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 this final rule in the **Federal Register**. This final 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: December 20, 2002.

Debra Edwards,

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. 321(q), 346(a) and 371.

2. Section 180.368 is amended by designating the existing paragraph (b) as paragraph (b)(1) and adding a new paragraph (b)(2) to read as follows:

§ 180.368 Metolachlor; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.*

(1) * * *

(2) Time-limited tolerances are established for the combined residues (free and bound) of the herbicide s-metolachlor [(S)-2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide], its R-enantiomer and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound in connection with the use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance is specified in the following table. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ Revocation Date
Sweet potato	0.2	12/31/04

* * * * *

[FR Doc. 03–5 Filed 1–2–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0335; FRL–7285–2]

Lambda-cyhalothrin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of the pyrethroid lambda-cyhalothrin, 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer expressed as epimer of lambda-cyhalothrin, a 1:1 mixture of (S)-α-cyano-3- phenoxybenzyl-(Z)-(1S,3S) -3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3- phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate in or on wild rice, grass forage, and grass hay. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on wild rice and pasture grass. This regulation establishes maximum permissible levels for residues of lambda-cyhalothrin and its epimer in these food commodities. The tolerances will expire and are revoked on December 31, 2005.

DATES: This regulation is effective January 3, 2003. Objections and requests for hearings, identified by docket ID number OPP–2002–0335, must be received on or before March 4, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703)308–9367; e-mail address: sec-18-mailbox@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a Federal or State government agency involved in administration of environmental quality programs (i.e., Departments of Agriculture, Environment, etc). Potentially affected entities may include, but are not limited to:

• Federal or State Government Entity, (NAICS 9241), i.e., Departments of Agriculture, Environment, etc.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0335. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the'' **Federal Register**'' listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml__00/Title__40/40cfr180_(_00.html, a beta site currently under development.

An electronic version of the public docket is available through EPA's

electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408 (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for combined residues of the insecticide lambda-cyhalothrin and its epimer, in or on wild rice at 1.0 parts per million (ppm), grass forage at 5.0 ppm and grass hay at 6.0 ppm. These tolerances will expire and are revoked on December 31, 2005. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

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. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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) of the FFDCA 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) of the FFDCA 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 the 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 the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Lambda-Cyhalothrin on Wild Rice and Pasture Grass and FFDCA Tolerances

The State of Minnesota requested the use of lambda-cyhalothrin on wild rice to control unusually high populations of riceworms because the registered alternatives were ineffective. The State of New York requested the use of lambda-cyhalothrin to control alfalfa weevil (*Hypera postica*), Armyworms (*Spodoptera spp.*) and Potato leafhopper (*Empoasca fabae*) on alfalfa/clover/grass mixed stands. The use of insecticides is the only practical means of controlling the three major pests that infest alfalfa/clover/grass mixed stands and there are no pesticides registered to control insect pests in these stands of mixed of alfalfa/clover/grass. Experts estimate a 35% yield loss if these mixed stands are not protected. EPA has authorized under section 18 of FIFRA the use of lambda-cyhalothrin on wild rice for control of rice borers in Minnesota and pasture grass for control of alfalfa weevil, armyworms and potato leafhoppers on alfalfa/clover/grass mixed stands in New York. After having reviewed the submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of lambda-cyhalothrin in or on wild rice and grass forage and grass hay. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerances under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with section 18 of FIFRA. 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 these tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these tolerances will expire and are revoked on December 31, 2005, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on wild rice, grass forage and grass hay 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 these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether lambda-cyhalothrin meets EPA's registration requirements for use on wild rice and pasture grass or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of lambda-cyhalothrin by a State for special local needs under section 24(c) of FIFRA. Nor do these tolerances serve as the basis for any States other than Minnesota and New York to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 of FIFRA as identified in 40 CFR part 166. For additional information regarding the emergency exemption for lambda-cyhalothrin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D) of the FFDCA , 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 lambda-cyhalothrin and to make a determination on aggregate exposure, consistent with section

408(b)(2) of the FFDCA, for time-limited tolerances for the combined residues of lambda-cyhalothrin and its epimer in or on wild rice at 1.0 ppm, grass forage at 5.0 ppm and grass hay at 6.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA/SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for lambda-cyhalothrin used for human risk assessment is shown in the following Table 1:

TABLE 1.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR LAMBDA-CYHALOTHRIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General population including infants and children)	NOAEL = 0.5 mg/kg/day UF = 100 Acute RfD = 0.005 mg/kg/day	FQPA SF = 1 aPAD = acute RfD/FQPA SF = 0.005 mg/kg/day	Chronic oral study in the dog (lambda-cyhalothrin) LOAEL = 3.5 mg/kg/day based on clinical signs of neurotoxicity (ataxia) observed from day 2, three to seven hours post-dosing.
Chronic Dietary (All populations)	NOAEL = 0.1 mg/kg/day UF = 100 Chronic RfD = 0.001 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD/FQPA SF = 0.001 mg/kg/day	Chronic oral study in the dog (lambda-cyhalothrin) LOAEL = 0.5 based on gait abnormalities observed in 2 dogs
Incidental Oral Short- and Intermediate-Term (1–30 Days and 1–6 Months) Residential Only	NOAEL = 0.1	LOC for MOE = 100 (Residential)	Chronic oral study in the dog (lambda-cyhalothrin) LOAEL = 0.5 based on gait abnormalities observed in 2 dogs
Dermal (All Durations;- Short-Term (1 to 7 days) - Intermediate- Term (1 week to several months) - Long-Term (several months to lifetime) (Residential)	dermal (or oral) study NOAEL= 10 mg/kg/day	LOC for MOE = 100 (Residential)	21–Day dermal toxicity study in the rat (lambda-cyhalothrin) LOAEL = 50 mg/kg/day based on clinical signs of neurotoxicity (observed from day 2) and decreased body weight and body weight gain
Inhalation (All Durations; - Short-Term (1 to 7 days) - Intermediate-Term (1 week to several months) - Long-Term (several months to lifetime) (Residential)	inhalation (or oral) study NOAEL= 0.3 μg/L (0.08 mg/kg/day) (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	21–Day inhalation study in rats (lambda-cyhalothrin) LOAEL = 3.3 μg/L (0.90 mg/kg/day) based on clinical signs of neurotoxicity, decreased body weight gains, increased incidence of punctuate foci in the cornea, slight reductions in cholesterol in females and slight changes in selected urinalysis parameters.
Cancer (oral, dermal, inhalation)			Classification: Group D chemical (not classifiable as to human carcinogenicity)

*The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Currently established tolerances for residues of lambda-cyhalothrin are listed under 40 CFR 180.438 and include permanent tolerances on plants ranging from 0.01 ppm on soybeans to 6.0 ppm on alfalfa hay, corn forage, and tomato pomace (dry or wet). Tolerances are also established on animal commodities ranging from 0.01 ppm in eggs, poultry meat, and poultry meat by-products (mbyp) to 5.0 ppm in milk fat (reflecting 0.2 ppm in whole milk). The Agency has recently established additional tolerances for lambda-cyhalothrin on a number of commodities ranging from 0.05 ppm on sugarcane to 3.0 ppm on peanut hay. Risk assessments were conducted by EPA to assess dietary exposures from lambda-cyhalothrin in food as follows:

i. *Acute exposure.* 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 Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. A refined Tier 3 probabilistic acute dietary risk assessment was conducted for all currently registered and proposed lambda-cyhalothrin food uses. For the acute dietary risk analysis the entire distribution of residue field trial data was used for not-blended or partially-blended commodities; average residue field trial data was used for blended commodities; information from cooking and processing studies were used when available; and market share data for proposed and established tolerances was used.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. For the chronic dietary risk analysis the average of the residue field trials, information from cooking and processing studies, and market share data were used.

iii. *Cancer.* The data base for carcinogenicity is considered complete, and no additional studies are required at this time. The requirements for oncogenicity studies in the rat and the mouse with lambda-cyhalothrin have been satisfied by a combined chronic/oncogenicity study in rats and an oncogenicity study in mice, both conducted with cyhalothrin. Lambda-cyhalothrin has been classified as a Group D chemical (not classifiable as to human carcinogenicity) with regards to its carcinogenic potential.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of the FFDCA, EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA 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: Condition 1, 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; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, 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 PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

A detailed description of how the Agency used PCT information in this assessment can be found in the lambda-cyhalothrin pesticide tolerance document published on September 27, 2002 (67 FR 60902; FRL–7200–1) in Unit III.C.1.iv.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, 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 regional consumption of food to which lambda-cyhalothrin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for lambda-cyhalothrin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of lambda-cyhalothrin.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to

produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will generally use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to lambda-cyhalothrin they are further discussed in the aggregate risk sections below. The compounds to be regulated in drinking water are lambda-cyhalothrin and degradate XV (parent hydroxylated in the 4-position of the phenoxy ring).

Based on the FIRST, PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of lambda-cyhalothrin and its degradate XV for acute exposures are estimated to be 0.62 parts per billion (ppb) for surface water (0.51 ppb lambda-cyhalothrin and 0.11 ppb degradate XV) and 0.012 ppb (0.006 ppb lambda-cyhalothrin and 0.006 ppb degradate XV) for ground water. The EECs for chronic exposures are estimated to be 0.098 ppb for surface water (0.09 ppb lambda-cyhalothrin and 0.008 ppb degradate XV) and 0.012 ppb for ground water (0.006 ppb lambda-cyhalothrin and 0.006 ppb degradate XV).

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). The residential exposure/risk assessment evaluated both proposed and existing uses for lambda-cyhalothrin. Existing uses on turf, in gardens, on golf courses, and for structural pest control were qualitatively assessed, but a quantitative calculation was only completed for postapplication exposure on treated turf because this scenario is expected to have the highest associated exposures. This screening level tool is protective for all residential exposures, even the handler scenarios, because the dose levels for children playing on treated lawns are thought to exceed those expected for all other scenarios. For postapplication exposure, all residential MOEs were well above the Agency target MOE of 100 for the inhalation, dermal, and oral routes and therefore do not exceed EPA's level of concern (range 700 to 14,700). Additionally, when total MOEs were aggregated, MOEs were still not of concern (MOEs for children = 500 and for adults = 3,000).

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA 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 lambda-cyhalothrin 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, lambda-cyhalothrin 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 lambda-cyhalothrin 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).

C. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure 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.

2. *Developmental toxicity studies*. In a developmental toxicity study in rats, the maternal NOAEL was 10 mg/kg/day and the LOAEL was 15 mg/kg/day based on uncoordiniated limbs, reduced body weight gain and food consumption. The developmental NOAEL was 15 mg/kg/day, highest dose tested (HDT) and the developmental LOAEL was >15 mg/kg/day.

In a developmental toxicity study in rabbits, the maternal NOAEL was 10 mg/kg/day and the LOAEL was 30 mg/kg/day based on reduced body weight gain and food consumption. The developmental NOAEL was 30 mg/kg/day, HDT and the developmental LOAEL was >30 mg/kg/day.

3. *Reproductive toxicity study*. In a 3–generation reproduction study in rats, the parental/offspring NOAEL was 1.5 mg/kg/day and the LOAEL was 5.0 mg/kg/day based on decreased parental body weight and body weight gain during premating and gestation periods and reduced pup weight and weight gain during lactation. The reproductive NOAEL was 5.0 mg/kg/day (HDT)

4. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with cyhalothrin and there is no evidence of increased susceptibility of young rats in the reproduction study with cyhalothrin.

5. *Conclusion*. Through the use of bridging data, the toxicology database for lambda-cyhalothrin is complete. The Agency has determined that the special FQPA safety factor should be reduced to 1x because as noted above, there is no evidence of increased susceptibility of rat or rabbit fetuses following in utero exposure in the developmental studies with cyhalothrin and there is no evidence of increased susceptibility of young rats in the reproduction study

with cyhalothrin. The Agency concluded there are no residual uncertainties for pre- and/or postnatal exposure. The RfDs and other endpoints established for risk assessment are protective of pre-/postnatal toxicity following exposure to cyhalothrin.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to lambda-cyhalothrin in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of lambda-cyhalothrin on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to lambda-cyhalothrin will occupy 41% of the aPAD for the U.S. population, 24% of the aPAD for females 13 years and older, 71% of the aPAD for all infants <1 year old and 82% of the aPAD for children 1-6 years old. In addition, despite the potential for acute dietary exposure to lambda-cyhalothrin in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of lambda-cyhalothrin in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 2 of this unit:

TABLE 2.— AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO LAMBDA-CYHALOTHRIN

Population Subgroup	aPAD mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population (total)	0.005	40.86	0.62	0.012	103
All Infants (<1 year) Children 1-6 years	0.005 0.005	71.22 82.36	0.62 0.62	0.012 0.012	14 9
Children 7-12 years	0.005	46.09	0.62	0.012	27
Females 13-50 Males 13-19	0.005 0.005	23.83 27.61	0.62 0.62	0.012 0.012	114 127
Males 20+ years	0.005	21.69	0.62	0.012	137
Seniors 55+	0.005	21.85	0.62	0.012	137

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to lambda-cyhalothrin from food will utilize 8.2% of the cPAD for the U.S. population, 11.7% of the cPAD for all infants < 1 year old and 21.8% of the cPAD for children 1-6 years old. Based the use pattern, chronic residential exposure to residues of lambda-cyhalothrin is not expected. In addition, despite the potential for chronic dietary exposure to lambda-cyhalothrin in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of lambda-cyhalothrin in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit:

TABLE 3.— AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO LAMBDA-CYHALOTHRIN

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population (total)	0.001	8.2	0.098	0.012	32
All Infants (< 1 year)	0.001	11.7	0.098	0.012	9

TABLE 3.— AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO LAMBDA-CYHALOTHRIN— Continued

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Children 1-6 years	0.001	21.8	0.098	0.0 12	8
Children 7-12 years	0.001	12.9	0.098	0.012	9
Females 13-50	0.001	5.7	0.098	0.012	28
Males 13-19	0.001	7.9	0.098	0.012	32
Males 20+ years	0.001	6.0	0.098	0.012	33
Seniors 55+	0.001	5.8	0.098	0.012	33

3. *Short and intermediate-term risk*. Aggregate risk for short- and intermediate-term durations of exposure includes food, drinking water, and residential exposure pathways. The residential exposure pathway includes dermal, inhalation, and incidental oral (hand-to-mouth-type inadvertent exposure) routes of exposure. This aggregate risk assessment included lawn post-application exposure, considered the scenario with the highest potential for exposure and is a day 0 screening level assessment.

Lambda-cyhalothrin is currently registered for use(s) that could result in short and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for lambda-cyhalothrin.

Using the exposure assumptions described in this unit for short and intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 879 for adults, 239 for children 1-6, and 302 for infants <1 year old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of lambda-cyhalothrin in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 4 of this unit:

TABLE 4.— AGGREGATE RISK ASSESSMENT FOR SHORT AND INTERMEDIATE-TERM EXPOSURE TO LAMBDA-CYHALOTHRIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short and Intermediate-Term DWLOC (ppb)
Adults	879	100	0.098	0.012	31
Child (1-6)	239	10 0	0.0 98	0 .012	6
Infant (<1 yr)	302	100	0.098	0.012	7

5. *Aggregate cancer risk for U.S. population*. Lambda-cyhalothrin has been classified as a Group D chemcial (not classifiable as to human carcinogenicity) with regards to its carcinogenic potential.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to lambda-cyhalothrin residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are no Codex, Canadian, or Mexican MRLs established for residues of lambda-cyhalothrin in plant or animal commodities. Codex MRLs for cyhalothrin are established for several commodities which are unrelated to this action. Therefore, a discussion of compatibility with U.S. tolerances is not relevant at this time.

VI. Conclusion

Therefore, the tolerances are established for the combined residues of lambda-cyhalothrin and its epimer in or on wild rice at 1.0 ppm, grass forage at 5.0 ppm and grass hay at 6.0 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made.

The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0335 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before March 4, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). 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.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3.*Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by the docket ID number OPP–2002–0335, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a 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(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Regulatory Assessment Requirements

This final rule establishes time-limited tolerances under section 408 of the FFDCA. 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the FFDCA, 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10,

1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final 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: December 20, 2002.

Debra Edwards,

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. 321(q), 346(a) and 371.

2. Section 180.438 is amended by alphabetically adding commodities to the table in paragraph (b) to read as follows:

§ 180.438 Lambda-cyhalothrin; tolerances for residues.

* * * * *

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

Commodity	Parts per million	Expiration/ Revocation Date
* * *	* *	* *
Grass, forage	5.0	12/31/05
Grass, hay	6.0	12/31/05
Rice, wild	1.0	12/31/05

* * * * *

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