Commodity	Parts per million	Expiration/ Revocation Date
* * * * * * *		
Cattle, fat	0.01	6/30/00
Cattle, mbyp	0.01	6/30/00
Cattle, meat	0.01	6/30/00
Goats, fat	0.01	6/30/00
Goats, mbyp	0.01	6/30/00
Goats, meat	0.01	6/30/00
Grapefruit	0.5	6/30/00
Grapefruit pulp, dried.	4.0	6/30/00
Grapefruit oil	35	6/30/00
Hogs, fat	0.01	6/30/00
Hogs, mbyp	0.01	6/30/00
Hogs, meat	0.01	6/30/00
Horses, fat	0.01	6/30/00
Horses, mbyp	0.01	6/30/00
Horses, meat	0.01	6/30/00
* * * * * * *		
Sheep, fat	0.01	6/30/00
Sheep, mbyp	0.01	6/30/00
Sheep, meat	0.01	6/30/00
* * * * * * *		

* * * * *

[FR Doc. 99–2207 Filed 1–28–99; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300780; FRL–6056–2]

RIN 2070–AB78

Lambda-cyhalothrin; Pesticide Tolerances for Emergency Exemptions

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

SUMMARY: This regulation establishes a time-limited tolerance for the combined residues of lambda-cyhalothrin and its epimer in or on flax, barley, canola, and sugarcane. 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 flax, barley, canola, and sugarcane. This regulation establishes maximum permissible levels for residues of lambda-cyhalothrin in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and are revoked on December 31, 2000.

DATES: This regulation is effective January 29, 1999. Objections and requests for hearings must be received by EPA on or before March 30, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300780], 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–300780], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic 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 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300780]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, 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: Rm. 272, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9367, e-mail: ertman.andrew@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408 and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), is establishing a tolerances for the combined residues of the insecticide lambda-cyhalothrin and its epimer, in or on flax seed at 0.1 parts per million (ppm), barley bran at 0.2 ppm, barley grain at 0.05 ppm, barley hay at 2.0 ppm, barley straw at 2.0 ppm, canola seed at 0.1 ppm and sugarcane at 0.03 ppm. These tolerances will expire and are revoked on December 31, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Findings

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 in this preeamble and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

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

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

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide

chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

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

II. Emergency Exemption for Lambda-cyhalothrin on Flax, Barley, Canola, and Sugarcane and FFDCA Tolerances

North Dakota declared a crisis for the use of lambda-cyhalothrin on flax to control grasshoppers. The emergency was due to a lack of control of this pest with other registered alternatives. Grasshopper infestations in 1998 were significantly greater than in 1997 and conditions require treatment with lambda-cyhalothrin.

Several states declared crises for the use of lambda-cyhalothrin on barley to control the Russian wheat aphid. Although there are several registered alternative products available, each has disadvantages, including lack of efficacy, that lead to the states requesting the use of lambda-cyhalothrin. The states assert that without the use of lambda-cyhalothrin, they will incur significant economic losses.

Two states declared crises for the use of lambda-cyhalothrin on canola to control flea beetles. The applicants stated that flea beetles are significant pests of seedling canola and damage the plants by feeding on leaf tissue, stems and pods.

Sugarcane yield loss from the sugarcane borer is estimated at 60% unless adequately controlled. Registered alternatives can cause secondary outbreaks of aphids due to toxicity to non-target arthropods (parasites and predators). EPA has authorized under FIFRA section 18 the use of lambda-cyhalothrin on flax for control of grasshoppers, barley for control of the Russian wheat aphid, canola for control of flea beetles in several states, and sugarcane for control of the sugarcane borer in Louisiana. 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 flax, barley, canola, and sugarcane. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency 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 under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on flax, barley, canola, and sugarcane 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 flax, barley, canola, and sugarcane 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 FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than North Dakota, Minnesota, Colorado, Idaho, and Louisiana to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for lambda-cyhalothrin, contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of 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), for a time-limited tolerance for combined residues of lambda-cyhalothrin and its epimer on flax seed at 0.1 ppm, barley bran at 0.2 ppm, barley grain at 0.05 ppm, barley hay at 2.0 ppm, barley straw at 2.0 ppm, canola seed at 0.1 ppm, and sugarcane at 0.03 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 lambda-cyhalothrin are discussed in this unit.

B. Toxicological Endpoint

1. *Acute toxicity*. The acute dietary RfD is 0.005 milligrams/kilogram/day (mg/kg/day) based on a chronic toxicity study in dogs. The systemic No Observed Adverse Effect Level (NOAEL) was determined to be 0.5 mg/kg/day based on gait abnormalities. An uncertainty factor of 100 was applied.

2. *Short- and intermediate-term toxicity*. The short- and intermediate-term dermal toxicity NOAEL was determined to be 10.0 mg/kg/day based on mortality, clinical signs and effects on body weight and food consumption in a 21–day dermal rat study. An acceptable MOE will be $\geqq$ 100.

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for lambda-cyhalothrin at 0.001 mg/kg/day. This RfD is based on a No Observed Adverse Effect Level (NOAEL) of 0.1 mg/kg/day in a chronic toxicity study in dogs. Symptoms included neurotoxicity, ataxia and convulsions. An uncertainty factor of 100 was applied.

4. *Carcinogenicity*. Lambda-cyhalothrin has been classified by the Agency as a group D carcinogen (''not classifiable as to human carcinogenicity'').

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established under 40 CFR 180.438 for residues of lambda-cyhalothrin and its epimer expressed as: a 1:1 mixture of (*S*)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer a 1:1 mixture of (*S*)-α-cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclo-propanecarboxylate and (*R*)-α-cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclo-propanecarboxylate in numerous plant commodities at levels ranging from 0.01 to 6.0 ppm; in the fat of cattle, goats, hogs, horses, and sheep at 3.0 ppm; in the meat and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.2 ppm; milkfat at 5.0 ppm (reflecting 0.2 ppm in whole milk); and in poultry fat, meat, meat byproducts, and eggs at 0.01 ppm. Food additive tolerances have been established for residues of lambda-cyhalothrin in all food items (other than those already covered by a higher tolerance as a result of use on growing crops) in food handling establishments (0.01 ppm), dried hops (10.0 ppm), corn grain flour (0.15 ppm), sunflower oil (0.30 ppm), and wheat bran (0.2 ppm). Feed additive tolerances for residues of lambda-cyhalothrin on sunflower hulls (0.50 ppm), tomato pumice (6.0 ppm), and wheat bran (0.2 ppm) have been established under 40 CFR 180.438. Risk assessments were conducted by EPA to assess dietary exposures and risks from lambda-cyhalothrin as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

An acute dietary (food) risk assessment was performed that used a tier three analysis (i.e., Monte Carlo) of the Novigen DEEM (Dietary Exposure Evaluation Model) system, which employed both percent crop treated data and processing data in the calculation. Flax was added to the analysis at the 100% crop treated level. The residue value for flax was taken from canola which is another seed oil. The DEEM analysis evaluates individual food consumption as reported by respondents in the USDA Continuing Surveys of Food Intake by Individuals (CSFII) conducted in 1989 through 1991. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure.

Resulting exposure values (at the 99.9th percentile) and percentage of the acute RfD occupied range from 28% for nursing infants (<1 year old) up to 72% for non-nursing infants (<1 year old). EPA generally has no concern for exposures below 100% of the RfD (when the FQPA safety factor has been removed, as it has in this case).

ii. *Chronic exposure and risk.* A tier three DEEM chronic exposure analysis was performed using anticipated residues, percent crop treated, and processing data. The analysis evaluates individual food consumption as reported by respondents in the USDA CSFII conducted in 1989 through 1991. The model accumulates exposure to the chemical for each commodity and expresses risk as a function of dietary exposure.

The existing lambda-cyhalothrin tolerances (published, pending, and including the necessary Section 18 tolerances) result in Anticipated Residue Contributions (ARCs) that are equivalent to the percentages of the Chronic RfD ranging from 2% for nursing infants (<1 year old) up to 19% for children (1–6 years old). As noted above, the Agency generally has no concern for exposures below 100% of the RfD (when the FQPA safety factor has been removed).

Section 408(b)(2)(E) 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), 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) states that the Agency may use data on the actual percent of food treated (PCT) for assessing chronic dietary risk only if the Agency can make the following findings: 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; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated as required by the section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used a tier three DEEM analysis provided by the petitioner. This analysis was performed using anticipated residues, percent crop treated, and processing data.

The Agency believes that the three conditions, discussed in section 408 (b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of the PCT, the Agency is reasonably certain that that the percentage of the food treated is not likely to be underestimated. The 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. *From drinking water.* Estimated Environmental Concentrations (EECs) for lambda-cyhalothrin residues were determined to be 0.095 µg/L for acute surface water and 0.003 µg/L for chronic surface water.

i. *Acute exposure and risk.* [As mentioned previously, the acute risk for ''food only'' does not exceed EPA's level of concern. Drinking water levels of concern (DWLOC) for acute dietary exposure range from 14 µg/L for infants and children up to 120 µg/L for the U.S.

population (48 states). These levels are substantially higher than the surface water EEC (0.095 µg/L). Therefore, the risk from acute aggregate exposure to lambda-cyhalothrin does not exceed EPA's level of concern.

ii. *Chronic exposure and risk*. As is the case with acute risk, the chronic risk for ''food only'' does not exceed EPA's level of concern. DWLOC for chronic dietary exposure range from 8 µg/L for infants and children to 32 µg/L for the U.S. population. These levels are substantially higher than the highest chronic water EEC (0.003 µg/L). Chronic residential exposures to lambda-cyhalothrin are not expected for current registered uses. Therefore, chronic aggregate exposure to lambda-cyhalothrin does not exceed EPA's level of concern.

3. *From non-dietary exposure*. Lambda-cyhalothrin is currently registered for use on several non-food sites that include general pest control (crack/crevice/spot), termiticide, landscape, turf ornamentals, commercial ornamentals, golf course turf, and unoccupied agricultural premises. A risk assessment was performed for post application activities on lawns treated with lambda-cyhalothrin previously. At the time that this assessment was completed, exposures from lawn use were considered to be a ''worst case'' estimate of exposure from high-end of the registered residential uses.

i. *Chronic exposure and risk*. Chronic residential exposures to lambda-cyhalothrin are not expected for currently registered uses and thus a risk assessment is not required.

ii. *Short- and intermediate-term exposure and risk*. Short-term exposure and risk assessments were conducted by the Agency. The oral MOEs for infants and children was 3,500; the dermal MOEs were 1.5 million for the U.S. population and 7,810 for infants and children; and the inhalation MOEs were 15,000 for the U.S. population and 4,800 for infants and children. All of the above MOEs are well above the acceptable short term MOE of 100.

The Agency also conducted intermediate-term exposure and risk assessments. The oral MOEs for infants and children was 700; the dermal MOEs were 1.5 million for the U.S. population and 7,810 for infants and children; and the inhalation MOEs were 15,000 for the U.S. population and 4,800 for infants and children. All of the above MOEs are well above the acceptable short term MOE of 100.

4. *Cumulative exposure to substances with common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether 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 more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk*. The acute risk for ''food only'' does not exceed the Agency's level of concern, taking up 32% of the RfD for the U.S. population. The DWLOC for acute dietary exposure is 120 µg/L for the U.S. population, well above the maximum acute EEC of 0.095 µg/L.

2. *Chronic risk*. Using the ARC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to lambda-cyhalothrin from food will utilize 7% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The DWLOCs for chronic risk were calculated to be 32 µg/L for the U.S. population, well above the maximum chronic EEC of 0.003 µg/L. Chronic residential exposures to lambda-cyhalothrin are not expected for currently registered uses and thus a risk assessment is not required.

3. *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.

i. *Short-term aggregate risk (food + water + residential)*. MOEs for dietary and residential exposures are well above the acceptable short-term MOE of 100 and the short-term aggregate DWLOCs are higher than average surface water EECs. Therefore, short-term aggregate risk does not exceed EPA's level of concern.

ii. *Intermediate-term aggregate risk (food + water + residential)*. MOEs for dietary, residential exposures are well over the acceptable short-term aggregate MOE of 100 and the intermediate-term aggregate drinking water DWLOCs are higher than average surface water EECs. Therefore, intermediate-term aggregate risk does not exceed EPA's level of concern.

4. *Aggregate cancer risk for U.S. population*. Because lambda-cyhalothrin has been classified as a group D carcinogen, ''not classifiable as to human carcinogenicity,'' this risk assessment is not required.

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

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

1. *Safety factor for infants and children*—i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of lambda-cyhalothrin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using

the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. From the developmental toxicity study in rats, the maternal (systemic) NOAEL was 10 mg/kg/day. The maternal Lowest Observed Adverse Effect Level (LOAEL) of 15 mg/kg/day was based on decreased body weight gain and decreased food consumption. The developmental (fetal) NOAEL was > 15 mg/kg/day at the highest dose tested (HDT).

From the developmental toxicity study in rabbits, the maternal (systemic) NOAEL was 10 mg/kg/day. The maternal LOAEL of 30 mg/kg/day was based on decreased body weight gain. The developmental (fetal) NOAEL was > 30 mg/kg/day (HDT).

iii. *Reproductive toxicity study*. From the 3-generation reproductive toxicity study in rats, both the parental (systemic) and reproductive (pup) NOAELs were 1.5 mg/kg/day. Both the parental (systemic) and reproductive (pup) LOAELs were 5 mg/kg/day. They were based on a significant decrease in parental body weight (systemic) or a significant decrease in pup body weight (reproductive). The developmental NOAEL was 5 mg/kg/day (HDT).

iv. *Pre- and post-natal sensitivity*. The toxicology data base for lambda-cyhalothrin 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 3-generation reproductive toxicity study in rats.

v. *Conclusion*. Based on the above, EPA concludes that reliable data support the use of the standard hundredfold margin of uncertainty factor and that an additional uncertainty factor is not warranted at this time.

2. *Acute risk*. The acute risk for ''food only'' does not exceed the Agency's level of concern, taking up from 28% of the RfD for nursing infants <1 year old to 72% for non-nursing infants <1 year old. The DWLOC for acute dietary exposure is 14 µg/L for the infants and children, well above the maximum acute EEC of 0.095 µg/L.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to lambda-cyhalothrin from food will utilize from 2% of the RfD for nursing infants <1 year old to 19% of the RfD for children 1–6 years old. 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. The DWLOC for chronic dietary exposure is 8 µg/L for the infants and children, well above the maximum chronic EEC of 0.003 µg/L. Chronic non-dietary, non-occupational exposures to lambda-cyhalothrin are not expected for currently registered uses and thus a risk assessment for this exposure portion was not conducted.

4. *Short- or intermediate-term risk*. The short- and intermediate-term risk estimates for infants and children do not exceed the Agency's level of concern.

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

IV. Other Considerations

A. Metabolism In Plants and Animals

Data on plant metabolism show that lambda-cyhalothrin is metabolized by cleavage of the ester linkage to form cyclopropane carboxylic acids and the corresponding phenoxybenzoic acid and/or 3-phenoxybenzyl alcohol. The residues to be regulated are lambda-cyhalothrin and its epimer as specified in 40 CFR 180.438.

Studies of lambda-cyhalothrin metabolism in ruminants and poultry have been reviewed. In addition to the plant metabolites, lambda-cyhalothrin animal metabolites include 3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2-hydroxymethyl-2-methylcyclopropane-carboxylic acid (OH-CPA) and 4-hydroxy-3-phenoxybenzoic acid (4′-OH-3-PBAcid).

Lambda-cyhalothrin is the major component of the residue, except in the kidney and liver of ruminants and liver of poultry. In addition to the plant metabolites, 3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2-hydroxymethyl-2-methylcyclopropane-carboxylic acid (OH-CPA) and 4-hydroxy-3-phenoxybenzoic acid (4′-OH-3PBAcid) may be present in significant quantities. A residue transfer study in which cows were fed dietary levels of 8, 25 or 80 ppm lambda-cyhalothrin demonstrated that, at ≤ 8 ppm, OH-CPA levels in tissue would not exceed 0.01 ppm. The Agency has determined that animal metabolites do not need to appear in the tolerance expression at this time. As with plants, the residues to be regulated are lambda-cyhalothrin and its epimer.

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

C. Magnitude of Residues

Residues are not expected to exceed 0.1 ppm in flax seed; 0.05 ppm in barley grain; 0.2 ppm in barley, bran; 2 ppm in barley, straw; 2 ppm in barley, hay; 0.10 in canola seed; and 0.03 ppm in sugarcane as a result of these section 18 uses.

D. International Residue Limits

No Codex MRLs for residues of lambda-cyhalothrin have been established (only cyhalothrin). No Canadian MRLs have been established for residues of lambda-cyhalothrin. Mexico has not established tolerances for residues of lambda-cyhalothrin on flax, only on cottonseed (0.05 ppm). Therefore, harmonization is not an issue.

V. Conclusion

Therefore, the tolerance is established for combined residues of lambda-cyhalothrin and its epimer in flax seed at 0.1 parts per million (ppm), barley bran at 0.2 ppm, barley grain at 0.05 ppm, barley hay at 2.0 ppm, barley straw at 2.0 ppm, and canola seed at 0.1 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408 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 30, 1999, 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 under the ''ADDRESSES'' section (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). 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 tolerance objection fee waivers, contact James Tompkins, 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: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300780] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

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

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

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

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under 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). 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 specficed by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

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

B. Executive Order 12875

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

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

Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

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

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

IX. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: January 13, 1999.

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 § 180.438, by revising 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
Barley, bran	0.2	12/31/00
Barley, grain	0.05	12/31/00
Barley, hay	2.0	12/31/00
Barley, straw	2.0	12/31/00
Canola, seed	0.1	12/31/00
Flax, seed	0.1	12/31/00
Sugarcane	0.03	12/31/00

* * * * *

[FR Doc. 99–2208 Filed 1–28–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW–FRL–6219–2]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Final Exclusion

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is granting a petition submitted by Occidental Chemical Inc. (Occidental), to exclude from hazardous waste control (or delist) certain solid wastes. The wastes being delisted consist of Rockbox Residue, and Limestone Sludge. This action responds to Occidental Chemical's petition to delist these treated wastes on a ''generator specific'' basis from the lists of hazardous waste. After careful analysis, the EPA has concluded that the petitioned wastes are not hazardous wastes when disposed of in Subtitle D landfills/surface impoundments. This exclusion applies to Rockbox Residue and Limestone Sludge generated at Occidental Chemical's Ingleside, Texas facility. Accordingly, this final rule excludes the petitioned wastes from the requirements of hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA) when disposed of in Subtitle D landfills/surface impoundments but imposes testing conditions to ensure that the future-generated wastes remain qualified for delisting.

EFFECTIVE DATE: January 29, 1999.

ADDRESSES: The public docket for this final rule is located at the Environmental Protection Agency Region 6, 1445 Ross Avenue, Dallas, Texas 75202, and is available for viewing in the EPA Freedom of Information Act review room on the 7th floor from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding Federal holidays. Call (214) 665–6444 for appointments. The reference number for this docket is ''TXDEL–OCCIDENTAL.'' The public may copy material from any regulatory docket at no cost for the first 100 pages and at a cost of $0.15 per page for additional copies.

FOR FURTHER INFORMATION CONTACT: For general information, contact Bill Gallagher, at (214) 665–6775. For technical information concerning this notice, contact Jon Rinehart, Environmental Protection Agency, 1445 Ross Avenue, Dallas, Texas, (214) 665–6789.

SUPPLEMENTARY INFORMATION:

I. Background

A. Authority

Under 40 CFR 260.20 and 260.22, facilities may petition the EPA to remove their wastes from hazardous waste control by excluding them from the lists of hazardous wastes contained in §§ 261.31 and 261.32. Specifically, § 260.20 allows any person to petition the Administrator to modify or revoke any provision of parts 260 through 265 and 268 of Title 40 of the Code of Federal Regulations; and § 260.22 provides generators the opportunity to petition the Administrator to exclude a waste on a ''generator-specific'' basis from the hazardous waste lists. Petitioners must provide sufficient information to EPA to allow the EPA to determine that the waste to be excluded does not meet any of the criteria under which the waste was listed as a hazardous waste. In addition, the Administrator must determine, where he/she has a reasonable basis to believe that factors (including additional