V_g=volume of gasoline with which the blendstock is blended.

(iii) For each parameter required by the complex model, calculate the parameter value that would result by combining, at the blendstock volume fraction (F), the blendstock with a gasoline having properties equal to the refinery's or importer's baseline, using the following formula:

$$CP_j = \frac{\left(BAP_j \times V_g\right) + \left(BLP_j \times V_b\right)}{V_g + V_b}$$

Where:

CP_j=calculated value for parameter j
BAP_j=baseline value for parameter j
BLP_j=value of parameter j for the blendstock or oxygenate
$_j$=each parameter required by the complex model

(A) The baseline value shall be the refinery's ''summer'' or ''winter'' baseline, based on the ''summer'' or ''winter'' classification of the gasoline produced as determined under paragraphs (g)(5) or (g)(6) of this section. In the case of a refinery that is aggregated under paragraph (h) of this section, the refinery baseline shall be used, and not the aggregate baseline.

(B) The sulfur content and oxygen wt% computations under paragraph (g)(3)(iii) of this section shall be adjusted for the specific gravity of the gasoline and blendstock using specific gravities of 0.749 for ''summer'' gasoline and of 0.738 for ''winter'' gasoline.

(C) In the case of ''summer'' gasoline, where the blendstock is ethanol and the volume fraction calculated under paragraph (g)(3)(ii) is equal to or greater than 0.015, the value for RVP calculated under paragraph (g)(3)(iii) of this section shall be 1.0 psi greater than the RVP of the gasoline with which the blendstock is blended.

(iv) Using the summer or winter complex model, as appropriate, calculate the exhaust toxics and NO_X emissions performance, in mg/mi, of:

(A) A hypothetical gasoline having properties equal to those calculated in paragraph (g)(3)(iii) of this section (HEP); and

(B) A gasoline having properties equal to the refinery's or importer's baseline (BEP).

(v) Calculate the exhaust toxics and NO_X equivalent emissions performance (EEP) of the blendstock, in mg/mi, using the following equation:

$$EEP_j = \frac{HEP_j - \left(BEP_j * (1 - F)\right)}{F}$$

Where:

EEP_j=equivalent emissions performance of the blendstock for emissions performance j

BEP_j=emissions performance j of a gasoline having the properties of the refinery's baseline.

HEP_j=emissions performance j of a hypothetical blendstock/gasoline blend

F=blendstock volume fraction

j=exhaust toxics or NO_X emissions performance

(vi) For each blendstock batch, the volume, and exhaust toxics and NO_X equivalent emissions performance (EEP) shall be included in the refinery's compliance calculations.

* * * * *

(8) *Emissions performance of conventional gasoline with parameters outside the complex model valid range limits.* Notwithstanding the provisions of § 80.45(f)(2), in the case of any parameter value that does not fall within the complex model range limit in § 80.45(f)(1)(ii), the refiner or importer shall determine the emissions performance of the batch using the following parameter values:

Parameter outside the range limit	Parameter value to use for calculating	
	Exhaust toxics	NO_X
Sulfur	Test value[1]	Test value.[1]
RVP (summer only):		
< 6.4 psi	6.4 psi	6.4 psi.
> 11.0 psi	Test value[1]	Test value.[1]
Aromatics	Test value[1]	Test value.[1]
Olefins	Test value[1]	Test value.[1]
Benzene	Test value[1]	Test value.[1]
E200:		
< 30%	Test value[1]	30%
> 70%	70%	Test value.[1]
E300 < 70%	Test value[1]	Test value.[1]

[1] Test value is the value for a parameter determined pursuant to paragraph 80.101(i)(1)(i) of this section.

* * * * *

(j) *Evasion of standards through exporting and importing gasoline.* Notwithstanding the requirements of this section, no refiner or importer shall export gasoline and import the same or other gasoline for the purpose of evading a more stringent baseline requirement.

12. Section 80.104 is amended by adding paragraph (a)(2)(xi) to read as follows:

§ 80.104 Recordkeeping requirements.

* * * * *

(a) * * *

(2) * * *

(xi) In the case of blendstocks that are included in refinery compliance calculations using the procedures under § 80.101(g)(3), documents that reflect the volume of blendstock and the volume of gasoline with which the blendstock is blended.

* * * * *

[FR Doc. 97–34097 Filed 12–30–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300595; FRL–5762–1]

RIN 2070–AB78

Hexythiazox; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of hexythiazox (trans-5-(4-

chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety in or on strawberries. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on strawberries. This regulation establishes a maximum permissible level for residues of hexythiazox in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on July 1, 1998.

DATES: This regulation is effective December 31, 1997. Objections and requests for hearings must be received by EPA on or before March 2, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300595], 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–300595], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300595]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: David Deegan, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9358, e-mail: deegan.dave@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for combined residues of the insecticide hexythiazox (trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety , in or on strawberries at 3.0 part per million (ppm). This tolerance will expire and is revoked on July 1, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

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

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

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

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

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

II. Emergency Exemption for Hexythiazox on Strawberries and FFDCA Tolerances

The state of California petitioned EPA to invoke provisions of FIFRA section 18 to allow emergency use of the chemical hexythiazox (Savey Ovicide/Miticide 50–WP, EPA Reg. No. 10163–208, manufactured by Gowan) on 18,000 acres of strawberries in California to control two-spotted spider mites. EPA reviewed this request and concluded that the state is suffering from an urgent and non-routine situation, qualifying for use of the requested product under section 18. EPA's review concluded that there are no effective alternative chemicals available to growers with which they can control this pest on strawberries. On November 14, 1997, EPA authorized California to allow hexythiazox to be used on 18,000 acres of strawberries to control two-spotted spider mites. The exemption expires on April 1, 1998.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of hexythiazox in or on strawberries. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on July 1, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on 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 this tolerance is being approved under emergency conditions EPA has not made any decisions about whether hexythiazox meets EPA's registration requirements for use on strawberries or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of hexythiazox by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than California to use this pesticide on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for hexythiazox, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

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

A. Toxicity

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

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

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

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

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

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

nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

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

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

B. Aggregate Exposure

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

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

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of hexythiazox and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of hexythiazox (trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety on 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*. An acute dietary risk assessment is not required, since EPA did not identify an acute toxicological endpoint.

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

3. *Chronic toxicity*. EPA has established the RfD for hexythiazox at 0.025 mg/kg/day. This RfD is based on a one year feeding study in dogs with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100. The Lowest Observed Eeffect Level (LOEL) of 12.5 mg/kg/day was based on hypertrophy of the adrenal cortex in both sexes.

4. *Carcinogenicity*. Hexythiazox has been classified as a Group C chemical (possible human carcinogen) by EPA, based on an increased incidence of female mouse liver tumors. EPA uses the Q_1* approach to assess this risk. The Q_1* is 0.039 mg/kg/day^{-1}.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.448) for the combined residues of hexythiazox (trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide), in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from hexythiazox as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The acute dietary (food only) risk assessment is not required for this pesticide use, as the EPA did not identify an acute dietary risk endpoint.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, EPA has made conservative assumptions -- 100% of strawberries, in addition to cotton seed commodities (oil and meal) (previously approved under provisions of section 18) and apple commodities will contain residues of hexythiazox and its metabolites and those residues will be at the level of the tolerance. Percent crop treated data were utilized for pear commodities. These conservative assumptions result in an overestimate of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative exposure assessment.

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

Subgroup	Percent
U.S. Population	<1
Nursing Infants	<1

Subgroup	Percent
Non-Nursing Infants (<1 year old)	<1
Children (1–6 years old)	<1
Children (7–12 years old)	<1

The subgroups listed above are: (1) the U.S. population (48 states); and (2) those for infants and children; and (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

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

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

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

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

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

EPA does not have, at this time, available data to determine whether hexythiazox has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, hexythiazox does not appear to produce a toxic metabolite produced by other substances. According to information evaluated related to this action, hexythiazox is a member of the thiazolidinone class of pesticides and there are no other members of this class. For the purposes of this tolerance action, therefore, EPA has not assumed that hexythiazox has a common mechanism of toxicity with other substances.

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

1. *Chronic risk.* Using the conservative exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, EPA has concluded that dietary exposure (food only) to hexythiazox will utilize <1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to hexythiazox in drinking water EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to hexythiazox residues.

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

D. Aggregate Cancer Risk for U.S. Population

Based on published tolerances (none are currently pending) and this proposed section 18 use, an upper bound lifetime dietary (food only) cancer risk estimate of 9.6×10^{-7} was calculated for the hexythiazox regulated residue. The calculation used the conservative exposure assumptions described above for generating ARC's and amortized the cancer risk over a 70–year lifetime (i.e., 5/70, for this 1st year section 18 use). This section 18 use contributes 4.1×10^{-6} to the upper bound lifetime dietary (food only) cancer risk and 2.9×10^{-7} if the cancer risk is amortized over a 70–year lifetime.

The cancer risk estimate for the existing hexythiazox uses plus the amortized risk estimate for strawberries does not exceed EPA's level of concern.

EPA believes the registered uses do not constitute a chronic exposure scenario. Thus, no non-dietary, non-occupational chronic exposure to hexythiazox is expected, or is a factor in aggregate cancer risk .

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

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

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

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

b. *Rabbits*. In the rabbit developmental toxicity study, the maternal (systemic) NOEL was 1080 mg/kg/day at the highest dose tested (HDT). The developmental (fetal) NOEL was 1080 mg/kg/day at the highest dose tested.

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

iv. *Pre- and post-natal sensitivity*. The pre- and post-natal toxicology data base for hexythiazox is complete with respect to current toxicological data requirements. There are no pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2–generation rat reproductive toxicity study. In the developmental study in rats, the developmental NOEL and LOEL is the same as the maternal NOEL and LOEL demonstrating that no extra-sensitivity for infants and children is present. In rabbits, there are no maternal or developmental effects up to the limit dose of 1080 mg/kg/day HDT. In the 2–generation reproductive toxicity study in rats, there are no pup effects at doses below maternal effects and the common effects in both pups and parental animals decreased body weight also demonstrates that there is no extra-sensitivity for infants and children.

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

2. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to hexythiazox from food will utilize less than 1% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to hexythiazox in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Therefore, taking into account the completeness and reliability of the toxicity data, the conservative exposure assessment and the fact that residential uses do not fall under a chronic exposure scenario, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to hexythiazox residues.

V. Other Considerations

A. Metabolism In Plants and Animals

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

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

B. Analytical Enforcement Methodology

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

C. Magnitude of Residues

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

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

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

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

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

D. International Residue Limits

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

E. Rotational Crop Restrictions

Strawberries are not normally rotated in southern California. Thus, rotational crop considerations are not an issue for this section 18.

VI. Conclusion

Therefore, the tolerance is established for combined residues of hexythiazox (trans-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) in strawberries at 3.0 ppm.

VII. Objections and Hearing Requests

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

Any person may, by March 2, 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.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300595] (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 Rm. 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

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

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

IX. Regulatory Assessment Requirements

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

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

X. Submission to Congress and the General Accounting Office

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

List of Subjects in 40 CFR Part 180

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

Dated: December 19, 1997.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.448, paragraph (b) is amended by adding and alphabetically inserting the following commodity to the table to read as follows:

§ 180.448 Hexythiazox; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
* *	* * *	* *
Strawberries	3.0	7/1/98

* * * * *

[FR Doc. 97–34104 Filed 12–30–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–5941–6]

National Oil and Hazardous Substances Pollution Contingency Plan National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of deletion for North Hollywood dump superfund site, Shelby County, Tennessee, from the national priorities list.

SUMMARY: The Environmental Protection Agency (EPA) Region 4 announces the deletion of the North Hollywood Dump Superfund Site from the National Priorities List (NPL), Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). EPA and the State have determined that all appropriate Fund-financed responses under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended, have been implemented and that no further cleanup is appropriate. Moveover, EPA and the State have determined that remedial actions conducted at the site to date have been protective of public health, welfare and the environment. This deletion does not preclude future action under Superfund.

EFFECTIVE DATE: December 31, 1997.

FOR FURTHER INFORMATION CONTACT: Robert Morris, Site Manager, U.S. Environmental Protection Agency, Region 4, North Site Management Branch, 61 Forsyth Street, S.W., Atlanta, Georgia 30303, (404) 562–8794.

SUPPLEMENTARY INFORMATION: The Site to be deleted from the NPL is: North Hollywood Superfund Site in Shelby County, Tennessee.

A Notice of Intent to Delete for this site was published on October 10, 1997, (62 FR 52961). The closing date for comments on the Notice of Intent to Delete was November 10, 1997. EPA received no comments.

EPA identifies sites that appear to present a significant risk to the public health, welfare and the environment and it maintains the NPL as the list of those sites. Any site deleted from the NPL remains eligible for Fund-financed remedial actions in the future. Section 300.425(e)(3) of the NCP states that Fund-financed actions may be taken at sites deleted from the NPL. Deletion of a site from the NPL does not affect responsible party liability or impede agency efforts to recover costs associated with response efforts.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous waste, Hazardous substances, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: December 16, 1997.

A. Stanley Meiburg,

Deputy Regional Administrator, Region 4.

For reasons set out in the preamble, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

1. The authority citation for part 300 continues to read as follows:

Authority: 42 U.S.C. 9601–9657; 33 U.S.C. 1321(c)(2); E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p 351; E.O. 12580, 52 FR 2923; 3 CFR, 1987 Comp., p. 193.

Appendix B—[Amended]

2. Table 1 of Appendix B to Part 300 is amended by removing the site for North Hollywood Dump, Memphis, Tennessee.

[FR Doc. 97–33743 Filed 12–30–97; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

41 CFR Parts 101–42 and 101–43

RIN 3090–AF39

Criteria for Reporting Excess Personal Property

AGENCY: Office of Governmentwide Policy, GSA.

ACTION: Temporary regulation; extension of effective date.

SUMMARY: The General Services Administration (GSA) is extending Federal Property Management Regulations provisions regarding criteria for reporting excess personal property to GSA.

DATES: Effective date: The temporary regulation published January 15, 1997 was effective from January 15, 1997 through January 15, 1998. The period of effectiveness is extended through January 15, 1999.

FOR FURTHER INFORMATION CONTACT: Martha Caswell, Office of Governmentwide Policy, GSA, 202–501–3828.

SUPPLEMENTARY INFORMATION: FPMR Temporary Regulation H–29 was published in the **Federal Register** and became effective January 15, 1997, 62