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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300480A; FRL–5751–5]

Aminoethoxyvinylglycine; Pesticide Tolerances; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: In the **Federal Register** of May 7, 1997 (62 FR 24835) (FRL–5713–5), EPA established time-limited tolerances for residues of the plant regulator aminoethoxyvinylglycine in or on the food commodities apples and pears. The reference dose (RfD) was incorrectly stated. This document corrects the RfD. On page 24836, column three, third full paragraph, line 11, the RfD was incorrectly stated as ''0.0002''; the correct RfD is ''0.002.''

FOR FURTHER INFORMATION CONTACT: Denise Greenway, Biopesticides and Pollution Prevention Division (7511W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 5-W57, CS #1, 2800 Crystal Drive, Arlington, VA 22202, 703–308–8263, e-mail: greenway.denise@epamail.epa.gov.

List of Subjects in Part 180

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

Dated: October 15, 1997.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300570; FRL–5752–4]

RIN 2070–AB78

Tebuconazole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of tebuconazole in or on sunflower seed and sunflower oil. This action is in response to an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on sunflowers. This regulation establishes a maximum permissible level for residues of tebuconazole in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on September 30, 1998.

DATES: This regulation is effective October 29, 1997. Objections and requests for hearings must be received by EPA on or before December 29, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300570], 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–300570], 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 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–300570]. 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: Daniel Rosenblatt, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9375, e-mail: rosenblatt.dan@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for residues of the fungicide tebuconazole, in or on sunflower seed and sunflower oil at 0.2 and 0.4 parts per million (ppm). These tolerances will expire and are revoked on September 30, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerances 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 Tebuconazole on Sunflower Seeds and Sunflower Oil and FFDCA Tolerances

Agriculture officials in states where the sunflower is produced commercially have identified sunflower rust, caused by the pathogen *Puccinia helianthi*, as a severe threat to crop yields. Information on the anticipated yield loss if tebuconazole were not used indicates that losses would be quite significant. One state suggested that losses could be as high as 80% for specific locations. Earlier this year, the States of Kansas, Colorado, and North Dakota determined that conditions may be favorable for a sunflower rust outbreak. Consequently, these states invoked their authorities pursuant to 40 CFR 166.40 to declare a crisis situation. EPA considered the health and safety implications of these actions and permitted the crisis actions to go forward. Therefore, EPA has authorized under FIFRA section 18 the use of tebuconazole on sunflower seed and sunflower oil for control of rust (*Puccinia helianthi*) in Colorado, North Dakota, and Kansas.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of tebuconazole in or on sunflower seed and sunflower oil. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on emergency exemptions in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on September 30, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on sunflower seed and sunflower oil 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 these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether tebuconazole meets EPA's registration requirements for use on sunflower or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of tebuconazole by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Colorado, North Dakota and Kansas to use this pesticide on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for tebuconazole, 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% 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 less than a 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 tebuconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of tebuconazole on sunflower seed and sunflower oil at 0.2 and 0.4 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

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

1. *Acute toxicity.* For acute dietary risk assessment, OPP recommended use of the developmental NOEL of 10 mg/kg/day from the developmental toxicity study in mice. Effects observed at the lowest observed effect level (LOEL) of 30 mg/kg/day are an increased number of runts and fetuses with malformations of the skull, brain, and spinal cord. The

population subgroup of concern for this acute dietary risk assessment is females (13+ years old).

2. *Short - and intermediate - term toxicity.* [OPP has determined that short- and intermediate-term inhalation risk assessments and short-term dermal risk assessments are appropriate for non-occupational, non-dietary routes of exposure. OPP recommends that the NOEL of 1,000 mg/kg/day, taken from the dermal developmental toxicity study in mice, be used for the short-term dermal MOE calculations. This NOEL was the highest dose tested in the study. For short- and intermediate-term inhalation MOE calculations, OPP recommends using the NOEL of 0.0106 mg/L/day (1.75 mg/kg/day), based on liver toxicity and piloerection at the LOEL of 0.1558 mg/L/day (25.7 mg/kg/day) in the 3-week inhalation rat toxicity study.

3. *Chronic toxicity*. EPA has established the RfD for tebuconazole at 0.03 milligrams/kilogram/day (mg/kg/day). This RfD is based on the NOEL of 2.96 mg/kg/day from a 1-year dog feeding study. Adrenal effects (fatty change and hypertrophy) were observed at the LOEL of 4.39 mg/kg/day. An uncertainty factor (UF) of 100 was applied to account for both interspecies and intra species variability.

4. *Carcinogenicity*. OPP's Cancer Peer Review Committee (CPRC) has determined that tebuconazole is a Group C (possible human carcinogen) chemical, based on mouse liver tumors in both sexes (adenomas and carcinomas in males and carcinomas in females) at 280 mg/kg/day, the highest dose tested. OPP recommends using the RfD approach for quantification of human risk. Therefore, the RfD is deemed protective of all chronic human health effects, including cancer.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.474) for parent tebuconazole (*alpha*-[2-(4-chlorophenyl)-ethyl]-*alpha*-1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol), in or on a variety of raw agricultural commodities The established levels range from 0.05 ppm in barley, oat and wheat grain to 4.0 ppm in cherries and peanut hulls. Risk assessments were conducted by EPA to assess dietary exposures and risks from tebuconazole 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. For the purpose of assessing potential acute dietary risks, tolerance level residues and 100% of crop treated to estimate the TMRC for major identifiable subgroups of consumers. An MOE of 889 was calculated for females 13+ years, the populations subgroup of concern. The high end exposure value was 0.01125 mg/kg/day.

ii. *Chronic exposure and risk.* For the purpose of assessing potential chronic dietary exposure from tebuconazole, EPA assumed tolerance level residues and 100% of crop treated to estimate the TMRC for major identifiable subgroups of consumers. The tolerances for tebuconazole result in a TMRC that is equivalent to the following range of RfD percentages: U.S. populations (48 states) 6% to non-nursing infants (<1 year old) 32%.

2. *From drinking water.* There are no groundwater data for tebuconazole. In addition, no maximum concentration levels or Health Advisories have been established for the pesticide.

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 tebuconazole to exceed the RfD even with the inclusion of the tolerances being granted in this document. The Agency has therefore concluded that the potential exposures associated with tebuconazole 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.* Tebuconazole is not currently registered for indoor or outdoor residential uses. Thus, no non-dietary, non-occupational exposure is expected.

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 tebuconazole 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, tebuconazole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that tebuconazole has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* EPA has concluded that for the population subgroup of concern, females 13+ years), acute aggregate exposure to tebuconazole from existing and proposed food uses will result in an MOE of 889. Despite the potential for exposure to tebuconazole in drinking water, EPA does not expect the aggregate exposure to exceed the level of concern for acute dietary exposure. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to tebuconazole residues.

2. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to tebuconazole from food will utilize 6% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants less than 1 year old (discussed below). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to tebuconazole in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to tebuconazole residues.

D. Aggregate Cancer Risk for U.S. Population

Tebuconazole has been classified as a Group C (possible human carcinogen) chemical by EPA, with the recommendation that the RfD approach be used to assess cancer risk. A quantitative cancer risk was not performed because human health risk concerns due to long-term exposure to tebuconazole residues are adequately addressed by the aggregate chronic exposure analysis using the RfD.

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

1. *Safety factor for infants and children—* i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of tebuconazole, 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 maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard 100-fold safety factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold 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.

ii. *Developmental toxicity studies.* From the rat developmental study, the maternal NOEL was 30 mg/kg/day, based on increased liver weight at the LOEL of 60 mg/kg/day. The developmental NOEL was 30 mg/kg/day, based on delayed ossification and supernumerary ribs at the developmental LOEL of 60 mg/kg/day. In the rabbit developmental study, the maternal NOEL was 30 mg/kg/day, based on decreased weight gain and food consumption at the maternal LOEL of 100 mg/kg/day. The developmental NOEL was 30 mg/kg/day, based on increased resorptions due to post-implantation loss at the developmental LOEL of 100 mg/kg/day. The maternal NOEL in the mouse study was 10 mg/kg/day, with reduced hematocrit occurring at the maternal LOEL of 30 mg/kg/day in the oral development toxicity study. The developmental NOEL was 10 mg/kg/day, with effects at the LOEL of 30 mg/kg/day being an increased number of runts, and fetuses with malformations of the skull, brain and spinal cord.

iii. *Reproductive toxicity study.* In the 2-generation rat reproduction study, the parental NOEL was 15 mg/kg/day, based on decreased body weight and increased spleen weight at the LOEL of 50 mg/kg/day. The reproductive NOEL was 15 mg/kg/day, with decreased body weight of neonates being the effect at the LOEL of 50 mg/kg/day.

iv. *Pre- and post-natal sensitivity.* The pre- and post-natal toxicology data base for tebuconazole is complete with respect to current toxicological data requirements. The developmental toxicity studies in rats, rabbits, and mice had developmental findings occurring at the same dose levels (NOELs and LOELs) as maternal effects, indicating no extra pre-natal sensitivity.

The reproductive toxicity study in rats did not demonstrate any extra pre- or post-natal sensitivity to infants and children since the NOEL and LOEL of 15 and 50 mg/kg/day, respectively, were the same for both parental and pup toxicity. Additionally, the decreased body weight gain in parental animals was also observed in pups.

v. *Conclusion.* Based on the above, EPA concludes that reliable data support use of the standard 100-fold uncertainty factor and that an additional safety factor is not needed to protect infants and children.

2. *Acute risk.* The acute dietary (food only) MOE for females 13+ years (accounts for both maternal and fetal exposure) was calculated to be 889. This MOE calculation was based on the developmental NOEL in mice of 10 mg/kg/day. Maternal effects observed at the LOEL of 30 mg/kg/day included a reduced hematocrit. This assessment assumed 100% crop-treated with tolerance level residues on all treated crops consumed, resulting in a significant over-estimate of dietary exposure. No data were available for potential exposures of tebuconazole in drinking water. However, EPA does not expect that aggregate exposure (food plus water) would result in an unacceptable acute dietary MOE. EPA concludes that the large acute dietary MOE provides assurance that there is a reasonable certainty of no harm for both females 13+ years and the pre-natal development of infants.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to tebuconazole from food will utilize between 9% for children (7-12 years old) to 32% for non-nursing infants (less that 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 tebuconazole in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to tebuconazole residues.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of tebuconazole residues in plants and animals is adequately understood. The residue of concern in plants is tebuconazole per se. In ruminants and poultry, the residue of concern is the parent compound and its 1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol metabolite (HGW 2061).

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expressions. The gas chromatographic method entitled ''Gas Chromatographic Method for Determination of Residues of Tebuconazole in Crops, Processed Products, Soil and Water'' is adequate to enforce time-limited tolerances for tebuconazole per se residues in/on sunflower seed and oil to support compliance efforts. The gas chromatographic method entitled ''An Analytical Residue Method for the Determination of Tebuconazole and HWG 2061 Residues in Bovine and Poultry Tissues, Milk and Eggs'' is adequate to enforce the time-limited tolerances presently established for the combined residues of tebuconazole and HWG 2061 in animal commodities.

C. Magnitude of Residues

Residues of tebuconazole per se are not expected to exceed 0.2 ppm in sunflower seed as a result of this use. Sunflower hulls and forage do not require regulation as they are not considered livestock feed items.

D. International Residue Limits

There are no Canadian, Mexican, or Codex maximum residue limits for tebuconazole on sunflowers.

E. Rotational Crop Restrictions

Product labels for tebuconazole are to carry a plant back interval of 120 days after the last application for crops which are not on the label.

VI. Conclusion

Therefore, tolerances are established for residues of tebuconazole in sunflower seed and sunflower oil at 0.2 ppm and 0.4 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 December 29, 1997, 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 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–300570] (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 Hwy., 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 time-limited tolerances under FFDCA section 408(1)(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 (1)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

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 17, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

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

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

2. In § 180.474, paragraph (b)(1) is amended by alphabetically adding the following commodities to the table to read as follows:

§ 180.474 Tebuconazole; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* (1) * * *

Commodity	Parts per million	Expiration/Revocation Date
* * *	* *	* *
Sunflower oil	0.4	9/30/98
Sunflower seed	0.2	9/30/98
* * *	* *	* *

* * * * *

[FR Doc. 97–28656 Filed 10–28–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300555; FRL–5745–5]

RIN 2070–AB78

Lambda-cyhalothrin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of lambda-cyhalothrin and its epimer in or on barley grain, barley bran, barley hay and straw, canola seed, and sugarcane. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on barley, canola, and sugarcane in Louisiana and Montana. This regulation establishes maximum permissible levels for residues of lambda-cyhalothrin in the above-mentioned food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective October 29, 1997. Objections and requests for hearings must be received by EPA on or before December 29, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP–300555, 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–300555], 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 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–300355. 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.