EFFECTIVE DATE: This rule is effective on February 13, 1998.

FOR FURTHER INFORMATION CONTACT: Elizabeth Armour, EPA Region IX, at (415) 744–1730.

SUPPLEMENTARY INFORMATION:

I. Background

Section 801 of the CRA precludes a rule from taking effect until the agency promulgating the rule submits a rule report, which includes a copy of the rule, to each House of Congress and to the Comptroller General of the General Accounting Office (GAO). EPA recently discovered that it had inadvertently failed to submit the above rule as required; thus, although the rule was promulgated on November 6, 1997, **Federal Register** document, by operation of law, the rule did not take effect on December 8, 1998, as stated therein. Now that EPA has discovered its error, the rule is being submitted to both Houses of Congress and the GAO. This document amends the effective date of the rule consistent with the provisions of the CRA.

The November 6, 1997, rule specifies that a revised SIP to meet the serious area requirements is due to be submitted by December 8, 1998, based on the need to meet the deadline for the attainment date for serious areas—November 19, 1999. Since the change in effective date of the rule has no impact on the reasons EPA established the December 8, 1998, revised SIP submission date, and since the State has been on notice of this action since the November 6, 1997, final rule was published in the **Federal Register**, EPA is not changing the December 8, 1998, deadline for submitting SIP revisions.

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, an agency may issue a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because EPA merely is correcting the effective date of the promulgated rule to be consistent with the congressional review requirements of the Congressional Review Act as a matter of law and has no discretion in this matter. Thus, notice and public procedure are unnecessary. The Agency finds that this constitutes good cause under 5 U.S.C. 553(b)(B). Moreover, since today's action does not create any new regulatory requirements and affected parties have known of the underlying rule since November 6, 1997, EPA finds that good cause exists to provide for an immediate effective date pursuant to 5 U.S.C. 553(d)(3) and 808(2).

II. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). Because this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). EPA's compliance with these statutes and Executive Orders for the underlying rule is discussed in the November 6, 1997, **Federal Register** document.

Pursuant to 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, 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 General Accounting Office; however, in accordance with 5 U.S.C. 808(2), this rule is effective on February 13, 1998. This rule is not a ''major rule'' as defined in 5 U.S.C. 804(2).

This final rule only amends the effective date of the underlying rule; it does not amend any substantive requirements contained in the rule. Accordingly, to the extent it is available, judicial review is limited to the amended effective date. Pursuant to section 307(b)(1) of the Clean Air Act, challenges to this amendment must be brought within 60 days of publication of the amendment.

Dated: February 6, 1998.

Carol Browner,

Administrator.

[FR Doc. 98–3754 Filed 2–12–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300608; FRL–5767–7]

RIN 2070–AB78

Lambda-cyhalothrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the combined residues of the pyrethroid lambda-cyhalothrin and its epimer in or on alfalfa forage at 5.0 parts per million (ppm); alfalfa hay at 6.0 ppm; leaf lettuce at 2.0 ppm; brassica head and stem subgroup (broccoli, Chinese broccoli, Brussels sprouts, cabbage, Chinese (napa) cabbage, Chinese mustard, cauliflower, caval broccolo, and kohlrabi) at 0.4 ppm; replaces the term ''grain dust'' with ''aspirated grain fractions'' with a tolerance of 2.0 ppm; and increases the tolerance for poultry fat from 0.01 ppm to 0.03 ppm. Zeneca Ag Products requested these tolerances under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective February 13, 1998. Objections and requests for hearings must be received by EPA on or before April 14, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300608], 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–300608], 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. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by

sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300608]. 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: Stephanie Willett, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5419, e-mail: willett.stephanie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 11, 1997 (62 FR 37234–37246)(FRL–5728–7), 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 pesticide petition (PP) number 5F4588 for lambda-cyhalothrin tolerances on alfalfa, leaf lettuce, brassica subgroup, aspirated grain fractions, and an increase in the current poultry fat tolerance by Zeneca Ag Products, 1800 Concord Pike, P.O. Box 15458, Wilmington, Delaware 19850–5458. This notice included a summary of the petition prepared by Zeneca Ag Products, as required under the FFDCA as amended by the Food Quality Protection Act (FQPA) of 1996. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.438 be amended by establishing tolerances for the combined residue of the insecticide, lambda-cyhalothrin and its epimer in or on raw agricultural commodities (RACs) alfalfa forage at 5.0 ppm; alfalfa hay at 6.0 ppm; leaf lettuce at 2.0 ppm; head and stem Brassica crop subgroup at 0.4 ppm; aspirated grain fractions at 2.0 ppm; and increasing the existing tolerance for poultry fat from 0.01 ppm to 0.03 ppm. The change in terminology from ''grain dust'' to ''aspirated grain fractions'' was recommended by the EPA, since the term ''grain dust'' is not used. The tolerance for aspirated grain fractions includes a mixture of all aspirated grains for which the pesticide has a tolerance, and should be established at the highest current tolerance set for any grain dust, which is 2.0 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 percent 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 hundredfold MOE is based on the same rationale as the hundredfold 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 three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

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

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

B. Aggregate Exposure

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

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). EPA's assessment of the dietary exposures and risks associated with establishing the tolerances 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 and its epimer are discussed below. Note that the studies discussed below were conducted using either cyhalothrin or lambda-cyhalothrin. Cyhalothrin and lambda-cyhalothrin are basically the same chemical, the differences are found in their stereo chemistry and the number of isomers in each mixture. Cyhalothrin consists of four stereo isomers in each mixture. Cyhalothrin consists of four stereo isomers while lambda-cyhalothrin is a mixture of the two isomers. The two lambda-cyhalothrin isomers are contained in cyhalothrin, they represent 40% of the cyhalothrin mixture. The major studies submitted to the Agency were conducted with cyhalothrin. However, these studies are used in support of registration for both mixtures. There is some evidence, based on subchronic studies in rats, that the two mixtures are not biologically different with respect to their mammalian toxicity.

1. *Acute toxicity.* Acute toxicity studies with the technical grade of the active ingredient lambda-cyahothrin: oral LD_{50} in the rat at 79 milligram per kilogram (mg/kg) (males) and 56 mg/kg (females) - Toxicity Category II; dermal LD_{50} in the rat at 632 mg/kg (males) and 696 mg/kg females - Toxicity Category II; primary eye irritation study showed mild irritation - Toxicity Category II; and primary dermal irritation study showed no irritation - Toxicity Category IV.

2. *Mutagenicity.* 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. *Reproductive and developmental toxicity.* i. In a three-generation reproduction study, rats were fed diets containing cyhalothrin at 0, 10, 30 or 100 ppm (approximately 0, 0.5, 1.5 or 5.0 milligram per kilogram per day (mg/kg/day)). Parental toxicity was observed as decreased mean body weight and body weight gain during the premating and gestation periods at 5.0 mg/kg/day. There were no other treatment-related effects. Offspring toxicity was observed as reduced mean pup weight and pup weight gains during lactation, again at 5.0 mg/kg/day. No other treatment-related effects were observed. The reproductive and parental NOELs are 1.5 mg/kg/day and the reproductive and parental lowest observed effect level (LOELs) are 5.0 mg/kg/day. The developmental NOEL is 5.0 mg/kg/day (highest dose tested (HDT)).

ii. In a rabbit developmental toxicity study, rabbits were given gavage dose levels of cyhalothrin at: 0, 3, 10, 30 mg/kg/day during the gestation period (days 6 through 18). The maternal NOEL was 10 mg/kg/day and the maternal LOEL was 30 mg/kg/day based on decreased

body weight gain (48% of controls) during the dosing period. The developmental NOEL was 30 mg/kg/day (HDT). No developmental effects were observed.

iii. In a rat developmental study rats were given gavage dose levels of cyhalothrin at: 0, 5, 10, 15 mg/kg/day during the gestation period (days 6 through 15). The maternal NOEL was 10 mg/kg/day and the maternal LOEL was 15 mg/kg/day based on reduced body weight gain (70% of control) and food consumption (as low as 76%) during the dosing period. The developmental NOEL was greater than 15 mg/kg/day (HDT). No developmental effects were observed.

4. *90–day feeding study*. i. In a 90–day feeding study rats were fed, lambda-cyhalothrin at doses of 0, 10, 50 or 250 ppm (0, 0.5, 2.5, 12.5 mg/kg/day). The animals were examined once daily for clinical signs of toxicity. Body weights, food consumption, hematological and clinical chemistry parameters, urinalysis parameters, organ weights, and macroscopic and microscopic observations were recorded. Body weight gain and food consumption were significantly reduced for both sexes at 12.5 mg/kg/day. There was also a slight but statistically significant reduction in food efficiency in females at this dose level. The NOEL is 2.5 mg/kg/day and the lowest effect level (LEL) is 12.5 mg/kg/day based on reduction in body weight gain and food consumption in both sexes and food efficiency in females.

ii. In another 90–day feeding study in rats cyhalothrin was fed at doses of 0, 10, 50 or 250 ppm (0, 0.5, 2.5, 12.5 mg/kg/day). The animals were examined for clinical signs of toxicity. Body weights, food consumption, hematological and clinical chemistry parameters, urinalysis parameters, organ weights, and macroscopic and microscopic observations were recorded. Body weight gain was significantly reduced in males at 12.5 mg/kg/day. Body weight gain was also significantly reduced in females at this level, but only during the first week. Body weight gain was not significantly affected at lower dose levels. The NOEL is 2.5 mg/kg/day and the LEL is 12.5 mg/kg/day based on decreased body weight gain.

5. *28–day study*. In a 28–day study in the mouse, cyhalothrin was fed to mice in the diet as a range-finding study for carcinogenicity at 0, 5, 25, 100, 500, or 2,000 ppm (0, 0.65, 3.30, 13.5, 64.2 or 309 mg/kg/day for males and 0, 0.80, 4.17, 15.2, 77.9 or 294 mg/kg/day for females).The NOEL is 500 ppm and the LEL is 2,000 ppm based on mortality, clinical signs of toxicity, decreases in body weight gain and food consumption, changes in hematology and organ weights and minimal centrilobular hepatocyte enlargement.

6. *21–day dermal toxicity study*. In a 21–day dermal toxicity study rats were exposed dermally to doses of 1, 10, or 100 mg/kg of lambda-cyhalothrin (reduced to 50 mg/kg after two or three applications) 6 hours/day. No significant signs of skin irritation was observed at any dose level. Two male rats were found dead after three applications of 100 mg/kg. There was no evidence prior to death, at postmortem examination, or from histopathology, of the possible cause of death, but it is thought likely to be due to pyrethroid toxicity. Dosage was reduced to 50 mg/kg/day for the remaining 18 applications. Animals dosed with 50 mg/kg/day displayed clinical signs of slight general toxicity (bizarre behavior, paw flicking, splayed gait, sides pinched in, thin, tip-toe gait, reduced stability, dehydration and reduced splay reflex). Effects on body weight gain and food consumption were also seen in males at this dose level. No toxicologically significant treatment-related effects were observed at any other dose level. The NOEL is 10 mg/kg/day and the LEL is 100/50 mg/kg/day based on death (at 100 mg/kg/day only), clinical signs of toxicity and decreased body weight gain and food consumption.

7. *21–day inhalation study*. In a 21–day inhalation study rats were exposed nose-only for 6 hours/day, 5 days/week to lambda-cyhalothrin at 0.3, 3.3, or 16.7 µg/L. The NOEL was 0.3 µg/L and the LOEL was 3.3 µg/L based on decreased body weight gains (high dose males) and food consumption (high dose, both sexes), clinical signs of toxicity (paw flicking, tail erections, tiptoe gait, lachrymation or salivation), punctate foci on cornea (both sexes, mid- and high dose), raised prothrombin time, changes in hematology, clinical chemistry and urinalysis parameters and a slight increase in the incidence of alveolitis in females.

8. *12–month chronic/carcinogenicity feeding study*. In a 12–month chronic/carcinogenicity feeding study dogs were fed dose (by capsule) levels of lambda-cyhalothrin at 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. *24–month chronic feeding/carcinogenicity study*. In a 24–month chronic feeding/carcinogenicity study rats were fed diets containing 0, 10, 50, and 250 ppm (0, 0.5, 2.5 or 12.5 mg/kg/day) of cyhalothrin. The LEL for chronic toxicity in rats is 12.5 mg/kg/day and the NOEL is 2.5 mg/kg/day. There was no indication of carcinogenic effects observed under the conditions of the study.

10. *Carcinogenicity study*. In a carcinogenicity study mice were fed dose levels of 0, 20, 100, or 500 ppm (0, 3, 15, or 75 mg/kg/day) of cyhalothrin 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 was observed. 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.

12. *Neurotoxicity studies.* Neurotoxicity studies will be required under a special data call-in letter pursuant to section 3(c)(2)(B) of FIFRA. Although these data are lacking, EPA has sufficient toxicity data to support these tolerances and these additional studies will not significantly change its risk assessment.

B. Toxicological Endpoints

1. *Acute toxicity*. For acute dietary risk assessment, EPA used a systemic NOEL of 0.5 mg/kg/day based on gait abnormalities in dogs on day 2 in the chronic toxicity study.

2. *Short - and intermediate - term toxicity*. For short-and intermediate-term MOE's EPA recommends us of a NOEL of 10.0 mg/kg/day from the 21-day dermal toxicity based on systemic toxicity at 50 mg/kg/day (LOEL). A dermal absorption rate of 25% was used based on weight of evidence available for structurally related pyrethroids. EPA used a NOEL of 0.3 µg/L from the 21–day inhalation study in rats based on clinical signs indicative of neurotoxicity (paw flicking) tail erections, and tiptoe gait) at 3.3 µg/L.

3. *Chronic toxicity*. EPA has established the reference dose (RfD) for lambda-cyhalothrin at 0.001 mg/kg/day

based on clinical signs of neurotoxicity (ataxia, convulsions) seen at the LEL of 0.5 mg/kg/day. This RfD is based 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: (i) lambda-cyhalothrin was not tested at adequate dose levels for carcinogenicity testing in the mouse, and (ii) 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. 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. (The tolerances in 40 CFR 185.1310 and 186.3765 were removed and transferred to 40 CFR 180.438 on November 26, 1997, (62 FR 63010)(FRL–5755–5)). 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. The acute dietary exposure assessment for lambda-cyhalothrin used Monte Carlo modeling incorporating anticipated residue and percent crop treated refinements. The acute dietary Margin of Exposure (MOE) calculated at the 99.9th percentile for the most highly exposed population subgroup (nonnursing infants < 1 year old) is 139. The MOE calculated at the 99.9th percentile for the general U.S. population is 311. EPA concludes that there is a reasonable certainty of no harm for MOE of 100 or greater. Therefore, the acute dietary risk assessment for lambda-cyhalothrin indicates a reasonable certainty of no harm.

ii. *Chronic exposure and risk.* The RfD used for the chronic dietary analysis is 0.001 mg/kg/day. The chronic dietary exposure assessment used anticipated residues and percent crop treated information. The chronic dietary exposure estimate for the overall U.S. population was calculated to be 0.000068 mg/kg/day, which utilized 6.8% of the RfD for the U.S. population. For the most highly exposed population subgroup (children 1–6 years old), chronic dietary exposure was estimated at 0.000192 mg/kg/day, which utilized 19.2% of the RfD.

EPA notes that the acute dietary risk assessments used Monte Carlo modeling (in accordance with Tier 3 of EPA June 1996 ''Acute Dietary Exposure Assessment'' guidance document) incorporating anticipated residues and percent crop treated refinements. The chronic dietary risk assessment used percent crop treated information and anticipated residues. Section 408 (b)(2)(E) authorizes EPA to consider available data and information on the anticipated residue 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. Section 408(b)(2)(F) allows the agency to use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings: (a) 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; (b) that the exposure estimate does not underestimate the exposure for any significant subpopulation and; (c) where data on regional pesticide used 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.

The percent of crop treated estimates for lambda-cyhalothrin were derived from Federal and market survey data. EPA considers these reliable. A range of estimates are supplied by this data and the upper end of this range was used for the exposure assessment. By using this upper estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluation of the exposure of significant subpopulations including several regional groups. Review of this regional data allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To meet the requirement for data on anticipated residues, EPA will issue a Data Call-In (DCI) notice pursuant to FFDCA section 408(f) requiring submission of data on anticipated residues in conjunction with approval of the registration under FIFRA.

2. *From drinking water.* Laboratory and field data have demonstrated that lambda-cyhalothrin is immobile in soil and will not leach into groundwater. Other data show that lambda-cyhalothrin is virtually insoluble in water and extremely lipophilic. As a result, EPA concludes that residues reaching surface waters from field runoff will quickly adsorb to sediment particles and be partitioned from the water column. Further, a screening evaluation of leaching potential of a typical pyrethroid was conducted using EPA's Pesticide Root Zone Model (PRZM1). Based on this screening assessment, the potential concentrations of a pyrethroid in groundwater at depths of 1 and 2 meters are essentially zero (<< 0.001 parts per billion (ppb)). Surface water concentrations for pyrethroids were estimated using PRZM3 and Exposure Analysis Modeling System (EXAMS) using standard EPA cotton runoff and Mississippi pond scenarios. The maximum concentration predicted in the simulated pond was 0.052 ppb Concentrations in actual drinking water would be much lower than the levels predicted in the hypothetical, small, stagnant farm pond model since drinking water derived from surface water would normally be treated before consumption.

i. *Acute exposure and risk.* The acute drinking water exposure and risk estimates are 0.000022 mg/kg/day (MOE 22,876) and 0.000042 mg/kg/day (MOE 11,956) for the overall population and non-nursing infants <1 year, respectively.

ii. *Chronic exposure and risk.* The chronic drinking water exposure and risk estimates are 0.000000 mg/kg/day (0.0% RfD utilized) and 0.000000 mg/kg/day (0.0% of RfD utilized) for the overall population and non-nursing infants < 1 year, respectively.

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. Analyses were conducted which included an evaluation of potential non-dietary (residential) applicator, post-application and chronic dietary aggregate exposures associated with lambda-cyhalothrin products used for residential flea infestation control and agricultural/commercial applications. In the case of potential non-dietary health risks, conservative point estimates of nondietary exposures, expressed as total systemic absorbed dose (summed across inhalation and incidental ingestion routes) for each relevant product use category (i.e. lawn care) and receptor based on the toxicity endpoints selected by EPA for lambda-cyhalothrin, inhalation and incidental oral ingestion absorbed doses were combined and compared to the relevant systemic NOEL for estimating MOEs.

4. *Short- and intermediate term exposure and risk.* EPA used a NOEL of 0.3 µg/L (0.05 mg/kg/day) from the 21–day inhalation toxicity study in rats. The LOEL 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. For short- and intermediate-term dermal exposure MOE calculations, EPA used a NOEL of 10.0 mg/kg/day based on systemic toxicity at 50 mg/kg/day (LOEL). The MOE is 100.

The short and intermediate-term non-dietary aggregate (non-dietary + chronic dietary (food and water)) MOEs for lambda-cyhalothrin indicate a substantial degree of safety. The total non-dietary (inhalation + incidental + ingestion + dermal) MOEs for post-application exposure for the lawn care products evaluated was estimated to be >15,000 for adults, 7,200 for children 1-6 years old, and 7,000 for infants < 1 year. It can be concluded that the potential non-dietary and aggregate (non-dietary + chronic dietary) exposures for lambda-cyhalothrin are associated with substantial margins of safety.

5. *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 pyrethroids class of insecticide, 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.

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

1. *Acute risk.* The acute aggregate risk assessment takes into account exposure from food and water. The acute aggregate MOE calculated at the 99.9th percentile for the U.S. population is 307. The Agency generally has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger. EPA concludes that there is a reasonable certainty that no harm will result from acute aggregate exposure to lambda-cyhalothrin residues.

2. *Chronic risk.* Aggregate chronic exposure is the sum of chronic exposure from food and water. Using the exposure assumptions described above, EPA has concluded that aggregate exposure to lambda-cyhalothrin from food and water will utilize 6.8% 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. EPA concludes that there is a reasonable certainty that no harm will result from chronic aggregate exposure to lambda-cyhalothrin residues.

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. For lambda-cyhalothrin the aggregate MOE (inhalation + incidental oral + chronic dietary) summed across all product use categories was estimated to be 14,000 for the U.S. population. EPA concludes that the aggregate short- and intermediate-term risks do not exceed levels of concern, and that there is reasonable certainty that no harm will result from aggregate exposure to lambda-cyhalothrin residues.

E. 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.

F. 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 three-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 hundredfold uncertainty (safety) factor is designed to account for inter-species extrapolation and intra-species variability. EPA believes that reliable data support using the standard hundredfold 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.* i. 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).

ii. 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 study.* From the three-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 three-generation reproductive toxicity study in rats. 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.

4. *Acute risk.* The aggregate acute MOE calculated at the 99.9th percentile for non-nursing infants < 1 year old is 138. In a conservative policy, the Agency has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger. Therefore, the Agency has no acute aggregate concern due to exposure to lambda-cyhalothrin.

5. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to lambda-cyhalothrin from food will utilize 19.2 percent of the RfD for children 1-6 years. 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. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to lambda-cyhalothrin residues.

6. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background level) plus short-term and intermediate term residential exposure. The aggregate MOE was estimated to be 6,300 for children 1-6 years old, and 6,800 for infants < 1 year old. EPA concludes that the aggregate short- and intermediate-term risks do not exceed levels of concern, and that there is reasonable certainty that no harm will result from aggregate exposure to lambda-cyhalothrin residues.

G. Endocrine Disruption

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect on 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 screening and testing programs 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 enduse products for endocrine disrupter effects.

III. Other Considerations

A. Metabolism in Plants and Animals

The metabolism of lambda-cyhalothrin in plants and animals is adequately understood for the purposes of these tolerances. 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.

B. Analytical 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 (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M. St., SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm. 119FF, Jefferson Davis hwy., Arlington, VA 22202, 703–305–5805.

C. Magnitude of Residues

Field residue data reflecting the application of lambda-cyhalothrin to alfalfa, leaf lettuce, and Brassica subgroup crops are acceptable in quantity, quality and location to support the proposed tolerances. Based on the transfer of residues from a worst-case diet consisting of various animal feed items containing residues of lambda-cyhalothrin and its epimer, the existing tolerances for meat, milk, poultry and eggs are acceptable, with the exception of poultry fat. An increase in the poultry

fat tolerance from 0.01 ppm to 0.03 ppm is needed.

D. International Residue Limits

No Codex maximum residue levels (MRLs) for residues of lambda-cyhalothrin have been established for alfalfa, leaf lettuce, or brassica subgroup crops. Mexico has not established MRLs for residues of lambda-cyhalothrin. Canada has established tolerances for residues of lambda-cyhalothrin on broccoli and cabbage at 0.4 ppm, which are the same levels as the U.S. tolerance.

IV. Conclusion

Therefore, as set forth in this document, tolerances are established for lambda-cyhalothrin and its epimer in or on alfalfa forage at 5.0 ppm; alfalfa hay at 6.0 ppm; leaf lettuce at 2.0 ppm; brassica head and stem subgroup (broccoli, Chinese broccoli, Brussels sprouts, cabbage, Chinese (napa) cabbage, Chinese mustard, cauliflower, caval broccolo, and kohlrabi) at 0.4 ppm; ''aspirated grain fractions'' at 2.0 ppm; and the tolerance for poultry fat is increased from 0.01 ppm to 0.03 ppm.

V. Objections and Hearing Requests

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

Any person may, by April 14, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Docket and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300608] (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 (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 tolerances 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 are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance 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: January 29, 1998.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I, part 180 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, the table to paragraph (a)(1) is amended by adding entries for alfafa forage; alfalfa hay; aspirated grain fractions; brassica, head and stem subgroup; lettuce, leaf; by revising the entries for poultry, fat; and by removing the entries for sorghum, grain dust; and wheat, grain dust, and broccoli and cabbage, to read as follows:

§ 180.438 Lambda-cyhalothrin; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
Alfalfa, forage,	5.0
Alfalfa, hay	6.0
Aspirated grain fractions	2.0
Brassica, head and stem subgroup,.	0.4
* * *	* *
Lettuce, leaf	2.0
* * *	* *
Poultry Fat	0.03
* * *	* *

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[FR Doc. 98–3751 Filed 2–12–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300617; FRL–5771–1]

RIN 2070–AB78

Benoxacor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of benoxacor (4-(dichloroacetyl)-3,4-dihydro-3-methyl-2*H*-1,4-benzoxazine at 0.01 part per million (ppm) when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor. It also removes time limitations for residues of benoxacor on the same commodities that expire on February 14, 1998. Novartis Crop Protection, Incorporated requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170).

DATES: This regulation is effective February 13, 1998. Objections and requests for hearings must be received by EPA on or before April 14, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300617], 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–300617], 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, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300617]. 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: Kerry B. Leifer, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 4W17, Crystal Station #1, 2800 Crystal Drive, Arlington, VA, (703) 308-8811, e-mail: leifer.kerry@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 30, 1992 (57 FR 29031), EPA established time-limited tolerances under section 408 of the FFDCA 21 U.S.C. 346a(d) for residues of benoxacor at 0.01 ppm when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor. These time-limited tolerances expired on December 1, 1996. In the **Federal Register** of November 5, 1996 (61 FR 56954) (FRL–5572–8), EPA issued a notice pursuant to section 408 of FFDCA 21 U.S.C. 346a(e) announcing the filing of pesticide petition (PP7E3489) for tolerances by Novartis Crop Protection, Incorporated, P.O. Box 18300, Greensboro, NC 27419. This notice included a summary of the petition prepared by Novartis, the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.460 be amended to extend the time-limited tolerances for residues of benoxacor at 0.01 ppm when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor from December 1, 1996, to December 1, 1998. On February 21, 1997 (62 FR 7941) (FRL–5583–4), EPA established time-limited tolerances for benoxacor at 0.01 ppm when used as an inert ingredient (safener) in pesticide formulations containing metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor with an expiration date of February 14, 1998.