency currently lacks sufficient residential-related exposure data to complete a comprehensive residential risk assessment for many pesticides, including fenarimol.

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

1. *Safety factor for infants and children*— a. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of fenarimol, EPA considered data from developmental toxicity studies in the rat and rabbit and a 3-generation reproduction study in the rat and reproduction studies in mice and guinea pigs. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional ten-fold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard 100-fold safety factor and not the additional ten-fold safety factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard safety factor.

b. *Developmental toxicity studies—Rats.* The maternal (systemic) NOEL was 13 mg/kg/day, based on decreased weight gain at the LOEL of 35 mg/kg/day. The developmental (fetal) NOEL was 13 mg/kg/day based on hydronephrosis at the LOEL of 35 mg/kg/day. Rabbits: The maternal (systemic) NOEL was 35 mg/kg/day, the highest dose tested (HDT). The developmental (fetal) NOEL was 35 mg/kg/day (HDT).

c. *Reproductive toxicity study—Rats.* In a 3-generation rat reproduction study, the maternal (systemic) NOEL was 5.0 mg/kg/day, based on increased gestation time, and delayed onset of parturition at the LOEL of 17.5 mg/kg/day. The developmental (pup) NOEL was 5.0 mg/kg/day, based on decreased pup survival and hydronephrosis at the LOEL of 17.5 mg/kg/day. The reproductive NOEL was 2.5 mg/kg/day, based on anti-fertility effects in males, and dystocia in females at the LEL of 5.0 mg/kg/day.

d. *Pre- and post-natal sensitivity.* Based on the developmental toxicity studies discussed above, for fenarimol there does not appear to be a special sensitivity for pre-natal effects. However based on the developmental finding of hydronephrosis in the rat study, an acute dietary risk assessment was performed for females 13+ years of age.

Based on the reproductive toxicity studies discussed above and other reviewed data for fenarimol, there does not appear to be a special sensitivity for post-natal effects. The major reproductive findings in the rat (post-natal male infertility and dystocia and related effects in females) were concluded to be species-specific findings by the Agency. Reproduction studies in mice, rabbits, and guinea pigs did not demonstrate the reproductive concerns. Mechanistic data also substantiate the species-specific conclusion.

e. *Conclusion.* The EPA concludes that reliable data support use of the standard 100-fold margin of exposure/uncertainty factor and that an additional

margin/factor is not needed to protect infants and children.

2. *Acute risk.* The acute dietary MOE (food only) was calculated to be 1300 for females 13+ years (accounts for both maternal and fetal exposure). These MOE calculations were based on the developmental NOEL in rats of 13 mg/kg/day. This risk assessment assumed 100% crop-treatment with tolerance level residues on all treated crops consumed, resulting in an over-estimate of dietary exposure. The large acute dietary MOE calculated for females 13+ years provides assurance that there is a reasonable certainty of no harm for females 13+ years. Despite the potential for exposure to fenarimol in drinking water, the Agency does not expect the aggregate exposure (food plus water) to exceed the Agency's level of concern for acute dietary exposure.

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

4. *Short- or intermediate-term risk.* Based on the registered uses of fenarimol short and/or intermediate term exposure scenarios may exist. However, the Agency currently lacks sufficient residential-related exposure data to complete a comprehensive residential risk assessment for many pesticides, including fenarimol.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue of fenarimol in filberts has not been directly determined. Metabolism studies with fenarimol in apples and cherries indicate that the parent compound is the only significant residue. For the purpose of this tolerance, EPA will translate these data to filberts. For this tolerance only, EPA concludes that the residue of concern in filberts is parent fenarimol. There are no livestock feedstuffs derived from filberts. Thus, the livestock metabolism and magnitude of residues in meat, milk, poultry and eggs are not a concern for this section 18.

B. Analytical Enforcement Methodology

Analytical methodology exists for the enforcement of currently established tolerances for fenarimol.

C. Magnitude of Residues

Residues of fenarimol are not expected to exceed 0.02 ppm in/on filberts as a result of this section 18 use.

D. International Residue Limits

There are no Codex, Mexican or Canadian Maximum Residue Limits (MRL) for fenarimol in/on filberts. Thus, harmonization with Mexico and Canada are not an issue for this section 18.

VI. Conclusion

Therefore, the tolerance is established for residues of fenarimol in filberts at 0.02 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 January 20, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300559] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

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

record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408 (l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

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

X. Submission to Congress and the General Accounting Office

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

List of Subjects in 40 CFR Part 180

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

Dated: October 30, 1997.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In §180.421, by alphabetically adding ''Filberts'' to the table in paragraph (b) to read as follows:

§180.421 Fenarimol; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.*

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Commodity	Parts per million	Expiration/Revocation Date
Filberts	0.02	12/31/98
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[FR Doc. 97–30252 Filed 11–17–97; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 97

[ET Docket No. 93–62; FCC 97–303]

Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation

AGENCY: Federal Communications Commission.

ACTION: Correcting amendment.

SUMMARY: On September 12, 1997 (62 FR 47960), the Commission published final rules in the *Second Memorandum Opinion and Order*, which deals with the transition period for implementing new guidelines for human exposure to radiofrequency (RF) electromagnetic fields; and the criteria for determining whether amateur radio stations must perform routine environmental evaluations for human exposure to RF fields. The Commission is correcting the amendatory language and table to ensure that the amendments are properly incorporated in the 1998 revision of the Code of Federal Regulations.

EFFECTIVE DATE: October 15, 1997.

FOR FURTHER INFORMATION CONTACT: Robert F. Cleveland, Office of Engineering and Technology, Federal Communications Commission, (202) 418–2464.

SUPPLEMENTARY INFORMATION:

Background

The Commission is correcting § 1.1307(b)(4) and § 97.13(c)(1) of the Commission's rules, 47 CFR 1.1307(b)(4) and 47 CFR 97.13(c)(1), as modified in *Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation, Second Memorandum Opinion and Order*, published in **Federal Register** 62 FR 47960, September 12, 1997, and 62 FR 49557, September 22, 1997. The first rule deals with the transition period for implementing new guidelines for human exposure to radiofrequency (RF) electromagnetic fields. This rule, as published, omits language that was needed to clarify the Commission's policy on implementation of the new guidelines. The second rule deals with criteria for determining whether amateur radio stations must perform routine environmental evaluations for human exposure to RF fields.

Need for Correction

The rule, as published, contained misleading language and an entry was missing from a table that is necessary for