determination on its Technology Transfer Network (TTN) bulletin board service.

(Sec. 111 and Sec.129, Clean Air Act (42 U.S.C. 7411))

Date: June 26, 1997.

David A. Ullrich,

Acting Regional Administrator.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300509; FRL–5728–8]

RIN 2070–AB78

Lambda-cyhalothrin; Time-Limited Pesticide Tolerance

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 rice. The names for lambda-cyhalothrin and its epimer are as follows: Lambda-cyhalothrin, a 1:1 mixture of (*S*)-alpha-cyano-3-phenoxybenzyl-(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl) -2,2-dimethylcyclopropanecarboxylate and (*R*)-alpha-cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*) -3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and Epimer of lambda-cyhalothrin, a 1:1 mixture of (*S*)-alpha-cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)-alpha-cyano-3-phenoxybenzyl-(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate. The Zeneca Ag Products requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1966 (Pub. L. 104–170). The tolerance will expire on November 15, 1997.

DATES: This regulation is effective July 9, 1997. Objections and requests for hearings must be received by EPA on or before September 8, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300509], 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 withthe Hearing Clerk identified by the docket control number, [OPP–300509], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300509]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: George T. LaRocca, Product Manager (PM) 13, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-6100, e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 19, 1997 (62 FR 7454; FRL–5585–5), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP 6F4769) for tolerance by Zeneca Ag Products, 1800 Concord Pike, P.O. 15458, Wilmington, DE 19850-5458. This notice included a summary of the petition prepared by Zeneca Ag Products, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.438 be amended by establishing a tolerance for combined residues of the insecticide lambda-cyhalothrin and its epimer (CAS NO. 91465–08–6; EPA Chemical NO. 128867), in or on rice grain at 1.0 parts per million (ppm), rice straw at 1.75 ppm, rice hulls at 5.0 ppm. Subsequent to this filing EPA recommended that the tolerance on rice straw be rounded off to 1.8 ppm.

I. Risk Assessment and Statutory Findings

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. . . .''

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

A. Toxicity

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

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD).

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

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

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

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

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

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

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

B. Aggregate Exposure

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

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of lambda-cyhalothrin and its epimer, 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 rice grain at 1.0 ppm, rice straw at 1.8 ppm, and rice hulls at 5.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information

concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by lambda-cyhalothrin are discussed below.

1. *Acute toxicity.* Acute toxicity studies with the technical gradeof the active ingredient lambda-cyahothrin: oral LD_{50} in the rat of 79 mg/kg (males) and 56 mg/kg (females), dermal LD_{50} in the rat of 632 mg/kg (males) and 696 mg/kg females, primary eye irritation study showed mild irritation and primary dermal irritation study showed no irritation.

2. *Genotoxicity.* The following genotoxicity tests were all negative: a gene mutation assay (Ames), a mouse micronucleus assay, an in-vitro cytogenetics assay, and a gene mutation study in mouse lymphoma cells.

3. A three-generation reproduction study in rats fed diets containing 0, 10, 30, and 100 ppm with no developmental toxicity observed at 100 ppm, the highest dose tested. The maternal NOEL and LOEL (lowest observed effect level) for the study are established at 30 (1.5 mg/kg/day) and 100 ppm (5 mg/kg/day), respectively, based upon decreased parental body weight gain. The reproductive NOEL and LOEL are established at 30 (1.5 mg/kg/day) and 100 ppm (5 mg/kg/day), respectively, based on decreased pup weight gain during weaning.

4. A developmental toxicity study in rats given gavage doses of 0, 5, 10, and 15 mg/kg/day with no developmental toxicity observed under the conditions of the study. The developmental NOEL is greater than 15 mg/kg/day, the highest dose tested. The maternal NOEL and LOEL are established at 10 and 15 mg/kg/day, respectively, based on reduced body weight gain.

5. A developmental toxicity study in rabbits given gavage doses of 0, 3, 10, and 30 mg/kg/day with no developmental toxicity observed under the conditions of the study. The maternal NOEL and LOEL are established at 10 and 30 mg/kg/day, respectively based on decreased body weight gain. The developmental NOEL is greater than 30 mg/kg/day, the highest dose tested.

6. A 90-day feeding study in rats fed doses of 0, 10, 50 and 250 ppm with a NOEL of 50 ppm and a LOEL of 250 ppm based on body weight gain reduction.

7. A 21-day study in rabbits exposed dermally to doses of 0, 10, 100, and 1,000 mg/kg/day, 6 hours/day, 5 days/week with a systemic NOEL >1,000 mg/kg/kg. There were no clinical signs of systemic toxicity at any dose level tested.

8. A 12-month feeding study in dogs fed dose (by capsule) levels of 0, 0.1, 0.5, 3.5 mg/kg/day with a NOEL of 0.1 mg/kg/day. The LOEL for this study is established at 0.5 mg/kg/day based upon clinical signs of neurotoxicity.

9. A 24-month chronic feeding/carcinogenicity study with rats fed diets containing 0, 10, 50, and 250 ppm. The NOEL was established at 50 ppm and LOEL at 250 ppm based on reduced body weight gain. There were no carcinogenic effects observed under the conditions of the study.

10. A carcinogenicity study in mice fed dose levels of 0, 20, 100, or 500 ppm (0, 3, 15, or 75 mg/kg/day) in the diet for 2 years. A systemic NOEL was established at 100 ppm and systemic LOEL at 500 ppm based on decreased body weight gain in males throughout the study at 500 ppm. The EPA has classified lambda-cyhalothrin as a Group D carcinogen (not classifiable due to an equivocal finding in this study). No treatment-related carcinogenic effects were observed under the conditions of the study.

11. *Animal metabolism*. Metabolism studies in rats demonstrated that distribution patterns and excretion rates in multiple oral dose studies are similar to single-dose studies. Accumulation of unchanged compound in fat upon chronic administration with slow elimination. Otherwise, lambda-cyhalothrin was rapidly metabolized and excreted. The metabolism of lambda-cyhalothrin in livestock has been studied in the goat, chicken, and cow. Unchanged lambda-cyhalothrin is the major residue component of toxicological concern in meat and milk.

B. Toxicological Endpoints

1. *Acute toxicity.* No endpoint was selected by EPA to assess acute dietary risk. EPA determined that this risk assessment was not required since there was no acute dietary end point of concern.

2. *Short - and intermediate - term toxicity.* As part of the hazard assessment process, EPA reviews the available toxicological database to determine the endpoints of concern for non-dietary exposure. For short- and intermediate-term inhalation margin of exposure (MOE) calculations, EPA used a NOEL of 0.3 µg/l (0.05 mg/kg/day) from the 21-day inhalation toxicity study in rats. The LEL of 3.3 µg/l was based on decreased body weight gains and clinical signs of toxicity including paw flicking, tail erections and tiptoe gait. EPA did not select an end point for short and intermediate term dermal exposure since in the 21-day dermal toxicity study, the NOEL was >1,000 mg/kg/day (limit dose).

3. *Toxicity endpoint for dietary exposure—Chronic toxicity*. EPA has established the reference dose (RfD) for lambda-cyhalothrin at 0.001 milligrams/kilogram/day (mg/kg/day). This RfD is based on on a 1-year oral study in dogs with a NOEL of 0.1 mg/kg/day and an uncertainty factor (UF) of 100. The LEL of 0.5 mg/kg/day was based on clinical signs of neurotoxicity (convulsions, ataxia, muscle tremors) and a slight increase in liquid feces.

4. *Carcinogenicity*. Based on the available carcinogenicity studies in two rodent species, lambda-cyhalothrin has been classified as a Group ''D'' chemical, ''not classifiable as to human carcinogenicity.'' Although lambda-cyhalothrin was not shown to be carcinogenic in either the mouse or rat, the EPA Hazard Evaluation Division (HED) RfD/PEER review committee based the ''D'' classification on: (1) lambda-cyhalothrin was not tested at adequate dose levels for carcinogenicity testing in the mouse, and (2) the equivocal nature of the findings with regard to the incidence of mammary adenocarcinomas. No additional cancer studies are being required at this time.

C. Exposures and Risks

1. *From food and feed uses.* The primary source of human exposure to lambda-cyhalothrin will be from ingestion of both raw and processed food commodities treated with lambda-cyhalothrin. Time-limited tolerances have been established in 40 CFR 180.438, 40 CFR 185.3765 and 40 CFR 186.3765 for combined residues of lambda-cyhalothrin and its epimer in or on a variety of food commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from lambda-cyhalothrin as follows:

i. *Acute exposure and risk*. An acute risk assessment was not conducted because the Agency has not identified an acute dietary endpoint of concern for lambda-cyhalothrin.

ii. *Chronic exposure and risk*. For purposes of assessing the potential chronic dietary and risk exposure estimates (DRES) for lambda-cyhalothrin on rice, EPA estimated chronic dietary exposure based on anticipated residues and percent crop treated (7% for rice) for several, but not all, commodities. The existing lambda-cyhalothrin tolerances plus the proposed rice use resulted in an Anticipated Residue Contribution (ARC) that is equivalent to the following percentages of the RfD:

	Percent of the RfD
U.S. Population	22%
Nursing Infants (<1 year old).	25%
Non-Nursing Infants (<1 year old).	70%
Children (1-6 years old)	50%
Children (7-12 years old)	33%
Hispanics	24%
Non-hispanic Others	27%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S population (48 states). As indicated above the proposed lambda-cyhalothrin tolerances result in an ARC that is up to 70% of the RfD for the most sensitive subpopulation (non-nursing infants (<1 year old)). The general population is 22 percent of the RfD.

Section 408(b)(2)(F) allows the Agency too use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings: (1) that the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues; (2) that the exposure estimate does not underestimate the exposure for any significant subpopulation and; (3) where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition the Agency must provide for periodic evaluation of any estimates used.

Percent of crop treated estimates are derived from federal and market survey data. EPA considers these data reliable. Typically a range of estimates are supplied and the upper end of this range is used for the exposure assessment. By using this upper end estimate of percent crop treated, EPA is reasonably certain that exposure is not underestimated for any significant subpopulation. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of this regional data allows EPA to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by EPA. EPA has made these findings when appropriate with respect to the proposed tolerance of lambda-cyhalothrin on rice. EPA has not provided for periodic reevaluation of the data on percent crop treated for lambda-cyhalothrin because this tolerance has a time-limitation.

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

3. *From non-dietary exposure.* Lambda-cyhalothrin is currently registered for use on the following residential non-food sites: general indoor/outdoor pest control (crack/crevice/spot), termiticide, ornamental plants and lawns around homes, parks, recreation areas and athletic fields, and golf course turf. Application of this pesticide in and around these sites is mainly limited to commercial applicators.

EPA lacks sufficient residential-related exposure data to complete a comprehensive residential risk assessment for many pesticides, including lambda-cyhalothrin. However, due to the following facts: (1) that lambda-cyhalothrin has a low vapor pressure (2×10^{-10} torr); (2) there are no acute toxicity endpoints identified; (3) no short- or intermediate-term dermal toxicity endpoint was identified; (4) high worker inhalation MOEs (which ranged from 1,000 to 6,800); and (5) the percentage of the RfD that is occupied by the pending and registered uses of this chemical is below 100; EPA has concluded that non-dietary, non-occupational uses of lambda-cyhalothrin would not pose a risk that exceeds EPA's level of concern.

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

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

Although lambda-cyhalothrin is structurally similar to other members of the synthetic pyrethroid class of insecticides, 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 have 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.

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

1. *Acute risks.* As indicated above, a risk assessment was not conducted because EPA has not identified an acute toxicity dietary endpoint for lambda-cyhalothrin.

2. *Chronic risk.* Using the exposure assumptions and risks described above, and taking into account the completeness and reliability of the toxicity data, EPA has concluded that dietary exposure to lambda-cyhalothrin will utilize 22% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to lambda-cyhalothrin in drinking water and via residential uses, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to lambda-cyhalothrin residues.

D. Aggregate Cancer Risk for U.S. Population

Lambda-cyhalothrin has been classified by EPA as a Group ''D'' chemical, ''not classifiable as to human carcinogenicity''. Therefore, this risk assessment was not conducted.

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

In assessing the potential for additional sensitivity of infants and children to residues of lambda-cyhalothrin, EPA considered data from developmental toxicity studies in rats and rabbits and a 3-generation reproductive toxicity study in rats. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during prenatal development. Reproduction studies provide information relating to pre- and post-natal effects from exposure to the pesticide, information 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 analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the no observed effect level (NOEL) in the animal study appropriate to the particular risk assessment. This 100-fold uncertainty (safety) factor is designed to account for inter-species extrapolation and intra-species variability. EPA believes that reliable data support using the standard 100-fold 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 factor.

1. *Developmental toxicity studies.* a. From the developmental toxicity study in rats, the maternal (systemic) NOEL was 10 mg/kg/day. The maternal LEL of 15 mg/kg/day was based on decreased body weight gain and decreased food consumption. The developmental (fetal) NOEL was >15 mg/kg/day at the highest dose tested (HDT).

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

2. *Reproductive toxicity studies.* From the 3-generation reproductive toxicity study in rats, both the parental (systemic) and reproductive (pup) NOEL's were 1.5 mg/kg/day. Both the parental (systemic) and reproductive (pup) LEL's 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.

3. *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.

Based on the above, EPA concludes that reliable data support the use of the standard 100-fold margin of uncertainty factor and that an additional uncertainty factor is not warranted at this time.

4. *Acute risk.* This risk assessment was not conducted because EPAhas not identified an acute toxicity dietary endpoint of concern for lambda-cyhalothrin.

5. *Chronic risk.* Using the exposure assumptions described above, EPA has concluded that the percent of the RfD that will be utilized by dietary exposure to residues of lambda-cyhalothrin ranges from 25% for nursing infants less than one year old, up to 70% for non-nursing infants less than 1 year old. Despite the potential for exposure to lambda-cyhalothrin in drinking water and via residential uses, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Therefore, taking into account the completeness and reliability of the toxicity data and the conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to lambda-cyhalothrin residues.

III. Other Considerations

A. Endocrine Effects

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

B. Metabolism In Plants and Animals

The metabolism of lambda-cyhalothrin in plants and animals is

adequately understood for the purpose of this tolerance. EPA has determined that plant and animal metabolites do not need to appear in the tolerance expression at this time. The residues to be regulated are lambda-cyhalothrin and its epimer as specified in 40 CFR 180.438.

C. Magnitude of Residues

Field residue data reflecting the application of lambda-cyhalothrin to rice are acceptable in quantity and quality and location in support of the proposed tolerances on rice grain, rice hulls, and rice straw. The existing tolerances for meat, milk, poultry and eggs are based on the transfer of residues from a worse-case diet consisting of various animal feed items containing residues of lambda-cyhalothrin and its epimer. No increase in the dietary burden of poultry and ruminants is expected from use on rice. Therefore, any secondary residues that might result in milk, meat, poultry and eggs would be covered by the existing tolerances on these commodities.

D. Analytical Enforcement Methodology

There is a practical analytical method available for determination of residues of lambda-cyhalothrin and its epimer. Adequate enforcement methodology (gas chromatography/electron capture detector) for plant and animal commodities is available to enforce the tolerances. EPA will provide information on this method to FDA. In the interim, the analytical method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm 1128, 1921 Jefferson Davis Hwy., Arlington, VA 22202, 703–305–5805.

E. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) for residues of lambda-cyhalothrin and its epimer in/on rice. Therefore, international harmonization is not an issue for this tolerance.

F. Rotational Crop Restrictions

Studies submitted in support of lambda-cyhalothrin registration show that significant residues (<0.01 ppm) will not be present in crops rotated 30 days after application of parent lambda-cyhalothrin. No additional rotational crop data are needed to support current registered application rates.

IV. Conclusion

A time limited tolerance is being established for lambda-cyhalothrin and its epimer, in/or on rice grain at 1.0 ppm, rice straw at 1.8 ppm, and rice hulls at 5.0 ppm. Tolerances are time limited to allow development and review of drinking water and cumulative exposure data. Based upon the information and data considered EPA concludes that the proposed time limited tolerances will be safe. Therefore the tolerances are established as set forth in this document.

V. Objections and Hearing Requests

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

Any person may, by September 8, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(I). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300509] (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 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

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

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

VII. Regulatory Assessment Requirements

This final rule establishes a time limited tolerance under FFDCA section 408(d) in response to a petition

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

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

VIII. Submission to Congress and the General Accounting Office

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

List of Subjects in 40 CFR Part 180

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

Dated: June 25, 1997.

James Jones,

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. Section 180.438 is revised to read as follows:

§ 180.438 Lambda-cyhalothrin; tolerances for residues.

(a) *General.* Time limited tolerances are established for residues of the insecticide lambda-cyhalothrin, a 1:1 mixture of (*S*)-alpha-cyano-3-phenoxybenzyl-(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl) -2,2-dimethylcyclopropanecarboxylate and (*R*)-alpha-cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and the Epimer of lambda-cyhalothrin, a 1:1 mixture of (*S*)-alpha-cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)-alpha-cyano-3-phenoxybenzyl-(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate on plants, as indicated in the following table. The tolerance will expire on the date specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Rice grain	1.0	November 15, 1997
Rice straw	1.8	November 15, 1997
Rice, Hulls	5.0	November 15, 1997

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97–17591 Filed 7–8–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300510; FRL–5729–3]

RIN 2070–AB78

Myclobutanil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of myclobutanil in or on peppers (bell and non-bell), peppermint and spearmint. 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 peppers (bell and non-bell) in California and peppermint and spearmint in Idaho and Washington. This regulation establishes a maximum permissible level for residues of myclobutanil 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 July 1, 1998.