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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300568; FRL–5750–9]

RIN 2070–AB78

Hexythiazox; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of hexythiazox (trans-5-(4-chlorophenyl) -*N*-cyclohexyl-4-methyl-2- oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl in or on cotton, undelinted seed, and cotton gin byproducts. 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 cotton in California. This regulation establishes a maximum permissible level for residues of hexythiazox 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 be revoked on October 1, 1998.

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300568], 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–300568], 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 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–300568]. 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: David Deegan, 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) 308–9358, e-mail: deegan.dave@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 combined residues of the insecticide hexythiazox (trans-5- (4-chlorophenyl) -*N*-cyclohexyl-4-methyl-2- oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl, in or on cotton, undelinted seed at 0.1 part per million; and on cotton gin byproducts at 2.0 part per million (ppm). This tolerance will expire and be revoked on October 1, 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 tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for hexythiazox on Cotton and FFDCA Tolerances

The state of California submitted a request to EPA on April 1, 1997 for a specific exemption from the requirements of FIFRA, allowed under provisions of section 18 of FIFRA, for the emergency use of hexythiazox on cotton to control various spider mites (strawberry spider mite *Tetranychus turkestani*, twospotted spider mite *T. urticae*, Pacific spider mite *T. pacificus*, carmine spider mite *T. cinabarinus*). The state contended that an emergency condition was likely to develop during the 1997 growing season, due to conditions which have developed over the past several years favoring spider mite infestations on cotton. The state's request detailed the lack of effective non-chemical control measures for this pest. Additionally, three of the four mite species have been shown to have developed resistance to alternative registered chemicals. Spider mites attack plants primarily as foliage feeders. This action reduces plant vigor and growth, which can lead to reduced yields and/or nonproductive crops. During the last several years, wetter than normal conditions have resulted in more vegetation outside the irrigated cotton fields. This habitat has supported larger numbers of plant bugs, including mites, which have inflicted increased losses on cotton fields. On May 29, 1997 EPA allowed the state to invoke it's crisis authority under FIFRA section 18 for the use of hexythiazox on cotton for control of spider mites in California. 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 hexythiazox in or on cotton. 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 be revoked on October 1, 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 cotton, undelinted seed, and cotton gin byproducts after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA while these tolerances were in effect. 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 hexythiazox meets EPA's registration requirements for use on cotton 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 hexythiazox 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 California 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 hexythiazox, 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 nursing and 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 hexythiazox and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of hexythiazox (trans-5-(4-chlorophenyl) -*N*-cyclohexyl -4-methyl-2- oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl on cotton, undelinted seed at 0.1 ppm, and cotton gin byproducts at 2.0 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 hexythiazox are discussed below.

1. *Acute toxicity.* An acute dietary risk assessment is not required, since EPA did not identify an acute toxicological endpoint.

2. *Short - and intermediate - term toxicity.* For short and intermediate-term Margin of Exposure (MOE) calculations, EPA recommended use of the maternal NOEL of 240 mg/kg/day from the developmental toxicity study in rats. At the LEL of 740 mg/kg/day, there was decreased food consumption, decreased body weight and increased ovarian weights.

3. *Chronic toxicity.* EPA has established the RfD for hexythiazox at 0.025 milligrams/kilogram/day (mg/kg/day). This RfD is based on a one year feeding study in dogs with a NOEL of 2.5 mg/kg/day and an uncertainty factor

of 100. The LOEL of 12.5 mg/kg/day was based on hypertrophy of the adrenal cortex (both sexes).

4. *Carcinogenicity*. Hexythiazox has been classified as a Group C chemical (possible human carcinogen) by the Cancer Peer Review Committee (CPRC), based on an increased incidence of female mouse liver tumors. The Committee recommended using the Q_1* approach. The Q_1* is 0.039 mg/kg/day^{-1}.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.448) for the combined residues of hexythiazox (trans-5-(4-chlorophenyl) -*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from hexythiazox 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 is not required for this pesticide use, as the EPA did not identify an acute dietary risk endpoint.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, EPA has made conservative assumptions -- 100% of cotton seed commodities (oil and meal) and apple commodities will contain residues of hexythiazox and its metabolites and those residues will be at the level of the tolerance. Percent crop treated data were utilized for pear commodities. These conservative assumptions result in an overestimate of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment.

The published tolerances for the regulated residue of hexythiazox, plus this proposed Section 18 use result in a Anticipated Residue Contribution (ARC) that is equivalent to the following percentages of the RfD:

U.S. Population	<1%
Nursing Infants	<1%
Non-Nursing Infants (<1 year old)	<1%
Children (1–6 years old)	<1%
Children (7–12 years old)	<1%

The subgroups listed above are: (1) the U.S. population (48 states); and (2) those for infants and children.

2. *From drinking water.* Based on information currently available to EPA, hexythiazox is considered persistent in soil. EPA's current data also indicates that hexythiazox and soil metabolites are not likely to leach to groundwater. There are no established Maximum Contaminant Levels for residues of hexythiazox in drinking water. No health advisory levels for hexythiazox in drinking water have been established.

Chronic exposure and risk. 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 hexythiazox 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 hexythiazox 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.* Hexythiazox is not currently registered for use on any residential non-food sites. The Agency does not expect there to be any meaningful non-dietary residential exposure to hexythiazox.

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 hexythiazox 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, hexythiazox does not appear to produce a toxic metabolite produced by other substances. According to information evaluated related to this action, hexythiazox is a member of the thiazolidinone class of pesticides and there are no other members of this class. For the purposes of this tolerance action, therefore, EPA has not assumed that hexythiazox has a common mechanism of toxicity with other substances.

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

1. *Chronic risk.* Using the conservative exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, EPA has concluded that dietary exposure (food only) to hexythiazox will utilize <1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants. 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 hexythiazox 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 hexythiazox residues.

2. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. EPA believes that uses of hexythiazox may constitute a short- and/or intermediate-term exposure scenario. However, the Agency is not, at this time, able to complete a comprehensive residential risk assessment for many pesticides, including hexythiazox. Because there are no residential non-food uses registered for hexythiazox, and because there are no other chemicals that share its class, and based on the lack of an identified acute toxicological endpoint for hexythiazox, and the low percentage (<1%) of the RfD occupied by food and water, in the best scientific judgment of EPA, short- and intermediate-term aggregate risk will not exceed the Agency's level of concern.

D. Aggregate Cancer Risk for U.S. Population

Based on published tolerances (none are currently pending) and this proposed section 18 use, an upper bound lifetime dietary (food only) cancer risk estimate of 5.9×10^{-7} was calculated for the hexythiazox regulated residue. The calculation used the conservative exposure assumptions described above for generating ARC's and amortized the cancer risk over a 70-year lifetime (i.e., 5/70, for this first year section 18 use). This section 18 use contributes 8.0×10^{-8} to the upper bound lifetime dietary (food only) cancer risk and 5.7×10^{-9} if the cancer risk is amortized over a 70-year lifetime.

The cancer risk estimate for the existing hexythiazox uses plus the amortized risk estimate for cottonseed commodities does not exceed EPA's level of concern. EPA believes the registered uses do not constitute a chronic exposure scenario. Thus, no non-dietary, non-occupational chronic exposure to hexythiazox is expected, or is a factor in aggregate cancer risk.

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 hexythiazox, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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

ii. *Developmental toxicity studies*— a. *Rats.* In the rat developmental study, the maternal (systemic) NOEL was 240 mg/kg/day. The maternal LOEL of 720 mg/kg/day was based on decreased food consumption and decreased body weight. The developmental (fetal) NOEL was 240 mg/kg/day. The developmental LOEL was based on slight delayed ossification.

b. *Rabbits.* In the rabbit developmental toxicity study, the maternal (systemic) NOEL was 1,080 mg/kg/day at the highest dose tested (HDT). The developmental (fetal) NOEL was 1,080 mg/kg/day at the highest dose tested.

iii. *Reproductive toxicity study. Rats.* In the 2-generation reproductive toxicity study in rats, the parental (systemic) NOEL was 20 mg/kg/day. The LOEL of 120 mg/kg/day was based on decreased body weight and decreased food consumption. The developmental NOEL was 20 mg/kg/day. The developmental LOEL of 120 mg/kg/day was based on decreased body weight and delayed maturation. The reproductive NOEL was 120 mg/kg/day at the highest dose tested.

iv. *Pre- and post-natal sensitivity.* The pre- and post-natal toxicology data base for hexythiazox is complete with respect to current toxicological data requirements. There are no pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation rat reproductive toxicity study. In the developmental study in rats, the developmental NOEL and LOEL is the same as the maternal NOEL and LOEL demonstrating that no extra-sensitivity for infants and children is present. In rabbits, there are no maternal or developmental effects up to the limit dose of 1,080 mg/kg/day HDT. In the 2-generation reproductive toxicity study in rats, there are no pup effects at doses below maternal effects and the common effects in both pups and parental animals decreased body weight also demonstrates that there is no extra-sensitivity for infants and children.

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

2. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to hexythiazox from food will utilize is less than 1% of the RfD for infants and children. 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 hexythiazox in drinking water and from non-dietary, non-occupational exposure, EPA does not

expect the aggregate exposure to exceed 100% of the RfD. Therefore, taking into account the completeness and reliability of the toxicity data, the conservative exposure assessment and the fact that residential uses do not fall under a chronic exposure scenario, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to hexythiazox residues.

V. Other Considerations

A. Metabolism In Plants and Animals

1. For the purpose of this section 18 request, the nature of the residue in plants is adequately understood. The residue of concern is hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (as specified in 40 CFR 180.448).

2. Although no livestock commodity tolerances are established, the nature of the residue in animals is considered to be understood. The residue of concern is hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety.

B. Analytical Enforcement Methodology

Adequate methods to enforce the tolerance expression have been submitted for publication in PAM II. The approved method is designated as AMR 985-87 which has been used in a variety of commodities. This method is available in PP 5F3254, and by request from U.S. EPA, IRSD/PIRIB (7502C), 401 M St., SW., Washington DC 20460.

C. Magnitude of Residues

1. Residues of hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parent compound) are not expected to exceed 0.10 ppm in/on cotton, undelinted seed. A time-limited tolerance is being established at this level.

2. It is unknown if residues will concentrate in processed products of cotton seed. Therefore, the tolerance level for the RAC has been adjusted to account for any possible concentration of the residue. Additional tolerances on processed products of cotton are not required for this section 18 request.

3. Residue data are not available for cotton gin byproducts. For the purpose of this section 18 request, EPA has estimated residue levels in cotton gin byproducts. A search by EPA of the data currently available indicates two chemicals for which tolerances are established on both cotton gin byproducts and cotton seed. One use is for an at-planting use of an insecticide. The other cotton seed/cotton gin byproducts tolerance pair, 6 ppm and 100 ppm respectively, was established for a preharvest desiccant use of a herbicide. Since this preharvest desiccant use would be considered a worst case scenario, the hexythiazox residues on cotton gin byproducts will be estimated based on the concentration factor from that use, $16.6 \times (100/6)$. Thus, EPA estimates that the residue level of hexythiazox on cotton gin byproducts will be 2 ppm. A time-limited tolerance is being established at 2 ppm for hexythiazox residues in/on cotton gin byproducts. EPA notes that residue data for hexythiazox in/on cotton gin byproducts will be required for a section 3 registration decision to be made.

4. Tolerances for secondary residues of hexythiazox in livestock commodities are not established. Livestock feedstuffs for cattle (dairy and beef), poultry (discussed below)and swine are derived from cotton (meal,seed, and hulls). The maximum dietary burden from established tolerances on apples and this time-limited tolerance are 0.53 ppm for beef cattle, and 0.51 ppm for dairy cattle. EPA has previously reviewed a hexythiazox feeding study in dairy cows, in which the only measurable residues were in kidney and liver. For the purpose of this time-limited tolerance, EPA has translated these data to swine commodities. Based upon available data, EPA would not expect detectable residues of hexythiazox and its metabolites in commodities derived from cattle (beef and dairy), and swine.

5. Poultry feedstuffs are derived from cotton (cotton seed meal). Data concerning the potential for secondary residues in poultry are available. The maximum dietary burden from poultry, resulting from use associated with this time-limited tolerance is 0.02 ppm. Hexythiazox tolerances are not established on other poultry feed items. Based upon the total radioactive residue levels from the poultry metabolism study, tolerances for secondary residues of hexythiazox in poultry commodities are not required for this section 18 request.

D. International Residue Limits

There are no Codex, Canadian or Mexican maximum residue limits established for hexythiazox and its metabolites on cotton seed. Thus, harmonization is not an issue for this time-limited tolerance.

E. Rotational Crop Restrictions

As hexythiazox is not registered for use on crops that are typically rotated, rotational crop data are not available and rotation crop restrictions are not present on the hexythiazox label. Therefore, EPA cannot determine the potential for uptake of residues into crops that may be rotated into hexythiazox treated fields. In the absence of data, the following rotational crop restriction has been added to the section 18 product label: ''In order to avoid illegal residues, do not rotate treated fields to crops, other than cotton, for one year following application of hexythiazox. After one year following application of Hexythiazox, any crops may be rotated into treated fields.''

VI. Conclusion

Therefore, the tolerance is established for combined residues of hexythiazox (trans-5-(4-chlorophenyl) -*N*-cyclohexyl-4-methyl-2- oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl in cotton, undelinted seed at 0.1 ppm, and on cotton gin byproducts at 2.0 ppm.

VII. Objections and Hearing Requests

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

Any person may, by January 26, 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 Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP–300568] (including comments and data submitted electronically as described below). 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 official rulemaking record is located at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can 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. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [OPP–300568]. Electronic comments on this rule may be filed online at many Federal Depository Libraries.

IX. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d). 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 this tolerance does 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 29, 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. Section 180.448 is amended as follows:

i. By designating the existing text as paragraph (a) and adding a heading.

ii. Adding paragraph (b) with a heading.

iii. Paragraphs (c) and (d) are added and reserved with headings.

§ 180.448 Hexythiazox; tolerances for residues.

(a) *General.* * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of the insecticide hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. These tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
cotton seed, undelinted	0.1	10/1/98
cotton gin byproducts	2.0	10/1/98

(c) *Tolerances with regional registrations.* [Reserved]

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

[FR Doc. 97–31104 Filed 11–25–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 185

[OPP–300584; FRL–5756–2]

RIN 2070–AB78

Deltamethrin and Tralomethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of deltamethrin and tralomethrin in or on: deltamethrin--cottonseed at 0.04 parts per million (ppm) and cottonseed oil at 0.2 ppm; and tralomethrin--broccoli at 0.50 ppm, cottonseed at 0.02 ppm, lettuce, head at 1.00 ppm, lettuce, leaf at 3.00 ppm, soybeans at 0.05 ppm, sunflower seed at 0.05 ppm and cottonseed oil at 0.20 ppm. It also removes time limitations for tolerances for residues of deltamethrin and tralomethrin on the same commodities that expire on November 15, 1997. AgrEvo USA Company requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1966 (Pub. L. 104-170). These tolerances were established under petition numbers PP 2F4055, PP 6F3436, PP 4F2993, and PP 6F3309.

DATES: This regulation is effective November 26, 1997. Objections and requests for hearings must be received by EPA on or before January 26, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, OPP–300584, 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–300584, 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 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–300584. 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: John Hebert, 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) 308–3068, e-mail: hebert.john@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On August 16, 1995 and September 15, 1985, EPA established time limited tolerances under section 408 of the Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346 a(d) and 348 for residues of deltamethrin (60 FR 42455) (FRL–4966–3) and tralomethrin (50 FR 37851) respectively, on cottonseed. These tolerances expire on November 15, 1997. AgrEvo USA Company, on September 15, 1997, requested that the time limitation for tolerances established for residues of the insecticides deltamethrin on cottonseed at 0.04 ppm and cottonseed oil at 0.2 ppm; and tralomethrin on broccoli at 0.50 ppm, cottonseed at 0.02 ppm, lettuce, head at 1.00 ppm, lettuce, leaf at 3.00 ppm, soybeans at 0.05 ppm, sunflower seed at 0.05 ppm and cottonseed oil at 0.20 ppm, be removed based on ecological and environmental effects data that they had submitted as a condition of the registration and time-limited tolerances. AgrEvo USA Company also submitted a summary of its petition as required under the FFDCA as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104–170). In the **Federal Register** of September 25, 1997 (62 FR 50337) (FRL–5848–2), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP) for a tolerance by AgrEvo USA Company. This notice included a summary of the petition prepared by AgrEvo USA Company (acting as registered US agent for Hoechst Schering AgrEvo, S. A., Little Falls Centre, 2711 Centerville Road, Wilmington, DE 19808, the registrant. There were no comments received in response to the notice of filing.

The basis for time limited tolerances that expire November 15, 1997, was given in the October 20, 1993 **Federal Register** (58 FR 54094). These time-limited tolerances were predicated on the expiration of pesticide product registrations that were made conditional due to lack of certain ecological and environmental effects data. The rationale for using time-limited tolerances was to encourage pesticide manufacturers to comply with the conditions of registration in a timely manner. There is no regulatory requirement to make tolerances time-limited due to the conditional status of a product registration under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) as amended. It is current EPA policy to no longer establish time limitations on tolerance(s) with expiration dates if none of the conditions of registration have any bearing on human dietary risk. The current petition action meets that condition and thus the expiration dates associated with specific crop tolerances are being deleted.

Deltamethrin and tralomethrin are being combined for analysis under FQPA because tralomethrin is rapidly metabolized by animals to deltamethrin as a result of debromination. Results of the rat metabolism study supports this action.

I. Risk Assessment and Statutory Findings

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