the mandate is unfunded, EPA must provide to the Office of Management and Budget (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 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 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 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 United States prior to today's publication of this 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, Feed additives, Food additives, Reporting and recordkeeping requirements.

Dated: October 6, 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 180.507(a) is amended by designating the text following the paragraph heading as paragraph (a)(1) and adding paragraph (a)(2) to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a) * * *

(2) *Time-limited tolerance.* A tolerance to expire on October 18, 1999, is established for the combined residues of azoxystrobin [methyl(*E*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] and its *Z* isomer in or on the following commodity.

Commodity	Parts per million	Expiration Date
Potatoes	0.03	October 18, 1999

* * * * *

[FR Doc. 98–27835 Filed 10–15–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300732; FRL–6035–2]

RIN 2070–AB78

Hexythiazox; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of hexythiazox [trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide] (CAS No. 78587–05–0) and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parts per million (ppm) of the parent compound) in or on dried hops. BASF Corporation, Agricultural Products requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective October 16, 1998. Objections and requests for hearings must be received by EPA on or before December 15, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300732], 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–300732], 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–300732]. 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: Beth Edwards, 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) 305–5400, e-mail: edwards.beth@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 17, 1998 (63 FR 38644)(FRL–6019–1), 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 (4E4411) for a tolerance on dried hops by BASF Corporation, Agricultural Products, P.O. Box 13528, Research Triangle Park, NC 27709. This notice included a summary of the petition prepared by BASF Corporation, as required under the FFDCA as amended by the Food Quality Protection Act (FQPA) of 1996. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.448 be amended by establishing a tolerance for residues of the insecticide hexythiazox, in or on dried hops at 2.0 parts per million (ppm).

This action pertains only to imported hops. There are no U.S. registrations for the use of hexythiazox on hops.

I. Risk Assessment and Statutory Findings

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....''

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).

II. 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 tolerance for residues of hexythiazox on dried hops 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. A battery of acute toxicity studies places technical grade hexythiazox in Toxicity Category IV for acute oral LD_{50} (LD_{50} > 5,000 milligram/kilograms (mg/kg)), Category III for dermal LD_{50} (LD_{50} > 5,000 mg/kg), Category III for inhalation LC_{50} (LC_{50} > 2.0 mg/L), Category III for primary eye irritation (showed mild irritation (reddened conjunctiva)), Category IV for dermal irritation (non irritant). Hexythiazox is a non-sensitizer.

2. In a 1–month feeding study in dogs, the No-Observed Adverse Effect Level (NOAEL) was 1.75 mg/kg/day and the Lowest Observed Adverse Effect Level (LOAEL) was 12.5 mg/kg/day, based on increased liver and adrenal weights.

3. In a 1–year feeding study in dogs, the NOAEL was 2.5 mg/kg/day and the LOAEL was 12.5 mg/kg/day, based on increased alkaline phosphatase, increased adrenal and liver weights, and liver and adrenal lesions.

4. In a carcinogenicity study in mice, the NOAEL was 36 mg/kg/day and the LOAEL was 215 mg/kg/day. Effects were decreased bodyweight in males and increased hepatocellular carcinomas and combined adenoma/carcinomas.

5. In a chronic feeding/carcinogenicity study in rats, the NOAEL (systemic) was 26 mg/kg/day and the LOAEL (systemic) was 180 mg/kg/day based on decreased body weight gain and increased liver weights in both sexes.

6. In a developmental toxicity study in rats, the maternal NOAEL was 240 mg/kg/day and the maternal LOAEL was 720 mg/kg/day based on increased ovarian weights. The developmental NOAEL was 240 mg/kg/day and the developmental LOAEL was 720 mg/kg/day based on decreased bone ossification.

7. In a developmental toxicity study in rabbits, the maternal NOAEL was 1,080 mg/kg/day (HDT); the maternal LOAEL was not determined. The developmental NOAEL was 1,080 mg/kg/day (HDT); the developmental LOAEL was not determined.

8. In a 2–generation reproduction study in rats, the parental NOAEL was 35 mg/kg/day and the parental LOAEL was 200 mg/kg/day based on decreased body weight gain, decreased food consumption and efficiency, and increased liver, kidney and ovarian weights. The reproductive NOAEL was 35 mg/kg/day and the reproductive LOAEL was 200 mg/kg/day based on decreased pup body weight during lactation, delayed hair growth and eye opening.

B. Toxicological Endpoints

1. *Acute toxicity*. A dose and endpoint for acute dietary risk assessment was not selected due to the lack of toxicological effects attributable to a single exposure (dose) in studies available in the data base including the developmental toxicity studies in rats and rabbits with hexythiazox.

2. *Short- and intermediate-term toxicity*. A dose or endpoint for short-, intermediate-, or long-term (non-cancer) dermal risk assessment was not selected because of the lack of appropriate endpoints and the lack of long-term exposure based on the current use pattern for hexythiazox.

Except for some acute inhalation toxicity studies, there are no inhalation toxicity studies available for use in selecting the dose and endpoint for this risk assessment. There are LC_{50} studies on the technical materials indicating a probable low toxicity.

3. *Chronic toxicity*. EPA has established the RfD for hexythiazox at 0.025 mg/kg/day. This RfD is based on a 1–year feeding study in dogs using a NOAEL of 2.5 mg/kg/day. The LOAEL was 12.5 mg/kg/day based on increased alkaline phosphatase, increased adrenal and liver weights, and liver and adrenal lesions.

4. *Carcinogenicity*. Hexythiazox is classified as a Group C chemical (possible human carcinogen) with a $Q_1^* = 2.22 \times 10^{-2}$ mg/kg/day. This was based on hepatocellular carcinomas in female mice.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.448) for the residues of hexythiazox, on apples at 0.02 ppm and pears at 0.30 ppm. There are also Section 18 uses for cotton, strawberries and dates. Risk assessments were conducted by EPA to assess dietary exposures from hexythiazox as follows:

The following assumptions were used in the chronic dietary (food) risk assessment: Tolerance level residues for dried hops, and all other commodities with published, pending, permanent or time-limited hexythiazox tolerances; and, percent crop-treated information for commodities with permanent tolerances. Thus, this risk assessment should be viewed as partially refined. Further refinement using anticipated residue values would result in a lower estimate of chronic (non-cancer) dietary exposure (food only).

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings:

a. That the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue.

b. That the exposure estimate does not underestimate exposure for any significant subpopulation group.

c. If data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated as required by the section 408(b)(2)(F), EPA may require registrants to submit data on percent crop treated.

The Agency used percent crop treated (PCT) information as follows:

A routine chronic dietary exposure analysis for dried hops was based on 6–8% of crop treated for apples, 1–5% of crop treated for pears, < 1% of crop treated for cotton, < 1% of crop treated for grapes, and < 1% of crop treated for peaches. These data were derived from Doane and Maritz. This action pertains to dried hops grown in Germany and imported to the United States. There are no available data on hexythiazox use on hops which would be imported to the United States.

The Agency believes that the three conditions listed Unit II.C.1.a.-c. of this preamble have been met. With respect to Unit II.C.1.a., the percent of crop treated estimates are derived from Federal and private market survey data which are reliable and have a valid basis. 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 the crop treated, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. As to Unit II.C.1.b. and c., regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the consumption of food bearing hexythiazox in a particular area.

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. Due to the lack of toxicological effects attributable to a single exposure (dose) in studies available in the data base including the developmental toxicity studies in rats and rabbits, there is no acute risk.

ii. *Chronic exposure and risk*. The Reference dose (RfD) used for chronic dietary analysis is 0.025 mg/kg/day. This assessment was done using the Dietary Risk Evaluation System (DRES) with the 1977–78 food consumption data. This chronic dietary (food) risk assessment used the following assumptions: (a) Tolerance level residues for the proposed tolerance and all other commodities with published, pending, permanent or time-limited, hexythiazox tolerances; and, (b) percent crop-treated information for commodities with permanent tolerances. Thus, this risk assessment should be viewed as partially refined. Further refinement using anticipated residue values would result in a lower estimate of chronic (non-cancer) dietary exposure (food only).

The following table 1 summarizes the estimated dietary exposures for the U.S. population and those population subgroups that include infants and children. There are no population subgroups with risk estimates above that of the U.S. population.

TABLE 1.— CHRONIC (NON-CANCER) DIETARY EXPOSURE AND RISK FOR HEXYTHIAZOX

Subgroup:	Exposure (mg/kg bwt/day)	Percent Chronic RfD
U.S. Population (48 States)	0.00012	<1%
Nursing Infants (< 1 year old)	0.000028	<1%
Non-nursing Infants (< 1 year old)	0.00012	< 1%
Children (1 to 6 years old)	0.00020	< 1%
Children (7 to 12 years old)	0.00014	< 1%

2. *From drinking water*. This action pertains only to imported hops. There are no U.S. registrations for the use of hexythiazox on hops. No residues of hexythiazox from this use will be expected to appear in U.S. drinking water.

There are no Maximum Contaminant Levels (MCL) or Health Advisory (HA) levels established for residues of hexythiazox in drinking water. Hexythiazox is relatively immobile and not persistent.

i. *Acute exposure and risk*. Due to the lack of toxicological effects attributable to a single exposure (dose) in studies available in the data base including the developmental toxicity studies in rats and rabbits, there is no acute risk.

ii. *Chronic exposure and risk*. The estimated average concentration of hexythiazox in surface water (56–day average - for chronic exposure) is 0.28 parts per billion (ppb). The ground water screening level for hexythiazox is

0.00147 ppb. These estimates are based upon an application rate of 0.187 lbs active ingredient/acre (ai/A). This is the maximum application rate requested for the emergency exemptions for use on hops and dates. EPA used the Generic Estimated Environmental Concentration (GENEEC- simulates the transport of a pesticide off the agricultural field) model to estimate the chronic environmental concentration of hexythiazox residues in surface water, and the SCI-GROW (Screening Concentration In GROund Water) model to estimate the concentration of hexythiazox residues in ground water. SCI-GROW is a prototype model for estimating ''worst case'' ground water concentrations of pesticides. SCI-GROW is biased in that studies where the pesticide is not detected in ground water are not included in the data set. Thus, it is not expected that SCI-GROW estimates would be exceeded. It should be noted that the GENEEC model was designed for use in ecological risk assessment. It is not an ideal tool for use in drinking water risk assessment. GENEEC could overestimate actual drinking water concentrations. Thus, this model should be considered a screening tool.

The Agency has calculated drinking water levels of concern (DWLOC's) for chronic (non-cancer) exposure to hexythiazox in drinking water for various population subgroups. The DWLOC's for hexythiazox (chronic exposure) are summarized in the following table 2.

TABLE 2.— DRINKING WATER LEVELS OF CONCERN FOR CHRONIC (NON-CANCER) EXPOSURE TO HEXYTHIAZOX

Population Subgroup	Dietary Exposure (mg/kg bwt/day)	Max. Exposure from Water (mg/kg bwt/day)	Body-weight (kg)	Daily Water Consumption (Liters)	DWLOC (µg/L)
U.S. Population (48 States)	0.00012	0.025	70	2	870
Females (20 yrs and older, not pregnant or nursing)	0.000099	0.025	60	2	750
Children (1 – 6 years old)	0.00019	0.025	10	1	250

To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DRES) was subtracted from the chronic RfD (0.025 mg/kg bwt/day) to obtain the acceptable chronic (non-cancer) exposure to hexythiazox in drinking water. DWLOC's were then calculated using default body weights and drinking water consumption figures as indicated in columns 4 and 5 of table 2 above. Therefore, the DWLOC's do not exceed EPA's levels of concern.

The Agency has calculated a drinking water level of concern (DWLOC) for chronic (cancer) exposure to hexythiazox in surface and ground water for the U.S. population (48 States). The DWLOC for hexythiazox (cancer exposure) is summarized in the following table 3.

TABLE 3.— DRINKING WATER LEVELS OF CONCERN FOR CHRONIC (CANCER) EXPOSURE TO HEXYTHIAZOX

Population Subgroup	Dietary Exposure (mg/kg bwt/day)	Max. Exposure from Water (mg/kg bwt/day)	Body-weight (kg)	Daily Water Consumption (Liters)	DWLOC (µg/L)
U.S. Population (48 States)	0.000019	0.000026	70	2	0.91

To calculate the DWLOC for chronic (cancer) exposure relative to a chronic (cancer) toxicity endpoint, the chronic (cancer) dietary food exposure was subtracted from the maximum allowable hexythiazox exposure relative to the Q_1* to obtain the acceptable chronic (non-cancer) exposure to hexythiazox in drinking water. The maximum allowable hexythiazox exposure is calculated to be 0.000045 mg/kg bwt/day (i.e. negligible risk level (1.0×10^{-6}) divided by the Q_1* (0.0222 mg/kg bwt/day^{-1})). The DWLOC was then calculated using default body weights and drinking water consumption figures as indicated in columns 4 and 5 of table 3 above.

3. *From non-dietary exposure.* This action pertains to an import tolerance. In addition, hexythiazox is not registered for any residential uses. Therefore, there is no risk associated with non-dietary exposure.

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.''

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 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).

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

1. *Chronic risk*. Using tolerance level residues and percent crop treated 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. There are no population subgroups with risk estimates above that of the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to 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.

The following table 4 summarizes the estimated dietary exposures for the U.S. population and those population subgroups that include infants and children.

TABLE 4.— CHRONIC (NON-CANCER) DIETARY EXPOSURE AND RISK FOR HEXYTHIAZOX

Subgroup	Exposure (mg/kg bwt/day)	Percent Chronic RfD
U.S. Population (48 States)	0.00012	< 1%
Nursing Infants (< 1 year old)	0.000028	< 1%
Non-nursing Infants (< 1 year old)	0.00012	< 1%
Children (1 to 6 years old)	0.00020	< 1%
Children (7 to 12 years old)	0.00014	< 1%

The estimated average concentration (highest value) of hexythiazox in surface and ground water (0.28 ppb) is less than EPA's levels of concern for hexythiazox in drinking water (870, 750 and 250 ppb) as a contribution to chronic (non-cancer) aggregate exposure. Therefore, taking into account the present uses and the use proposed in this action, EPA concludes with reasonable certainty that residues of hexythiazox in drinking water (when considered along with other sources of chronic (non-cancer) exposure for which EPA has reliable data) would not result in unacceptable levels of chronic (non-cancer) aggregate human health risk estimates at this time.

EPA bases this determination on a comparison of estimated average concentrations of hexythiazox in surface water to back-calculated ''levels of concern'' for hexythiazox in drinking water. The estimates of hexythiazox in surface and ground water are derived from water quality models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of concern in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of hexythiazox residues in drinking water as a part of the chronic (non-cancer) aggregate risk assessment process.

Despite the potential for hexythiazox exposure from water, EPA concludes that there is a reasonable certainty that no harm will result to infants, children, or adults from chronic (non-cancer) aggregate exposure to hexythiazox residues.

2. *Aggregate cancer risk for U.S. population*. The assumptions of this carcinogenic dietary (food) risk assessment are the same as discussed above under Chronic (non-cancer) Risk (food only). Exposure data for strawberries, cotton seed oil and cotton seed meal were amortized over 6 years (second year section 18) for this cancer exposure assessment; the exposure estimate for dates was amortized over 5 years (first year section 18). EPA assumes a duration of 5 years for first year section 18 requests. For repeat section 18 requests, the duration is considered to be the number of years that previous section 18s have been granted for that commodity plus 5 years. For the U.S. population (48 States), the hexythiazox dietary exposure is estimated to be 0.019 g/kg bwt/day. This exposure estimate results in a cancer risk estimate (food only) of 4.3×10^{-7}.

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 partially refined percent crop treated estimates were used for this action, the Agency believes that the cancer risk is overestimated.

The estimated average concentration (highest value) of hexythiazox in surface and ground water (0.28 ppb) is less than EPA's level of concern for hexythiazox in drinking water as a contribution to chronic (cancer) aggregate exposure (0.91 ppb). Therefore, taking into account the present uses and the use proposed in this action, EPA concludes with reasonable certainty that residues of hexythiazox in drinking water (when considered along with other sources of chronic (cancer) exposure for which EPA has reliable data) would not result in unacceptable levels of chronic (cancer) aggregate human health risk estimates at this time. EPA bases this determination on a comparison of estimated average concentrations of hexythiazox in surface and ground water to a back-calculated ''level of concern'' for hexythiazox in drinking water. The estimates of hexythiazox in surface and ground water are derived from water quality models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, a level of concern in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of hexythiazox residues in drinking water as a part of the chronic (cancer) aggregate risk assessment process.

Despite the potential for hexythiazox exposure from water, EPA concludes that there is a reasonable certainty that no harm will result to infants, children, or adults from chronic (cancer) aggregate exposure to hexythiazox residues.

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.

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 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 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 (strain not specified) received hexythiazox (NA-73) in gum Arabic by gavage at dose levels of 0, 240, 720, or 2,160 mg/kg/day from G.D. (gestation day) 7–17. The maternal NOAEL was 240 mg/kg/day. The maternal LOAEL was 720 mg/kg/day based on increased ovarian weights. The developmental NOAEL was 240 mg/kg/day. The developmental LOAEL was 720 mg/kg/day based on reduced bone ossification. In a developmental toxicity study in rabbits, pregnant NZW rabbits (12–14/dose) received hexythiazox (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 at the highest dose tested. Both maternal and developmental NOAEL's were 1,080 mg/kg/day, the highest dose tested.

iii. *Reproductive toxicity study*. In a reproductive toxicity study, Fisher rats (20–30/dose group) were fed hexythiazox (NA–73) in the diet at doses of 0, 60, 400, or 2,400 ppm (0, 5, 35 or 200 mg/kg/day) for 2–generations. No reproductive toxicity was noted. The parental (systemic) NOAEL was 35 mg/kg/day. The parental (systemic) LOAEL of 200 mg/kg/day was based on decreased body weight gain, food consumption and food efficiency as well as increased liver, kidney and ovarian weights. No histopathological changes were noted in the ovaries. The reproductive NOAEL was 35 mg/kg/day. The reproductive LOAEL was 200 mg/kg/day based on decreased pup body weight during lactation, in addition to delays in hair growth and eye opening.

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. 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.

v. *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. Considering this and the fact that no pre- or post-natal toxicity was shown, EPA concluded that infants and children would be safe without the aditional tenfold safety factor.

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, 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.

III. Other Considerations

A. Metabolism in Plants and Animals

Additional plant metabolism data were not submitted for this tolerance. Metabolism studies have been submitted and reviewed in conjunction with petitions for hexythiazox tolerances on apples, grapes, citrus and pears. In studies with foliar application, there was very little translocation of hexythiazox from the leaves. Recovery of residues for hexythiazox and its hydroxylated metabolites was 95% in apple leaves 91 days after application, 69 and 63% in pear and citrus leaves 90 days after application, and 92% in grape leaves 56 days after application. Given the fairly limited metabolism of hexythiazox observed in these crops and that hops is a minor crop, the Agency concludes that the nature of the residue is understood for the purposes of this tolerance. The residue of concern is hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety. Livestock feedstuffs are not derived from hops (OPPTS 860.1000). Thus, the nature of the residue in livestock is not of concern for the proposed tolerance.

B. Analytical Enforcement Methodology

BASF has proposed Method 343/1 for enforcement of the proposed tolerance. An independent laboratory validation of this method was performed by Horizon Labs (MRID 439235–02). Satisfactory recoveries were obtained by the independent laboratory. The method has been successfully validated by the Agency. Minor deficiencies (additional interference testing for 3 ais and minor revisions) concerning this method are outstanding. The Agency concludes an adequate method (Method 343/1, MRID 439235–01.) is available for enforcement purposes; this method is available from PIRIB/IRSD.

Data concerning the recovery of hexythiazox via the FDA Multiresidue Methods of PAM I have been submitted. Hexythiazox is recoverable by the FDA multiresidue methods. Data concerning the recovery of hexythiazox metabolites (PT–1–8, PT–1–2 and PT–1–4) via the FDA Multiresidue Methods have not been submitted. The Agency concludes adequate analytical methods are available to enforce the proposed tolerance for residues of hexythiazox and its metabolites in/on imported hops (dried). The Agency further concludes submission of the additional multiresidue data for hexythiazox metabolites will not be required for this tolerance on imported hops.

C. Magnitude of Residues

Four trials were performed in Bavaria (MRID 433616–04). Ordoval was diluted in water to 0.045% and applied at a rate of 3,333 litres/hectare (L/ha) (150 g ai/ha, 1X) using a mistblower. Hops were harvested 28 days after application and kiln dried. The dried hops were processed into beer, resulting in the fractionation of residues into spent hops, brewers yeast, dregs and beer. Currently, residue data for processed hops products are not required. Samples were analyzed using BASF Method 343. The method was validated at 0.5 and 10 ppm. The average recoveries were 79.8 ± 16.1% (n=8) for fresh hops and 69.6 ± 15.2% (n=2) for dried hops. The maximum residue observed in the treated dried hops was 1.53 ppm.

Five trials were performed in Bavaria (MRID 433616–05). Ordoval was diluted in water to 0.045% and applied at a rate of 3,333 L/ha (150 g ai/ha, 1X) using a mistblower. Hops were harvested 27 days after application and kiln dried. Samples were analyzed using BASF Method 343. The method was validated at 0.5 and 1.0 ppm (fresh) or 1.0 and

10.0 ppm (dried). The average recoveries were 77.9 ± 20.6% (n=6) for fresh hops and 82.3 ± 4.8% (n=2) for dried hops. The maximum residue observed in the treated dried hops was 0.79 ppm.

The maximum residue observed in dried hops was 1.53 ppm. These data support the establishment of a 2.0 ppm tolerance for residues of hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety in/on hops cones, dried.

D. International Residue Limits

There is no Codex proposal, nor Canadian or Mexican limits for residues of hexythiazox on hops. Therefore, a compatibility issue is not relevant to the proposed tolerance. However, Codex limits are established for hexythiazox per se on other crops. As the U.S. enforcement method converts hexythiazox and its metabolites to a common moiety, harmonization would require new enforcement methodology to be developed and validated.

IV. Conclusion

Therefore, the tolerance is established for residues of hexythiazox in/on dried hops at 2.0 ppm.

V. 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 15, 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.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300732] (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 Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at: opp-docket@epamail.epa.gov.

E-mailed objections and hearing requests 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 in this unit 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.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. 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 on the basis of a petition under FFDCA section 408(d), 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 actions 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.

VIII. 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. In § 180.448 by revising paragraph (a) to read as follows:

§ 180.448 Hexythiazox; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the miticide hexythiazox, trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parts per million of the parent compound) in or on the following commodities:

Commodity	Parts per million
Apples	0.02
Hops	2.0
Pears	0.30

* * * * *

[FR Doc. 98–27841 Filed 10–15–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 745

[OPPTS–62158B; FRL–6040–1]

RIN 2070–AD11

Lead; Fees for Accreditation of Training Programs and Certification of Lead-based Paint Activities Contractors; Withdrawal of Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; withdrawal.

SUMMARY: Due to receipt of adverse comments, EPA is withdrawing a final rule published in the **Federal Register** of September 2, 1998, that would have established fees for accreditation of training programs and certification of lead-based paint activities contractors under the authority of section 402(a)(3) of the Toxics Substances Control Act.

DATES: The final rule published September 2, 1998 (63 FR 46668) is withdrawn as of October 16, 1998.

FOR FURTHER INFORMATION CONTACT: Mike Wilson, National Program Chemicals Division (Mail Code 7404), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (202) 260–4664; fax number: (202) 260–0770 or by e-mail: wilson.mike@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 2, 1998 (63 FR 46668) (FRL–6017–8), EPA issued a final rule under Title IV of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2683, 2682, and 2684). Section 402(a)(3) of TSCA directs EPA to promulgate regulations which establish fees to recover for the U.S. Treasury the Agency's cost of administering and enforcing the standards and requirements applicable to lead-based paint training programs and contractors engaged in lead-based paint activities.

EPA published the action as a final rule without prior notice and