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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300720; FRL–6030–3]

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 metabolite containing (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety in or on dates, hops, and strawberries. 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 dates and strawberries in California, and on hops in Idaho, Oregon and Washington. This regulation establishes a maximum permissible level for residues of hexythiazox 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. These tolerances will expire and be revoked on September 15, 2000.

DATES: This regulation is effective October 13, 1998. Objections and requests for hearings must be received by EPA on or before December 14, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300720], 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–300720], 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. 119, Crystal Mall #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–300720]. 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 sections 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 in or on hops at 2.0 ppm, dates at 0.1 ppm, strawberries at 3.0 parts per million (ppm). These tolerances will expire and be revoked on September 15, 2000. 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 Dates, Hops, and Strawberries and FFDCA Tolerances

The state of California has petitioned EPA to allow the emergency use of hexythiazox on both strawberries and

dates, to control various mite species. The states of Idaho, Oregon, and Washington petitioned EPA to allow the emergency use of hexythiazox on hops to control mites. EPA reviewed these requests, and concluded that emergency conditions either did exist, or were likely to occur, in each state for their subject requests. Therefore, EPA has authorized under FIFRA section 18 the use of hexythiazox on dates, hops, and strawberries for control of mites in California, Idaho, Oregon and Washington.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of hexythiazox in or on dates, hops, and strawberries. In doing so, EPA considered the 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 safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemptions in order to address urgent non-routine situations, and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and be revoked on September 15, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on dates, hops, and strawberries after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. 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 these tolerances are being approved under emergency conditions EPA has not made any decisions about whether hexythiazox meets EPA's registration requirements for use on dates, hops, and strawberries or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve 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, Idaho, Oregon, and Washington to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing 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. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the Final Rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997)(FRL–5754–7) .

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of these actions. 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 metabolite containing (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety on hops at 2.0 ppm, dates at 0.1 ppm, and strawberries at 3.0 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*. No appropriate endpoint attributable to a single exposure (dose) was identified from oral toxicity studies including the developmental rat and rabbit studies.

2. *Short - and intermediate - term toxicity.* For Margin of Exposure (MOE) calculations, there are no dermal toxicity studies available. No maternal or developmental toxicity was seen in rats (2,160 milligrams/kilogram/day (mg/kg/day) or in rabbits (1,080 mg/kg/day). For inhalation risk, there were no inhalation toxicity studies available. Therefore, EPA has determined that this combined (dermal and inhalation) risk assessment was not required. The default value of 100% is being used for dermal penetration in the absence of data.

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for hexythiazox at 0.025 mg/kg/day. This RfD is based on a 1-year feeding study in dogs with a no observed adverse effect level (NOAEL) of 2.5 mg/kg/day and an uncertainty factor of 100. The lowest observe effect level (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), based on an increased incidence of female mouse liver tumors. For this chemical, EPA uses the $Q1^*$ approach. The $Q1^*$ was calculated to be 2.2×10^{-2} mg/kg/day.

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 metabolite containing (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety, in or on apples (0.02 ppm) and pears (0.30 ppm). In addition, the following time-limited tolerances have been established related to previous section 18 exemptions that were granted in 1997: cottonseed, undelinted (0.1 ppm, exp. date 10/1/99), cotton gin by-products (2.0 ppm, exp. date 10/1/99), and strawberries (3.0 ppm, exp. date 7/1/98) (63 FR 17099, April 8, 1998) (FRL–5779–2). 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 1-day or single exposure. Because no appropriate endpoint attributable to a single exposure (dose) was identified from oral toxicity studies, including the developmental rat and rabbit studies, EPA has determined that there is a reasonable certainty of no harm resulting from risk of acute exposure to hexythiazox.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, EPA has made conservative assumptions -- 100% of dates and hops, and all other commodities having hexythiazox tolerances will contain hexythiazox residues, and those residues will be at the level of the tolerance -- which results in an overestimation of human dietary

exposure. This assessment assumes that all commodities are 100% crop treated with the exception of pears, which are 4% crop treated. Thus, in making a safety determination for this tolerance, EPA is taking into account this partially refined exposure assessment.

The existing hexythiazox tolerances (published, pending, and including the necessary section 18 tolerance(s)) result in an Anticipated Residue Contribution (ARC) that is equivalent to the following percentages of the RfD:

Population Subgroup	ARC (mg/kg/day)	%RfD
U.S. Population (48 States).	0.000129	<1%
Nursing Infants (<1 year old).	0.000111	<1%
Non-Nursing Infants (<1 year old).	0.000228	<1%
Children (1-6 years old).	0.000230	<1%
Children (7-12 years old).	0.000161	<1%

The subgroups listed above are: (1) the U.S. population (48 states); and (2) those for infants and children. No other population subgroups utilized a greater percentage of the RfD than did the U.S. population (48 states).

Cancer risk. Using a Q1* of 0.0222 $(mg/kg/day)^{-1}$ and the partially refined exposure estimates described above, the cancer risk estimate for the U.S. population is $5.5x10^{-7}$. The contribution of hexythiazox exposure resulting from these section 18 uses has been amortized for 5 years for the purposes of this section 18 only. In addition, exposure resulting from section 18's currently in effect for cotton and strawberries has been amortized for 6 years for the purposes of this section 18 only. (Note: EPA assumes a duration of 5 years for new section 18's. For repeat 18's, the number of years that previous section 18's have been granted is added to 5 years.) This cancer risk estimate is less than the Agency's level of concern. It is normally not the Agency's policy to amortize exposure data for risk calculations when establishing tolerances. However, because tolerance level residues and percent crop treated estimates were used for this action, the Agency believes that the cancer risk is overestimated.

2. *From drinking water.* Based on information available to EPA, hexythiazox is relatively persistent and not mobile. 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.

Based on the chronic dietary (food) exposure estimates, chronic drinking water levels of concern (DWLOC) for hexythiazox were calculated. EPA has used drinking water exposure numbers based on generic expected environmental concentration (GENEEC) and SCIGROW modeling using the application rate of 0.187 lb a.i./A. For surface water, the chronic (average 56 day) value is 0.28 µg/L (0.28 ppb). The groundwater screening concentration is 0.00147 µg/L (1.47 ppt).

It is current EPA policy that the following subpopulations be addressed when calculating DWLOC: U.S. Population (48 States), any other adult populations whose %RfD is greater than that of the U.S. population, Males (13+ years old), Females (13+ years old), and all infants/children. In the dietary risk evaluation system (DRES) report these last three subpopulations are further broken down into various subgroups. The subgroups which are listed are those which have the highest food exposure of all the subgroups in each subpopulation.

3. *Cancer risk.* The cancer risk estimate (food only) of 5.5×10^{-7} does not exceed EPA's level of concern. In EPA's best scientific judgment, considering the conservative nature of the GENEEC surface water number of 0.28 µg/L, there is not expected to be concern for residues of hexythiazox in drinking water if actual monitoring data were available.

4. *From non-dietary exposure.* Hexythiazox is not currently registered for use on any residential non-food sites.

5. *Cumulative exposure to substances with common mechanism of toxicity.* Hexythiazox is a member of the thiazolidinone class of pesticides. There are no other members of this class of pesticides.

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. For the purposes of this tolerance action, therefore, EPA has not assumed that hexythiazox has a common mechanism of toxicity with other substances. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the Final Rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to hexythiazox from food will utilize <1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is 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 hexythiazox in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

Based on risk estimates for food, EPA calculated a drinking water level of concern (DWLOC) of 870 µg/L. Drinking water numbers are based on GENEEC and SCIGROW modeling. For surface water, the chronic (average 56 day) value is 0.28 µg/L (0.28 ppb). The groundwater screening concentration is 0.00147 µg/L (1.47 ppt). These values are substantially lower than the DWLOCs calculated by EPA. There are no registered residential uses for hexythiazox. Therefore the aggregate risk for food + water + residential use does not exceed EPA's level of concern.

2. *Aggregate cancer risk for U.S. population*. The cancer risk estimate (food only) of 5.5 x 10^{-7} does not exceed EPA's level of concern. In addition, in EPA's best scientific judgment, considering the conservative nature of the GENEEC surface water number of 0.28 µg/L, there is not expected to be concern for residues of hexythiazox in drinking water if actual monitoring data were available. Furthermore, the GENEEC surface water number is lower than the 0.71 µg/L DWLOC calculated for cancer.

3. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to hexythiazox residues.

4. *Endocrine disrupter effects.* EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

D. 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 2-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 margin of exposure (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.* In a developmental toxicity study, 24 pregnant rats received NA-73 in gum arabic by gavage at dose levels of 0, 240, 720 or 2,160 mg/kg/day from GD 7-17. Maternal LOEL was 720 mg/kg/day (increased ovarian wts.). The maternal NOAEL was 240 mg/kg/day. The developmental LOEL was 720 mg/kg/day (reduced ossification). The developmental NOAEL was 240 mg/kg/day.

iii. In a developmental toxicity study in rabbits, pregnant NZW rabbits (12-14/dose) received NA-73 at dose levels of 0, 120, 360 or 1,080 mg/kg/day from GD 6 to 18. No maternal or developmental toxicity was noted at 1,080 mg/kg/day (NOAEL at the Limit dose).

iv. *Reproductive toxicity study.* In a reproductive toxicity study, Fisher rats (20-30/dose group) were fed NA-73 in the diet at doses of 0, 60, 400 or 2,400 ppm (0, 5, 33 or 200 mg/kg/day) for 2-generations. No reproductive toxicity was noted. The systemic LOEL was 2,400 ppm or 200 mg/kg/day (decreased body wt. gain, food consumption and food efficiency as well as increased liver, kidney and ovarian wts.). No histopathological changes were noted in the ovary. The reproductive NOAEL was 400 ppm (35 mg/kg/day). The reproductive LOEL was 2,400 ppm (decreased pup body weight during lactation, delay in hair growth and eye opening).

v. *Pre- and post-natal sensitivity.* The pre- and post-natal toxicology data base for hexythiazox is complete with respect to current toxicological data requirements. The results of these studies indicate that infants and children are not more sensitive to exposure, based on the results of the rat and rabbit developmental toxicity studies as well as the 2-generation reproductive toxicity study in rats. Therefore, the 10X safety factor to account for increased sensitivity of infants and children has been removed by EPA for this chemical.

vi. *Conclusion*. There is a complete toxicity database for hexythiazox and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Chronic risk.* Using the exposure assumptions described above, EPA has concluded that aggregate exposure to hexythiazox from food will utilize <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.

3. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to hexythiazox residues.

IV. Other Considerations

A. Metabolism In Plants and Animals

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.

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. The method involves separation by high performance liquid chromotography (HPLC) followed by ultraviolet (UV) detection at 225 nm. This method is available in PP 5F3254 and by request from U.S. EPA, OPP/IRSD/PIRIB (7502C), 401 M St., SW., Washington, DC 20460.

C. Magnitude of Residues

Residues of hexythiazox and its regulated metabolites are not expected to exceed 0.1 ppm in/on dates, 2.0 ppm in/on hops, or 3.0 ppm in/on strawberries as a result of this section 18 use. Secondary residues are not expected in animal commodities as no feed items are associated with these section 18 uses.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits (MRL) for hexythiazox on either dates or hops. Thus, harmonization is not an issue for this section 18.

E. Rotational Crop Restrictions

Dates and hops are not routinely rotated to other crops. Nor are strawberries grown in southern California. Therefore, rotational crop restrictions are not applicable.

V. 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 metabolite containing (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety in/on hops at 2.0 ppm, dates at 0.1 ppm, strawberries at 3.0 ppm.

VI. 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 14, 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 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.

VII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300720] (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 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C) Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

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

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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

Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

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

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: October 1, 1998.

James Jones,

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 by adding alphabetically to the table in paragraph (b) entries for ''dates,'' and ''hops,'' and by revising the entry for ''strawberries'' to read as follows:

§ 180.448 Hexythiazox; tolerances for residues

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
* * *	* *	
Dates	0.1	9/15/00
Hops	2.0	9/15/00
Strawberries	3.0	9/15/00

* * * * *

[FR Doc. 98–27397 Filed 10–9–98; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 97–242; RM–9192]

Radio Broadcasting Services; Eastland, Baird, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Cowboy Broadcasting LLC substitutes Channel 236C3 for Channel 236A; reallots Channel 236C3 from Eastland to Baird, Texas, as the community's first local aural service, and modifies petitioner's license for Station KVMX(FM) to specify Baird as its community of license. See 62 FR 66324 (December 18, 1997). Channel 263C3 can be allotted to Baird, Texas, in compliance with the Commission's minimum distance separation requirements with a site restriction of 0.3 kilometers (0.2 miles) north to